Department of Defense Chemical, Biological, Radiological, and Nuclear Defense Program

Annual Report to Congress

May 2004

Executive Summary

This Annual Report of the Department of Defense (DoD) Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Program, or CBRNDP, provides information in response to several reporting requirements. First, this report is provided in accordance with 50 USC 1523. (The complete reporting requirement is detailed at annex K.) This report is intended to assess:

(1) the overall readiness of the Armed Forces to fight in a chemical-biological warfare environment and steps taken and planned to be taken to improve such readiness; and,

(2) requirements for the chemical and biological warfare defense program, including requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical and biological weapons.

This report supplements the DoD Chemical and Biological Defense Program FY05 President's budget, February 2004, which has been submitted to Congress.[1]

Second, section 2.7 of this report addresses the requirement to provide information on the costs incurred by, and payments made to, each contractor or other entity engaged in the production, storage, distribution, or marketing of the anthrax vaccine administered by the Department of Defense.[2]

Third, in response to a reporting requirement by the Senate Armed Services Committee[3], DoD provides a report, which includes an analysis of the capacity and versatility of the test and evaluation (T&E) infrastructure to meet the requirements of current and planned chemical and biological defense research and development programs, including facilities for testing equipment with live agents and simulants and for animal testing; and, an identification of any actions needed to meet testing requirements. This report is provided as Annex J.

Finally, a performance plan for FY03–05 is provided under a separate cover. This performance plan demonstrates compliance with the Government Performance and Results Act (GPRA), and provides detailed information demonstrating linkage between research, development, and acquisition programs and the operational missions of the warfighter.

The DoD CBRNDP is a key part of a comprehensive national strategy to counter the threat of CBRN weapons as outlined in *The National Strategy to Combat Weapons of Mass Destruction*, December 2002. The national strategy is based on three principle pillars: (1) Counterproliferation to Combat WMD Use; (2) Strengthened Nonproliferation to Combat WMD Proliferation; and, (3) Consequence Management to Respond to WMD Use. The DoD

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[1] Annex G details the CBRNDP budget and expenditures. For FY05, the total budget request is $1.197 billion, of which $0.560 billion is for procurement, and $0.637 billion is for research, development, test, and evaluation.

[2] National Defense Authorization Act for Fiscal Year 2001 - Authorization Conference Report (H.R. Rep. No. 106-945, page 719), Joint Biological Defense Program – Special Report on anthrax vaccine costs, acquisition strategy, and related issues.

[3] FY04 Senate Armed Services Committee (SASC) Authorization Report (S. Rpt. 108-46 Report Language, p. 239)

CBRNDP provides research, development, and acquisition (RDA) programs primarily to support the first and third pillars. In support of counterproliferation, the DoD CBRNDP provides operational capabilities tailored to the unique characteristics of the various chemical and biological weapons, including emerging threats, in support of passive defense, force protection, and consequence management missions. These capabilities provide U.S. forces the ability to rapidly and effectively mitigate the effects of a CBRN attack against our deployed forces. In support of counterproliferation, the DoD CBRNDP provides capabilities to respond to the effects of WMD use against our forces deployed abroad, and in the homeland. In addition, the DoD CBRNDP supports the "1-4-2-1" force planning construct articulated in the *Department of Defense Annual Report to the President and the Congress*, September 2002. Put succinctly, the DoD CBRNDP will support "1-4-2-1" force planning to accomplish the following:

- "The United States will maintain sufficient military forces to protect its people, territory, and critical defense-related infrastructure against attacks from outside its borders, as U.S. law permits." (that is, **1**);
- "Deter aggression in four critical theaters: Europe, Northeast Asia, the Asian littorals, and the Middle East/Southeast Asia" (that is, **4**);
- "Swiftly defeat aggression in any two theaters of operation in overlapping timeframes" (that is, **2**); and,
- "Decisively defeat an adversary in one of the two theaters, including the ability to occupy territory or set the conditions for a regime change" (that is, **1**).

System-specific requirements to support the 1-4-2-1 force planning construct are not available at this time. The Services are conducting a study this year that will provide the analytical basis for defining requirements for each Service and for total Joint requirements. Capabilities developed and fielded by the CBRNDP in support of OPERATION IRAQI FREEDOM, as well as lessons learned from this operation, are documented in Chapter 3 and Annex G of this report.

The threat from CBRN weapons is comprised of a complex variety of *chemical* weapons—including nerve, blood, blister, and choking agents, toxic industrial chemicals, and novel threat agents—*biological* weapons—including viruses, bacteria, ricketssial, and toxin agents, and potentially novel or genetically engineered agents, as well as emerging infectious diseases—and *radiological and nuclear* weapons, including "dirty bombs." The threat is complicated by the numerous potential means of delivering these weapons, including bombs, spray devices, missiles, or novel delivery devices. In addition, more than 20 states and several non-state organizations may have or be pursuing CBRN weapons capabilities that could pose threats to U.S. forces operating abroad or within the United States. The unique physical, toxicological, destructive, and other properties of each type of CBRN threat requires that operational and technological responses be tailored to the threat and to the diverse requirements of military operations supporting national security and homeland security missions.

The FY05 President's Budget Submission for the DoD CBRNDP builds on the existing capabilities fielded to protect U.S. forces against CBRN threats. The CBRNDP budget provides a *balanced investment strategy* that includes investment in procurement of capabilities to protect U.S. forces in the near-term (FY05), investment in advanced development to protect

U.S. forces in the mid-term (FY06–09), and investment in basic research and the science and technology base to protect U.S. forces through the far term (FY10–19) and beyond. Chapter 2 provides modernization tables for each commodity area—contamination avoidance, battlespace management, individual and collective protection, decontamination, medical systems, and consequence management—summarizing planned progress through the far-term as a result of the RDA investment. The FY05 CBRNDP budget provides a *balanced investment* that provides the comprehensive array of systems and capabilities balanced among the operational capabilities to ***Sense*** (Reconnaissance, Detection, and Identification), ***Shape*** (Battlespace Management), and ***Shield*** (Individual & Collective Protection), and ***Sustain*** (Decontamination and Restoration) U.S. forces for passive defense, force protection, and consequence management missions.

In FY05, the CBRNDP will start or continue procurement on a variety of CBRN defense systems intended to provide U.S. forces with the best available equipment to survive, fight, and win in CBRN contaminated environments. Systems *beginning* procurement in FY05 include the Joint Effects Model (JEM)—an advanced hazard prediction and effects capability —and the Joint Protective Aircrew Ensemble (JPACE)—a CBRN protective clothing ensemble intended for use by all military aviators and aircrew for all fixed wing and rotary wing requirements. Programs *continuing* procurement include:

- *Joint Service General Purpose Mask (JSGPM)* – a lightweight protective mask incorporating state-of-the-art technology to protect ground forces from current and future threats.
- *Joint Warning and Reporting Network (JWARN) Block I* – a warning technology which will collect, analyze, identify, locate, report, and disseminate CBRN threat information
- *Joint Service Mask Leakage Tester (JSMLT)* – a one-man portable device that is capable of determining serviceability, proper fit, and identifying defective components of current and future CBRN protective masks.
- *Joint Service Lightweight Integrated Suit Technology (JSLIST)* – individual protective ensemble.
- *NBC Reconnaissance Vehicle (NBCRV)* – an improved CBRN Reconnaissance Vehicle with remote/early warning and data fusion capabilities
- *Joint Biological Agent Identification and Diagnostic System (JBAIDS)* – nucleic acid based diagnostic capability.
- J*oint Biological Point Detection System (JBPDS)* – an automatic, programmable long line source and point/mobile capability to detect and identify bio-agents.
- *Biological defense vaccines (Anthrax Vaccine Adsorbed)* – Acquisition of FDA licensed vaccines to protect against threat agents.
- *Chemical Biological Protected Shelter (CBPS)* – a highly mobile, rapidly deploy¬able shelter system designed to be used for Level I and II divisional and non-divisional forward area medical treat¬ment facilities.
- *Shipboard Collective Protection System (CPS) Backfit* – a program to protect critical spaces of amphibious assault ships.
- *Joint Collective Protective Equipment (JCPE)* – use the latest technologies in air purification, environmental controls, and power generation to improve and/or standardize current collective protection.

Technologies currently in advanced development (Budget Activities 4 and 5) provide leading edge systems that will enhance CBRN defense capabilities for U.S. forces in all CBRN defense missions in the mid-term by providing new capabilities or provide improvements to existing systems. Key systems in advanced development in FY05 include:

- *Artemis* – an active laser standoff chemical agent detection system.
- *Joint Service Lightweight Chemical Agent Detector (JSLSCAD)* – a passive standoff chemical detection system.
- *Joint Chemical Agent Detector (JCAD)* – an improved, all-agent programmable automatic point detection; portable monitor, miniature detectors for aircraft interiors; interior ship spaces; wheeled and tracked vehicles; and individual soldiers.
- *Joint Effects Model (JEM)* – an integrated hazard prediction and effects capability.
- *Joint Operational Effects Federation (JOEF)* —a risk management tool to the warfighter,
- *Joint Service Family of Decontamination Systems (JSFDS)* – a family of capabilities to decontaminate large areas, vehicles, personnel equipment, and skin.
- *Joint Service Sensitive Equipment Decontamination (JSSED)* – a capability for decontaminating sensitive interiors, electronics, avionics, and other sensitive equipment.
- Advanced anti-convulsants and biological defense vaccines, including recombinant botulinal toxin vaccine, equine encephalitis vaccine, next generation anthrax vaccine, and recombinant plague vaccine as part of the Joint Vaccine Acquisition Program (JVAP),
- Critical Reagents Program (CRP) to support development of reagents for biological detection and diagnostic systems,
- JBPDS updgrades, to include an increased number of agents detected and identified with increased sensitivity, lower false positive rates; smaller and lighter with increased reliability.
- *Joint Biological Standoff Detection System (JBSDS)* – an automated biological remote detection and early warning capability.
- JBAIDS enhancements to include a broader range of threat detected.
- JWARN upgrades, to include interoperability by all Services.
- JCPE technology improverments.
- *Joint Protective Aircrew Ensemble (JPACE)* – improved individual protection for the warfighter.
- Joint Service Aircrew Mask (JSAM) – Improved respiratory protection for aviators.
- JSGPM – Upgrades to planned mask..

The CBRNDP also supports numerous Defense Technology Objectives (DTOs), which represent the key science and technology base programs for demonstrating advanced capabilities in the near-term (FY04–05) and mid-term (FY06–09). An inventory of DTOs includes capabilities for Advanced Absorbents for Protection Applications, Detection of CB Contamination on Surfaces, Medical Countermeasures for Encephalitis Viruses, Vesicant Agents, and Brucellae, Therapeutics Based on Common Mechanisms of Pathogenesis, Alternative Delivery Methods for Recombinant Protein Vaccines (and Plague Vaccine candidates), CB Agent Water Monitors & Lightweight CB Detection, Acitivity-Based Detection and Diagnostics, Immune Building Program, Self-Detoxifying Materials for CB

Protective Clothing, High Resolution Nowcasting for CB and Environmental Hazards Prediction, Improved Oxime, advanced medical CB prophylaxes, smallpox therapeutics, and advanced decontamination capabilities.

In addition to efforts described above, the CBRNDP has significantly strengthened efforts for improving DoD Installation Force Protection against CBRN threats. DoD has programmed resources to address 200 installations from FY05–FY09. The FY05 increment to support additional procurement of CBRN defense equipment for force installation protection is $104.9 million.

The FY05 program continues to support the consequence management (CM) mission. CM projects fund the development of the Unified Command Suite (UCS) and Analytical Laboratory System (ALS) Block upgrades. CM funding provides for the modernization to address objective operational capabilities for the National Guard WMD Civil Support Teams (CSTs), the Reserve Component (RC) Reconnaissance, and RC Decontamination Teams. It provides full funding for: (1) type-classified protection, detection, and training equipment; (2) development and fielding of upgraded analytical platforms for the detection, identification, and characterization of chemical, biological, and radiological agents used by terrorists in a civilian environment; (3) development and fielding of communication capabilities that are interoperable with other- federal, state, and local agencies; (4) testing and evaluation to ensure that the systems fielded are safe and effective; and, (5) program management funds.

Finally, this year has represented the first year of the implementation of a new management and oversight structure for the CBRNDP. This new structure presents a more streamlined and efficient process that is intended to support the development and fielding of the next generation of chemical and biological defense capabilities for the second decade of the joint program. The key organizations, relationships, and processes are described in Chapter 1 of this report.

Overall, the FY05 President's budget achieves a structured, executable, and integrated medical and non-medical joint CBRNDP that balances urgent short-term procurement needs that include securing the homeland from terrorist attack, and long-term S&T efforts to mitigate future CBRN attacks. The program supports the Department's commitment to full dimensional protection for all the fighting men and women operating at home and abroad under the threat of chemical and biological weapons. All of these capabilities are integrated as a family of systems essential to avoid contamination and to sustain operational tempo on an asymmetric battlefield, as well as satisfy emerging requirements for force protection and consequence management. In summary, the DoD CBRNDP remains committed to establishing the optimal balance between the near-term requirements to field modernized equipment, and the need to protect and replenish our long-term investment in technology.

OVERVIEW OF THE REPORT

The ***Introduction*** provides a background of the rationale and purpose of the DoD CBRNDP. This section summarizes the key counterproliferation priorities and the current CBRN warfare threats to U.S. forces. Intelligence documents tailored to the threat are essential for developing and updating requirements for CBRN defense programs. Each CBRN defense research, development, and acquisition effort funded within the program responds to a defined or validated threat. Variations among chemical and biological agents and each agent's unique

physical, toxicological, destructive, and other properties such as means of delivery require a capabilities-based response. Intelligence efforts continue to emphasize collection and analysis of nations' dual-use chemical and biological industrial capabilities and develop the indications and warning of adversarial use or diversion of dual-use capabilities to weapons programs.

Chapter 1 describes the accomplishments, processes, and issues related to program management and oversight. This chapter provides an overview of the re-organization of the CBRNDP management structure that was initiated in 2003 and is being implemented during 2004.

Chapter 2 provides information on medical and non-medical CBRN defense requirements and research, development, and acquisition programs. This chapter outlines plans and strategies for the development and acquisition of capabilities in each of the program commodity areas, including contamination avoidance, individual protection, collective protection, modeling and simulation, medical chemical defense, and medical biological defense. In addition, this chapter includes a "Special Report on Anthrax Vaccine Costs, Acquisition Strategy, and Related Issues" in Section 2.8 in accordance with the request for information as stated in the National Defense Authorization Act for FY01—Authorization Conference Report (106-945, Section 217, Joint Biological Defense Program, p. 719). Research, development, and acquisition efforts to address homeland security, especially the threat from bioterrorism, are described at the end of this chapter.

Chapter 3 provides an analysis of CBRN defense logistics posture. The analysis reviews the status of quantities, characteristics, and capabilities and limitations of all fielded CBRN defense equipment, industrial base requirements, procurement schedules, and problems encountered. ***Annex G*** provides detailed logistics data. This chapter reflects the logistics status at the end of FY03. Assessments are being conducted during FY04 to determine the specific warfighter requirements based on the "1-4-2-1" force sizing structure and additional mission requirements for force protection, consequence management, and homeland security.

Chapter 4 assesses the status of CBRN defense training and readiness conducted by the Services. Each of the Services' training standards and programs is reviewed. In accordance with Section 1702 of Public Law 103-160 (50 USC 1522), all CBRN warfare defense training activities of the DoD have been consolidated at the U.S. Army Chemical School.

Chapter 5 provides information on the status of DoD efforts to implement the Chemical Weapons Convention, which was ratified by the United States and enforced as of 1997. This chapter also includes a summary of plans and activities to provide assistance to other countries in response to an appeal by another State Party to the Chemical Weapons Convention, pursuant to Article X of the Chemical Weapons Convention.

Finally, there are several annexes to this report. ***Annexes A through F*** provide detailed information on Joint- and Service-unique NBC defense equipment, including (A) contamination avoidance, (B) modeling and simulation, (C) protection, (D) decontamination, (E) medical programs, and (F) homeland security and installation protection programs. Detailed descriptions are provided for systems and equipment that have been fielded, are in production, or are under development. ***Annex H*** provides a summary of funds appropriated, budgeted, and expended by the DoD CBRNDP. This information supplements information in Chapter 3. ***Annex I*** provides a statement regarding chemical and biological defense programs involving human subjects as

required by 50 USC 1523. As detailed in the annex, no such testing has been conducted in over two decades, and none is planned. ***Annex J*** provides a description and assessment of the test and evaluation infrastructure of the CBRNDP in accordance with Congressional requirements stated in the FY04 Senate Armed Services Committee Authorization Report (S. Rpt. 108-46 Report Language, p. 239). ***Annex K*** provides the text of the congressional language requiring this report. ***Annex L*** provides a list of the many acronyms and abbreviations that are used throughout this report.

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I. PURPOSE OF REPORT

In accordance with 50 USC 1523, this report provides Congress with an assessment of the overall readiness of the Armed Forces to fight in a chemical and biological warfare environment. This is the eleventh report submitted under 50 USC 1523.*

II. GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

As a separate volume from this report, the Department of Defense (DoD) Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Program—or CBRND—provides a performance plan and assessment for the period of FY03–FY05. This performance plan demonstrates compliance with the requirements of the Government Performance and Results Act (GPRA), which requires agencies to submit an annual performance plan to Congress. This plan establishes a *process* by which the CBRNDP can measure the effectiveness of the various projects under the CBRNDP and assessing their contributions to the operational goals and the mission of the program. This process provides a tool for identifying strengths and weaknesses in the development and execution of programs. This plan also will act as a reference document to aid in the effective oversight and management of the program. The plan serves the purpose of providing an assessment of the performance of the most recently completed fiscal year (FY03) and provides the performance targets against which activities conducted during FY04 and FY05 will be assessed.

VISION, MISSION, AND GOALS OF THE CBRNDP

Combat weapons of mass destruction through a strong chemical, biological, radiological, and nuclear defense program.

Figure 1. CBRN Defense Program Vision

This vision statement provides focus and direction to chemical and biological defense research, development, and acquisition efforts within the CBRNDP. The vision statement for the CBRNDP has been revised to reflect changes in the national security strategy that have occurred as a result of the terrorist attacks of September 11, 2001 and the anthrax-contaminated letters in 2001. While the principal focus of the CBRNDP vision is on threats to the warfighter, the vision recognizes the increasing role that DoD personnel and assets will play in support of missions that have not been the traditional domain of the military, namely, DoD support to homeland security. A key aspect of DoD's role in homeland security is a recognition that DoD will support and rely on other federal agencies, as well as state and local emergency responders and private organizations in response to terrorist and others threats to the U.S. homeland.

* The text of 50 USC 1523, *Annual report on chemical and biological warfare defense* is included at Annex K.

The *Department of Defense Annual Report to the President and the Congress*, 2002 outlines a paradigm shift in force planning that resulted from changes outlined in the *Quadrennial Defense Review*, September 2001. The force planning contruct is know as the **1-4-2-1 Force Planning Construct**. Put succinctly, the DoD CBRNDP will support "1-4-2-1" force planning to accomplish the following:

- "The United States will maintain sufficient military forces to protect its people, territory, and critical defense-related infrastructure against attacks from outside its borders, as U.S. law permits." (that is, **1**);
- "Deter aggression in four critical theaters: Europe, Northeast Asia, the Asian littorals, and the Middle East/Southeast Asia" (that is, **4**);
- "Swiftly defeat aggression in any two theaters of operation in overlapping timeframes" (that is, **2**); and,
- "Decisively defeat an adversary in one of the two theaters, including the ability to occupy territory or set the conditions for a regime change" (that is, **1**).

In order to support the 1-4-2-1 force planning construct and to implement to program vision, **Figure 2** defines the mission for the CBRNDP. Over the next year, the Department will review this mission and the supporting operational goals to address its evolving role in combating terrorism and homeland security. Specific equipment requirements to support the 1-4-2-1 force planning construct are in the process of being defined.

Provide CBRN defense capabilities to effectively execute the *National Strategy for Combating Weapons of Mass Destruction*. Ensure all capabilities are integrated and coordinated within the Interagency community.

Figure 2. CBRN Defense Program Mission

A key element in providing a means to establish progress in fulfilling the program mission is the definition of corporate goals for the CBRNDP, as shown in **figure 3**. Corporate goals provide the broad warfighter requirements for CBRN defense operations. These operational goals provide direction for the development, acquisition, and fielding of CBRN defense equipment. The CBRNDP thus develops, acquires, and fields equipment that meets warfighter requirements while reducing acquisition costs and time of development.

The response to the threat of CBRN weapons must be based on the nature of this threat, not just where the threat occurs. A key part of DoD's strategy is to stem the proliferation of such weapons and to develop an effective capability to deal with these threats. To focus the response to the threat, DoD and the intelligence community have completed several classified reports providing assessments of chemical and biological threats to U.S. forces. To minimize the effect of these threats, DoD continues to improve defensive capabilities. These continuing improvements also contribute to our overall deterrence by demonstrating to an adversary that use of CBRN agents or weapons provides little or no military advantage. The DoD CBRNDP continues to work toward increasing the capabilities of Joint Forces to survive and continue their mission during conflicts that may involve the use of CBRN agents or weapons.

- **Goal 1: Develop CBRN defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule.**
- **Goal 2: Develop and support a science and technology base program that integrates the DoD and other Federal Agency CBRN defense research efforts.**
- **Goal 3: Oversee DoD CBRN defense modeling and simulation efforts.**
- **Goal 4: Improve DoD CBRN defense management practices – become a high performance organization.**

Figure 3. CBRN Defense Program Corporate Goals

CBRN defense capabilities are integrated as a family of systems to avoid contamination, to sustain operational tempo on an asymmetric battlefield, and to mitigate the consequences of an attack. Sound Joint doctrine and realistic training remain fundamental to defense against CBRN weapons. U.S. forces must have numerous capabilities in order to respond and deploy quickly to various worldwide needs. Counterproliferation capabilities are required by forces to meet worldwide needs, and CBRN defense is integral to counterproliferation capabilities. The Department's priorities for Counterproliferation capabilities are shown in **Table 1**. Capabilities supported by the CBRNDP are highlighted in **bold**.

Table 1. 2003 Combatant Commander Prioritized Counterproliferation Requirements

Rank	Counterproliferation Requirement
1	Timely collection, analysis, and dissemination of Strategic, Operational and Tactical level actionable intelligence to support counterproliferation and counterterrorism.
2	**Detection, identificaiton, characterization, location, prediction and warning of CW and BW agents.**
3	**Enable sustained operations in an WMD emvironment through decontamination, and individual and collective protection.**
4	**Medical protection, training, diagnosis, treatment, surveillance and countermeasures against NBC agents, to include surge manufacturing capability and stockpile availibility of vaccines, pretreatments, therapeutics and other medical products.**
5	Support for Special Operations including WMD/M interdiction.
6	**Defense against, and detection, characterization and defeat of paramilitary, covert delivery, and terrorist WMD capabilities (including protection of critical CONUS and OCONUS installations).**
7	Ballistic and cruise missile active defense.
8	**Consequence management in response to use of WMD (including civil support in response to domestic WMD contingencies).**
9	Detection, location, and tracking of WMD/M and related materials, components and key personnel.
10	Target planning for WMD/M targets.
11	Detection, location, characterization, defeat and elimination of WMD/M, NBC/M and related facilities while minimizing collateral effects.
12	Detection, location, characterization, and defeat of HDBT while minimizing collateral effects.
13	Prompt mobile target detection and defeat.
14	Protection of WMD/M and WMD/M-related materials and components.
15	Support to export control activities of the U.S. Government.
16	Support to inspection and monitoring activities of arms control agreements and regimes and other nonproliferation initiatives.

III. THE CURRENT CHEMICAL AND BIOLOGICAL WARFARE THREAT

Following is an unclassified summary as adapted from the report by the Central Intelligence Agency (CIA), *Unclassified Report to Congress on the Acquisition of Technology Relating to Weapons of Mass Destruction and Advanced Conventional Munitions*.* The CIA report provides analyses of WMD activities of several countries, including Iran, Iraq, North Korea, Libya, Syria, Sudan, India, and Pakistan. The report also provides analyses on key supplier countries, including Russia, China, and North Korea. The report also provides an analysis of CBRN terrorism, and an analysis of proliferation of WMD technologies resulting from emerging states and non-state actors. These analyses are summarized below.

CBRN Terrorism

The threat of terrorists using CBRN materials remained high. Many of the 33 designated foreign terrorist organizations and other nonstate actors worldwide have expressed interest in CBRN. Although terrorist groups probably will continue to favor long-proven conventional tactics such as bombings and shootings, the arrest of ricin plotters in London in January 2003 indicated that international mujahidin terrorists were actively plotting to conduct chemical and biological attacks. (It is not clear whether ricin attacks against Congressional offices, and perhaps other locations, were related.) Increased publicity surrounding the anthrax incidents since the September 11 attacks has highlighted the vulnerability of civilian and government targets to CBRN attacks. One of our highest concerns is al-Qa'ida's stated readiness to attempt unconventional attacks against us. As early as 1998, Usama Bin Ladin publicly declared that acquiring unconventional weapons was "a religious duty."

Individuals from terrorist groups worldwide undertook poison training at al-Qa'ida sponsored camps in Afghanistan and have ready access to information on chemical, biological, radiological, and to some extent, even nuclear weapons, via the Internet, publicly available scientific literature, and scientific conferences, and we know that al-Qa'ida was working to acquire some of the most dangerous chemical agents and toxins. A senior Bin Ladin associate on trial in Egypt in 1999 claimed his group had chemical and biological weapons. Documents and equipment recovered from al-Qa'ida facilities in Afghanistan show that Bin Ladin had a more sophisticated unconventional weapons research program than was previously known.

We also know that al-Qa'ida has ambitions to acquire or develop nuclear weapons and was receptive to any outside nuclear assistance that might become available. In February 2001, during the trial on the al-Qa'ida bombings of the American Embassies in Tanzania and Kenya, a government witness—Jamal Ahmad Fadl—testified that al-Qa'ida pursued the sale of a quantity of purported enriched uranium (which in fact probably was scam material) in Sudan in the early 1990s.

We assess that terrorist groups are capable of conducting attacks using crude radiological dispersal devices—i.e., ones that would not cause large-scale casualties, even though they could cause tremendous psychological effects, and possibly create considerable economic disruption as well. In addition, we are alert to the very real possibility that al-Qa'ida or other

* This report is updated every six months and is available on the internet at http://www.cia.gov/cia/publications/bian/pdfs/721report_jan-june2003.pdf.

terrorist groups might also try to launch conventional attacks against the chemical or nuclear industrial infrastructure of the United States to cause panic and economic disruption.

Emerging State and Non-State Suppliers

As nuclear, biological, chemical, and ballistic missile-applicable technologies continued to be more available around the world, new sources of supply emerged that made the challenge of stemming WMD and missile proliferation even more complex and difficult. Nuclear fuel-cycle and weapons-related technologies have spread to the point that, from a technical view, additional states may be able to produce sufficient fissile material and to develop the capability to weaponize it. As developing countries expanded their chemical industries into pesticide production, they also advanced toward at least latent chemical warfare capability. Likewise, additional non-state actors became more interested in the potential of using biological warfare as a relatively inexpensive way to inflict serious damage. The proliferation of increasingly capable ballistic missile designs and technology posed the threat of more countries of concern developing longer-range missiles and imposing greater risks to regional stability.

In this context, there was a growing concern that additional states that have traditionally been recipients of WMD and missile-related technology might have followed North Korea's practice of supplying specific WMD-related technology and expertise to other countries or by going one step further to supply such expertise to non-state actors. Even in cases where states took action to stem such transfers, there were growing numbers of knowledgeable individuals or non-state purveyors of WMD-and missile related materials and technology, who were able to act outside government constraints. Such non-state actors were increasingly capable of providing technology and equipment that previously could only be supplied directly by countries with established capabilities.

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Chapter 1

Department of Defense CBRN Defense Program Management and Oversight

1.1 INTRODUCTION

In accordance with 50 USC 1522, research, development, and acquisition (RDA) of chemical, biological, radiological, and nuclear (CBRN) defense programs* within the Department of Defense (DoD) are overseen by a single office within the Office of the Secretary of Defense. The Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs, ATSD(NCB), serves as this single office. This chapter describes the management and oversight processes and activities related to the effective oversight and management of the Department's CBRN Defense Program (CBRNDP). The CBRNDP mission is to provide CBRN defense capabilities to effectively execute the *National Strategy for Combating Weapons of Mass Destruction*. Ensure all capabilities are integrated and coordinated within the interagency community.

1.2 MANAGEMENT IMPLEMENTATION EFFORTS

Following the FY94 National Defense Authorization Act (P.L. 103-160, Section 1703), the DoD implemented a process to consolidate, coordinate, and integrate CBRN defense requirements and programs of the Military Departments into a single DoD CBRN defense program Through the 1994 Joint Service Agreement on Nuclear, Biological, and Chemical (NBC) Defense Management, the Military Services established a program management structure to ensure that Service operational needs were fully integrated and coordinated from their inception and that duplication of effort is eliminated from NBC defense research, development, and acquisition (RDA) programs. As the program management structure evolved, the CBRNDP was re-organized to provide a more streamlined and efficient oversight and management structure. The roles and responsibilities of all departmental organizations are detailed in the "Implementation Plan for the Management of the Chemical and Biological Defense Program," which was approved on April 22, 2003. The Department will review the plan in 2004 to make any necessary improvements or changes. The new processes, roles, and responsibilities are described in Section 1.3.

* While the scope of the public law specifically addresses only chemical and biological defense RDA activities, DoD planning also includes radiological and nuclear defense along with chemical and biological defense in its planning activities, hence the CBRN Defense Program. The only current radiological and nuclear defense capabilities include legacy systems limited to the detection of radiation. Medical radiological defense research and hardening of equipment against nuclear effects fall outside the scope of the CBRN Defense Program.

1.3 KEY ORGANIZATIONAL RELATIONSHIPS, ROLES, AND RESPONSIBILITIES

Key organizational relationships within the DoD CBRNDP are portrayed in **Figure 1-1**. The CBRNDP management structure applies to the processes (1) to conduct planning, programming, budgeting, and execution of CBRN defense *research, development and acquisition*, (2) to establish military *requirements* for CBRN defense, (3) to *test and evaluate* CBRN defense programs, (4) to manage chemical and biological defense *science and technology* programs, (5) from program analysis and integration, and (6) for program oversight.

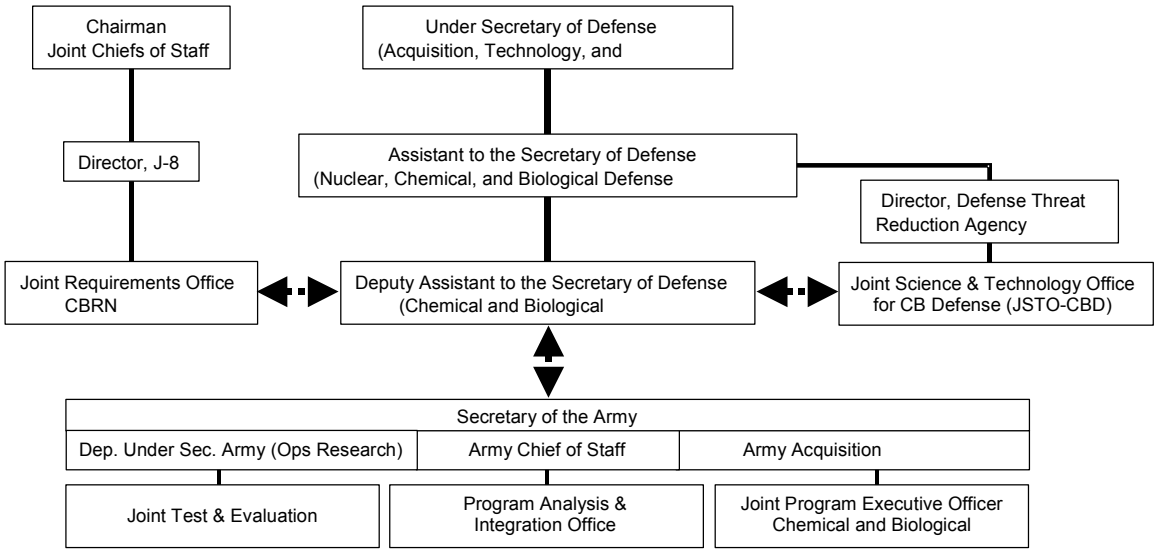

Figure 1-1. CBRNDP Management & Oversight Structure

This section summarizes selected roles and responsibilities of key individuals and organizations within the CBRNDP. The JRO-CBRN Defense was formally established on October 1, 2002. The JRO-CBRN Defense charter was approved on February 4, 2003. The establishment of a JPEO-CBD that reports through the Army Acquisition Executive was directed on September 19, 2002. The specific roles and responsibilities are detailed in the implementation plan for the management of the DoD CBRNDP, which was approved on April 22, 2003.

1.3.1 Under Secretary of Defense for Acquisition, Technology & Logistics, USD(AT&L)

The USD(AT&L) serves as the Defense Acquisition Executive (DAE) for the DoD CBRNDP. As the DAE, the USD(AT&L) serves as the Milestone Decision Authority (MDA) for the overall program and key selected systems—also referred to as "sentinel" programs.

While total CBRNDP funding surpasses the funding threshold of a Major Defense Acquisition Programs (MDAP), the CBRNDP is not categorized as an MDAP since no individual system reaches this funding threshold. USD(AT&L) funding oversight is tailored by creating an "index of systems" to measure performance of CBRNDP functional areas. These index systems are referred to as "Sentinel" systems. A Sentinel System is a program in advanced development, that represents a balance of *cost*, *complexity*, and *criticality* to justify the USD(AT&L) monitoring the cost, schedule, and performance of the Sentinel system as an

indicator of the general programmatic health, not just cost, which is the primary criteria for MDAPs.. The current Sentinel Systems are:

- Joint Biological Point Detection System (JBPDS),
- Joint Chemical Agent Detector (JCAD),
- Joint Service Lightweight Nuclear, Biological, Chemical Reconnaissance System (JSLNBCRS),
- Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD),
- Joint Warning and Reporting Network (JWARN),
- Joint Service Family of Decontamination Systems, (JSFDS),
- Next Generation Anthrax Vaccine, and
- Smallpox Vaccine.

A summary of Sentinel System performance is provided in the CBRNDP Performance Plan. The USD(AT&L) delegates Milestone Decision Authority to the Army Acquisition Executive, which are managed by the JPEO-CBD (described below), for remaining programs within the CBRNDP. In contrast to the previous organization, the new structure maintains two MDAs in a vertically integrated chain-of-command, rather than multiple MDAs that were horizontally coordinated.

USD(AT&L) responsibilities include (1) approving Overarching CBRNDP Strategic Plan, (2) establishing a CBRNDP Overarching Integrated Product Team (OIPT) within the Office of the Secretary of Defense, (3) Chair DAE Oversight Reviews for the CBRNDP, and (4) approve recommended Program Objectives Memorandum (POM) and submit to Secretary of Defense.

1.3.2 Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, ATSD(NCB)

The ATSD(NCB) serves as the single focal point within the Office of the Secretary of Defense (OSD) responsible for overall oversight, coordination and integration of the DoD CBRNDP in accordance with 50 USC 1522. The ATSD(NCB) serves as the permanent chair of the CBRNDP Overarching Integrated Process Team (OIPT). The OIPT process supports overall CBRNDP oversight. The OIPT will oversee the following Working IPTs (WIPTs):

- *Joint Requirements*—Chaired by the JRO-CBRN Defense,
- *Science and Technology*—Chaired by DTRA(CB),
- *Test and Evaluation*—Chaired by the CBRNDP Test and Evaluation Executive,
- *Advanced Concept Technology Demonstration Oversight Group*—Chaired by Deputy Under Secretary of Defense for Advanced Systems and Concepts.

Additional WIPTs may be formed by the OIPT to address specific issues. WIPTs are advisory bodies and will convene as required to address specific issues that need resolution. WIPTs will not convene as part of the normal coordination process. Unresolved issues will be elevated to the OIPT in a timely manner. Membership in the OIPT and WIPTs includes all appropriate OSD, Service, Joint Staff, and Defense Agency stakeholders. In addition, the CBRNDP has established a Council of Colonels, which will serve as a Joint *ad hoc* body to address issues and Service concerns regarding all aspects of the CBRNDP.

The ATSD(NCB) provides technical oversight of CBRNDP science and technology base (S&T) programs and reviews these programs. Science and technology programs are reviewed annually through the Technology Area Review and Assessment (TARA). The TARA includes a review of S&T programs by an independent panel of experts from academia, national laboratories, and other organizations. This panel provides assessments of key projects, overall areas within the program, and identifies any major findings or issues related to S&T.

The Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, DATSD(CBD), is the principal deputy to the ATSD(NCB) for CBRNDP matters, and the primary staff action office for ATSD(NCB) responsibilities. As the principal deputy, the DATSD(CBD) also supports the USD(AT&L) in carrying out its MDA and oversight responsibilities for the CBRNDP.

1.3.3. Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRN) Defense

The JRO-CBRN Defense began official duties on October 1, 2002. The official charter was approved on February 4, 2003. The JRO-CBRN Defense coordinates with the combatant commands and Services to develop Joint CBRN requirements, and overarching CBRN defense architecture and a joint capabilities roadmap. The JRO-CBRN Defense defines the required system interoperabilities and operational architectures and validates the development of Joint CBRN defense capabilities through both simulation and technology demonstrations. These efforts will be documented in a Joint CBRN Defense Modernization Plan for validation by the Joint Requirements Oversight Council (JROC).

The JRO-CBRN Defense is a single office within DoD under the Chairman of the Joint Chiefs of Staff responsible for planning, coordination, and approval of joint CBRN defense operational requirements and serving as the focal point for Service, combatant command, and Joint Staff requirements generation. These responsibilities include development of CBRN defense operational requirements, joint operational concepts, and architectures for passive defense, consequence management, force protection, and homeland security.

1.3.4 Military Departments

Each of the Military Departments—Army, Air Force, and Navy, including the Marines Corps—plan and execute CBRN defense programs, from basic research through procurement and sustainment. In fulfilling their responsibilities, the Military Departments ensure coordination and integration with other CBRN defense organizations. Following are selected responsibilities of the Military Departments within the CBRNDP.

- Validate Joint operational concepts and develop Service-sponsored CBRN defense requirements documents using the guidance set forth in the Joint CBRN Defense Modernization Plan. Where new materiel requirements are identified, submit requirement documents to the JRO and recommend for inclusion into the Modernization Plan.
- Include the participation of the JRO as early as possible in the concept development phase for potential CBRN defense requirements.
- Provide acquisition and fielding data for respective CBRN defense requirements to the JRO during development of the DoD CBRNDP Program Objectives Memorandum (POM).

- Support development of Service annexes to Joint CBRN defense requirement documents.
- Provide representatives to all appropriate CBRN defense meetings and organizations.
- Conduct CBRN defense training, readiness, and sustainment.
- Participate in the review, development and validation of the Modernization Plan, Joint Future Operational Capabilities, and the Joint Priority Lists.
- Perform Lead Service responsibilities to support Joint Programs as assigned by the JPEO-CBD. Figure 1-2 illustrates current Lead Service responsibilities to support Joint Programs.

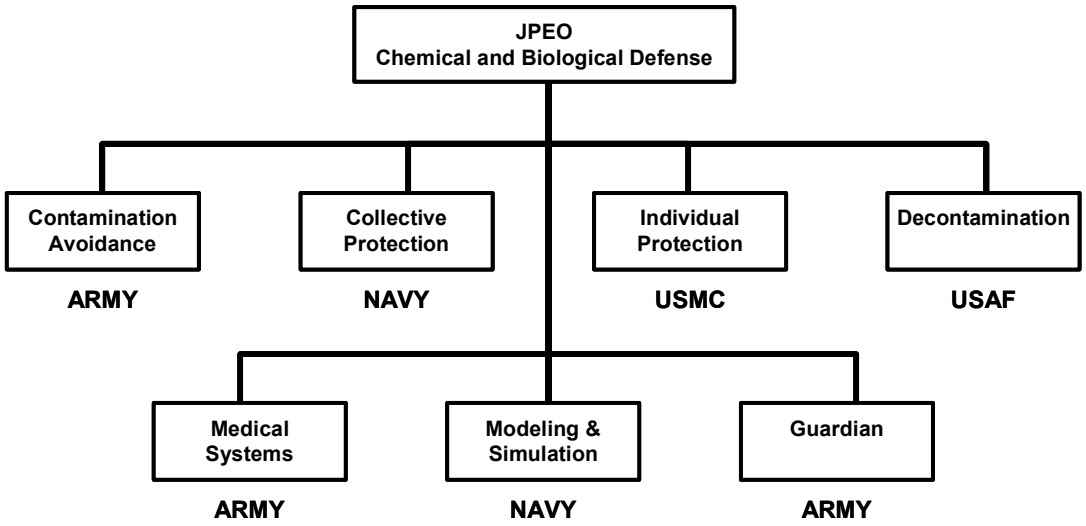

Figure 1-2. Lead Service Responsibilities for Joint Program Management within the JPEO-CBD

The military departments play a critical role in the execution of all phases of research, development, and acquisition. The military departments provide the essential infrastructure, which includes personnel with unique scientific, technical, and management expertise, and the laboratory and test facilities to meet the demands of developing and fielding CBRN defense equipment. ***Annex J*** of this report provides a detailed description and assessment of the military's chemical and biological defense test and evaluation infrastructure, and the supporting laboratory infrastructure. These include capabilities for handling live chemical and biological agents and conducting a variety of tests. Selected key military facilities, for which more detail is provided in Annex J, include the following:

- U.S. Army Edgewood Chemical and Biological Center (ECBC)
- U.S. Army Medical Research Institute of Infectious Disease (USAMRIID)
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)
- U.S. Navy Medical Research Center (NMRC)
- Naval Surface Warfare Center (NSWC), Dahlgren
- U.S. Air Force Operational Test & Evaluation Center (AFOTEC).

1.3.5 Army as Executive Agent

In accordance with 50 USC 1522, the Army serves as the Executive Agent for the CBRNDP and coordinates and integrates research, development, test and evaluation, and acquisition requirements of the military departments for CBRN defense programs of the DoD. The Secretary of the Army serves as both the Executive Agent for the CBRNDP, and the Assistant Secretary of the Army for Acquisition, Logistics and Technology, ASA(ALT), serves as the Army Acquisition Executive (AAE). Following are selected key responsibilities of Army as the Executive Agent.

- Review all funding for the CBRNDP.
- Review and recommend approval of the CBRNDP POM.
- Serve as the Milestone Decision Authority (MDA) for delegated programs, with authority to delegate to the JPEO-CBD. (Note: While the USD(AT&L) is designated as the single MDA for the CBPD, MDA status is delegated by the USD(AT&L) to the AAE. Thus there are two MDAs, though based on a single authority.)
- Serve as Joint Service Materiel Developer to coordinate and integrate acquisition for the CBRNDP through the JPEO-CBD.
- Provide Program, Analysis and Integration functions for the CBRNDP.
- Provide the Test and Evaluation Executive for the CBRNDP.
- Serve as the Joint Combat Developer for the CBRNDP through the JRO.

1.3.5.1. *Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD).* The JPEO-CBD reports to the AAE and serves as the CBRNDP Material Developer and oversees Life Cycle Acquisition Management for assigned system acquisition programs within the CBRNDP. The JPEO-CBD provides centralized program management and Joint Service acquisition program integration for all assigned non-medical and medical chemical and biological defense programs. Following are selected key responsibilities of the JPEO-CBD.

- Serve as the CBRNDP Milestone Decision Authority for delegated programs.
- Develop and approve program and acquisition strategies.
- Leverage existing or developmental Commercial-off-the-shelf (COTS) technology.
- Provide the planning guidance, direction, control, and support necessary to ensure systems are developed in accordance with DoD acquisition guidance.
- Integrate interoperability with civilian emergency response agencies in the planning, guidance, direction, and control of newly acquired systems whenever possible.
- Oversee the development, coordination, and commitment to an acquisition program baseline and ensure immediate reporting of all imminent and actual breaches of approved baselines. In addition, ensure development of a recovery plan.
- Prepare required input to POM, Budget Estimate Submission, President's Budget, and other required documentation. Support development of the annual Research, Development and Acquisition (RDA) Plan in coordination with DTRA S&T Manager and the Program Analysis and Integration Office.
- Prepare the Joint Logistics Support Plan for medical and non-medical programs for which JPEO-CBD maintains Life Cycle Management to include sustainment in cooperation with the Services and in coordination with the JRO.

- Establish Technology Readiness Levels (TRLs) and conduct reviews to identify opportunities for transition of chemical and biological S&T programs to acquisition in conjunction with DTRA.
- Ensure interagency cooperation and timely transition of technologies to advanced development programs in order to reduce development cycle times.

1.3.5.2. *Program Analysis and Integration Office (PAIO).* The PAIO supports the CBRNDP by providing analysis to the OSD oversight office, JRO-CBRN Defense, JPEO-CBD and DTRA. The PAIO provides independent analysis functions to all other elements of the CBRNDP under operational direction of the Army Deputy Chief of Staff for Programs (G8) as the Army Executive Agent.

In support of the CBRNDP OIPT, the PAIO provides independent analysis for decision-makers to enable review and recommendations concerning impacts to the overall integrated CBRNDP. This analysis includes the CBRNDP oversight process, published plans, and overall programmatic health of the CBRNDP. The PAIO will review and analyze fiscal programs, requirements, resource planning, and resource allocation for the program years. The PAIO also maintains the DoD CBRNDP Future Years Defense Program (FYDP) and provides support to the JRO-CBRN Defense for the POM build. PAIO supports the JPEO and the Program Managers to perform defense acquisition functions necessary to guide assigned programs through each milestone within approved baselines.

1.3.5.3. *Joint Test & Evaluation Executive*. The Joint CBRNDP Test and Evaluation Executive chairs the Test and Evaluation (T&E) Working Integrated Process Team (WIPT), which is overseen by the ATSD(NCB). The Deputy Under Secretary of the Army for Operations Research, DUSA(OR), serves as the T&E Executive. Members of the T&E WIPT include the Service T&E executive level representatives, JRO-CBRND, JPEO-CBD, DTRA S&T Executive, and the Director, Operational Test and Evaluation, DOT&E. This WIPT assists the CBRNDP T&E Executive to resolve major testing issues, which are then documented in TEMPs and Test Plans for DOT&E approval, as appropriate.

1.3.6 Defense Threat Reduction Agency (DTRA)

DTRA serves two key roles in support of the DoD CBRNDP—Funds Manager and Joint Science and Technology Manager. These roles are filled by DTRA's Chemical and Biological Defense Directorate, DTRA(CB), also designated as the Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD). The JSTO-CBD provides funds management functions under the oversight of the ATSD(NCB). JSTO-CBD also manages and integrates chemical and biological defense science and technology base (S&T) programs. S&T management responsibilities include the development and integration of S&T program in response to OSD and JRO-CBRN Defense guidance. The JSTO-CBD provides the necessary programming, planning, and budgeting documentation for chemical and biological defense S&T programs. The JSTO-CBD works with the JPEO-CBD to ensure effective transition of S&T efforts to advanced development. The JSTO-CBD also participates in Armed Services Biological Research and Management (ASBREM) Committee meetings to ensure coordination between medical and non-medical S&T programs. Other JSTO-CBD responsibilities include providing a DoD CBRN defense S&T liaison with various organizations (to include DARPA, industry, academia, and other government agencies), providing support for DoD CBRN defense

S&T international programs, and providing management and integration of CBRN defense ACTDs.

1.4 COORDINATION WITH RELATED PROGRAMS AND INITIATIVES

The DoD CBRNDP coordinates efforts with other U.S. government agencies and with other nations to achieve its mission to ensure all CBRN defense capabilities are integrated and coordinated within the interagency community. This section provides an overview of some key cooperative efforts.

1.4.1 Other U.S. Government Organizations

Several organizations within the U.S. government are developing CBRN defense technologies. Three organizations with which the CBRNDP currently has formal coordination efforts include: (1) the Defense Advanced Research Projects Agency (DARPA), (2) the Counterproliferation Program Review Committee (CPRC), (3) the Technical Support Working Group (TSWG), (4) the Department of Homeland Security (DHS) Science and Technology Directorate, and (5) National Institute of Allergies and Infectious Diseases (NIAID). An overview of these programs is provided below. There also are other governmental agencies with interest in CBRN defense related programs with which the CBRNDP maintains various levels of coordination and cooperation. These include the National Security Council, Department of Health and Human Services (including the Food and Drug Administration, and the Centers for Disease Control and Prevention), U.S. Department of Agriculture, and the Department of Justice, among others.

1.4.1.1. *DARPA Biological Warfare Defense Program*. DARPA is charged with seeking breakthrough concepts and technologies that will impact our national security. DARPA's Biological Warfare (BW) Defense Program is intended to complement the DoD CBRN Defense Program by anticipating threats and developing novel defenses against them. The DARPA program is unique in that its focus is on the development of technologies with broad applicability against classes of threats. DARPA invests primarily in the early technology development phases of programs and the demonstration of prototype systems.

In accordance with 50 USC 1522, the Director of DARPA shall seek to avoid unnecessary duplication of activities under the program with chemical and biological warfare defense activities of the military departments and defense agencies and shall coordinate the activities under the program with those of the military departments and defense agencies. The DARPA BW Defense Program coordinates its efforts with numerous organizations, including the DATSD(CBD) and DTRA(CB) and by participation in the Technology Area Review and Assessment (TARA) process. As an example, the Advanced Diagnostics portion of the DARPA BW Defense Program is closely coordinated with the U.S. Army Medical Research and Materiel Command (USAMRMC) and attended meetings of the Common Diagnostic Systems interagency Scientific Steering Committee that participated in strategic planning for DTO CB.26 (Common Diagnostic Systems for BW Agents and Endemic Infectious Diseases). A panel of chemical and biological defense experts is routinely consulted by DARPA to evaluate programs and to ensure that National Institutes of Health (NIH) efforts are not being duplicated. DARPA also participates in the BW Seniors Group, which provides Government coordination outside of DoD and works closely with the military Services to ensure that technologies are

effectively transitioned into the hands of the user community. Additionally, the immune building program routinely coordinates activities across government including with the EPA and DHS.

1.4.1.2. *Counterproliferation Program Review Committee (CPRC).* The National Defense Authorization Act for Fiscal Year 1994 (Public Law 103-160, §16050) established the CPRC to optimize funding and ensure development and deployment of technologies and capabilities in support of U.S. counterproliferation policy and efforts, including efforts to stem the proliferation of WMD and to negate paramilitary and terrorist threats involving WMD. The CPRC is an interagency executive committee composed of the Secretary of Defense (Chair), the Secretary of Energy (vice chair), the Director of Central Intelligence, Chairman of the Joint Chiefs of Staff, and the ATSD(NCB) as the Executive Secretary. The CPRC Standing Committee, established in 1996, meets regularly to perform the duties and implement the recommendations of the CPRC. The Standing Committee is chaired by the ATSD(NCB). The DATSD(CBD) serves as the Executive Secretary. The Congressional mandate also directs the CPRC to identify and eliminate redundancies and uncoordinated efforts, establish program and funding priorities, encourage and facilitate interagency funding, and ensure DOE programs are integrated with operational needs of other government agencies. The CPRC is also charted to report annually to congressional defense committees on the activities and programs of the DoD, the DOE, the intelligence community and the Joint Chiefs of Staff related to enhancing U.S. capabilities to counter the proliferation of NBC WMD (including their means of delivery) and NBC terrorism.

1.4.1.3. *Technical Support Working Group***.** The TSWG is an interagency forum that identifies, prioritizes, and coordinates interagency and international research and development (R&D) requirements for combating terrorism. Policy oversight is provided by the Department of State and execution oversight is provided by DoD, specifically the Assistant Secretary of Defense for Special Operations and Low Intensity Conflict, ASD(SO/LIC). The TSWG rapidly develops technology and equipment to meet the high-priority needs of the combating terrorism community, and addresses joint international operational requirements through cooperative R&D with the United Kingdom, Canada, and Israel. The TSWG also has an effective outreach program so that state and local agencies can benefit from new technology developments.

TSWG membership includes representatives from nearly eighty organizations across the Federal Government. These representatives work together by participating in one or more of TSWG's nine subgroups. One of the subgroups is the Chemical, Biological, Radiological, and Nuclear Countermeasures (CBRNC) subgroup, which is co-chaired by representatives from the Federal Bureau of Investigation and the Intelligence Community. The CBRNC subgroup identifies and prioritizes interagency chemical, biological, radiological, and nuclear combating terrorism requirements, and identifies solutions for detection, protection, decontamination, containment, mitigation, and disposal.

The DoD CBRNDP and TSWG coordinate requirements and projects to maximize leveraging opportunities. However, equipment requirements for combating terrorism may differ from equipment requirements for the warfighter due to operational, regulatory, legal, and other considerations.

1.4.1.4. *Department of Homeland Security Science & Technology Directorate***.** The Department of Homeland Security (DHS) Science & Technology (S&T) Directorate was established as to

tap into scientific and technological capabilities in the United States to provide the means to detect and deter attacks using weapons of mass destruction. DHS S&T will guide and organize research efforts to meet emerging and predicted needs and will work closely with universities, the private sector, and national and federal laboratories. As part of the federal government re-organization that occurred with the establishment of DHS, the DHS S&T Directorate assumed responsibility for the management of the Chemical and Biological Nonproliferation Program (CBNP), which was established in 1997 in response to the *Defense Against Weapons of Mass Destruction Act* ("Nunn-Lugar-Domenici") passed by Congress in 1996. The CBNP was established to ensure the full engagement of the Department of Energy (DOE) National Laboratories in responding to the threat posed by chemical and biological weapons to U.S. civilians. DoD's programs complement the DHS S&T efforts by focusing on the needs of the military and military support to civilians. The strategy of the CBNP relies on close linkages between technology development and systems analysis and integration to systematically and comprehensively address the domestic chemical and biological terrorism threat. The CBNP is comprised of three key components:

- Definition of operational needs to guide the development and implementation of enhanced preparedness and response systems.
- Use of accelerated system demonstrations to enable rapid fielding of the best available systems and technologies to meet critical needs.
- Development of individual technologies to enhance capabilities across the full spectrum of chemical and biological threats.

Many technologies under development may support both CBNP and CBRNDP missions. There are formal agreements between the CBNP and CBRNDP to ensure that efforts are coordinated and duplication is avoided. Under the CPRC (see section 1.4.1.2) DoD and DOE formally coordinate CBRN defense technology development efforts through the development of technology roadmaps. To date, the following roadmaps have been completed:

- *Integrated CB Defense RDA Plan for Departments of Defense and Energy, Chemical & Biological Point Detection, Decontamination, and Information Systems*, April 2003.
- *Integrated CB Defense RDA Plan for Departments of Defense and Energy, CB Point Detection & Decontamination*. April 2002.
- *Integrated CB Defense RDA Plan for Departments of Defense and Energy, Biological Point Detection*, March 2001.

1.4.1.5. *National Institute of Allergies and Infectious Diseases (NIAID).* Prior to the anthrax letter attacks of 2001, the public sector has held relatively little interest in medical biological defense research, because identified biological warfare threats were of minor general medical interest and also because extensive and burdensome statutory safety measures are required in order to work with these agents. By the end of FY02, DoD medical biological defense research efforts included Small Business Innovative Research (SBIR) contracts and contract arrangements with 13 universities and 16 companies in the private sector, four of which are nonprofits. Funded agreements also existed with eight other governmental agencies. The most significant related federal effort resulted from the proposed investment of approximately $1.7 billion for a Counterbioterrorism Research Program to be managed by NIAID. However, NIAID has only a

modest research investment in this area while the DoD has the infrastructure and expertise necessary to support this effort. Furthermore, NIAID's strategic plan overlaps significantly with DoD efforts. To that end, the NIAID and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the lead laboratory for medical biological defense research, have entered into an agreement to coordinate portions of their biodefense research and development programs including a shared animal facility, cooperative development of vaccines, drugs, alternate therapies and diagnostics, and development of standardized strain collections.

1.4.1.6. *Other Interagency Coordination*. The CBRNDP participates in efforts to coordinate research, development, and other efforts related to CBRN defense with other organizations throughout the federal government. Following are some highlights of these coordination efforts:

- *The InterAgency Board for Equipment Standardization and Interoperability* (known as the IAB), is a partnership with federal, state, and local agencies focused on the capabilities necessary for fire, medical, and law enforcement responses to WMD terrorism.
- Interagency Agreements with departments of Justice's Office Domestic Preparedness to purchase equipment in support of Justice's grant program.
- The White House Office of Science and Technology Policy chaired Weapons of Mass Destruction Program, Research and Development Subgroup.

1.4.2 International Cooperation

The CBRNDP participates in numerous international cooperative and collaborative efforts to leverage technology development and to achieve commonality, interoperability, and systems integration among U.S. allies and coalition partners. (In addition, there are numerous cooperative efforts in doctrine and training, which are described in Section 4.2 of this report.) In order to exchange information or conduct government to government cooperation, an appropriate agreement must be in place. Types of agreements include (1) Data Exchange Agreements (DEAs), (2) Foreign Military Sales, (3) Engineer and Scientist Exchange Programs, (4) Foreign Comparative Testing, (5) Technology Development Project Agreements, (6) equipment and material loans, and (7) Research, Development and Acquisition Memoranda of Understanding (MOU). **Table 1-1** lists examples of international cooperative efforts in FY03.

During FY03, the United States participated in numerous international cooperative research and development efforts. Highlights of these efforts include (1) 50 DEAs with 15 countries, (2) eight Technology Development Project Agreements in place or in development, (3) two MOUs, (4) 10 equipment and material loans, and (5) four exchanges under the Engineer and Scientist Exchange Program.

All cooperative agreements yield benefits to all participants in the agreement. In addition, there have been numerous CBRN defense capability gains from FY98 and through FY02 as a result of international cooperation. During FY02 under the Foreign Comparative Testing (FCT) program, the Canadian Reactive Skin Decontaminating Lotion (RSDL) that was successfully tested under the Foreign Comparative Testing (FCT) program in FY02 has been licensed as a medical device by the Food and Drug Administration (FDA), and is now in final development and will be fielded during FY04. The FCT is the same program that saw successful procurement of the NBC Reconnaissance System (Fox Vehicle), Improved Chemical

Agent Monitor (ICAM), the Automatic Chemical Agent Detector and Alarm (ACADA) and components of the Biological Integrated Detection System (BIDS).

Table 1-1. International Cooperative Efforts in Chemical and Biological Defense.

- Smallpox Vaccine Development and Acquisition.
- CB Suit Permeation.
- Next Generation Biological Detection Technologies.
- CB Clothing Testing.
- New Technologies for CB Agent Monitoring in Aqueous Environments.
- Testing of CB Protective Clothing in a Hot and Humid Environment.
- Combined Casualty Models.
- NBC Recon Vehicle Logistics.
- Challenge Levels.
- Ecotoxicology due to CW Agents and Remediation of Soil and Water.
- Medical Countermeasures to CB Agents.
- Detection of Contamination on Surfaces.
- Toxic Industrial Chemicals.
- CB Events in Operations Other Than War.
- Collective Protection.
- Effects of Wearing Individual Protective Equipment (IPE) in a Hot/Dry Environment.
- Fate and Effect of Chemical Agents.
- Next Generation Plague Vaccine.
- Standoff CB Detection.
- Detection of Mid-Spectrum Agents.

1.5 CBRN DEFENSE MODELING & SIMULATION OVERSIGHT

On 1 November 2000 the DepSecDef, delegated authority for accrediting all common use chemical and biological modeling and simulations within the Department to the USD(AT&L), who in turn has delegated this responsibility to the DATSD(CBD). The DATSD(CBD) is responsible for approving all common use[1] CB models and simulations employed by the Department or used in support of DoD planning, decision support, training, and operations. Specific responsibilities and authority is as follows:

a. Overall responsibility for collecting, coordinating, integrating, and approving requirements for departmental common use chemical/biological models and simulations.
b. Overall responsibility for reviewing, and the attendant authority for approving, rigorous independent verification and validation standards, development plans, and implementation plans for departmental common use chemical/biological models and simulations.
c. Overall responsibility and authority for directing the development, maintenance, and certification of data for chemical/biological program needs, including those of modeling and simulation.
d. Responsibility and specific authority for accrediting common use chemical/biological models and simulations for general classes of application (class accreditation). This does not replace or eliminate the need for accreditation of models and simulations for specific application scenarios (user accreditation).

To minimize unnecessary duplicative model and simulation developmental efforts within the Department, only common use CB model and simulation efforts approved for

[1] The phrase "common use models and simulations" refers to all models and simulations developed by or for or used by or on behalf of any DoD organization other than those that are of purely speculative purpose. This is deliberately more encompassing than the DoD Directive 5000.59 definition ("Provided by a DoD component to two or more DoD components").

development will be eligible for eventual class accreditation. Only those common use CB models and simulations verified, validated, and accredited by the DATSD(CBD) for general classes of applications may be fielded and utilized by the Department of Defense.

Cooperation in these endeavors with other federal agencies is encouraged, especially with the Federal Bureau of Investigation, the Department of Energy, and the Department of Commerce. However, models and simulations, including object code and data, must be accredited by the USD (AT&L) before being used by or on behalf of the Department of Defense.

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Chapter 2

Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Requirements and Research, Development, and Acquisition Program Status

2.1 INTRODUCTION

This chapter describes Joint Service CBRN defense requirements and research, development, and acquisition (RDA) programs and the status of these programs—from science and technology base through procurement. This chapter is organized according to how these RDA programs are managed and Congressional funds are appropriated. That is, RDA programs and plans are funded within the framework of the six operationally oriented commodity areas. These commodity areas (and the section within this chapter) are:

- Contamination Avoidance (2.2)
- Battlespace Management (2.3)
- Decontamination (2.4)
- Individual Protection (2.5)
- Collective Protection (2.5)
- Medical Systems (2.6)

In addition, this chapter (Section 2.7) provides a report on anthrax vaccine costs, acquisition strategy, and related issues. The six commodity areas above address the traditional warfighting activities outlined in Joint Publication 3-11, *Joint Operations in a NBC Environment*. In section 2.8, this report addresses specific activities related to CBRN defense homeland security and force protection.

The Joint Staff Joint Requirements Office for CBRN Defense (JRO-CBRND) completed a baseline capabilities assessment of warfighting operational activities in 2003. This assessment will be expanded in future assessments to include operational activities in support of homeland security, force protection, and other areas. The 2003 assessment developed a Joint Enabling Concept that outlines four operational elements—Sense, Shape, Shield, and Sustain. Core capabilities for ***sense*** include reconnaissance, detection and identification; ***shape*** includes battlespace management; ***shield*** includes individual and collective protection, and medical prophylaxes and pre-treatments, and ***sustain*** includes decontamination, restoration, and post-exposure medical capabilities (that is, therapeutics and diagnostics). The linkage between these joint functional concepts and the commodity areas is illustrated in Figure 2-1.

When a valid operational need has been identified the Services examine the range of non-material solutions first (Doctrine, Organization, Training, Leadership, Personnel) within the Joint CBRN Defense construct in order to provide the most effective force while operating in a CBRN environment. If it is determined that none of the non-material options meet the required need, equipment or materiel solutions are pursued through the materiel acquisition process. The research and development modernization process will identify technological approaches that may result in a new operational capability or an upgrade to an existing operational capability.

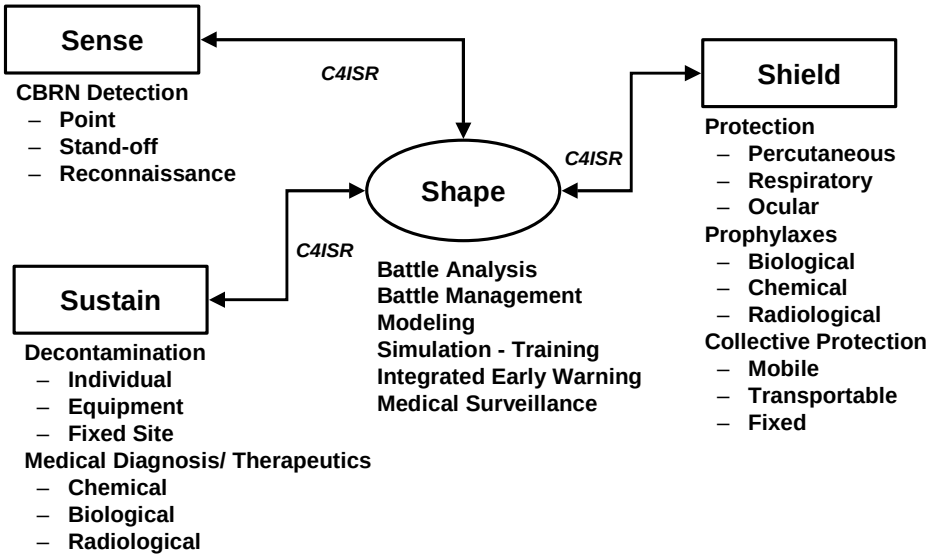

Figure 2-1 Joint CBRN Defense Enabling Concept and Supporting Core Capabilities

In accordance with the Department of Defense report, *Military Transformation: A Strategic Approach*, November 2003, the CBRNDP is pursuing a strategy of innovation that includes three components:

- *Continuous small steps* – Incremental capability enhancements generally termed "modernization"
- *Many medium jumps* – Significant capability improvements within the current American Way of War
- *A few big jumps* – New rule sets that leverage new sources of military power, creating a new American Way of War

A key element of modernization includes the need to reduce cycle time in the acquisition of new systems or the integration of emerging technologies into existing systems. The use of open systems and architectures, the emphasis on commercial standards and practices, and adoption of commercial off-the-shelf systems when applicable, allows the Department to shorten the acquisition cycle time. The program acquisition process reduces lifecycle costs through practices such as design-to-cost and concurrent engineering to ensure that equipment is easy to maintain and repair even with the inherent complexity in most new systems.

"Medium jumps" include a variety of initiatives within the CBRNDP, including the use of Advanced Concept Technology Demonstrations (ACTDs), such as the Portal Shield ACTD, which resulted in the successful fielding of a networked biological detection system to meet specific installation protection needs. In addition, block upgrades allow for the insertion of new capabilities within existing systems or platforms.

"Big jumps" include approaches to pursuing advanced technologies to significantly improve CBRN defense capabilities for the warfighter in all operational environments. This includes a continuous investment in the science and technology (S&T) base to prevent technological surprise, as well as acquisition strategies, such as the CB Defense Initiative Fund, to

solicit advanced technologies and approaches from non-tradition industrial, scientific, and academic sources.

A key programmatic and management tool within the science and technology base for supporting transformation is the use of key projects known as Defense Technology Objectives (DTOs). A DTO is a project (or a collection of closely related projects supporting a specific objective) that clearly states a specific set of objectives, the schedule, costs, specific warfighter payoffs (stated quantitatively against two or more metrics), and the customers for whom the technology is being developed (*e.g.*, the JRO-CBRND or a specific Combatant Commander). DTOs represent high priority projects that are consistent with the DoD S&T strategy and with User guidance as expressed in the CBRN Defense Joint Future Operational Capabilities (JFOCs) and the Joint Staff-developed CBRN Defense Baseline Capability Assessment (BCA) capability gaps. In addition to providing the foundation for the S&T program, the DTO construct is also a major source for fulfilling Government Performance and Results Act (GPRA) requirements. DTOs are proposed, reviewed, and updated annually.

Two types of DTOs exist—*applied technology* and *enabling technology*. An applied technology DTO is product oriented and targets specific technology advancements to be developed or demonstrated in support of a needed operational capability. An enabling technology DTO focuses on the development of knowledge to address a specific issue, and is a necessary intermediate step to achieve an operational capability.

Medical CBRN S&T efforts increasingly rely on enabling technology DTOs to evaluate multiple medical countermeasure technologies at the laboratory level, in order to select to one or more lead technologies for further evaluation in a follow-on applied technology DTO and before committing to rigidly controlled pivotal nonclinical studies. In medical programs, the applied technology DTO is intended to bring a mature medical countermeasure candidate forward for transition into advanced development and preparation of an investigational new drug (IND), evaluation in human clinical trials, and eventually, FDA licensure of a medical chemical and biological defense product for use by joint service members.

In addition to the use of DTOs, the CBRN defense technology base incorporates basic and applied research, including studies involving CBRN threat agents and toxicology, which supports development across all commodity areas. Understanding established and emerging CBRN threats is a critical factor supporting the overall CBRN defense program. Toxicological and pathological determination of operationally significant exposures to threat agents is fundamental to developing target requirements for materiel solutions across all commodity areas.

Within the science and technology base, the CBRNDP uses the Small Business Innovative Research (SBIR) program to elicit innovative solutions from the small business community that addresses chemical and biological defense technology gaps confronting DoD and that develop technologies having high commercialization potential in the private sector. (Information on CBD SBIR projects is provided in section 5.2.7 of the DoD CBRNDP Performance Plan.) SBIR topics are developed in each of the following capability areas to address both chemical and biological threats: detection; protection (individual and collective); decontamination; modeling & simulation; and supporting science (basic research). Additionally, specific program areas include chemical and biological defense medical technologies that address pretreatments, therapeutics; diagnostics; and emerging threats.

2.2 CONTAMINATION AVOIDANCE (Reconnaissance, Detection, and Identification)

The commodity area of contamination avoidance includes capabilities for CBRN reconnaissance, detection, and identification. For fixed sites where contamination cannot be avoided or for missions requiring operations in a contaminated environment, reconnaissance, detection, and identification are critical to ensure that forces can assume the optimal protective posture so that they can continue to sustain operations and rapidly identify and decontaminate (if possible or necessary) affected areas, equipment, and personnel. Sensors for the individual warfighter and systems capable of detecting multiple agents and characterizing new agents are being developed. Advances in technology are being pursued in the areas of chemical and biological standoff detection, early warning detection, miniaturization, and interconnectivity; enhancements in detection sensitivity, interference rejection, logistics supportability, and affordability are also being addressed. The following sections detail contamination avoidance science and technology efforts, modernization strategy, and Joint Service programs.

2.2.1 Contamination Avoidance Science and Technology Efforts

2.2.1.1 Goals and Timeframes. The goal of contamination avoidance is to provide a real-time capability to detect, identify, characterize, quantify, locate, and warn against all known or validated CBRN warfare agent hazards (see **Table 2-1**). To meet near-term needs, a number of sensor technologies are being optimized while alternative detection technologies mature. Mid-term technologies focus on developments to improve tactical detection and identification capabilities for both chemical and biological warfare agents. Far-term science and technology efforts focus on multi-agent sensors for CBRN agent detection and remote/early warning CBRN detection. These far-term objective technologies seek to integrate chemical and biological point and remote/early warning detection modules into a single system, the Joint Modular CB Detection System. Research and development efforts seek to optimize and balance system sensitivity, size/weight, cost, power consumption, signature suppression and false alarm rate. Ultimately the goal is direct integration of CBRN detectors as a single system into various platforms linked into command, control, communication, computer, and intelligence (C^4I) networks.

As identified in the *Defense Technology Area Plan* and the *Joint Warfighting Science and Technology Plan*, the following are Defense Technology Objectives (DTOs) focused on near and mid-term science and technology goals.

New and Ongoing DTOs:*

- Stand-off Biological Aerosol Detection
- Chemical Biological Agent Water Monitor
- Lightweight Integrated CB Detection
- Detection of CB Contamination on Surfaces
- Activity-Based Detection and Diagnostics (DARPA program)
- Wide Area Aerial Reconnaissance for Chemical Agents

Completed DTOs:

- Automated Genetic Identification
- Biological Warfare Defense Sensor System (DARPA program)
- Terrorist Chemical/Biological Countermeasures (TSWG program)

* DTO descriptions are provided in Annex A.

Table 2-1. Contamination Avoidance Science and Technology Strategy

By 2004	By 2009	By 2014
• Complete Milestone A for Joint Chem/Bio Agent Water Monitor. • Complete technology downselection for system concept (s) in meeting Joint Modular Chem/Bio Detection system (JMCBDS). • Demonstrate laser enhanced RAMAN technology to detect the presence of chemical agents on surfaces). • Demonstrate enhanced aerogel-based biological agent sample collection capability. • Continue development of the Joint Biological Standoff Detection System (JBSDS) Block I.	• Demonstrate Chemical Imaging Sensor for wide area detection. • Complete development and initiate production of Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD). • Complete development of Artemis (Chemical Agent Standoff Detection System). • Complete development and initiate production of Joint Chemical Agent Detector (JCAD). • Complete development of Block II Joint Biological Point Detection System (JBPDS). • Complete fielding of JBSDS Block I. • Complete development of the JBSDS Block II. • Complete fielding of Portal Shield production systems to 21 critical sites.	• Demonstrate integration of chemical and biological agent detection modules into a single sensor suite. • Complete fielding of the Block II JBPDS. • Complete development of CB water monitor. • Initiate development of the Joint Modular Chem/Bio Detection System (JMCBDS).

2.2.1.2 Potential Payoffs and Transition Opportunities. Future CBRN detection systems will provide the capability to detect, identify in real time, map, quantify, and track all known CBRN contamination in a theater of operations. This will enable commanders to avoid CBRN contamination, determine the need for and verification of effective reconstitution procedures, and assume the appropriate protection required to continue fighting and sustain their mission with minimal performance degradation and casualties. CBRN detection technologies have dual use potential in Occupational Environmental Health Surveillance for monitoring air pollution, noxious fumes inside enclosed areas, and municipal water supplies.

2.2.1.3 Major Technical Challenges. The major technical challenges are in the areas of biological collection, detection and identification, including remote/early warning sensing, improved agent discrimination and quantification, sample processing, interferent (*i.e.*, false positive and negative alarms) and ambient biological background rejection. Size, weight, and power reduction of detectors, power generation and consumption, development of integrated biological and chemical detection systems, and the fusion of sensor data with mapping, imagery, and other data for near real-time display of events are other challenges.

There are two critical challenges facing biological agent detection. Current technologies require a *high level of logistical support* and *lack discrimination in biological standoff detection*. The challenge in reducing logistical support stems from dependence on reagents and tradeoffs among size, weight, and power requirements of the systems. Several efforts are aimed at providing minimum reagent requirements with higher sensitivity, better stability, and fewer supporting reagents, and scientific and engineering strategies to reduce size, weight, and power requirements, especially in the sample collections components. There are several factors directly limiting the ability to discriminate biological agents using standoff detection technologies. Key factors include: (1) a lack of fundamental data in understanding the spectral properties of biological warfare agents, (2) range limitations due to atmospheric absorption, and (3) natural background interference. Over the last two years, a number of strategies and concepts have been developed to improve the discrimination capability of standoff detection for biological materials.

2.2.2 Contamination Avoidance Modernization Strategy

The increased lethality and heightened operational tempo of future battlespaces demand responsive detection and warning capabilities in order to reduce force degradation caused by CBRN contamination. These capabilities—which encompass reconnaissance, detection, identification, and reporting—are critical for force readiness and will continue to be emphasized by the DoD community in the near and far term. **Table 2-3** shows the roadmap of DoD requirements for contamination avoidance, and highlights capabilities being developed and procured in the near term, and developmental programs that are planned to be available in the mid to far-term. Fielded legacy systems maintained by the Services through their operations and maintenance (O&M) accounts are not indicated in this table. While the near-term requirements primarily address service-specific needs, those in the mid to far-terms primarily address Joint Service needs.

Early detection and warning are keys to avoiding CBRN hazards. As a result, DoD is investing in RDA efforts to provide the warfighters real-time capabilities to detect, identify, quantify, and warn against all CBRN warfare hazards. Real time detection of biological agents is currently unavailable and is unlikely in the near to mid-term, though investment efforts are focused on reducing detection times. The near to mid term focus is on developing stand-alone detectors and sensors, system miniaturization, improved sensitivity and specificity, agent characterization, range, decreased false alarm rate, and decreased operation and support costs. This focus will facilitate the integration of chemical detectors into personal warfighter gear (Objective Force Warrior Program (OFW)), CBRN detectors onto various air, sea, and ground platforms, and integration of detectors into automated warning and reporting networks. Table A-1 in Annex A provides an overview of current and planned RDA efforts and Service involvement. Fielded legacy systems maintained by the Services through their O&M accounts are described in the annex.

2.2.3 Joint Service Contamination Avoidance Programs

Within the Joint CBRN Defense Program, Service contamination avoidance needs are addressed by eleven fully coordinated joint projects. **Table 2-2** highlights Joint programs; Service-unique programs are italicized. The Joint Programs are:

- Automatic Chemical Agent Detection Alarm (ACADA).
- Joint Chemical Agent Detector (JCAD).
- Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD).
- Artemis (Chemical Agent Standoff Detection System).
- Joint Biological Point Detection System (JBPDS).
- Joint Biological Standoff Detection System (JBSDS).
- Joint Service Light NBC Reconnaissance System (JSLNBCRS).
- Joint Warning and Reporting Network (JWARN).
- Joint Chemical Biological Agent Water Monitor (JCBAWM).
- Joint Portal Shield.
- Critical Reagents Program.

2.2.4 Other Contamination Avoidance Programs

The Multimission Sensor (MMS) Program uses existing radars to provide early warning of a suspected CBRN event to allow timely dispatch of a dedicated CBRN sensor to confirm or deny the existence of the CBRN event. The MMS Program is composed of four parts: Chemical and Biological Advanced Situational Awareness Program (CB ASAP), Homeland Defense Chemical and Biological Umbrella (HD CBU), Chemical and Biological Portable Radar (CBPR), and the Research & Technology (R&T) Enhancement Efforts. CB ASAP is the military part of the program while HD CBU supports the civilian need. CBPR can support the military need, the civilian need, or both. The R&T Technology Enhancement Efforts includes the scientific work (di-electric constant and settling rate studies) to support the military and the civilian sides of the program.

As part of the HD CBU Program, the MMS Team conducted water release trials at Canadian River, Oklahoma from November 13-17 2003. These tests were conducted in coordination with The Oklahoma City Emergency Operation Center (EOC), Environmental Protection Agency (EPA), Massachusetts Institute of Technology Lincoln Laboratories (LL), and Federal Aviation Administration (FAA). These tests are the third in a series of tests designed to evaluate the feasibility of radars for early warning of chemical or biological release. The data collected will be used to develop and validate the radar early warning software. Only water was disseminated from a crop duster flying specific routes utilizing pre-determined release rates and aircraft speeds.

2.2.5 Defense Advanced Research Projects Agency (DARPA) Programs

There are four related programs within DARPA (three ongoing and one recently concluded) that contribute to the development of advanced sensor technology: BW defense environmental sensors, tissue-based biosensors, pathogen genome sequencing, and microfluidic molecular systems.

DARPA BW Defense Environmental Sensors Program. DARPA is developing technologies to enable bioagent detection and identification to include environmental sensors, optically based biosensors, tissue-based biosensors, pathogen genome sequencing, and microfluidic molecular systems.

One approach involves the development of high performance, deep ultraviolet semiconductor laser diodes to be used in compact, reliable, and inexpensive biosensors based on the principles of laser induced fluorescence and ultraviolet resonance-enhanced Raman spectroscopy. The new semiconductor laser diodes will enable the practical use of multiple excitation sources in a single compact sensor, thereby leading to a reduction in false alarms. These sensors will be able to detect viruses, bacteria, and toxins. This program is in its second year of a four-year effort.

Technologies using universal polymerase chain reaction (PCR) probes are being developed to permit the detection and identification of known threats as well as to provide significant potential for identifying engineered agents. Another effort, seeking to use ribosomal RNA to eliminate the need for amplification, is developing a multiplexed chip to reveal BW agent family, genus, and species on a single chip; the chip is structured to take advantage of the environmental hierarchical phylogenetic classification of microorganisms.

A mass spectrometer is being miniaturized for potential use in identifying BW agents and contaminants without the use of liquids, with the goal of establishing end-to-end time faster than one minute. A desktop mass spectrometer using an infrared (IR) laser analysis of the biological sample has been developed by DARPA and commercialized for analysis of biological agents. These systems may be automated for unattended operations.

Another line of research is the integration of several technologies to provide significant improvements in bio-detector capabilities. The DARPA spectral sensing of biological aerosols (SSBA) program is exploring combinations of technologies such as aerodynamic particle focusing, ultrasonic focusing, fluorescence lifetime measurement, mass spectroscopy, and Raman spectroscopy, in conjunction with advanced signal processing to capitalize on potential synergies. Detection technologies that provide information on BW agent pathogenicity, antibiotic resistance and viability are also being developed under the DARPA biological detection program.

DARPA is developing several new technologies for the detection and identification of chemical warfare agents and toxic industrial chemicals in a building environment. Novel approaches to infrared and ion mobility spectroscopy offer the potential for significantly increased sensitivity and reduced false alarms.

DARPA is developing technologies to enable the detection of bioagents in a handheld device through the utilization of advanced isothermal detection methods for DNA, RNA and protein based threats. This technology will enable the realization of a handheld device, operated by military personnel in field environments that will be capable of identifying biological weapon threats across the entire threat spectrum including bacteria, viruses and toxins at the same level of performance currently achieved in the laboratory.

DARPA Activity Detection Technologies Program. DARPA is exploring the development of activity detection systems which report on functional consequences of exposure (mechanism and activity) to a wide spectrum of chemical or biological toxins, whether they are living or dead, or whether they have been bioengineered and are currently undetectable by other means (antibodies, nucleic acid sequencing). These systems incorporate enzyme based, cellular or tissue based assays, and a number of technical issues are being addressed in the program including (1) the fabrication of biocompatible matrices and interfaces for the long-term retention of cell and tissue function, (2) pattern recognition from critical pathways responsible for the processing of toxins, (3) sampling strategies to accurately extract and present the toxin from air, liquid, or solid samples, and (4) systems integration into a functional device. One current focus of the program is the use of neuronal and immunological cells and tissues as detectors for such devices. Engineering of cells and tissues of these origins, including stem cells, is proceeding in order to optimize sensor performance requirements and fabricate prototype devices for testing and evaluation.

DARPA Pathogen Genome Sequencing Program. DARPA is sequencing the genomes of high threat BW agents. This effort, undertaken with broad community interaction, will support DARPA BW Defense research activities and is intended to satisfy the needs of DoD components, the Intelligence Community, and other governmental organizations. Interest is focused on BW pathogens, and selected non-pathogenic near neighbors thought to be important to establish

a basis for low false alarm detection and identification. The work also contributes to the development of advanced unconventional pathogen countermeasures.

DARPA Microfluidic Molecular Systems Program. This program had the goal of developing micro total analysis systems through focused research on microfluidic, chip-scale technologies. This program concluded in FY02. Several demonstrable handheld prototypes, such as a programmable microfluidic system for remote sensors, were tested. Automated sample collection and sample preparation are key front-end processes for early biological agent detection, whether it is by immunoassays, DNA assays, or tissue-based assays. To scale down these processes into miniaturized, multiplexed detection systems, microfluidic chip-scale components was the aim of this program. Microfluidic components/devices that were investigated include chip-scale micropumps/valves, particle separation filters, fluidic interconnects, fluidic manipulation of hybridized microbeads, controlled mixing/dosing, *etc*.

Table 2-2. Contamination Avoidance Modernization Strategy

	Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
Chemical Point Detection	• Surface off-gas sampling capability (ICAM) • Automatic point detection of nerve and blister agents (ACADA) • Navy-*Ship based improved automatic point detection of nerve/blister (IPDS)*		• Improved, all-agent programmable automatic point detection; portable monitor, miniature detectors for aircraft interiors; interior ship spaces; wheeled and tracked vehicles; and individual soldiers (JCAD)	• Improved surface contamination monitor • Detection of CB contamination in water (Joint Chemical Biological Agent Water Monitor, JCBAWM)
Biological Point Detection	• Navy-*Ship based Interim Biological Agent Detector (IBAD)* • Army-*Biological Integrated Detection System (BIDS)*	• Detection System, Biological Agent: Joint Portal Shield provides an automated network biological detection capability to protect high value fixed sites. • Automatic long line source and point/mobile biodetection to detect and identify bio-agents; programmable (JBPDS Block I)	• Complete development of Block II JBPDS – increase number of agents detected and identified with increased sensitivity, lower false positive rates; smaller and lighter with increased reliability. • Program start (FY09) for Joint Modular Chem/Bio Detection System (JMCBDS)– small lightweight biodetector – networked system.	• Automatic point biodetection, to detect and identify; programmable (JBPDS Block II) • Automated, integrated detection of both biological and chemical agents in a single sensor package (Joint Modular Chemical/Biological Detector System, JMCBDS) • JCBAWM (See above)
CBRN Reconnaissance and CB Remote and Stand-off Detection	• Improved CBRN Reconnaissance Vehicle with remote/early warning and data fusion capabilities (M93A1)	• Lightweight passive stand-off detection for chemical agent vapors (JSLSCAD)	• Add biological detection and identification capabilities (JSNBCRS P3I) • Light reconnaissance vehicle (JSLNBCRS) • Integrated CBRN detection (point/standoff)/identification/ sampling (Army-NBCRV Block II/IAV-NBCRV) • Automated biological remote detection and early warning capabilities (JBSDS Block I)	• Automated biological remote detection and early warning capabilities (JBSDS Block II) • Artemis (Chemical Agent Stand-off Detection System), detection, ranging, and mapping of chemical rains, vapors and aerosols • Wide area detection • Single, fully-integrated multifunctional NBC Recon platform with NBC Unmanned Ground Vehicle System (UGVS) capability (IAV-NBCRV)
Radiation Detection	• Army, Marine Corps-AN/PDR-75, AN/VDR-2 RADIAC • Army-AN/PDR-77 RADIAC • Air Force-ADM-300A • Navy-Multi-function RADIAC	• Army, Marine Corps -*Compact, digital whole body radiation measurement (AN/UDR-13)*		• Stand-off radiation detection and measurement • Portable radiation meter

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (italicized text).
2. Where applicable, systems which meet requirements are listed following the entry.

* continuing procurement in near term.

2.3 BATTLESPACE MANAGEMENT

The Battlespace Management area seeks to develop the capability to use automatic collection and fusion of information from all CBRN defense assets throughout the battlespace and integrate that with other relevant battlespace information and C^4I systems. It will integrate threat information, CBRN sensor and reconnaissance data, protective posture data, environmental conditions, medical surveillance, and other data pertaining to the CBRN conditions in the battlespace. The end result of this capability is the rapid dissemination and display of operationally meaningful information to commanders and units at all levels to support decision making related to the CBRN Defense mission, such as joint force protection, restoration of operational tempo, and casualty care treatment.

Warning and reporting is a critical component of this capability. It provides the critical link between CBRN detection and CBRN protection and provides situational awareness to the commander. Warning and reporting provides the hardware and software to connect detection systems into the overall command and control architecture. Additionally, it provides information and analysis capabilities to enhance hazard forecasting and assessment, and operational decision-making. The goal of warning and reporting is to provide sufficient, accurate, and timely information to commanders at all levels through early and direct warning capabilities so they can assume appropriate protective postures and develop options to continue mission-essential operations.

The Services have agreed to expedite development of this capability by integrating ongoing hardware and software into a Joint Warning and Reporting Network (JWARN). The JWARN will provide Joint forces with a comprehensive analysis and response capability to minimize the effects of hostile CBRN attacks or accidents/incidents. It will provide the operational capability to employ CBRN warning technology which will collect, analyze, identify, locate, report, and disseminate CBRN threat information. JWARN will be compatible with and integrated with Joint/Service C4ISR systems and networks. To improve the prediction of CBRN hazard effects, JWARN will utilize the Joint Effects Model (JEM) and the Joint Operational Effects Federation (JOEF) simulator.

The JWARN Block I effort began fielding the first version of software in FY98. The JWARN Block II effort commenced in FY01. The JWARN program achieved a Milestone B (MS B) decision in July 2003. Subsequent to MS B, a contract was awarded and the acquisition strategy was revised. Currently, the acquisition strategy is awaiting approval by the USD(AT&L). The new acquisition strategy will eliminate the incremental development of JWARN and combine Block II and Block III into one increment and will address hardware and software integration onto Service designated platforms and installation at fixed sites.

An integrated warning and reporting network will enhance the overall approach used in the chemical biological defense strategy. The enhancements will come from a warning and reporting network that is linked to numerous point detectors, such as JCAD (FY09), which will identify and quantify chemical threats, and which will be cued by early warning systems, such as JSLSCAD and Artemis. The JWARN Block III effort includes a JWARN Component Interface Device (JCID), which provides connectivity to legacy and developmental CBRN sensors/detectors via wire and/or wireless communication. The information from all the sensor systems in the operational theater becomes available to various command levels with

appropriate levels of resolution determined by the command decision needs. For example, a fixed facility commander can determine the appropriate level of protective posture by monitoring the direction of an ongoing attack or the effects of weather in moving contamination in a post attack situation.

Battlespace Management also provides tools for the warfighter to understand a specific challenge and evaluate proposed solutions. These systems provide the warfighter with a full spectrum of capabilities to automatically create warning reports and situational awareness from sensory input, and perform hazard analyses, operational effects analyses, and accurate training. Modeling and simulation capabilities are used to provide situational awareness, to provide hazard warning and prediction, and for planning or modification of operations. In the future, modeling and simulation capabilities will be used to provide warfighters and decision makers at every level of command with the ability to analyze courses of action immediately prior to or in concert with response objectives. In addition, modeling and simulation aids in the assessment of Joint and Multi-Service doctrine, training, materiel development, and equipment design (i.e., Simulation Based Acquisition). Modeling and simulation is also used to support warfighter training and the training of battle staffs using larger conflict simulations. In the latter aspect, modeling and simulation is used to perform and support analyses of CBRN defense operations within the context of larger military operations. Analytic systems such as models are also critical components of larger systems, such as JWARN and command and control systems. These efforts also support simulation-based acquisition in the development of critical CBRN defense capabilities.

The following sections provide a summary of the Information System science and technology efforts, modernization strategy, and Joint Service programs, which support the Battlespace Management area.

2.3.1 Information Systems Science and Technology Efforts

The Information Systems science and technology efforts include four sub-areas to fully meet the CBRN Defense Joint Future Operational Capabilities (JFOCs). A primary JFOC focus is on capabilities to provide improved battlespace management, characterization of the CBRN environment, information systems, and simulation based acquisition. To provide improved characterization of the CBRN environment, efforts are continuing to provide advanced hazard assessment methodologies, to address specific environmental flow regime issues (such as high altitude and urban transport and diffusion (T&D) methodologies) and to support first principle physics, chemistry, and meteorology efforts. Battlespace Management information systems technologies are addressing operational effects and processes for fixed site simulations, as well as advances in conflict simulation methodologies and distributed information systems. The technology base efforts also leverage information on weapons effects, medical, and larger DoD Modeling and Simulation communities to address source term and toxicology, interoperability and architectural issues. [NOTE: Dispersion is the combination of T&D. T&D only refers to the airborne behavior of a contaminant. The DoE uses transport and fate to address additional physical processes. Hazard assessment includes all of these factors, plus the inclusion of source characterization and toxicity.]

2.3.1.1 Goals and Timeframes. The goals of CBRND information systems science and technology efforts are as follows:

- support the warfighter directly through existing C^4I networks and information systems,
- support the operational and national command authority with CBRND environment decision systems,
- support DoD level theater and warfare simulation efforts, and
- support materiel acquisition programs with Simulation Based Acquisition (SBA) tools and architectures.

Table 2-3 shows specific efforts supporting theses goals. Current modeling capabilities are designed to support warfighter efforts to conduct scenario simulations prior to engagements and to train in a realistic manner. Recent advances allow CBD planning to be folded into larger conflict simulation and consequence management tools. SBA tools will be used for detectors in conjunction with other CBD environment models to assess acquisition strategies for several Service/Joint detector and platform acquisition programs. The next generation T&D methodologies will provide a multi-fidelity capability, which will allow the warfighter increased flexibility and more responsiveness to threat and hazard predictions. The far-term capabilities will include a near-real-time operational hazard prediction capability. An ongoing effort in modeling is the incorporation of specific advances in the characteristics of contamination avoidance, decontamination, medical and protection systems into models so that warfighters are able to evaluate and plan for advances. Integrated conflict simulation capabilities are also envisioned to meet theater and strategic simulation requirements.

Table 2-3. Information System Science and Technology Strategy

By 2004	By 2011	By 2016
• Demo improved VLSTRACK Version 3.2 for CHEMRATS • Continue efforts with MESO and CBW Computational Fluid Effects (CBW-CFX) technologies • Demonstrate Sea port of debarkation capability: Simulation Training and Analysis For Fixed Sites (STAFFS) • Initiate Joint Effects Model (JEM) acquisition program • Provide an urban dispersion model to JEM • Develop common accreditation standards for models	• Demonstrate and transition MESO and CBW-CFX methodologies to JEM • Demonstrate and transition STAFFS • Demonstrate and transition Joint Medical NBC Decision Support Tool to JOEF • Detection Simulation-Based Acquisition (SBA) application transitioned to Virtual Prototyping Systems (VPS) • Collective Protection SBA application to VPS • Virtual Emergency Response Training System (VERTS) transitioned to Training Simulation Capability (TSC) Block I • Demonstrate emerging advanced information system technologies	• Demonstrate advanced system architectures for JEM and JOEF • Demonstrate real-time, course-of-action decision making options technology • Demonstrate micro scale weather forecast hazard prediction capability • Demonstrate mobile forces CBD operational effects capability • Demonstrate emerging advanced info systems technologies • Decontamination SBA applications transitioned to VPS

Defense Technology Objectives (DTOs) with a modeling & simulation (M&S) or Information System focus include:

- DTO CB.43, Chemical and Biological Warfare Effects on Operations,
- DTO CB.55, Chemical and Biological Hazard Environment Prediction,
- DTO CB.42, Environmental Fate of Agents, and
- DTO CB.62, Hazard Prediction with Nowcasting.

The objective of DTO CB.43 is to develop a general-purpose model of the operations of large fixed-site facilities [air bases, aerial ports of debarkation (APODs) and seaports of debarkation (SPODs)], with the capability to represent CBRN hazards and their operational impacts. DTO CB.55 will focus on needed methodologies for advanced real-time hazard prediction capabilities. DTO CB.42 will provide required data for accurately predicting the fate of chemical agents on surfaces of military interest. DTO CB.62 will provide the high-resolution meteorological forecasting capabilities that are only required for CBRN operational decision making processes.

2.3.1.2 Potential Payoffs and Transition Opportunities. Future information systems will enhance C4ISR systems with a level of situational awareness with significant improvements including: accurate information, knowledge, and predictions of threats, the environment, operational alternatives and effects in real time, accelerated time, or as required. This will enable commanders to control the battle, analyze the need for CBRND actions, verify effective deployment of CBRND assets and reconstitution procedures, assume the appropriate protection required to continue operations, and sustain their mission with minimal performance degradation and casualties. CBRN M&S technologies have dual use potential, e.g., predicting and responding to civil support concerns such as terrorist activities, air pollution alerts, toxic industrial chemical (TIC) releases, both outside and inside enclosed areas, and the safeguard of municipal water supplies. The key payoffs of M&S include: (1) commanders and battle staffs are better trained and able to analyze alternate courses of action with advanced simulations, (2) there is less confusion and more consistent decision making via use of a federation of analytical and real time CBD environment M&S tools, (3) CBRND systems and operational concepts match requirements more closely because warfighter feedback is captured earlier in the development cycle under the tenets of SBA, and (4) 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

2.3.1.3 Major Technical Challenges. Major technical challenges for M&S include the following: (1) modeling and validating the effects of complex and urban terrain on CBRN hazards, (2) modeling and validating high altitude threat intercept effects, (3) modeling and validating human effects and small unit behaviors in a CBRN environment, (4) modeling and validating effects of low level and long term exposures, (5) effectively quantifying the effects that CBRN hazards have on complex fixed site operations, (6) integrating CBRN effects and operations with C4I systems for training and operations, (7) interjecting CBRN effects into combat and materiel evaluation simulations with adequate fidelity without bringing the simulations to a standstill, and (8) developing engineering level models of CBRN defense equipment that can participate in distributed simulations to support SBA from inception to system retirement.

2.3.2 Battlespace Management Modernization Strategy

The CBRN Battlespace Management modernization strategy has been divided into two major pieces: The Warning and Reporting (W&R) Systems and the Modeling and Simulation (M&S) Systems. During FY2001, the JSMG and the JSIG prepared a Draft *Modeling and Simulation Master Plan* that details the modernization strategy and RDA efforts for M&S within the CBRNDP. **Table 2-4** shows the roadmap of DoD requirements for both warning and reporting and modeling and simulation, and highlights capabilities being developed and procured and the

near term and developmental programs that are planned to be available in the mid to far-term. Legacy systems that are still maintained by the Services are not indicated here.

W&R systems combine hardware with information systems solely as a result of the need to create the physical means to automatically provide sensor system data to the information system and consequently to provide the resulting information in an effective manner to the human operator. Therefore, W&R systems have evolved from platform based (ANBACIS and MICAD) efforts to the more generic JWARN system hosted on C4ISR systems with the capability of receiving data from or controlling all legacy and future CBRN sensors. Like M&S Systems, W&R systems though capable of stand-alone operation, are typically hosted on other major hardware and software systems.

The M&S Master Plan also highlights coordination efforts with other organizations throughout the Department. As a result of the oversight responsibilities for all DoD CBD M&S efforts being assigned to the DATSD(CBD) in November 2000 (see section 1.5 for details), there were several key changes to the CBD M&S program. The CBD M&S program includes efforts from technology base through full-scale system development and demonstration. The Joint Effects Model (JEM) program is based upon the proven technologies of existing agent hazard assessment models and the emerging operational requirements document, which articulates the Joint Service needs. The JEM program achieved Milestone A in May 2001.

The Joint Operational Effects Federation (JOEF) program achieved Milestone A in February 2002. JOEF will be the acquisition program that addresses operational consequence analysis requirements. JOEF will use JEM to predict or analyze the nature of the hazard area, but will take that information and use a federation of other models and simulations to meet a specific operational commander's or other authority's needs. The combination of JEM and JOEF will meet the entire spectrum of the users needs for analytical M&S systems.

Analysis and training are the keys to being prepared for and responding to a CBRN event. As a result, DoD is concentrating RDA efforts on providing its warfighters and decision makers with analytical systems to predict or forensically analyze events and courses of action for the full spectrum of CBRN threats. In the near term, efforts are focused on taking advantage of technology development in hazard assessment methodologies to provide interim accreditation for a number of analysis regimes. In addition, efforts in operational effects and SBA will be prepared to transition to full scale development programs. In the mid-term, first priority has been given to transitioning the most mature technologies to the new start JEM and JOEF programs. These will provide accredited, common use hazard information systems by the years 2005 and 2007 respectively. Largely due to the maturity of the technologies, requirements and the vision for them, the SBA and Training Systems Capability (TSC) will be addressed behind those for analysis. However, both SBA and TSC are also functionally and structurally dependent upon the analytical systems so a delay in their start is appropriate. Table B-1 in Annex B provides an overview of RDA efforts and Service involvement.

The management challenge involves the coordination and consolidation of numerous previously uncoordinated RDA efforts across the Services and Agencies. This strategy, led by the JPEO through the M&S Commodity Area Manager, established in April 2000, has already resulted in the initiation of the above mentioned Joint Service RDA efforts.

Table 2-4. Battlespace Management Modernization Strategy

	Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
Warning and Reporting Systems	• Automated, standardized warning and reporting (JWARN Block I) • MICAD Fox vehicle system	• Automatic CBRN warning and reporting interoperable with all Services (JWARN Block II)	• Integrated and automatic warning and reporting (JWARN Block III) • Updated MICAD vehicle system • JSLNBCRS embedded JWARN system	
Hazards Analysis	• Counterforce hazard prediction (HPAC 4.0) • Passive defense hazard analysis (VLSTRACK 3.1)	• High altitude intercept analysis (PEGEM) • Urban environment analysis (MIDAS-AT) • CONUS facilities analysis (D2PC)	• Integrated VLSTRACK, HPAC, and D2PC hazard prediction and effects capability (JEM Block 1) • Increase capability to analyze high altitude intercepts and urban environments (JEM Block 2)	• Multi-fidelity hazard prediction, to move at will from global, to theater, to battle, to building, to individual scale analyses (JEM Block 3) • Micro-scale event analysis (JEM Block 4)
Operational Effects Analysis		• Fixed site analysis (STAFFS) • Medical resources analysis (CREST) • Mobile forces analysis (NCBR Simulator)	• Integrated fixed site and medical simulations with JWARS and JSIMS (JOEF Block I)	• Mobile forces simulations incorporated into the federation (JOEF Block 2) • Automated C4I system integration (JOEF Block 3)
Simulation Based Acquisition Systems		• Navy-Ship based analysis (CWNavSim) • Point and stand-off detector systems (NCBR Simulator)	• Detection (VPS Block 1) • Biological detection and identification capabilities (VPS Block 2)	• Protection and decontamination (VPS Block 3&4)
Training Simulation Systems		• Virtual Emergency Response Training System (VERTS)	• VERTS Capability becomes Training Simulation Capability (TSC) Blocks 1 and 2 • Individual and crew training systems (TSC Block 2)	• Integrated training systems for battle staffs and commanders (TSC Block 3)

2.4 DECONTAMINATION

When contamination cannot be avoided, personnel and equipment may need to be decontaminated to reduce, eliminate or neutralize hazards after CBRN weapons employment. Decontamination systems provide a force restoration capability for units that become contaminated. Recently, an oxidative decontaminant has been approved for interim fielding in response to an urgent need statement from Central Command. Simultaneously, two commercial application systems have been tested and one fielded in response to a second urgent need statement. Technology advances in sorbents, coatings, catalysts, and physical removal will reduce logistics burden, manpower requirements, and lost operational capability associated with decontamination operations. The following sections detail CBRN decontamination science and technology efforts, modernization strategy, and Joint Service programs.

2.4.1 Decontamination Science and Technology Efforts

2.4.1.1 Goals and Timeframes. The goal of decontamination science and technology is to develop technologies to support a key Joint Future Operational Capability (JFOC)—Restore (Decontamination of Equipment/Facilities/Large Areas) JFOC. This capability will eliminate toxic materials or their effects without performance degradation to the contaminated object and will be non-corrosive, environmentally safe, and lightweight (see **Table 2-5**). This area includes decontamination of personnel, individual equipment, tactical combat vehicles, aircraft, ships, facilities, and fixed sites. Decontamination technologies currently being pursued include non-chlorine based oxidants, catalysts that improve reactivity, decontaminants that are effective in both fresh and brackish water, improved reactive sorbents, and nanoparticle technology. Non-ozone depleting fluorocarbons and solvent wash technologies are being investigated for sensitive equipment decontamination, while thermal approaches, solvent wash technologies, and solvent suspensions of reactive nanoparticles are among the candidates being evaluated as a decontaminant for interior spaces of vehicles such as aircraft. In 2003, a Congressionally directed program was initiated to examine vaporous phase hydrogen peroxide as a decontaminant for interior spaces to include military items such as aircraft and the interiors of buildings. New oxidative decontamination formulations that are effective against both chemical and biological agents are being developed through DTO CB.44, Oxidative Formulations. These potential decontaminants will also be nontoxic, non-corrosive, and environmentally safe. CBRN contamination survivability of materiel would also be enhanced.

Table 2-5. Decontamination Science and Technology Strategy

By 2004	By 2009	By 2016
• Demonstrate oxidative decontaminants for chemical and biological agents	• Demonstrate Sensitive Equipment Decon Systems for interior spaces • Demonstrate concentrated oxidative decontaminants • Demonstrate Family of Applicators • Demonstrate the next generation of reactive sorbent powders	• Demonstrate new self-decontaminating materials • Demonstrate improved thorough decon materials • Demonstrate aircraft and other vehicle interior decontamination • Demonstrate personnel decontaminant

Contamination control involves investigating procedures that minimize the extent of contamination pickup and transfer, and that maximize the ability to eliminate the contamination pickup on the move as well as during decontamination operations. During FY03, increased

emphasis was placed on aircraft decontamination, especially analyzing material compatibility concerns, as part of the Joint Service Sensitive Equipment Decontamination program, the Restoration of Operation (RestOps) ACTD (DTO. D.22), and other DoD sponsored studies such as the Large Frame Aircraft Decontamination Demonstration (LFADD) project.

2.4.1.2 Potential Payoffs and Transition Opportunities. 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 reconstitute personnel and equipment more quickly to increase combat efficiency and lessen the 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 toxic industrial chemical contamination and implications to domestic scenarios, are being exploited.

2.4.1.3 Major Technical Challenges. There are two key technical challenges associated with chemical and biological decontamination. The first is the development of decontaminants that are reactive, non-aqueous, non-corrosive, safe for use on sensitive equipment, able to decontaminate a broad spectrum of chemical and biological agents, environmentally safe, and pose no unacceptable health hazards. The second technical difficulty is the development of decontamination systems that effectively clean all surfaces and materials, while at the same time reduce the manpower and logistics burden.

2.4.2 Decontamination Modernization Strategy

The goal of the CBRN Decontamination program area is to provide technology to remove and detoxify contaminated material without damaging combat equipment, personnel, or the environment. Decontamination systems provide a force restoration capability for contaminated units. Existing capabilities rely upon the physical application and rinse down of decontaminants on contaminated surfaces. Existing systems are effective against a wide variety of threat agents, yet are slow and labor intensive and present logistical, environmental, material, and safety burdens. In addition, existing systems are inadequate for electronic equipment decontamination, deficient for large area, port, and airfield decontamination, and rely on Decontamination Solution 2 (DS2) and water or bleach-based aqueous systems. To improve capabilities in this functional area, the Joint Services have placed emphasis upon new decontaminating technologies that reduce existing manpower and logistics requirements. These technologies are safer on the environment, the warfighter, and equipment. **Table 2-6** shows the roadmap for modernizing decontamination systems in DoD, and highlights capabilities being developed and procured in the near term, and developmental programs that are planned to be available in the mid to far-term. Legacy systems that are still maintained by the Services are not indicated here.

A Decontamination Master Plan provides a roadmap that integrates RDA efforts with non-RDA efforts, including policy, doctrine, standards, and revised tactics, techniques and procedures. Research and development of non-corrosive, all-agent multipurpose decontaminants and decontaminating systems for combat equipment, aircraft, and personal gear remains a priority. Alternative decontamination approaches, such as sensitive equipment decontamination methods and large-scale decontamination systems attract interest across the Services. Table D-1 in Annex D provides an overview of Joint Service RDA efforts and Service involvement.

2.4.3 Joint Service Decontamination Programs

The Army has developed the M291 skin decontamination kit as a replacement for the M258A1 decontamination kit for all Services, and has introduced the M295 for improved personal equipment decontamination. The M295 provides the warfighter a fast and non-caustic decontamination system for personal gear. An adsorbent that is more reactive and has higher capacity of absorbing contamination was developed and completed to improve the performance of the M295 kit. The M295 kit filled with the new sorbent became available for requisition in January 2000.

In the near- and mid-term, DoD continues to research new multi-purpose decontaminants as a replacement for bulk caustic Decontamination Solution 2 (DS2) and for corrosive High Test Hypochlorite (HTH) and Super Tropical Bleach (STB). New technologies, such as reactive decontaminating systems, oxidative formulations, and enhanced sorbents are being explored and may offer operational, logistical, cost, safety, and environmental advantages over current decontaminants. Present shipboard chlorine-based decontaminant solutions pose an unacceptable corrosion risk to naval aircraft. Current procedures require the use of fresh water and normal aircraft detergent solutions.

Ideally, new decontaminant formulations must be extremely reactive with dwell times under 15 minutes and be effective at a pH below 10.5 in order to minimize corrosion. Potential new solutions-based approaches consist of organic, aqueous and mixed organic-aqueous systems, which use catalytic and oxidative chemistries. Some promising decontaminants under consideration are organized assemblies incorporating monoethanolamine-type moieties, non-chlorine containing oxidants, such as stabilized peroxides, peroxycarboxylic acids and dioxiranes, and liquid slurries or suspensions of nanoparticles in organic solvents.

In the far-term, the Services are seeking non-aqueous decontamination systems to provide for sensitive equipment decontamination at mobile and fixed sites. Additionally, there is interest and exploratory research in coatings, which can reduce or eliminate the necessity of manual decontamination. The ultimate goal of this coatings effort is to develop a chemically or possibly electrically reactive coating to apply on equipment when operating under high CBRN threat conditions. This coating would then provide immediate decontamination on contact with CBRN agents, thus reducing the hazard without any actions required at that time by the warfighter. A detailed description of the decontamination projects is provided in Annex D.

2.4.4 Other Decontamination Programs

In the near-term, the Army is rebuilding the M12A1 Power Driven Decon Apparatus and selectively replacing the M17 Lightweight Decon System with a Commercial-Off-The-Shelf Technology. Similarly, the Marine Corps and Navy have procured and are fielding an M17 Lightweight Decontamination System that can be operated with Military Standard fuels. The M100 Sorbent Decon System began fielding in February 2002. This decontamination system replaces the M11/M13 DAP and associated DS2 used in immediate decon. This system consists of a non-toxic and non-corrosive, powder-based system that provides greater coverage than the M11 at 33% less weight.

Table 2-6. Decontamination Modernization Strategy

	Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
Personal Equipment Decontam-inants	• M291 Skin Decontaminating Kit • M295 Individual Equipment Decontaminating Kit • M100 Sorbent Decontamination System	• More reactive, high capacity adsorbent (M291/M295) • Army-*Higher efficiency decon methods (Sorbent Decon)*	• Non-caustic, non-corrosive decontaminant for personnel and equipment	
Bulk Decontam-inants	• Decontaminating Solution 2 (DS2) • High Test Hypochlorite (HTH) • Supertropical Bleach (STB)	• Non-caustic, non-corrosive, easy to store and manufacture multipurpose decontaminants	• Decontaminants for fixed sites • Navy -*Less caustic capability*	• Mission tailored decontaminants • Navy -*Contamination resistant shipboard materials* • Army -*Environmentally acceptable replacement for DS2*
Expedient Delivery Systems	• M11, M13 Portable Decontaminating Apparatus		• Auto-releasing coatings; reduces skin contact hazard & labor requirements • Hand held and man portable decontaminant applicator systems for operational decontamination	• Self-decontaminating, auto-releasing coatings; reduces man-power and logistic requirements eliminates skin contact hazard
Deliberate Delivery Systems	• M17 Lightweight Decontamination System • M12A1 Power Driven Decontamination Apparatus	• High pressure water wash; improved decontaminant dispenser (increased vehicle throughput) • Army –*Rebuild M12A1 Power Driven Decon Apparatus; Replace M17 Lightweight Decon System* • Interim fielding of a commercial off the shelf lightweight decontamination system to replace and supplement the M17 LDS • Interim fielding of a commercially developed unit to perform terrain decontamination	• Rapid large scale decon capability for fixed sites; reduced manpower and logistic burden • Non-aqueous capability for electronics, avionics and other sensitive equipment	• Vehicle interior decon capability• Army -*Waterless decon capability for electronics and avionics* • Air Force - *Sensitive equipment decontamination system for aircraft interiors* • Large scale fixed location decontamination systems for use at fixed site facilities

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (*italicized text*).
2. Where applicable, systems that meet requirements are listed following the entry.

2.5 PROTECTION

When early warning is not possible or units are required to occupy or traverse contaminated environments, protection provides life sustainment and continued operational capability in the CBRN contaminated environment. The two types of non-medical protection are individual and collective.

- ***Individual protective equipment*** includes protective masks and clothing. Protective masks with reduced respiratory stress, improved protection, compatibility with weapon sighting systems, and reduced weight and cost are being developed. Technology advances are being pursued to produce mask systems that provide enhanced vision capabilities, laser/ ballistic protection, and further reduction in logistics and physiological burden. Lightweight masks for short term operations or emergency escape are also being evaluated. Protective clothing and integrated suit ensembles are being developed that will improve protection, reduce the physiological burden, have extended durability, and have less weight and heat stress burden than present systems.
- ***Collective protection equipment*** consists of various types of protective filters, entry/exit portals, and air movement devices that provide purified air to a wide range of applications, including transportable shelter systems. Collective protection in the form of overpressure can be applied to mobile and fixed command posts, medical facilities, rest and relief shelters, buildings/fixed sites, vehicles, aircraft, and ships. Lightweight shelters integrated with air purification, thermal and environmental control and power generation for medical treatment facilities have been developed and are in production. Technology improvements are being pursued to reduce power requirements and improve filtration capacity against current and future CBRN hazards. Technologies that reduce weight, volume, cost, and improve the deployability of shelters and air purification systems are also being pursued.

2.5.1 Protection Science and Technology Efforts

2.5.1.1 Individual Protection Goals and Timeframes. The goal of the individual protection area is to reduce the physiological burden associated with wearing protective equipment while maintaining, and potentially improving, the already high level of protection against CBRN warfare agents and radiological particles (see **Table 2-7**). Individual protection equipment must also provide protection against emerging threats, such as novel agents or toxic industrial chemicals (TICs). To achieve these goals, key physiological performance requirements for the design and evaluation of clothing and respirators are being established. New barrier and filtration materials and selectively permeable materials are being developed and evaluated to accommodate these performance requirements. Maximizing the protection afforded by mask filters is being addressed by DTO CB.36, Universal End-of-Service-Life Indicator for Mask Filters. The technology is expected to have applications for collective protection and clothing also. Incorporation of agent reactive catalysts and biocides into CB protective materials for increased protection is being addressed by DTO CB.45, Self-Detoxifying Materials for CB Protective Clothing.

Table 2-7. Protection Science and Technology Strategy

By 2004	By 2009	By 2016
• Continue development of selectively permeable membranes as a viable alternative to adsorbent lined permeable materials for clothing • Demonstrate improved filtration media and advanced filter bed configurations for protective mask and collective protection applications • Demonstrate advanced adsorbents and filter bed configurations to provide protection against a wider spectrum of CBRN hazards	• Investigate reactive materials as a means of self-detoxifying clothing and shelters • Investigate residual life/end of service-life indicators for mask filters, collective protection filters, and clothing • Investigate lightweight, low cost materials, airlocks and advanced closures for shelters • Investigate technologies to protect building occupants from both internal/external threats CB/hazardous material.	• Investigate membrane/ adsorbent composites for clothing and shelter • Investigate nontraditional filtration (non-adsorbent based and/or non-single pass) for collective protection applications • Investigate protective shelter materials to replace general purpose (non-protective) shelter materials

2.5.1.2 Collective Protection (CP) Goals and Timeframes. The goals of the collective protection area are to (1) reduce the weight, size and power requirements of CP systems, (2) reduce the logistical burdens associated with the maintenance of CP filters, (3) improve protection capabilities against current and emerging threat agents, including TICs, and (4) improve the deployability of transportable shelter systems (see **Table 2-8**). To achieve these goals, improvements to system components (including transportable shelters) are being investigated along with improvements to the current vapor and particulate filtration media. Regenerative vapor and particulate filtration materials processes are being investigated to eliminate the need for filter change and improve the capability against any battlespace CBRN hazards. The primary effort for investigating adsorbents for both single-pass and regenerative filtration applications is articulated in DTO CB.08 Adsorbents for Protection Applications. Additionally, DTO CB.40, DARPA's Immune Building Program is developing technologies and methods to protect building occupants from both internal and external release of hazardous materials or CBRN threat. Collective Protection strategy will also address transportable shelter systems by investigating improved and self-decontaminating shelter materials, improved seaming processes, and improved closures and airlocks. Also a new DoD-JPEO Readiness Installation Protection Program (GUARDIAN) will incorporate CP technologies.

2.5.1.3 Potential Payoffs and Transition Opportunities. Individual and collective protection investments will result in 1) improved respiratory and percutaneous (skin) protection with reduced physiological and psychological burden to the individual warfighter, 2) improved air purification systems and technologies for collective protection shelter applications, 3) extended operation in an CBRN contaminated environment, 4) improved capability against current and emerging threats, and 5) reduced logistics burden associated with weight, volume, power, and consumables.

2.5.1.4 Major Technical Challenges. Integrating CBRN protection into future weapon systems necessitates tradeoffs between performance requirements and limitations of materials and designs. Integral respiratory protection requires tradeoffs between physiological performance parameters such as pulmonary function, field of regard, speech intelligibility and anthropometric sizing against constraints such as cost, size/weight, protection time, and

interfacing with other equipment. Residual life/end-of-service life indicators must exhibit sensitivity to a broad range of threats while being environmentally stable and low cost. CBRN protective clothing development requires balancing the physiological and psychological burden imposed upon the warfighter with maximum obtainable CBRN hazard protection. Reactive materials for clothing and shelter applications must be stable, broad spectrum, and fast acting. Significant advancements have been made in improving the weight/bulk and power requirements of personal cooling systems, but further work in this area is needed. Air purification and shelter systems require tradeoffs with respect to performance, user requirements, size, weight and power constraints, as well as longer life. Threats such as TICs increase the need for additional protection and makes the challenge of improving physiological performance, size, and weight constraints more difficult. Consequently, threat versus design tradeoffs become essential as well as tailoring of equipment to meet the threat. Maintaining toxic free areas for mobile, transportable and fixed sites will require new materials/processes with emphasis on systems development. New sealing processes and closures as well as developing improved airlock designs are critical to collective protection.

2.5.2 Protection Modernization Strategy

Forces cannot always avoid CBRN hazards. Therefore, individuals and warfighting units must be provided materiel to protect them from the effects of these lethal agents. Protection must be effective against all known threats with minimal degradation to the performance of personnel, weapons, or equipment. Protective measures allow our forces to maintain combat superiority in CBRN contaminated environments. A summary of protection modernization capabilities is provided in **Table 2-9**, which highlights current and planned developmental programs that will provide new or enhanced capabilities in the near through far-term, as well as capabilities that are being procured or are currently fielded.

The goal of the protection RDA area is to provide equipment that allows U.S. forces to operate in a CBRN contaminated environment with minimal degradation of the warfighters' performance. Near-, mid-, and far-term objectives are to reduce physiological and logistical burdens while maintaining/improving current protection levels.

Protective masks will be improved to reduce breathing resistance, thus enhancing ability to perform mission tasks. Mask systems will require increased CBRN survivability and compatibility with combat or personal equipment. Future respiratory systems, such as the Joint Service Aircrew Mask (JSAM) and Joint Service General Purpose Mask (JSGPM) will require enhanced compatibility with life support equipment and tactical systems, and JSAM with fixed and rotary wing aircraft. They will also require the capability to protect against TICs as well as traditional CBRN warfare agents. In the future, the focus will be on integrated respiratory protective ensembles, which offer optimal compatibility with personal, tactical, and crew support systems. Key technologies for future mask systems include mask filter service life indicator, advanced materials, improved adsorbents, and improved models and test technologies for protection assessment.

Future protective clothing ensembles for U.S. forces will require reductions in bulk and weight without any loss of protection or durability. As an evolutionary program the JSLIST intends to meet these future requirements by introducing evolutionary technologies such as the chemical glove upgrade into JSLIST chemical protective ensemble solutions as those

technologies mature. These technology insertions, which will include enhanced performance, will be accomplished as JSLIST RDT&E Joint Service projects.

Collective protection equipment (CPE) development efforts are focused on CBRN protection systems at the crew, unit, and platform level. New CPE systems will be smaller, lighter, less costly, and more easily supported logistically. New systems are required to provide clean environments for critical operations (*i.e.*, where individual protective equipment (IPE) otherwise places an unacceptable burden upon the warfighter in performing duties) and for essential rest and relief. Modernization efforts will concentrate on: (1) improvements to current vapor and particulate filtration media to extend filter life and to offer improved performance against current and/or emerging threats, (2) advanced air purification (vapor and particulate) technologies, integrated with environmental control, to greatly reduce the logistical burden and offer greatly improved performance against current and postulated threats, (3) increased application of collective protection systems onto mobile and transportable platforms and in fixed facilities within the Joint Services, (4) improved transportable shelter system with integrated power/environmental control/filtration, (5) improvements to current collective protection systems to reduce weight, volume, and power requirements, and (6) standardization of filters within the joint services to address storage and procurement concerns. Efforts are in place to support major weapons systems developments, such as the U.S. Army's Future Combat System, Comanche, Crusader, Bradley, Breacher, Heavy Assault Bridge, Future Scout and Cavalry System, the USMC Advanced Amphibious Assault Vehicle (AAAV), and other advanced weapons platforms.

2.5.3 Joint Service Protection Programs

Joint programs are shown in **Table 2-8**; Service-unique programs are italicized. A detailed description of Joint IPE and CPE programs is provided in Annex C.

Individual Protection

Individual Protection is comprised of technologies in the following categories: Surface Protection Ensembles, Aviation Protection Ensembles, Surface Respiratory Protection, Aviation Respiratory Protection, and Universal "Common" Individual Protective Equipment.

Surface Protection Ensembles. Future protective clothing ensembles for Warfighters will require deductions in bulk and weight without any loss of protection or durability. As an evolutionary program the Joint Service Lightweight Integrated Suit technology (JSLIST) intends to meet these future requirements by inserting revolutionary technologies into JSLIST chemical protective ensemble solutions as those technologies mature. These technology insertions, which will include enhanced performance, will be accomplished as JSLIST RDT&E projects.

The JSLIST Alternative Source Qualification (JASQ) is a congressionally mandated government-industry partnering effort to seek additional sources for JSLIST materials. JASQ candidates that successfully complete all testing requirements will be considered for inclusion on a Qualified Products List (QPL). In addition, two Industry Initiated Demonstration Products (IIDP) using semi-permeable membranes are being tested in order to determine the research and development (R&D) potential and for possible consideration in next-generation CBRN suit technology.

The Joint Program Manager for Individual Protection (JPM IP) is pursuing an Alternative Footwear Solution (AFS) designed to provide a common CBRN protective footwear that will meet the requirements of the Joint Services. CBRN protective footwear is a system, with legacy footwear, such as the GVO/BVO and fishtails, providing needed protection until the Multipurpose Overboot (MULO), and an improved shipboard boot are available in sufficient quantities. The AFS program, when fielded, will replace legacy CBRN protective footwear across the Joint Services.

The Multipurpose Protective Sock (MPS) is part of the JSLIST ensemble. MPS will fulfill the JSLIST and Joint Service Protective Aircrew Ensemble (JPACE) requirement for a launderable chemical/biological (C/B) protective sock for wear under service footwear. MPS may also be a key component of future JSLIST Alternative Footwear Solutions, to include investigation of a C/B resistant combat boot that when worn in combination with a protective sock could provide the required C/B footwear protection for the Warfighter. Individuals who cannot complete their missions while wearing protective vinyl overboots will wear MPS in conjunction with their service foot wear.

The JSLIST Block 2 Glove Upgrade (JB2GU) will provide hand protection against liquid, vapor, and aerosol CBRN agents, semi-permeable or selectively permeable to prevent excessive moisture buildup and improve user comfort. It is will be flame resistant and its performance will not be degraded by exposure to petroleum, oils, and lubricants (POL) or field contaminants. The JB2GU system will meet all service requirements for NBC protective gloves as stated in both JSLIST and Joint Protective Air Crew Ensemble (JPACE) ORDs. The Block 2 Glove effort will improve upon the Block 1 Glove by incorporating more robust testing and provides a glove solution that satisfies a broader set of user requirements, i.e., JSLIST ORD requirements for ground and shipboard use and JPACE requirements for aviation use. The JB2GU will be designed to achieve a fully integrated interface with the sleeves of JSLIST and JPACE NBC suits and will be compatible with the MOPP exchange/dirty doffing and doctrinal decontamination tactics, techniques, and procedures used for those ensembles.

Aviation Protection Ensembles. The Joint Protective Aircrew Ensemble (JPACE) is a CBRN and fire resistant protective clothing ensemble in development and is intended for use by all USN, USMC, USAF, USA, and USSOCOM aviators and aircrew for all fixed wing and rotary wing requirements. JPACE will provide aviators with a modern capability that replaces the impregnated undergarment and CWU-66/77P, using proven JSLIST technology. Army and Marine Combat Vehicle Crewmen are establishing requirements for use of this garment. JPACE will increase the protection provided over existing garments while reducing heat stress and system weight. JPACE will fully integrate with the Joint Service Aircrew Mask (JSAM), legacy masks, JSLIST Glove Upgrades, MULO, or the CBRN overboot. The JPACE will utilize a block upgrade acquisition approach. Block 1 will provide chemical protection from all liquid, particle, vapor and aerosol CBRN agents, provide CBRN protection over a 16 hours mission and be flame retardant. Block 2 will address the Rotor wash Protection Key Performance Parameter (KPP) requirement.

Surface Respiratory Protection. Currently there is a DTO to develop a low cost End-of-Service-Life Indicator (ESLI) for use in CBRN protective mask filters that will indicate to the user that a mask filter has been contaminated and has a limited if any remaining service life.

The Joint Service General Purpose Mask (JSGPM) will be a lightweight protective mask incorporating state-of-the-art technology to protect ground forces from future threats. Key requirements include: 24 hour CBRN protection, lower breathing resistance and reduced weight and bulk. The mask components will be designed to minimize the impact on the wearer's performance and maximize the ability to interface with future Service equipment and protective clothing.

The Joint Service Chemical Environment Survivability Mask (JSCESM) will be a lightweight complement to the JSGPM. It will provide commanders at all levels with greater options for protection, especially in Operations Other Than War (OOTW). It will provide an inexpensive/disposable, emergency mask for use in CBRN situations confronting the warfighter while operating in low CBRN threat conditions and for medical care providers and patients in instances when using the standard service mask is not practical. It is envisioned that warfighters in special operations or in non-combat roles will carry the JSCESM during deployment when an CBRN threat is possible, but unlikely. This mask will be a one size fits all and it will provide limited protection based on agent concentrations for approximately 6 hours.

Aviation Respiratory Protection. The Joint Service Aircrew Mask (JSAM) will provide aircrew members with individual head-eye-respiratory protection against CBRN warfare agents and radiological particles and, for high performance aircraft, will provide aircrew protection from the effects of high rates of acceleration and possible GLOC (G-force induced loss of consciousness). JSAM will be compatible with current and planned CBRN ensembles and existing life support equipment, provide flame and thermal protection, reduce heat stress imposed by existing CBRN protective masks, and allow the CBRN protective portion of the respirator to be donned/doffed in flight. JSAM will have two variants—one for rotary wing and one for fixed wing applications—and will replace all existing Service aircrew CBRN respirators.

The Army is fielding the M48 protective mask to replace the M43 series masks. The M48 is for Apache pilots. It provides a lightweight motor blower unit, uses a standard battery, and provides increased protective capability.

In the near-term, the Army is replacing the M43 mask for the general aviator (non-Apache applications) with the Aircrew Protective Mask, M45. The M45 is lighter and less expensive than the M43 and features CBRN protection without the aid of force ventilated air.

Universal "Common" Individual Protective Equipment. The Joint Service Mask Leakage Tester (JSMLT) is a one-man portable device that is capable of determining serviceability, proper fit, and identifying defective components of current and future CBRN protective masks. This system will provide an expeditionary capability currently not available to the Joint Services that will quantitatively and qualitatively test protective mask for defects and fit by measuring the performance of the mask against known standards. The capability will be provided at the unit or maintenance section level.

The Joint Service Container Refilling System (JSCRS) would provide the Warfighter with the capability to refill containers with water while conducting operations in a CBRN contaminated environment. A block upgrade approach would enable refilling of canteens, 5-gallon water cans, and other containers from larger water carriers such as a 5-gallon water can, M149, and the 400-gallon wheeled water trailer with water in a CBRN contaminated

environment without contamination. With today's chemical protective garments and masks enabling 24 hours of protection for the warfighter, the requirement for hydration of the Warfighter is crucial. JSCRS, to date, remains a critical unmet capability that seeks to improve combat efficiency during extended operations in contaminated environments.

Collective Protection (CP)

The Services currently use the M20A1 Simplified CPE and the M28 shelter liners to provide CP collective protection to existing structures. Environmental control is also being added to selected applications. The M20A1 CPE provides resistance to liquid and vapor agents and allows expansion of protection area and has been fielded. CP EMEDS and CP DEPMEDS are joint programs to integrate environmentally controlled collective protection into already fielded Army and Air Force field hospitals in order to sustain medical operations in a CBRN contaminated environment for 72 hours. The M28 Simplified CPE has been integrated into CP DEPMEDS and CP EMEDS field hospitals.

CP DEPMEDS integrated chemical protection into existing Tent Extendable Modular Personnel (TEMPER)-based medical tents and shelters through the addition of M28 Simplified CPE, chemically protected heaters and air conditioners, and alarms. CP DEPMEDS also includes CBRN protected water distribution and latrine systems. A Milestone C (Type Classification) action was approved 5 September 2003, including Full New Material Release (NMR) approval for CP DEPMEDS. An urgent operational need is validated to support Operation Enduring Freedom for six systems; new equipment training and fielding was initiated January 2003 and is still ongoing.

The CP EMEDS program is an effort to insert environmentally controlled collective protection into currently fielded hospital shelters. The role of CP EMEDS, as part of the Air Force Theater Hospital (AFTH), is to provide individual bed-down and theater-level medical services for deployed forces or select population groups within the entire spectrum of military operations. CP EMEDS are modular packages, tailored to meet theater requirements, by providing a flexible hospitalization capability. The CP EMEDS +25 has the capability to provide 24-hour sick call, 25 inpatient beds, and emergency medical care to a population at risk of 3,000–5,000. The CP EMEDS provides a contamination free environment where medical treatment can be rendered to personnel without the encumbrance of individual protective equipment.

The Chemically and Biologically Protected Shelter (CBPS) is a highly mobile, rapidly deployable shelter system designed to be used for Level I and II divisional and non-divisional forward area medical treatment facilities. The system is self contained/self-sustaining. It is permanently integrated with a M1113 Expanded Capacity Vehicle (ECV) with a Lightweight Multipurpose Shelter. The vehicle tows a trailer and generator set. The vehicle transports a CBRN protected airbeam supported soft shelter, self-contained environmental support and power generation system, a crew of four and gear, and medical equipment. The CBPS presently is in production to meet an urgency of need requirement. Milestone C (Type Classification) was approved 5 September 2003, including Full New Material Release (NMR) approval for the CBPS. Currently, an Urgent Operational Need has been validated and 64 systems have been fielded to support Operation Enduring Freedom; new equipment training and fielding was initiated January 2003 and is ongoing. Mid-term objectives are to initiate development of CBPS to support medical treatment for Airborne, Air Assault and Heavy Divisions.

Other near to mid-term collective protection efforts, such as the Joint Collective Protection Equipment (JCPE) will use the latest technologies in air purification, environmental controls, and power generation to improve and/or standardize current collective protection equipment so that it is lighter, more efficient, more affordable and less logistically burdensome. The Joint Expeditionary Collective Protection system (JECP) will be the next generation lightweight, modular, easily transportable, self-supporting collective protection shelter that will provide relief from psychological and physiological stresses during sustained operations in a contaminated environment. Redesign and concept tradeoff assistance regarding advanced filtration technologies, such as Pressure Swing Adsorption (PSA) and Catalytic Oxidation (CatOx) has been provided to the USMC AAAV and U.S. Army advanced vehicle efforts. The USAF is currently undergoing a major upgrade to their mobile and fixed site collective protection capabilities.

2.5.4 Defense Advanced Research Projects Agency (DARPA) Protection Programs

This thrust focuses on destroying or neutralizing pathogens and toxins before they enter the body. For example, both personal and collective protection air purification systems under development will have significantly enhanced performance relative to the conventional carbon/ HEPA-filtered gas masks and catalytic oxidizer-based systems in use today. These existing systems suffer from a number of drawbacks including poor selectivity, slow adsorption kinetics, the need for expensive containment techniques, relatively low capacity, and high pressure drops. DARPA is developing air purification systems that (1) provide filtration media with lower pressure drops, greater capacity, improved retention, and possible neutralization of the pathogens using designer carrier systems—such as microfibrous materials—and designer sorbent materials (tailored pore size and pore chemistry for personal protection), (2) destroy and neutralize chemical and/or biological agents using a small catalytic oxidation reactor, and (3) provide a design for personal protection for the next generation of a joint service mask or masks designed for first responders, based on a paper-making technique, using highly advanced microfibrous, sorbent-based, felt-like filters. These filters also lend themselves to fabricating low-cost, foldable/ portable emergency smoke hoods with extended gas sorption capabilities and regenerable, biological pathogen-destroying and gas-sorbing aircraft cabin and collective protection filters. The small thermocatalytic air purifier intended for collective protection shelters is being further developed by the Joint Service CBRN Defense technology transition program with improved prototypes being developed under U.S. Army RDECOM's auspices.

DARPA is also developing a number of innovative approaches to disinfect and purify water in the field from any source. These approaches include the use of mixed oxidants combined with novel and improved filtration methods. A pen-sized or cap-sized mixed chemical oxidant unit kills or inactivates microbial pathogens, prevents re-growth of microbial contaminants for days after initial treatment, and provides an order of magnitude improvement in disinfection effectiveness against spores compared with chlorine or iodine; a thick film adsorbent removes volatile organics and a direct (forward) osmosis membrane filters undesirable mineral content, pesticides and spore forming bacteria to cover all CBRN requirements. The mixed oxidant solution can also disinfect equipment, utensils, and possibly wounds inflicted on an individual, though the efficacy and safety of wound disinfection would need to transition to advanced development to be demonstrated in clinical trials and eventual FDA approval. During

2001–2002, the mixed oxidant water disinfection pens were field tested by the Marines in Afghanistan. In the near-term, the USAF and Special Operations forces plan to evaluate the device for Escape and Evasion kits. The mixed oxidant water disinfection pens also may be dispensed as part of a backpack-worn, on-the-move, next generation hydration system compatible with the current fighting load carrier and body armor requirements. Recently, a larger scale prototype of the same mixed oxidant technology successfully demonstrated the ability to purify water on board the USS Enterprise. For improved filtration, newly discovered methods to fabricate and treat the surface of carbon are exploited to create far superior performance (lower pressure drops, contact efficiency, improved viral absorption rates) than existing activated carbon granules. Supplementing soldier-centric water purification devices (such as the disinfection pen and a small desalination handpump) designed to provide potable water from conventional sources (puddles, streams, lakes and the sea), recently started programs are dealing with harvesting water from unconventional sources (e.g., water from atmospheric moisture and from combusted hydrocarbons). Highly man-portable devices are being developed to provide at least 3.5 liters of potable water per soldier per day where no surface or subsurface sources of water are available, helping to eliminate 50% of water logistics requirements for the single soldier or small groups of warfighters on demand, at any place and at any time.

Projects in the area of decontamination and neutralization are developing methods for destroying agents in a non-corrosive manner without using extremely high power or harmful chemicals. Current decontamination methods either employ concentrated bleach that can be corrosive to materials, people, and electronics or else methods that use extremely high power lasers, lamps, or discharges. One approach in the DARPA program is the development of BCTP—an emulsion made from water, soybean oil, Triton X 100 detergent, and the solvent tri-n-butyl phosphate—that is benign to humans, plants, animals, and electronics but quickly kills bacteria, spores, and most viruses. Stable, highly effective biological enzyme/polyurethane foam mixtures are also being explored for their ability to neutralize both biological and chemical threat agents and for the decontamination of exposed personnel and materiel.

In addition, under DTO CB.40, Immune Building Program, DARPA is developing technologies and systems to allow military buildings to actively respond to attacks by agents of chemical or biological warfare so as to (1) protect human occupants from the lethal effects of the agent, (2) restore the building to function quickly after the attack, and (3) preserve forensic evidence about the attack. The program focus is on the challenging problem of protection from covert agent release inside buildings. Enabling buildings to respond actively, in real time, to the presence of threat agents will not only greatly reduce the effectiveness of such attacks, but will also make the buildings less attractive as targets. The program has developed a systems approach to protection of military buildings from attack by aerosolized CWA/BWA. This approach employs sensors to determine the presence of contaminant in the building, active HVAC strategies to minimize the spread of the contaminant, and advanced neutralization and filtration technologies to render it inactive. The program is developing and evaluating systems components and architectures in controlled tests to produce optimized protection architectures. These systems are transitioning to a demonstration in a functioning military building. This will embody the first operational “immune” building. The lessons learned from the program are being incorporated into a software-based toolkit with advanced simulation and design data tools

to permit the transfer of this knowledge and techniques across a wide spectrum of building types and to potential users.

2.5.5 Other Protection Programs

Programs supporting requirements of a single service are shown in **Table 2-8** as italicized entries. A detailed description of IPE and CPE projects is presented in Annex C.

Surface Protection Ensembles

The Army has approved fielding of the Self-Contained Toxic Environment Protective Outfit (STEPO). STEPO provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD), and Technical Escort Unit (TEU) personnel. The Army has also developed an Improved Toxicological Agent Protective (ITAP) ensemble that provides level B or C protection for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chemical environments (up to one hour), emergency life saving response functions, routine Chemical Activity operations, and initial entry and monitoring activities. The ITAP ensemble incorporates improvements in material and design. It includes a one-hour supplied air bottle system, which can be switched to a filtered air respirator when operators exit the area of high contamination. A Personal Ice Cooling System (PICS) has been developed for use with both the ITAP and STEPO.

Collective Protection

The Navy includes the Collective Protection System (CPS) on selected spaces on new construction ships. Currently the DDG-51, LHD-1, AOE-6, and LSD-41 ship classes are being built with CPS. The Navy also has the capability to backfit CPS on ships already in Service. The Selected Area Collective Protective System (SACPS) has been installed on selected LHA-1 class ships. The Ship CPS Backfit program continues to backfit selected spaces critical to amphibious ships with CPS. These spaces include hospital areas, command and control areas, and rest and relief areas. The Navy Shipboard Collective Protection Equipment (CPE) effort will increase the shipboard particulate filter life (from the current one or two years) to at least a three year service life, through the use of new particulate pre-filter materials and the use of new high efficiency particulate (HEPA) filter media. The Shipboard CPE will thus provide millions of dollars of savings in life cycle costs by reducing shipboard maintenance requirements and providing energy efficient fans. The Shipboard CPE transitioned to the JCPE in FY03.

Table 2-8. Protection Modernization Strategy

	Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
Surface Protection Ensembles	• CB Protective Overgarment Saratoga • Chemical Protective Undergarment (CPU) • Modified CPU (mCPU) • Joint Service Lightweight Integrated Suit Technology (JSLIST)—Overgarment • Battledress Overgarment (BDO) • STEPO • EOD Ensemble • Improved Toxicological Agent Protective (ITAP) • Joint Firefighter Integrated Response Ensemble (JFIRE) • Suit Contamination Avoidance Liquid Protective (SCALP) • 7, 14, and 25 mm Butyl Rubber Gloves • Black and Green Vinyl Overboot • Chemical Protective Footwear Cover	• Advanced protective suit technology; lighter, improved agent protection; reduced heat stress integrated with all respiratory systems. - Improved foot protection (MULO) - Improved hand protection	• Improved cutaneous protection • Service Life Indicator • Army –*Improved protection for short term use for special purposes (ITAP)* • Textile treatments for improved protection against bio threats	• Integrated multiple threat modular protection (chemical, biological, environmental, and flame) • Self-detoxifying clothing • Indication when protection is no longer required
Aviation Protection	• CWU-66/77P Aircrew Chemical Protective Suit • Aircrew Cape		• Improved protection for aviators (JPACE)	
Surface Respiratory Protection	• M40/M42 Protective Mask • MCU-2A/P	• Voice amplification; laser/ballistic eye protection; improved decontaminability, improved comfort (M40A1/M42A2)	• Reduced physiological and psychological burden, improved comfort, enhanced optical and communications, improved compatibility • Lightweight CB mask for low threat environments (JSCESM)	• Advanced Integrated Individual Soldier Protection system (Future Soldier System) • Improved multiple agent protection • Indication when protection is no longer required

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (italicized text).
2. Where applicable, systems that meet requirements are listed following the entry.

* Continuing procurement in the near-term

Table 2-8. Protection Modernization Strategy

(continued)

	Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
Aviation Respiratory	• MBU-19/P Aircrew Eye/Respiratory Protection (AERP) • M48 Aircraft Mask • CB Respiratory System (A/P22P-14(V)) • M45 Aircrew Protective Mask (ACPM)	• Army - *Aircrew mask compatible with Apache helicopter systems with a significantly lighter motor/blower unit (M48)* • Army -*Improved compatibility with aviation sighting/night vision systems; reduced logistics burden using non-blower systems, selected for Land Warrior (M45)*	• New mask systems for general purpose and aviation masks (JSGPM, JSAM)	
Universal "Common"	• Protection Assessment Test System (PATS) • Voice Communication Adapter		• End-of-Service-Life Indicator for Mask Filters • Improved mask leakage tester (JSMLT) • Improved/innovate material and aerosol test procedures/fixtures and models	
Collective Protection	• Transportable Collective Protection Systems (TCPS) • M20A1/M28 Simplified CP Equipment (CPE) • CB Protective Shelter (CBPS) (Medical) • Chemically Protected Deployable Medical Systems (CP DEPMEDS) • *Chemically Hardened air Transportable Hospital (CHATH)* • *Collective Protection for Expeditionary Medical shelter System (CP EMEDS)* • *Medium General Purpose Tent System* • Small Shelter System (SSS) Liner System • Shipboard Toxic Free Areas (Collective Protection System Backfit)	• Rapid insertion of technology improvements into existing equipment (JCPE) • Marine Corps -*Protection for all combat vehicles and unit shelters* • Army – *CBRN protection for tactical Medical units (CBPS).* *- Regenerable vapor filtration for Comanche,* *- Collective protection for advanced vehicle concepts.* • Air Force - *Upgrade/install collective protection into existing rest/relief shelters.* • Navy - *Backfit ships with contamination free protected zones - (Collective Protection System Backfit)*	• Improved filters to extend filter life, reduce maintenance and reduce logistical burden • Reduced logistics burden, improved protection against current and future threats • Improved current collective protection filters and equipment (JCPE) • Support medical treatment in a CB environment for Airborne, Air Assault, and Heavy Divisions (CBPS) • Lighter, more mobile, easier setup, more affordable shelters • Improved technologies from DARPA's Immune Building Program	• Family of advanced collective protective systems for vehicles, shelters, ships, and light forces • Regenerable/advanced protective filtration for vehicles/vans/shelters

1. All programs shown are joint or multi-service, unless indicated as a Service-unique effort (italicized text).
2. Where applicable, systems that meet requirements are listed following the entry.

* Continuing procurement in the near-term

2.6 CHEMICAL, BIOLOGICAL, AND RADIOLOGICAL MEDICAL DEFENSE SYSTEMS

2.6.1 Introduction

Many countries and terrorist groups have acquired the means to produce and deliver CBRN weapons. Proliferation increases the threat to deployed U.S. forces. Chemical warfare (CW) agents are available worldwide and include vesicants (blister agents), nerve, blood, and respiratory agents. Biological warfare (BW) agents include bacteria, viruses, rickettsiae, and toxins, many of which can be produced with basic knowledge of microbiology and access to a scientific laboratory or a pharmaceutical facility. Nuclear and radiological weapons can include strategic, tactical or improvised nuclear explosives, radiological dispersal devices that spread radioactive material via conventional explosives, or point sources surreptitiously concealed in high population areas causing exposures to unaware individuals. Exposure to multiple threats may result in synergistic effects.

Medical CBR defense research, development, and acquisition (RDA) programs are organized into chemical, biological, and radiological research. **Tables 2-9**, **2-10**, and **2-11** provide a summary of the programs in the planned modernization strategy through the far term, highlight capabilities being developed and procured in the near term, and developmental programs that are planned to be available in the mid to far-term. Fielded systems that are still maintained by the Services are not indicated here.

Along with individual and collective protection, medical systems forms the third area associated with the CBRN defense principle of protection. *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 chemical and biological defense requirements. Technology advances are being pursued in the creation and manufacturing of vaccines and pharmaceuticals that prevent the lethal and/or incapacitating effects of chemical and biological agents. Therapies that improve survival and facilitate return to duty are being developed. Also being developed are rapid portable diagnostics that will facilitate a quick medical response for exposed warfighters.

The medical CBRN defense RDA program has the following goals:

(1) Provide individual level medical protection and prevention to preserve fighting strength.
(2) Maintain technological capabilities to meet present requirements and counter future threats.
(3) Provide medical management of CB casualties to enhance survivability, and expedite and maximize return to duty.
(4) Sustain basic research that provides the knowledge upon which innovative diagnostics, prophylaxes, and therapies are developed.

DoD medical CBRN defense research and development programs have provided numerous products to protect and treat service members. Assessment methodologies enable threat evaluation and injury prediction. Medical prophylaxis and treatment strategies reduce performance decrements, injuries, and deaths of military personnel in the field, thus enabling

them to accomplish their missions, reducing the need for medical resources, and decreasing the probability of long-term health effects.

Specific initiatives programmed to improve CBRN defense medical readiness include:

- Development and implementation of a biological defense immunization policy for U.S. forces and other-than-U.S. forces.
- Increased focus of medical technology base research toward the development of antivirals, antibiotics, and toxin therapeutics.
- Continued cooperative and consultation with the U.S. Food and Drug Administration (FDA) for application of the new Animal Rule[1], which allows consideration of efficacy data derived from animal studies as surrogates for large-scale human efficacy trials to license drugs and biological products that cannot be ethically tested for efficacy in humans.
- Enhanced medical diagnostic capability for diseases/injuries caused by all agents.
- Studies to elucidate the toxicity and mechanism of action of non-traditional agents, and to determine the effectiveness of current medical countermeasures.
- Studies to evaluate the effects of exposure to low levels of chemical warfare agents (CWAs).
- Exploratory and advanced studies to develop effective preventive, assessment and treatment strategies to mitigate injuries from the spectrum of ionization radiation energies and qualities produced by either nuclear or radiological devices.
- Training of health care professionals for the medical management of chemical, biological, and radiological casualties.
- Effective procedures for the use of the best available medical countermeasures under the new FDA Emergency Use Authorization authority enacted by section 1603 of the National Defense Authorization Act for Fiscal Year 2004.

[1] 21 CFR Parts 314 and 601, Food and Drug Administration, "New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible." *Federal Register*: May 31, 2002 (Volume 67, Number 105), Rules and Regulations, Pages 37988-37998.

Table 2-9. Medical Chemical Defense Programs and Modernization Strategy

Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
▪ Licensed SERPACWA (Skin Exposure Reduction Paste against Chemical Warfare Agents). ▪ Soman nerve agent pretreatment pyridostigmine (SNAPP).		▪ Biomarkers of exposure for low levels of chemical warfare agents. ▪ Nerve agent catalytic "bioscavenger" (recombinant) pretreatment candidate. ▪ Next generation oxime candidate for nerve agent treatment. ▪ Therapeutic candidates for vesicant agent exposure. ▪ Vesicant agent prophylaxis candidate. ▪ Skin/wound decontamination product candidate. ▪ Improved assays to identify chemical agent exposure. ▪ Licensed advanced (improved) anticonvulsant.	▪ Licensed nerve agent "bioscavenger" (human butyrylcholinesterase) pretreatment. ▪ Licensed nerve agent catalytic "bioscavenger" (recombinant) pretreatment. ▪ Licensed next generation oxime. ▪ Licensed improved SERPACWA (aTSP). ▪ Licensed therapeutic for vesicant exposure. ▪ Licensed skin/wound decon product. ▪ Licensed vesicant agent prophylaxis. ▪ Licensed cyanide pretreatment. ▪ New assays to identify chemical agent exposure.

Table 2-10. Medical Biological Defense Programs and Modernization Strategy

Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
▪ Licensed antibiotic for exposure to anthrax (ciprofloxacin)	▪ Joint Biological Agent Identification and Diagnostic System (JBAIDS) Block I (nucleic acid-based analysis) production contract ▪ Anthrax vaccine amendment for new dosing schedule. (Effort sponsored by the CDC)	▪ Licensed smallpox (vaccinia virus, cell culture-derived) vaccine ▪ JBAIDS (Block II) (nucleic acid-based analysis and immunodiagnostic platforms) - continue work to gain FDA approval for use as a diagnostic device ▪ Initiate JBAIDS Block III FDA approval for use as a medical diagnostic device ▪ FDA approval of JBAIDS Assays for use in an analytic device ▪ FDA approval to add indications to licensed therapeutics for exposure to plague, anthrax and smallpox	▪ Licensed vaccines for VEE (virus subtypes IA/B, IE, IIIA), botulinum neurotoxins (A, B), plague, ricin, SEA/B, brucellosis, and anthrax (NGAV). Licensed vaccines for eastern and western equine encephalitis (EEE and WEE) ▪ Licensed filovirus vaccines (Marburg and Ebola) ▪ Multiagent vaccines against multiple BW threats and alternative delivery methods for vaccines and immunogens ▪ JBAIDS Block III production ▪ Licensed broad spectrum antibiotics, antivirals, and toxin therapeutics ▪ Licensed broad spectrum immunomodulator for biodefense against multiple threat agents including anthrax, plague.

Table 2-11. Medical Radiological Defense Programs and Modernization Strategy

Fielded Capabilities	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-20)
▪ Antiemetics for palliative treatment of nausea and vomiting. ▪ The Biodosimetry Assessment Tool (BAT) for collection and integration of biodosimetry data to support medical treatment decisions ▪ (Note: No non-toxic licensed products are available for definitive prevention or treatment of radiological injury.)	▪ Pre-clinical cGLP trials of broad-spectrum, nontoxic androstene steroid radioprotectant ▪ Improved cytogenetic markers, and automated sample processing and image analysis to reduce analysis time and increased throughput rate of biodosimetry system for definitive radiation dose assessment ▪ Antibiotics for post-exposure infectious sequelae. ▪ Licensed cytokine therapy for hematopoietic injury from radiation. ▪ First responder Radiological Assessment Triage (FRAT) providing a handheld device to provide data collection template for analysis of biodosimetric data.	▪ Clinical safety trials in humans for broad-spectrum, nontoxic androstene steroid radioprotectant ▪ Sustained, slow-release radioprotective drug formulation for extended protection ▪ Preclinical safety and efficacy testing of new-generation protectants and recombined biologics for prophylaxis and therapy of multi-organ radiation injuries ▪ Preclinical demonstration of multiplexed molecular biomarker assay for rapid biodosimetric screening of blood samples for radiation exposure, configured into rugged field-portable delivery platform	▪ Licensed products to reduce/prevent the spectrum of short- and long-term (cancer) injuries sustained from exposures to low to intermediate doses of ionizing radiation ▪ Pre-clinical efficacy demonstration of therapies for treating high-dose radiation injuries to the gastrointestinal and respiratory systems ▪ Highly automated and compact cytogenetic-based biodosimetry system for definitive radiation dose assessment in field hospitals ▪ Validation and licensure of molecular biomarker biodosimetry screening assay for forward field operations

2.6.2 Challenges in Medical CBRN Defense Programs

Medical prophylaxes, pretreatments, and therapies are necessary to protect personnel from the toxic or lethal effects of exposure to all validated threat agents and radiation emitting weapons, as well as other anticipated threats. Some of the challenges include the use of investigational new drugs, integration of DoD acquisition processes and FDA regulatory requirements, demonstration of medical products' efficacy, and the use of animals as subjects of research.

Executive Order 13139, "Improving Health Protection of Military Personnel Participating in Particular Military Operations," September 30, 1999, makes it the policy of the United States Government to provide military personnel with safe and effective vaccines, antidotes, and treatments that will negate or minimize the effects of exposure to a range of CBRN weapons as well as diseases endemic to an area of operations. This executive order establishes the procedures for the administration of investigational new drugs to members of the Armed Forces to include informed consent requirements and waiver provisions. DoD Directive 6200.2, *Use of Investigational New Drugs for Force Health Protection*, August 1, 2000, establishes policy for the use of investigational new drugs for force health protection, incorporating the requirements of 10 U.S.C. 1107, the Executive Order 13139, and the FDA interim final rule (21 CFR 50.23(d)).

During the past year, the acquisition life cycle of medical products developed by DoD was managed in accordance with DoD Directive 5000.1, *The Defense Acquisition System*, May 12, 2003, and DoD Instruction 5000.2-R, *Operation of the Defense Acquisition Systems,* May 12, 2003. In addition to adhering to DoD acquisition guidelines and regulations, development of medical products requires compliance with Title 21, Food & Drugs, Code of Federal Regulations (CFR), for manufacture, testing, and licensure of medical products. Successful development of medical CBRN defense products requires an integration of the two processes and an understanding of their differing requirements and purposes. A significant amount of time, 6–8 years, after an acquisition program has been initiated for a candidate medical countermeasure is normally required to conduct the necessary human clinical studies and develop and document the manufacturing processes needed to obtain FDA licensure.

Medical CBRN defense products are thoroughly tested and evaluated for their safety in accordance with FDA guidelines before administration to *any* personnel. All medical products must be safe to use and not degrade operational performance. In cases where adverse effects are known or possible, a decision must be made—and a risk accepted—of the potential effects of a medical product versus the catastrophic effects of CBRN weapons. Even in those cases where efficacy could not be studied in human clinical trials, the safety profiles of the products are well delineated. In many cases, the safety is well understood because the medical products have been widely used to treat other medical conditions. In 2002, the FDA amended the Code of Federal Regulations (CFR) to allow a process for considering the licensure of New Drug and Biological Products that were not able to meet the efficacy studies required by the FDA for product licensure under 21 CFR Sec. 312.21(2)(b). The amended rule[2] allows appropriate studies in animals in certain cases to provide substantial evidence of the effectiveness of new drug and biological

[2] Ibid. Full text of the new rule is available at http://www.fda.gov/cber/rules.htm.

products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances. This rule will apply when adequate and well-controlled clinical studies in humans cannot be ethically conducted and field studies are not feasible. In these situations, certain new drug and biologic products that are intended to reduce or prevent serious or life-threatening conditions may be approved for marketing based on evidence of effectiveness derived from appropriate studies in animals and any additional supporting data. The first successful application of the new "animal efficacy rule" occurred in February 2003 with FDA approval of Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP) to increase survival after exposure to soman nerve gas poisoning. Evidence of the effectiveness of SNAPP as a pretreatment for exposure to soman was obtained primarily from studies in monkeys and guinea pigs. The evidence shows that administration of the drug before exposure to soman, together with atropine and pralidoxime given after exposure, increases survival. FDA agreed that, based on the animal evidence of effectiveness, pyridostigmine bromide is likely to benefit humans exposed to soman. The safety of pyridostigmine bromide has been documented over years of clinical use in the treatment of myasthenia gravis, a neuromuscular disease.

While there are efforts to reduce reliance on animals as subjects of research (see Section 2.6.3), the use of animal models remains a critical aspect in the development of some medical products. One of the challenges in the development of some medical products is a continuing and growing lack of availability of specific non-human primates, which are frequently used and are the animal model of choice in many definitive efficacy studies of vaccines and therapeutics. DoD continues to investigate alternative models, including non-human primates other than those in short supply, other animal models, and non-animal models (*e.g.*, cell cultures). This investigation is intended to preclude potential resource limitations from slowing the development of medical CBRN defense products.

2.6.3 Reducing Reliance on the Use of Animals as Subjects of Research

Joint medical chemical defense research efforts utilize and develop technologies that will reduce, refine, or replace the use of animals in research. When possible, the research programs employ computerized molecular modeling, computer predictions, *in vitro* cell cultures, cell-free reaction systems, and various *in vitro* models to replace the use of animals. Statisticians evaluate all research proposals that use animals to ensure that the minimum number of animals required to obtain scientific validity are used. Animals lower on the phylogenetic scale (or the least sentient species) are used if the selection will permit attainment of the scientific objective. Additionally, a veterinarian with expertise in laboratory animal medicine reviews all procedures that might cause pain or distress in laboratory animals to determine the procedural modifications, analgesics and/or anesthetic regimens that could be incorporated to minimize pain or distress. Detailed protocols are comprehensively reviewed and approved by an Institutional Animal Care and Use Committee before experiments are initiated; the small percentage of protocols which specify the use of non-human primates undergo further scrutiny by the U.S. Army Medical Research and Materiel Command Animal Use Review Office. Policies and procedures of the Association for the Assessment and Accreditation of Laboratory Animal Care – International are rigorously enforced and followed. DoD policy requires that animal use be conducted in full compliance with the Animal Welfare Act and that animals are to be used in research only when scientifically acceptable alternatives are not available.

2.6.4 Joint Medical Chemical Defense Research

The mission of joint medical chemical defense research efforts is to preserve the health, safety, and combat effectiveness of warfighters by timely provision of medical countermeasures in response to joint service chemical warfare defense requirements.

2.6.4.1 Goals. The mission-specific goals of joint medical chemical defense research efforts include:

- Maintain technological capability to meet present requirements and counter future threats.
- Provide individual-level prevention and protection to preserve fighting strength.
- Provide medical management of chemical casualties to enhance survival and expedite and maximize return to duty.

2.6.4.2 Objectives. Objectives of joint medical chemical defense research efforts differ with the varying threats:

- For vesicant (or blister) agents, the objective is to develop a pathophysiological database on vesicant chemical agents and a working hypothesis on how damage occurs at the cellular level. Used with associated technologies, this approach will enable the formulation of definitive pretreatment and treatment strategies, and is expected to produce a realistic concept for medical prophylaxis, immediate post-exposure therapy, and topical protection. Alternatively, in dealing with liquid agent threat, active topical skin protectants (aTSPs) are being evaluated that will improve protection provided by the FDA-licensed Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) product by detoxifying any CW agent that penetrates the protective barrier.

- For nerve agents, one objective is the fielding of a safe and effective improved anticonvulsant. The advanced anticonvulsant will be more water soluble, will terminate seizures more quickly, will reduce the likelihood of seizure recurrence, and will prevent seizure-induced brain damage and subsequent behavioral incapacitation. Another objective is to field an advanced pretreatment effective against all nerve agents based on physiological scavengers such as the human enzymes butyrylcholinesterase (BuChE) or carboxylesterase (CaE). Ideally the prophylaxis would not require any follow-on treatment, and would have no adverse side effects. These naturally occurring enzymes, as well as acetylcholinesterase, are targets for nerve agents. Through bioengineering efforts, human BuChE and CaE have been mutated to forms that are not only less susceptible to inhibition by the nerve agents, but have the added capability to catalyze nerve agent breakdown. Another potential chemical warfare agent scavenger is human paraoxonase. This enzyme also is being bioengineered to make it more effective and decrease the time it takes to destroy nerve agent.

- For blood agents, the objective is to identify safe and effective pretreatments for protection from cyanide exposure.

- For respiratory agents, the objective is to develop prophylaxes and therapies by understanding pathophysiological changes after agent exposure.

2.6.4.3 Threats, Countermeasures, Technical Barriers, and Accomplishments. CW threats and countermeasures, as well as chemical defense research and development technical barriers and accomplishments, are outlined in Annex E (Section E.1). Countermeasures and diagnostic techniques for the effects of chemical weapons are shown in **Table 2-12**. Critical issues in medical chemical defense include the ability to protect U.S. warfighters from the very rapidly acting nerve agents and persistent vesicating agents as well as choking agents and respiratory agents. New threats are also emerging. The effectiveness of current countermeasures against non-traditional agents continues to be investigated.

Table 2-12. Medical Chemical Defense Countermeasures and Diagnostic Techniques

- ***Chemical Warfare Agent (CWA) Scavengers*** – Human enzymes that have been engineered to destroy nerve agents are being developed as nerve agent scavengers.
- ***Advanced Anticonvulsant*** – Benzodiazepines that are water soluble and long acting are being evaluated for improved control of nerve agent-induced seizure activity.
- ***Antivesicants*** – Countermeasures that provide reduction in mustard-induced blister formation, corneal opacity, dermal histopathology; and systemic effects are being evaluated.
- ***Laser debridement of vesicant burn injuries*** - Techniques and methodologies using laser technology to accelerate recovery from sulfur mustard injury are being developed.
- ***Effects of exposure to non-lethal levels of CWA*** – The probability and severity of medical effects of single and multiple low-level exposures to CWA are being evaluated.
- ***Non-Traditional Agents*** – Current medical regimens used for protection against the conventional nerve agents are being evaluated as countermeasures for non-traditional agents.
- ***Cyanide Countermeasures*** – Potential pretreatment compounds (*e.g.*, methemoglobin formers and sulfide donors) and regimen are being evaluated for safety and efficacy as pretreatments.
- ***Nerve agent antidotes*** – New nerve agent antidote compounds that are water soluble, have a broader spectrum of efficacy, and are more effective than current antidote compounds.
- ***Chemical Casualty Management*** - Technologies to assist in the diagnosis, prognosis, and management of chemical casualties are being developed.

2.6.5 Joint Medical Biological Defense Research

The mission of the joint medical biological defense research efforts is to develop medical countermeasures to protect U.S. forces and thereby deter, constrain, and defeat the use of biological agents against them. These research efforts are primarily directed against agents of biological origin that are validated military threats with a portion of the program directed against emerging or genetically engineered threats. The primary concern is the development of vaccines, therapeutic drugs and treatment regimens, and diagnostic capabilities (reagents, assay protocols, and devices), and other medical products that are effective against biological threat agents.

2.6.5.1 Goals. Mission-specific goals of joint medical biological defense research efforts include the following:

- Protecting U.S. forces warfighting capability during a biological attack or in a theater of operations contaminated by biological threat agents.
- Reducing vulnerability to validated and emerging threats by maintaining a strong technology base.
- Providing consultation for medical management of BW casualties.

2.6.5.2 Objectives. In accomplishing the goals of joint medical biological defense research, efforts are focused on three objectives:

- Maintaining technological capability to meet present requirements and counter future threats.
- Providing individual-level prevention and protection to preserve fighting strength.
- Providing training in medical management of biological casualties to enhance survival and expedite and maximize return to duty.

Joint medical biological defense research efforts respond to requirements and capabilities determined by the Joint Requirements Office for Chemical, Biological, Radiological and Nuclear Defense (JRO-CBRND).

Sophisticated technology base efforts for medical biological defense hold the promise of yielding important new products and technologies to protect U.S. forces against a wide range of biological threat agents. This includes research into alternative delivery methods that will reduce costs of vaccine production and simplify immunization protocols, and diagnostic capabilities (reagents, protocols, and devices) that can be deployed at forward sites to rapidly analyze clinical samples for the indications of biological warfare agents as well as infectious diseases of military importance.

Projects and technologies shared with the DOE are related to the strengths of DOE laboratories in developing advanced technologies in order to enable rapid detection of and response to a chemical or biological incident. While DOE focuses internal technology development efforts on the domestic threat, they actively support the DoD. The work spans DNA sequencing and biodetection to modeling and simulation, collaborating on projects such as x-ray crystallography and nuclear magnetic resonance imaging of BW agent antigens. The DNA sequencing efforts have led to advances in developing “lab on a chip” diagnostic technology for several BW threat agents. DOE is not involved in protection and treatment of personnel, but they are assisting DoD with drug/chemical database searches with the intent of identifying novel inhibitors of pathogens.

Since FY01, there has been an ongoing effort to transition medical research efforts from the DARPA program to joint medical biological defense research within the CBRNDP technology base for exploitation and further development. The overall goal is development of the most promising medical technologies to a level of technology readiness that supports transition out of technology base and into advanced development. Over the past three years that the DARPA transition initiative has been funded (FY01–FY03), technology base reviews of DARPA-funded programs in Biological Warfare Defense have led to selection of several DARPA research efforts in the Unconventional Pathogen Countermeasures and Tissue-Based Biosensors programs for transition to joint medical biological defense research efforts within the CBRNDP technology base. The selected programs include:

- Research to develop broad-spectrum vaccines by molecular breeding (gene shuffling) strategies; focused on cross-protection against pathogenic equine encephalitis viruses.
- A novel class of antimicrobial drugs that bind RNA targets involved in the disease process.

- High-level plant-based expression system for vaccine antigens and humanized monoclonal antibodies for biological threat agents.
- Proprietary B-cell sensing technology for rapid and sensitive medical diagnostics for biological threat agents and endemic diseases.
- In vivo countermeasures against biological toxin threats of the superantigen family (e.g., staphylococcal enterotoxin B) using a peptide or peptidomimetic antagonist.
- Investigation of small molecule anti-genomic therapeutics (SMATs) as countermeasures against a broad spectrum of BW threats, including genetically engineered threats.
- Small-molecule antibiotics that target the cell-cycle regulated methyltransferase (CcrM) DNA methyltransferase enzyme.
- Investigation using in silico screening methods of structurally diverse small-molecule inhibitors of the zinc endopeptidase of botulinum neurotoxin serotype A.
- Development of nonspecific immunomodulatory agents using a synthetic lipid A analog (aminoalkyl glucosaminide phosphate).

Bioengineering techniques are also being used to prepare a variety of recombinant vaccines against single threat agents that will be produced without the need to grow the actual threat agent during the vaccine production process. Several recombinant vaccines are scheduled for transition out of the technical base to advanced development and ultimately FDA licensure over the next ten years. The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) approved entry of two recombinant vaccine candidates, a recombinant plague vaccine candidate (F1-V fusion protein) and a genetically engineered VEE vaccine candidate (V3526), into Technology Development (TD) phase in July 2002. Continuing tech base research during FY03 under DTO CB.24, Medical Countermeasures for Encephalitis Viruses, demonstrated that VEE vaccine candidate, V3526, is cross-protective in animal models against pathogenic VEE virus subtypes IA/B, IIIA, and IE. This determination means that a single vaccine component (V3526) is all that may be required in a multivalent VEE vaccine. This DTO completed in FY03. The recombinant Protective Antigen (rPA) vaccine candidate developed by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) under DTO CB.33, Recombinant Protective Antigen Anthrax Vaccine Candidate, which completed in FY02, was selected by NIAID in FY02 for evaluation in clinical trials. An IND was submitted by NIAID in the second quarter of FY03 in support of phase I and II clinical trials and phase I clinical trials were initiated in the last quarter of FY03. The staphylococcal enterotoxin (SE) B vaccine candidate developed by USAMRIID remains poised for transition into advanced development. A pilot lot of the SEB vaccine candidate was prepared several years ago under DTO CB.23, Medical Countermeasures Against Staphylococcal Enterotoxin B, which completed in FY01, but there remains no advanced development funding to support development of an SEB vaccine.

In addition to DTO CB.24, two other DTO efforts were completed in FY03. DTO CB.31, Medical Countermeasures Against Brucellae, was focused on the development of a genetically characterized, live attenuated vaccine capable of eliciting cellular and humoral immunity against the BW threat of Brucella. The overall objective of the research effort, which was conducted at the Walter Reed Army Institute of Research (WRAIR), was to develop a Brucella vaccine that would be capable of protecting 90% of vaccinated warfighters against disease after aerosol exposure. A candidate was downselected which was demonstrated to protect

higher animal models from fever and bacteremia following a conjunctival dose of B. melitensis 16M that was 10,000-100,000 times the 50% infectious dose and 100 times the dose used in published estimates of the public health impact of a BW attack using B. melitensis. Data generated during the DTO research program have been collected and summarized in a read-ahead package for a pre-IND meeting with FDA. FDA concluded, based on the submitted read-ahead package, that the proposed vaccine candidate was insufficiently attenuated at immunologically effective doses. They therefore determined that this attenuated vaccine candidate should not be further developed.

DTO CB.34, Recombinant Plague Vaccine Candidate, was focused on preclinical research leading to development of the recombinant F1-V fusion protein plague vaccine candidate developed at USAMRIID. The F1-V vaccine candidate induced high levels of efficacy (80% survival) against aerosolized plague in immunized groups of cynomologus macaques. Antibodies to the fusion protein (mouse and NHP) were demonstrated to represent surrogate markers for efficacy by passive transfer into mice. Additionally, a competitive enzyme linked immunosorbent assay (ELISA) using monoclonal antibodies to both the F1 and V components of the vaccine was established as the basis of an *in vitro* assay for an immune correlate to protection. As stated above, the F1-V vaccine candidate entered the Technology development phase in July 2002.

Joint medical biological defense includes the following areas of research:

Pre-exposure Countermeasures: This area involves prophylactic measures undertaken to prevent illness and injury associated with exposure to bacterial, viral, and toxin threat agents. The primary focus in pre-exposure countermeasures research is the development of effective vaccines. The roles of various factors in stimulating cellular and humoral immunity are determined through study of specific genes or properties of threat agents. This knowledge provides tools for development of vaccine candidates as well as other pretreatment strategies, such as the use of immunomodulators, to prevent the pathogenic effects resulting from exposure to threat agents.

Post-exposure Countermeasures: Research efforts in this area are focused on developing safe, effective treatments to alleviate disease or injury associated with exposure to bacterial, viral, or toxin threat agents. Therapeutic measures may involve administration of antimicrobials, antivirals, antitoxins or generic compounds formulated to intervene at the pathogen's site of action. The knowledge necessary to develop such products requires in-depth research in the basic pathogenesis and physiology of the BW agents.

Diagnostics: Diagnostics research involves the investigation and evaluation of sensitive and specific methods for detection of organisms, toxins, antigens, and host responses to infection, such as antibodies, cytokine profiles, and genetic markers in biological clinical samples. The approaches in diagnostic research include the application of nucleic acid-based technologies (e.g., polymerase chain reaction analysis), immunodiagnostic platforms, and the use of microarray technologies. Research using microarray technologies is directed toward an understanding of host gene expression patterns and changes in the patterns shortly after exposure to biological agents that may provide very early markers of exposure before the sign and symptoms of infection are evident. Rapid identification tests and diagnostic methods for the identification of bacteria, viruses, and toxins and/or their antigens, metabolites, and analogs in

clinical specimens are major goals of this program area. Multiple targets for a biological organism enable a high level of specificity in diagnostic analyses. Research is also focused on ensuring that diagnostic assays currently in the tech base receive appropriate testing and validation prior to deployment and fielding, thus enabling Food and Drug Administration (FDA) approval of these medical devices when transition to the advanced developer. This effort included refining BW agent detection and medical diagnostic assays and reagents already transitioned to advanced development, resulting in better performance, sensitivity, and specificity of fielded systems and facilitating a rapid response to changing operational needs and requirements.

2.6.5.3 Threats, Countermeasures, Technical Barriers, and Accomplishments. A biological threat agent is defined as an intentionally disseminated living microorganism or toxin that can cause disease or death in humans, animals, or plants. Threat agents include a broad range of microorganisms (bacteria, rickettsiae, and viruses) and toxins of biological origin. Biological weapons are easy to make, difficult to detect, and can be very effective. Defense against this class of weapon is difficult, particularly when biological agents can produce casualties over an area of thousands of square kilometers. Biological agents could also be used with devastating effect in combination with nuclear, chemical, or conventional weapons.

Countermeasures and diagnostic techniques for biological threat agents are shown in **Table 2-13**. Details of the BW threats and countermeasures, as well as biological defense research and development technical barriers and accomplishments, are presented in Annex E (Section E.2). Critical elements of medical biological defense include the ability to protect U.S. forces from BW agents, to rapidly diagnose (in clinical specimens) infection or intoxication from agents, and to treat casualties. Currently, the most effective countermeasure is pre-deployment active immunization. Future threats, however, may involve genetically engineered biological weapons that may be easily produced, highly lethal, difficult to detect, and resistant to conventional therapies. An enemy's ability to rapidly produce genetically engineered threats exacerbates the current lead time for the identification of a medical technology solution, transitioning it to advanced development, and obtaining FDA licensure for the final medical product.

Use of vaccines, therapeutics, and diagnostic devices by the military requires approval by the FDA (or in some cases, use as an IND may be approved in compliance in accordance with DoD, FDA, and other relevant laws and regulations). Ensuring successful transfer and progress of the medical products through advanced development to FDA licensure often requires a significant technology base "tail" in support of advanced development activities, including the conduct of clinical trials, establishment of manufacturing procedures, and preparation of the Biological License Application and other required documentation. Technology base research to identify and develop potential vaccines/pre-treatments, drugs, and diagnostic reagents/assays must be conducted with submission for FDA licensure/approval as a goal. When appropriate, pivotal preclinical research studies in technology base must be conducted in accordance with current Good Laboratory Practices (GLP). In addition, research efforts must develop appropriate animal models for demonstrating safety and efficacy that correspond to the specific medical countermeasure. Appropriate animal models must include surrogate markers for protective efficacy in animal models that translate to human systems and that relate to expected battlefield challenge levels of threat agent. Also, assays that support demonstration of

potency during clinical trials must be developed. In summary, the successful proof-of-principle of a medical product may only lead to the successful fielding of that product when it is accompanied by appropriate preclinical and clinical data that demonstrate its safety and efficacy and when accompanied by chemistry, manufacturing, and controls documentation that support that it can be produced in a manner consistent with FDA's current Good Manufacturing Practices (cGMP) regulations.

Current Joint medical biological defense research includes the following research areas for the development of medical countermeasures:

- Characterize the biochemistry, molecular biology, physiology, and morphology of BW threat agents.
- Investigate the pathogenesis and immunology of the disease.
- Determine the mechanism of action of the threat agent in animal model systems.
- Select antigen(s) for candidate vaccines or other targets for therapeutic intervention.
- Develop and compare potential vaccine and chemo/immunotherapeutic candidates and characterize their effects in animal models.
- Develop surrogate markers of efficacy.
- Establish safety and efficacy data in animal models for candidate vaccines and therapeutics.
- Develop medical diagnostics for use in the field (rapid and portable), for confirmatory use, and for use in reference laboratories.

Technical shortcomings in the private sector include (1) limited number of high-level biological containment (BL-3 and BL-4) laboratory facilities to support biological defense research, (2) lack of widespread scientific expertise in biological defense, and (3) a continuing and growing lack of availability of Indian Rhesus macaques, the animal model of choice in many definitive efficacy studies of vaccines and therapeutics. These factors restrict the depth of expertise, facilities, and support available. Recent funding provided to the National Institute of Allergy and Infectious Diseases (NIAID) directed against bioterrorism has stimulated coordination and cooperation with the DoD medical biological defense research program. Initiatives are under way for close collaboration between scientists in both organizations. Additionally, cooperation at an organizational level between DoD and NIAID may alleviate some of the aforementioned shortcomings and facility and infrastructure constraints that currently confront medical CB defense research programs.

Table 2-13. Medical Biological Defense Countermeasures and Diagnostic Techniques

VACCINES

- *Killed* – killed or inactivated microorganism that is incapable of replicating but stimulates immunity.
- *Live, attenuated* – live organism, selected not to cause disease but able to stimulate immunity.
- *Toxoid* – toxin protein treated to inactivate its toxicity but retains its ability to stimulate immunity.
- *Recombinant* – gene coding for a protein that stimulates specific immunity to a BW agent is inserted into biological vector for production. Protein may be produced in high yields through bioengineering.
- *Deoxyribonucleic Acid (DNA)* – DNA is the chemical substance of which genes are composed. The definition of a gene is a section of DNA that codes for protein that stimulates specific immunity to a BW agent. In genetic vaccination (DNA vaccines), DNA produces the desired protein in recipient that stimulates immunity in the recipient.
- *Polyvalent/Multivalent/Multiagent* – mixture of antigens or vaccine constructs that protect against a number of different BW agents.
- *Vectored* – carrier organism bioengineered to confer immunity against a biological agent or multiple agents.
- *Replicon* – a vectored system in which portions of pathogen genes are combined with a portion of viral DNA and introduced into cells by the normal viral infectious mechanism. A replicon replicates a single time, after which it is eliminated, and elicits a protective immune response without causing disease.

ANTIBODY (ANTISERUM, ANTITOXIN)

- *Heterologous* – antibodies collected from animals (*i.e.*, different species than the recipient) repeatedly immunized against the BW threat. These antibodies must be treated to reduce the human immune response to them (serum sickness).
- *Homologous* – antibodies of human origin (*i.e.*, same species as the recipient) that provide protective immunity against the BW threat. These antibodies are not prone to stimulating serum sickness.
- *Monoclonal* – a cell culture technique for producing highly specific antibodies against a disease agent.
- *Bioengineered* – antigen binding site on the variable portion of an antibody elicited in a nonhuman system is combined with the nonvariable portion of a human antibody to produce a "humanized" antibody.

DRUGS

- *Antibiotics* – effective against bacteria
- *Antiviral compounds* – promising drugs in development by the pharmaceutical industry are being evaluated against viral threat agents.
- *Others* – compounds that offer new possibilities for protecting against and treating exposure to BW agents (such as drugs to treat intoxication from exposure to toxin agents or nonspecific, broad-spectrum treatments such as immunomodulators.)

DIAGNOSTIC TECHNOLOGIES

- *Immunological technologies* – These tests rely on antibodies for detecting the presence of molecular targets associated with the BW agent. They are easy to use, compact, rapid (minutes), and require little logistic support. This technology is currently used in outpatient clinics and doctor's offices. Immunodiagnostic technologies are useful in the diagnosis of intoxication from or exposure to toxin agents, to which antibodies can be prepared for use as reagents in immunodiagnostic devices.
- *Nucleic acid technologies* – Nucleic acid analyses, specifically the polymerase chain reaction (PCR), rely on the detection of segments of genes unique to BW agents to diagnose infection from or exposure to agents. These tests are extremely sensitive and specific, but currently require more support to perform. They are also useful in detecting bacterial and viral threat agents, which would contain DNA. These technologies are not useful for detecting toxin agents unless the clinical sample contains DNA from the toxin source organism, which would be highly unlikely.
- *DNA Microarray technologies* – Often referred to as "gene chips", this technology assesses the status of thousands of genes simultaneously for changes in level of gene expression. Events that occur immediately after exposure to a biological agent may be related to changes in gene expression when compared to baseline gene expression profiles.

2.6.5.4 Defense Advanced Research Projects Agency (DARPA) Programs. As one of its major program areas, DARPA is pursuing the demonstration and development of new biological warfare defense capabilities. Major thrusts include real-time (environmental) sensing medical countermeasures (developing barriers to prevent entry of pathogens into the human body; developing pathogen countermeasures to block pathogen virulence and to modulate host immune response; and development of an artificial immune system to rapidly develop vaccines against BW threats); and Advanced Medical Diagnostics for the most virulent pathogens and their molecular mechanisms. Medical countermeasures research also includes: (1) enhance existing vaccines or create new ones that respond to newly discovered signals of microorganisms or protect against many BW pathogens simultaneously, (2) develop new therapeutics to which resistance cannot be developed, (3) prime the human immune system to prevent many, if not all infections, and (4) develop ways of detecting the biosignatures of infection to permit earlier diagnosis, (5) development of an artificial immune system to rapidly develop vaccines against BW threats. A detailed description of DARPA's biowarfare defense research is included in Annex E.

2.6.5.5 DTRA Cooperative Biological Research Projects. The Cooperative Threat Reduction (CTR) Directorate of the Defense Threat Reduction Agency (DTRA) implements Cooperative Biological Research (CBR) projects in the former Soviet Union (FSU). At present, most of the projects are in Russia and are implemented through the International Science and Technology Center (ITSC) in Moscow. International collaboration on biodefense-related research is essential to the success of these projects. Each project has a DoD-collaborator, who regularly reviews the results of each project and openly exchanges ideas and new directions with their Russian counterparts. The long-term goal of the CBR program is to feed the results of these international collaborations into the US biodefense community. A new Memorandum of Agreement between DTRA and the US Army Medical Research Institute for Infectious Diseases (USAMRIID) facilitates future cooperation on these projects.

One of the projects is the development of a diagnostics test-kit at the Moscow-based Research Center for Molecular Diagnostics and Therapy. This is collaboration with USAMRIID and the Naval Research Laboratory (NRL). The goal of this project is to create a kit using specific monoclonal antibodies for diagnosis of such infectious diseases as tularemia, plague, and anthrax, but with a higher specificity and a more rapid response than existing kits.

Another successful project has developed antivirals for treating orthopoxviral infections. This project is at the State Research Center for Virology and Biotechnology (VECTOR), in collaboration with USAMRIID and the University of Maryland. Over 2000 chemicals have been synthesized and tested for antiviral activity against orthopox viruses. Three compounds have been shown to be more active in inhibiting the growth of variola viruses than currently available antiviral compounds. These compounds were transferred to the US for further testing and were shown to exceed the antiviral activity of cidofovir.

CTR also has promising projects involving Yersinia pestis (plague causative agent) lipopolysaccharide structural organization, antibody libraries for orthopoxviruses, a sampler to detect airborne microorganisms, and an aerosol DNA vaccine against hantavirus.

2.6.6 Medical Nuclear (Radiological) Defense Research Program

The mission of the Medical Nuclear Defense Research Program (MNDRP) is to conduct research in the field of radiobiology and related matters essential to the support of DoD and the Military Services. The primary repository of defense radiobiology expertise is the Armed Forces Radiobiology Research Institute (AFRRI). While these efforts may support the requirements of the warfighter as developed by the JRO-CBRND, AFRRI programs are not funded as part of DoD CBRNDP research programs.

2.6.6.1 Goals. The goals of the MNDRP are as follows:

- Produce effective medical countermeasures against the injuries sustained from exposures to a broad spectrum of ionization radiation qualities, doses and dose rates.
- Through effective medical countermeasures, provide Combatant Commanders with greater flexibility to conduct operations in radiological environments.
- Field a diagnostic biological dosimetry capability to rapidly assess the radiation exposure status of individuals and deployed units under field operating conditions.

2.6.6.2 Objectives. To accomplish the goals, program objectives are focused in the following areas

- Identify candidate pharmacologic agents for preventing or treating radiological injury through exploratory testing of compounds developed for other or related indications by industry and academia and that demonstrate a rational basis for probable efficacy in mitigating radiological injury.
- Concentrate efforts on developing preventive and treatment measures for the hematopoietic and gastrointestinal systems that are most susceptible to radiation exposures in the low to intermediate radiation dose ranges that represent the most probable threats and where the highest probability is for realizing near-term product solutions.
- Improve the utility of gold standard cytogenetic methods for definitive biodosimetric assessment of radiation doses through advances in sample preparation techniques and automated image analysis that will permit more widespread employment in routine laboratory settings and lead to an enhanced medical management capability for radiation casualties.
- Identify and develop novel molecular biomarkers of and analytical procedures for radiation exposure that can be measured from routine blood sample preparations using common instrumentation platforms that support immunochemical and polymerase chain reaction procedures, that provide a rapid, accurate and precise estimate of radiation dose, and that can be operated under field-deployed conditions.

The primary objective of this research is to address the major aspects of military operational requirements for dealing with radiation injuries. A nuclear threat agent is any weapon that causes detrimental medical effects by either direct external irradiation or by internal contamination with radioactive material. These agents include radiation dispersal weapons, which scatter radioactive material with conventional explosives; deliberate area contamination; destruction of a nuclear power plant; improvised nuclear devices; and traditional nuclear weapons. Operational requirements include programs in casualty

management, medical radioprotectants to diminish radiation injury, medical therapeutic regimens, biodosimetry, and radiation hazards assessment.

2.6.6.3 Threats, Countermeasures, Technical Barriers, and Accomplishments. Section E-3 of Annex E contains a comprehensive listing of countermeasures, technical barriers and accomplishments associated with this program. An overarching discussion of these topics and of the current nuclear/radiological threat environment is presented here as follows:

Threats

Although the end of the Cold War has diminished the prospect of strategic intercontinental nuclear war, today's environment presents an ever increasing threat of the use of nuclear or radiological weapons by rogue states or terrorist groups against the citizens of the United States, its armed forces and its allies anywhere in the world. Proliferation of nuclear technology is on the rise in third-world countries by governments with dubious intentions towards the U.S., and terrorist networks have become highly sophisticated and well funded, giving them the opportunity to acquire or develop radiological devices or improvised nuclear weapons such as criticality devices that can release extremely high prompt doses of neutron radiation. Radiological dispersal devices are within reach of anyone who can exploit the readily accessible sources of relatively unsecured radioactive materials, such as those commonly used in industry, medicine and research. Although the reactor vessels of nuclear power plants are hardened against breaches from explosive impacts, storage facilities for the highly radioactive spent fuel rods that they generate and store on site are not, and they are susceptible to sabotage that could spread clouds of radioactive material to populated areas down wind.

If counterproliferation and intelligence efforts fail to deter the use of a nuclear weapon, effective medical countermeasure must be available to treat casualties. Such devices would most likely be utilized against military, economic, or political targets (*e.g.*, an airbase, the seat of government, large population centers, or a commercial port city). In such scenarios, citizens outside the immediate lethal area would be exposed to the prompt high-dose mixed radiation field (neutron-gamma) of the initial explosion as well as to chronic radiation doses resulting from the residual radioactive fallout. The early effects of moderate- to high-dose radiation injury diminish the soldier's ability to fight and survive, while latent effects of all exposure doses increase an individual's risk of developing late-arising cancers. Effective radiation countermeasures must protect the warfighter from performance decrement and simultaneously diminish lethality and the long-term health effects of radiation injury.

Radiation dispersal events could include the destruction of a nuclear reactor or its storage facility, intentional contamination of a battlefield with nuclear waste, or dispersal of radiological materials in a terrorist bomb blast involving the use of conventional explosives. Most casualties in these scenarios would suffer non-lethal doses of external irradiation and some could become internally contaminated by the ingestion or inhalation of radionuclides. Conventional injuries from the bomb blast would complicate the management of such radiation exposures and further increase the risk of internal contamination. Prophylactic and therapeutic applications of novel pharmacological agents will increase survival and diminish the morbidity of individual soldiers wounded by radiation. A vibrant research program to further increase our understanding of the molecular and cellular damage induced by ionizing radiation is needed to

enhance the rational development of effective medical countermeasures against the newly arising radiological threats on the modern battlefield and in the homeland.

Countermeasures

Currently, no FDA licensed medical countermeasures exist to treat the injuries induced by ionizing radiation. Infectious sequelae from exposure to immune system suppressing doses of radiation or doses that begin to compromise the integrity of the gastrointestinal system are treated with conventional antibiotics. However, choosing the wrong antibiotic, such as one that is strongly effective against the beneficial intestinal anaerobes, actually can increase mortality after irradiation. Damage to the blood-forming system can be treated with the off-label use of hematopoietic cytokines on a case-by-case basis by individual physicians. These treatment modalities may be effective for injuries sustained at low to intermediate doses of prompt radiation but are not ideal. Also, the statutory restrictions that accompany off-label use of drugs make it impractical for widespread application in large patient populations. At higher doses of prompt radiation that cause severe injury to the gastrointestinal, pulmonary, circulatory and central nervous systems, and the total ablation of the bone marrow, few if any treatment options exist. Short of palliative treatment of symptoms to relieve pain and nausea, the only option available to treat high-dose injuries is bone marrow transplantation in an attempt to reconstitute critical blood forming elements. Attempts at bone marrow transplantation are currently heroic at best due to the many complications of managing transplant rejection and graft-versus-host disease, and the life-threatening complications from the other radiation-induced injuries not treated by the transplant.

Similarly, no licensed products exist that can be administered in a prophylactic regimen to prevent or reduce the severity of radiological injury and that are non-toxic. The only currently available option is an amifostine compound licensed for use to prevent or reduce the collateral damage to normal tissues in cancer patients undergoing chemotherapy and radiation therapy. At effective radioprotective doses, amifostine causes nausea and vomiting that would be operationally unacceptable in a fit fighting force, and it is therefore of little value to DoD.

In the area of biological dose assessment (biodosimetry), a cytogenetic procedure that measures a specific kind of radiation-induced chromosome aberration (dicentrics) in circulating lymphocytes is used to estimate the absorbed radiation dose in an individual. Although long recognized as the gold standard in radiobiology for the definitive assessment of radiation dose in a biological sample, the method is technically demanding and resource intensive. The procedure can only be effectively carried out in specialized laboratories by highly skilled individuals using tissue culture techniques, specialized cytogenetic staining methods and sophisticated microscopic image analysis. Analysis time from receipt of sample to final report is two to three days and sample throughput rate is limited. Although the assay is highly specific for radiation-induced aberrations and produces good accuracy and reproducibility in laboratories that have produced robust calibration curves, it depends on the harvesting and culturing of viable lymphocytes from the circulating blood, thus making it ineffective at high radiation doses that render lymphocytes non-viable.

Technical Barriers

The overarching technical barrier to developing effective countermeasures against the medical complications from exposure to ionizing radiation arises from the spectrum of organ

system injuries that accumulate as radiation dose increases. At lower doses, radiation causes mild hematopoietic injury that can be managed with standard, symptomatic therapy until recovery to normal levels of the clotting elements of the blood (platelets) and the infectious disease-fighting white blood cells. As radiation dose is increased, damage to the hematopoietic system becomes more severe, requiring intervention at the stem cell level with stimulatory growth factors (cytokines), and the gastrointestinal system becomes involved. The latter eventually leads to translocation of normal intestinal microflora into the circulatory system and life-threatening systemic infection in a host that is also immunocompromised. As the dose of radiation increases further, the gastrointestinal lining becomes severely compromised, leading to electrolyte and fluid imbalances that must be managed in addition to the translocation of microflora. Also, damage to the bone marrow eventually reaches a point where bone marrow transplant becomes the only option available to affect recovery of that organ system. Pulmonary, circulatory and central nervous system injuries complicate the medical challenge even further at yet higher doses of radiation. The most effective medical countermeasures against this spectrum of injuries will require a combined regimen of synergistic preventive and therapeutic interventions that must be developed and tested in *in vitro* studies and *in vivo* animal experiments. Final efficacy studies of successful drug candidates will have to be carried out under current good laboratory practices in compliance with the FDA's new efficacy rule for drugs that cannot be ethically tested for effectiveness in humans.

In the area of biological dosimetry, the first challenge is to identify new categories of prospective biomarkers for radiation dose that can be accurately measured in hours rather than days using readily available analytical techniques and that can be accomplished by less than highly trained technical personnel under field environments. Ideally, the new biomarkers should be of functional value in situations where the time between radiation exposure and sample collection is unknown and variable, and they should perform equally as well for all qualities of ionizing radiation. Once these criteria are met, the next challenge is to validate the performance of the new markers in human volunteers. Because of ethical considerations, these can only be individuals who are victims of radiation exposure accidents or who are undergoing radiation therapy. In the former case, uncertainty often accompanies the estimate of the actual dose received and the determination of whether the dose was received as a whole or partial body exposure. In the latter case, radiation therapy is administered at highly controlled and focused doses that do not represent the entire spectrum of radiation exposures needed for complete validation. Because of these limitations in data from human volunteers, data must also be obtained from highly controlled animal studies in which the entire spectrum of radiation exposures can be administered, and the results must then be correlated with the data from human subjects to arrive at a valid interpretation.

Accomplishments

Despite the technical challenges facing this area of research, the rate of progress in developing promising prophylactic and therapeutic countermeasures against radiological injury, and in advancing novel analytical technologies for biodosimetric assessment of radiation exposure has increased dramatically. Significant advances in medical science and biotechnology over the past decade are being brought to bear directly or indirectly to create solutions to the medical challenges of preventing and managing radiological injury. It is also important to recognize the nature of radiological injury in assessing the potential for developing

effective medical countermeasures. Although medical means cannot shield against the deposition of ionizing radiation energy into living tissues, detailed studies have shown that 70% –80% of radiation-induced injury is the result of secondary biochemical reactions cascading from the initial energy deposition event. More recent studies have elucidated the so called bystander effect in which soluble factors secreted by an irradiated cell impart a detrimental effect on un-irradiated neighboring cells. As alluded to above, different tissue types have differing susceptibilities to ionizing radiation, offering insight into the pathophysiological mechanisms of injury and the ability to tailor organ-specific medical interventions. This fundamental knowledge along with what is known about cellular damage surveillance and repair mechanisms, cell cycle regulation and reproductive mechanisms, and other regulatory pathways controlling cellular functions point to unprecedented opportunities for advancement that are limited only by resources.

Table 2-14 below summarizes in general terms the medical countermeasure approaches for addressing nuclear/radiological injuries:

Table 2-14. Medical Nuclear Defense Countermeasures

PRETREATMENTS
Free radical scavenging agents: Compounds that neutralize highly reactive oxygen species that are generated in tissues upon the deposition of ionizing radiation and that are a major cause of tissue damage.
Cell cycle regulatory control agents—Small molecular weight synthetic agents that modulate cell cycle regulatory checkpoints by reversibly arresting cell division to allow a cell's natural surveillance and repair mechanisms time to correct DNA damage before lethal mutations become incorporated into daughter cells.
Apoptotic inhibitory agents—Small molecular weight synthetic molecules that inhibit apoptotic pathways that are activated by ionizing radiation and that lead to programmed cell death.
THERAPIES
Antibiotics: Antimicrobial agents to effectively treat systemic infections caused by enteric microorganisms that translocate across damaged intestinal epithelium without affecting the beneficial anaerobic microorganisms of the intestinal tract.
Hematopoietic cytokines: Recombinant growth factors that stimulate the replication and maturation of hematopoietic progenitor cells to help reverse myelosuppression and to replenish blood platelets.
Epithelial growth factors: Recombinant growth factors that stimulate the regeneration of epithelial cells from basal progenitor cells.
DIAGNOSTIC TECHNIQUES
Cytogenetic dose assessment—Cytologic methods to estimate the absorbed dose of radiation based on microscopic imaging of aberrant chromosome morphologies arising from damage to nuclear DNA.
Molecular analyses—Quantitative analytical methods that measure alterations in blood protein levels, cellular messenger RNA levels, or DNA sequences (mutations), the degrees to which correlate with absorbed radiation dose.

2.7 JOINT BIOLOGICAL DEFENSE PROGRAM – SPECIAL REPORT ON ANTHRAX VACCINE COSTS, ACQUISITION STRATEGY, AND RELATED ISSUES

As part of the National Defense Authorization Act for Fiscal Year 2001 - Authorization Conference Report (H.R. Rep. No. 106-945, Joint Biological Defense Program, page 719), Congress requested the Department to submit a special report along with the Annual Report to Congress on the Chemical and Biological Defense Program. (Related activities of the Joint

Medical Biological Defense Research Program are described in Section 2.7.5 of this chapter and Annex E of this report.) The conferees requested the Department to provide information on the costs incurred by, and payments made to, each contractor or other entity engaged in the production, storage, distribution, or marketing of the anthrax vaccine administered by the Department of Defense. **Table 2-15** identifies all obligations associated with the manufacture of the Anthrax Vaccine Adsorbed (AVA). **Table 2-16** identifies storage costs, distribution, and marketing. **Table 2-17** identifies the status of the anthrax vaccination program.

Table 2-15. Obligation of Funds for Anthrax Vaccine Adsorbed ($ in millions)

System Cost Element	FY 02& Prior	FY 03	Total
BioPort Corporation			
Production	110.4	29.3	139.7
Redundancy	4.4	0.0	4.4
Post Approval Requirements	5.7	0.0	5.7
Process Validation/BLA Supplement Approval	77.8	0.0	77.8
Testing, Labeling, Shipping, & Security	14.6	1.8	16.4
Facility Renovation	4.5	4.9	9.4
Camber Corporation	11.4	4.7	16.1
SAIC	1.3	0.0	1.3
Program Management Support	3.9	1.3	5.2
Total	**234.0**	**42.0**	**276.0**

Table 2-16. Storage and Education Costs for Military Vaccination Programs (FY03 values include both anthrax and smallpox vaccination programs) ($ in millions)

AVIP Costs	FY00/FY01	FY02	FY03
Contract Personnel/ Support	6.5	4.5	5.9
Vaccine Distribution	0.7	0.7	1.0
Education	2.8	0.5	1.5
Program Research and Evaluation	5.2	4.0	5.8
VA-DoD Force Health Protection Initiative	1.1	3.8	4.1
Total	**16.3**	**13.5**	**18.3**

Table 2-17. Anthrax Vaccine Immunization Program (AVIP)

The AVIP web site provides a detailed account on the nature of the threat from anthrax (*Bacillus anthracis*), description of the vaccine, explanation of U.S. DoD policies regarding biological defense vaccines, U.S. DoD policies regarding the anthrax vaccine, immunization schedule, information on adverse event reporting, and other information related to the AVIP. The AVIP web site may be found on the internet at http://www.anthrax.mil/.

As of 29 March 2004, 4,102,286 doses of the vaccine have been administered to 1,634,041 persons. Also as of this date 171,191 service members have received 6 or more doses.

In December 1997, the Secretary of Defense announced plans to begin vaccinating Service personnel deployed in High-Threat Areas (HTAs) against the BW agent anthrax. Vaccinations for troops in Southwest Asia began in March 1998. Vaccinations for troops in Korea began in August 1998. The AVIP Agency was established in September 1998 to implement and monitor the DoD policy and Services' plans. Due to an unanticipated delay in release of FDA-approved vaccine, DoD slowed its implementation of the AVIP incrementally between July and November 2000 and June 2001.

BioPort received full approval of all aspects of their Biologics License Application supplement from the FDA on January 31, 2002. On the same date, FDA released three production lots of anthrax vaccine (BioThrax®). BioPort has earned FDA release of additional lots steadily since then.

DoD resumed the AVIP with a priority execution program, continuing with special mission units, vaccinating forces assigned/deployed to HTAs for more than 15 days and expanding the vaccinations to early deploying forces designated for this area of operations. People who deferred doses during the slow down period will resume their vaccination series where they left off; next doses are then counted from that point.

Additionally, **Table 2-18** provides similar information on the Department's smallpox vaccination program.

Table 2-18. Smallpox Vaccination Program (SVP)

The SVP web site provides a detailed account on the nature of the threat from smallpox (variola virus), description of the vaccine, explanation of U.S. DoD policies regarding biological defense vaccines, U.S. DoD policies regarding the smallpox vaccine, immunization schedule, information on adverse event reporting, and other information related to the SVP. The SVP website may be found on the internet at http://www.smallpox.mil/.
As of 29 March 2004, 610,877 doses of the vaccine have been administered after screening about 657,147 people for medical exemptions.
On December 13, 2002, the President announced the national smallpox vaccination program, a portion of which involved vaccinating military personnel in mission-critical roles. Vaccinations began 3 days after the President's announcement. The DoD program vaccinates troops before an attack, to ensure they are personally protected and can continue their missions. The program includes three main groups of people: more than 2,000 members of Smallpox Epidemic Response Teams (SERTs), more than 10,000 members of medical teams for military hospitals and large military clinics, and more than 500,000 military personnel who constitute mission-critical forces, principally focused on the U.S. Central Command area of responsibility.
In addition to the Smallpox Vaccination Program, DoD issued version 3.1 of the DoD Smallpox Response Plan (www.smallpox.mil/resource/SMAplan/SMAplan.asp) on September 29, 2002. This document consists of a base plan plus 10 detailed annexes. The plan describes DoD's global duties on military installations or during contingency operations, as well as military support to civil authorities. The plan helps DoD prepare for and respond to smallpox outbreak, regardless of magnitude or location. Plan allows for either ring-vaccination or wide-area vaccination as a means of outbreak control.

2.8 CBRN DEFENSE HOMELAND SECURITY AND FORCE PROTECTION PROGRAMS

This section is a new addition to the 2004 report and reflects the incorporation of those programs currently managed by JPEO-CBD (specifically by the Joint Program Manager – Guardian) and DTRA to address CBRN Defense Homeland Security and Force Protection. Specifically, this section provides descriptions of efforts and plans related to the following: (1) Joint Service Installation Pilot Project (JSIPP), (2) Installation Protection Program, and (3) National Guard Bureau Weapons of Mass Destruction Civil Support Teams (NGB WMD-CST) and U.S. Army Reserve (USAR) Recon and Decon Units equipment.

The CBRN Defense Homeland Security and Force Protection area seeks to provide urgently needed defensive capabilities to those DoD organizations and forces responsible for responding to CBRN events that affect the missions and people associated with DoD installations. The programs that constitute this thrust differ from the other CBRN defense areas in two ways: 1) They address the need for integrated families of fully developed CBRN systems and 2) they meet the needs of both the military and civilian personnel responsible for responding to CBRN events. From 32 National Guard Bureau Weapons of Mass Destruction Civil Support Teams (NGB WMD-CSTs) and USAR Recon and Decon units to installations as large as the Norfolk Naval complex, comprehensive, integrated approaches to meeting the

CBRN threats is imperative. The CBRN Defense Homeland Security and Force Protection area programs in WMD-CST, the JSIPP, and the Installation Protection Program (IPP) will provide both military and civilian first responders and commands with the ability to prepare for, make informed decisions and manage the consequences of a CBRN event. Of the three efforts, the IPP program is structured using a spiral acquisition strategy to expedite procurement and fielding of emerging capabilities. At this time, all of these efforts are focused on effectively fielding Government and Commercial-Off-the-Shelf technologies and products (GOTS/COTS) to meet the urgent need. However, the spiral nature of these efforts lends itself to upgrading and improving equipment and procedures on a continual basis. The IPP program expects to take advantage of improvements in technology as it happens within the supporting product areas. At the same time, improvements in analytical capabilities will impact the Simulation Based Acquisition tools and processes so that optimized use can be made of available resources.

2.8.1 CBRN Defense Homeland Security and Force Protection Science and Technology Efforts

The CBRN Defense Homeland Security and Force Protection area leverages science and technology 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 and Force Protection area will work with the CBRN S&T community and the associated product area JPM to prioritize investments and integrate requirements.

This strategy of supporting sub-system S&T will meet the vast majority of the area requirements. The exception to this is exemplified by the JSIPP effort, which addresses a primary technical concern of this program, the integration of systems or families of systems.

2.8.1.1 Goals and Timeframes. The goals of CBRN defense homeland security and force protection are to support the WMD-CSTs, and provide CBRN Defensive capabilities to over 200 DoD installations according to the schedule presented in **Table 2-19**.

Table 2-19. JSIPP & IPP Installation Schedule (new installations per year)

	FY03	FY04	FY05	FY06	FY07	FY08	FY09
JSIPP	9 *						
IPP		15	20	30	40	45	50

* Some of these pilot programs are included in later years installations

2.8.1.2 Major Technical Challenges. Technical challenges are based upon the production nature of the programs. Major technical challenges include the following: 1) Providing biological event identification and warning in time to prevent infection, vice detecting to treat those infected, in a cost effective manner, 2) Low cost, self-configuring communications for sensor networks, 3) Expeditious transition of emerging COTS capabilities, and 4) Comprehensive CBRN Simulation Based Acquisition System. The first two challenges are high on the DoD priority lists and being pursued by many sources. The third challenge may require particular attention from the JPEO and CBRN S&T communities to provide resources to readily evaluate COTS products against the Urgent Capabilities Document requirements. Lastly, Simulation Based Acquisition tools are currently fragmented across the individual system areas and an integrated SBA Analysis Process and tool set will require development. Due to the timeframes to meet the IPP Urgent Capabilities Document requirements, multiple

analysis teams will be required to produce analyses and trade-off studies leading to recommended Concept Designs for each of the 200 installations within the IPP. These efforts will require a standardized design analysis process that can provide predictable, consistent, high quality results. The current approach will make use of existing experts and tools to prototype the IPP Design Analysis Process in FY04 leading to more advanced and mature processes with on a semi-annual or annual schedule.

2.8.2 CBRN Defense Homeland Security and Force Protection Modernization Strategy

DoD efforts for CBRN Defense Homeland Security and Force Protection rely upon the integration of capabilities provided by the six operationally oriented commodity areas: Contamination Avoidance, Individual Protection, Battlespace Management, Collective Protection, Decontamination, and Medical Systems. As these commodity areas complete development of emerging capabilities, each product or system will be evaluated for its applicability to meeting the needs of the ongoing CBRN Defense Homeland Security and Force Protection efforts. Some potential contributions from other CBRN RDT&E programs are shown based upon their projected schedules in **Table 2-20**.

Table 2-20. Homeland Security and Force Protection Modernization Strategy

	NEAR (FY04-05)	MID (FY06-11)	FAR (FY12-19)
Installation Protection	• JSIPP and IPP to over 35 installations • GOTS/COTS: Approved for Service Use CBRN equipment and Systems	• IPP to over 165 additional installations • Use of emerging subsystem advances • Advanced SBA tools	• Use of automated Information Systems • Use of advanced CBRN sub-systems
WMD-CSTs	• Equip CBRNE equipment to the standing up of 12 new NGB WMD-CSTs starting in FY 04 and projected additional 11 new CSTs starting in FY 05 • Equip CBRNE equipment to the standing up of one USAR Decon Company starting in FY04 and complete in FY 05	• The testing and fielding of upgraded Analytical equipment for the Analytical Laboratory System (ALS) as Block I • The testing and fielding of upgraded Communications equipment in the Unified Command Suite (UCS) as Incremental I	• Possible Block II for the ALS • Possible Incremental II for the UCS

2.8.3 Joint Service CBRN Defense Homeland Security and Force Protection Programs

2.8.3.1 National Guard Bureau Weapons of Mass Destruction – Civil Support Teams (NGB WMD-CST): Public Law 104-201, 23 September 1996, subject: Defense Against Weapons of Mass Destruction Act of 1996. Defense Reform Initiative Directive (DRID) 25, dated 26 January 1998, approved implementation of the DoD Plan for Integration of the National Guard and Reserve Component into Domestic Weapons of Mass Destruction Terrorism Response. The Weapons of Mass Destruction - Civil Support Team (WMD-CST) mission is to support civil authorities at a domestic CBRNE incident site by identifying CBRNE agents/substances, assessing current and projected consequences, advising on response measures, and assisting with appropriate requests for state support to facilitate additional resources. The WMD-CST is a high-priority response unit supporting civil authorities in responding to a weapon of mass destruction (WMD) situation.

USAR Recon/Decon Units: Public Law 104-201, 23 September 1996, subject: Defense Against Weapons of Mass Destruction Act of 1996. DRID 25 approved implementation of the

DoD Plan for Integration of the National Guard and Reserve Component into Domestic WMD Terrorism Response. This plan specified that each Army Reserve Chemical Company will train a platoon-sized element to perform NBC Reconnaissance support to the local incident commander, and that each Chemical Company will train platoon sized elements to provide patient decontamination support to the local incident commander.

Chemical Company (Recon): FORSCOM message dated 241845Z JUN 02: On Order deploy to provide NBC reconnaissance support to the incident commander or Lead Federal Agency to detect and identify CBRN contamination. Provide CBRN reconnaissance support operations to include contamination surveys, agent/material sampling, and assistance with casualty search and extraction.

Chemical Company (Smoke/Decon): FORSCOM message dated 241845Z JUN 02: On Order deploy to conduct NBC personnel and casualty decontamination in support of the incident commander or Lead Federal Agency."

2.8.3.2 Joint Service Installation Pilot Project (JSIPP). The JSIPP will identify installation CBRNE improvements for the military Services' requirements generation process. It includes two procurement efforts. The first effort is the procurement and installation of CB detection equipment designed to provide the installation commander increased preparedness and situational awareness supporting decision-making during a CB incident. The second effort will equip and train emergency response elements in consequence management procedures for CBRNE incidents. JSIPP will provide guidance for training and exercises for installation CB defense efforts, collecting data and coordinating the assessments to support CB requirement recommendations for institutionalization throughout the Services. The JSIPP will provide CB defense force protection packages at nine installations (three per Service) in FY 03. It will also fund related installation support equipment, integrated logistics support (ILS), and operations and maintenance (O&M) and training. In addition to the CB defense force protection package, JSIPP will also provide each installation with equipment and training to enhance emergency response capabilities for CBRNE incidents on military installations. It will involve organizing, equipping, training, and conducting exercises for installation emergency response personnel.

The purpose of the JSIPP is to provide equipment and training to enhance detection, protection and emergency response capabilities for CBRNE incidents on DoD Installations. The project has four objectives:

a. Equip nine diverse DoD installations with CBRNE detection equipment.
b. Enhance DoD installation emergency response capabilities with emergency responder equipment and training for installation consequence management of CBRNE incidents
c. Collect data and refine concepts of operations (CONOPS) for CBRNE defense of similar DoD installations
d. Based on CONOPS refinement, provide recommendations on resource requirements (personnel, equipment, and logistics support) to support development of the appropriate Program Objective Memorandum (POM) submissions and future joint CBRN defense requirements to support installation CBRN defense preparedness and CBRNE emergency responder needs.

The Installations selected by Services are: Air Force; Warner-Robbins AFB, Pope AFB, Barksdale AFB, Army; Ft Campbell, Ft Lewis, Ft Gordon, Navy; NSWC Dahlgren, Naval Base San Diego, Marine Corps; Camp Lejeune.

The DATSD(CBD) and the ASD(HD) jointly provide policy oversight and program review and direction. To achieve project objectives and reduce technical and cost risks, a three-tiered approach was used. This approach optimizes CBRN and emergency responder equipment sets at each installation while providing varied equipment sets for requirements analysis purposes and providing sufficient funding for logistical support for CBRN detection equipment operations. The three tiers are:

a. Tier 1. Emergency responder equipment and training, CONOPs refinement and exercises. Tier 1 locations will not have CBRN detection equipment installed under JSIPP. Tier 1 Installations are: Army, Fort Gordon; Navy, NSWC Dahlgren; Air Force, Pope AFB.
b. Tier 2. In addition to emergency responder equipment and training, CONOPs refinement and exercises, Tier 2 installations receive chemical agent detectors/alarms, dry filter unit (DFU) biological agent collectors and a re-locatable biological agent analysis laboratory. Tier 2 Installations are: Army, Fort Lewis; Air Force, Barksdale AFB.
c. Tier 3. In addition to the same equipment fielded at Tier 2 installations, Tier 3 installations are given automatic biological agent detectors/alarms. Tier 3 Installations are: Army, Fort Campbell; Navy, NRSW San Diego, Camp Lejeune; Air Force, Warner-Robins AFB.

Equipment fielding is on-going and will be completed by the end of the first quarter of FY04. PM JSIPP will continue to provide operational and logistical support and to conduct training, CONOPs development/refinement and exercises through the end of first quarter FY05. JSIPP equipment and program management will transition to the Services/installations at this time.

2.8.3.3 Installation Protection Program (IPP): The JPEO-CBD /JPM Guardian IPP constitutes the DoD's first effort to field a full spectrum of NBC installation protection capabilities designed as a family-of-systems to military installations and DoD-owned or leased facilities. The JPM Guardian plans to procure Government and Commercial-Off-The-Shelf (GOTS/COTS) systems designed to meet the operational requirements as identified in the Urgent Requirements Capabilities Document (URC), 14 October 2003.

The IPP is designed to fill a critical gap in an installation's ability to react to a CBRN incident. This program will provide DoD prioritized installations with an integrated CBRN protection and response capability to reduce casualties, maintain critical missions, and effectively restore essential operations. JPM Guardian has an assigned mission to:

- Provide an effective CBRN detection, identification, warning, and protection system for each installation.
- Ensure integration of CBRN networks with existing Command, Control, and Communications, (C3) and augment capabilities to provide effective information management.

- Provide a CBRN capability that will allow for rapid restoration of critical installation operations.
- Protect DoD civilians, contractors, and other persons working or living on U.S. military installations and facilities from a WMD event.

The program is structured using a spiral acquisition strategy to expedite procurement and fielding. Technical risk will be reduced by focusing on mature GOTS/COTS technologies and products. This family of systems package will be fielded as a single, integrated system designed to meet the specific needs of the installation. The design will stress flexibility and the capability for future technology insertion.

2.8.4 Coordination with related CBRN Defense Homeland Security and Force Protection Programs

At the highest levels, these programs are coordinated by participation of the Services, Joint Staff and OSD staff elements in the Overarching Integrated Product Teams (OIPTs). At the operational level, coordination is accomplished by a near-continuous dialog between the Program management and the Services and installations. Joint, Service and Federal Agency IPTs have also been established for key functions within the IPP Program. Coordination has included the following Programs and Initiatives within DOD: Immune Building Program (DARPA); UNWD (DTRA/DOE); Bio-Net (DOD/DHS); the CBRNDP S&T Program (DTRA); RestOps and CASPOD ACTDs (DTRA); The Defense of Cities Study (DOE).

2.9 OPERATIONAL TESTING - PROJECT O49

Heightened awareness of the chemical and biological (CB) threat has resulted in increased requirements for CB defense information and operationally oriented data and analysis from the Services and the Unified Combatant Commands (UCC). One of DoD's most valuable assets for meeting these requirements is the *Joint/UCC Operational Testing* program (Project O49), based at the West Desert Test Center (WDTC) at U.S. Army Dugway Proving Ground (DPG), Utah. Project O49 is a joint service program funded through the CBRN Defense Program. Objectives are to: (1) plan, conduct, evaluate and report on laboratory analyses, field tests and technical assessments in response to user requirements; (2) serve as the DoD's Joint Contact Point for CB defense test and technical data; and (3) publish and maintain the many volumes of the CB Technical Data Source Book. Project O49 continues to upgrade the West Desert Technical Information Center (WDTIC) and coordinate with the Chemical-Biological Information Analysis Center (CBIAC) to vastly improve literature search and analysis capabilities.

Following are summaries of recent Project O49 operational tests:

- *Persistent Chemical Agents and Their Reactions with Surfaces (AR-330, AF-65)* will be conducted during 2004 at the WDTC at DPG for the U.S. Air Force (USAF). The objectives of this test are to determine the evaporation rate of five different CW agents, neat and thickened, from several warfighting surfaces.
- *Processing Cargo and Troops Through an Exchange Zone (Phases I, II) (TR-12)* was conducted by the Air Mobility Command. The objective was to determine if clean cargo and troops could be processed through an exchange zone without hindering transload

operations. Movement of cargo and troops through the exchange zone was evaluated for contamination. Phases IV, VIII of the exchange zone was conducted in September 2003 at Charleston Air Force Base by AMC and DPG. A modified exchange zone was erected where cargo, rolling stock, and troops were processed through the exchange zone, after which personnel were processed back into the clean zone through the contamination control area (CCA). The report was published in June 2003. Phases IV and V were scheduled to be executed in 2003; however, these phases have been reprogrammed for execution in FY05. Phases IV and V will validate the entire exchange zone process.

- *Operation Southern Breeze Field Test (MTMC-Cargo) (TR-4, TR-5)* was conducted during May 2001 at Charleston Naval Weapons Station, South Carolina for the US Transportation Command, in conjunction the Military Traffic Management Command (MTMC). The test objective was to determine how covering versus not covering cargo from a Large Medium Speed Roll On, Roll Off (LMSR) Ship affected the level of contamination and the amount of time needed to decontaminate the items. A report discussing three of the five critical operational issues was published in January 2003. A test to answer the remaining critical operational issues was conducted in FY03 and an abbreviated test report was published in August 2003.
- *Operation Southern Breeze Field Test (MSC-Ship) (TR-4, TR-5)* was conducted during July 2002 at Charleston Naval Weapons Station, South Carolina, for the Military Sealift Command (MSC). Test objectives were to (1) evaluate the extent of internal contamination allowed by the ventilation system of an LMSR Ship when contaminated with a simulated chemical agent and (2) evaluate the effectiveness of current decontamination and contamination avoidance procedures, and (3) evaluate the use of portable collective protection systems (M20A1s) as crew chemical rest and relief areas. The report was published in May 2003.
- *Field Test of the Casualty Decontamination Procedures (AF-58)* was conducted in November 2002 to field test the Wartime Medical Decontamination Teams Concepts of Operations. The report was published in April 2003.
- *Assessment of Live Biological Agents on Material Surfaces (AF-49)* was conducted in October through December 2003. The test objective was to evaluate the persistence of two high-threat biological agents on various surfaces under diurnal conditions. The test report is pending.
- *Large Frame Aircraft Decontamination* simulant methodology was successful and the field test was conducted in September 2003. The objective of this test was to examine decontamination technologies, tactics, techniques, and procedures (TTP) to determine the most appropriate means to decontaminate large frame aircraft.
- *Assessment of Interior Building Areas as Chemical Rest and Relief Areas (AF-60)* was a field test conducted at Osan Air Base, Korea in July 2003. The objective was to evaluate the level of safety provided by interior building shelters constructed according to PACAF procedures with regard to chemical agent vapors during a chemical warfare attack. Shelter areas were constructed inside ordinary facilities in accordance with the

HQ PACAF guidance concerning noncombatant evacuation operations personnel. The shelter area was challenged with BIS (VX simulant) and MeS (HD simulant). Concentration levels were monitored inside the shelter areas and outside the building in the dissemination zone. The test report is pending.

- *Contamination Prevention via Pressurization of Transport Category Aircraft (TR-04-01)* is schedule for field-testing in FY04. Pressurization of aircraft while on the ground during a chemical attack has been identified as a method to prevent/delay internal contamination. USTRANSCOM, HQ-AMC/J5 and DPG will be testing the feasibility of pressurizing a large frame aircraft (LFA) using external power sources other then the aircraft main engines or GTC/APU. DPG will be collection internal and external vapor sampling data of a simulant to determine the effectiveness of LFA pressurization during a simulated chemical environment.

2.10 CBRN DEFENSE RDA PROGRAMS REQUIREMENTS ASSESSMENT

ISSUE: **In order to make use of the efficacy data based on testing in animal models, which provides a mechanism for licensure of chemical and biological defense medical products when legal and ethical constraints prevent efficacy testing in humans, conformance with FDA requirements can no longer be the sole responsibility of the advanced developer.**

SOLUTION: FDA and DoD discussions regarding amending the Code of Federal Regulations to allow animal efficacy data to be used in lieu of large-scale human clinical efficacy trials produced a successful outcome when, in May 2002 the "Animal Efficacy Rule" was finalized and went into effect in July 2002 (21 CFR Parts 314 and 601, Food and Drug Administration, "New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible." Federal Register: May 31, 2002 (Volume 67, Number 105), Rules and Regulations, Pages 37988-37998.) The first successful application of the new rule occurred in February 2003, when FDA approved pyridostigmine bromide as a pre-treatment for the nerve agent soman, based on evidence of its effectiveness primarily from studies in monkeys and guinea pigs. This rule eliminated a major impediment faced by advanced developers of CBW-medical countermeasures. It has since become apparent, however, that in order to make most effective use of this rule, the DOD cannot wait until a medical product reaches the advanced developer (JVAP or MITS) before FDA-required data pertaining to manufacture, potency, safety and efficacy are developed. To do so could delay licensing of the product for years, and dramatically increase the cost of bringing the product to market. Instead, cognizance of FDA requirements with regard to both manufacturing and the animal efficacy rule must be part of the S&T plan for all proposed or postulated medical CBD countermeasures. Accordingly, CBRNDP S&T project planning and execution will include early and regular consultation between the S&T researchers, advanced developers, and the FDA. Such consultation will clarify the basic science work necessary to validate relevant animal models and surrogate markers of efficacy, as well as establish production methods that can be used for license application. Coordinated planning and execution at the S&T phase of medical product development will smooth transition to the advanced

developer, and shorten both the time and expense required to deliver safe and effective C/BW countermeasures to the warfighter.

ISSUE: **DoD lacks FDA-licensed vaccines against some BW threat agents.**

SOLUTION: DoD currently has two licensed vaccines for biological defense protection—Anthrax Vaccine Adsorbed (BioThrax™) and Smallpox Vaccine (Dryvax, Wyeth). For other biological defense vaccines, DoD awarded a prime systems contract to Dynport Vaccine Company (DVC). This contract establishes a single integrator to develop, license, produce, and maintain a stockpile of BD vaccines for protection against BW agents. DVC is required to obtain and maintain FDA licensure for all the vaccine products developed under this contract.

The contract was awarded in November 1997 and began with the development and licensure of three vaccines: Q fever, Tularemia, and Smallpox, and the storage of the current unlicensed BD vaccine stockpile (IND products). There are options for the development and licensure of ten other BD vaccines, which are programmed for development and licensure.

In July 2001, DoD submitted the "Report on Biological Warfare Defense Vaccine Research & Development Programs." This report addresses: 1) the implications of relying on the commercial sector to meet the DoD's biological defense vaccine requirements; 2) a design for a government-owned/contractor-operated (GOCO) vaccine production facility; 3) preliminary cost estimates and schedule for the facility; 4) consultation with the Surgeon General on the utility of such a facility for the production of vaccines for the civilian sector and the impact of civilian production on meeting Armed Forces needs and facility operating costs; and 5) the impact of international vaccine requirements and the production of vaccines to meet those requirements on meeting Armed Forces needs and facility operating costs.

As part of the DoD's vaccine initiative, DoD selected an independent panel of experts to assess the DoD acquisition of vaccine production programs and report their recommendations for improvement to the Deputy Secretary of Defense. The panel prepared a report to reflect its independent opinions for consideration by DoD. This report discusses vaccine industry constraints and concludes that the size and scope of the DoD program is too large for either DoD or industry alone. It recommends the application of a combined, integrated approach by DoD and industry, coupled with better alignment with industry best practices. DoD is working with the Department of Health and Human Services and other federal agencies to develop the requirements and plans for constructing a national biological defense vaccine production facility.

ISSUE: **Anthrax vaccination currently requires a primary series, six dose regimen spaced out over the course of 18 months, with an annual booster to maintain immunity. This protocol makes it difficult to complete before deployment of forces or to ensure that mobile forces, once deployed, are administered the proper regimen.**

SOLUTION: DoD conducted a successful pilot study evaluating a dosage regime using fewer doses of Anthrax Vaccine Adsorbed (BioThrax™). The results of this study were

presented to the Food and Drug Administration (FDA) in FY99. The results have been published in the peer-reviewed journal *Vaccine* (Phillip R. Pittman et al., Anthrax vaccine: immunogenicity and safety of a dose-reduction, route-change comparison study in humans. *Vaccine*. Vol. 20 (9-10) (2002) pp. 1412-1420). Congress has funded the Department of Health and Human Services to coordinate expanded, pivotal studies. The Centers for Disease Control and Prevention (CDC) is conducting these congressionally funded studies in a collaborative effort to study the safety and efficacy of vaccines used against biological agents. The study will address: (1) the risk factors for adverse events including differences in rates of adverse events between men and women; (2) determining immunological correlates of protection and documenting vaccine efficacy, and (3) optimizing the vaccination schedule and administration to assure efficacy while minimizing the number of doses required and the occurrence of adverse events. These studies are being conducted at five research centers: Emory University, Mayo Clinic, Baylor College of Medicine, University of Alabama-Birmingham and Walter Reed Army Institute of Research. Interim results are scheduled to be submitted to the Food & Drug Administration (FDA) in late 2004, with the final study data submitted to FDA in summer 2007, 5 years after enrollment of the last volunteer.

ISSUE: **Vaccination of U.S. military service personnel with the Anthrax Vaccine Adsorbed (BioThrax™) has been considered not fully effective and experimental by some. A ruling by a United States District Court for the District of Columbia gave the opinion that the anthrax vaccine should be classified as "investigational" with regard to protecting against inhalation anthrax.**

SOLUTION: On December 30, 2003, the Food and Drug Administration issued a Final Rule and Final Order Regarding Safety and Efficacy of Certain Licensed Biological Products Including Anthrax Vaccine. FDA's final order states that the efficacy analysis in the controlled clinical trial demonstrating the efficacy of the vaccine includes all cases of anthrax disease regardless of the route of exposure or manifestation of disease. This final rule and order make it clear that FDA does not regard the approved anthrax vaccine as "investigational" for protection against inhalation anthrax.

ISSUE: **The effects on humans resulting from the exposure to low doses of chemical agents, particularly organophosphorous (nerve) agents, are not clearly understood.**

***SOLUTION*:** During FY00, DoD established the Low Level Chemical Warfare Agent Working Group (LLCWG), which was chartered to provide advice on the research programs to understand the health effects of exposure to low-level chemical warfare agents, to prevent unnecessary duplication of research efforts, and to focus and direct scientific investigations to address operational issues. The LLCWG has developed the Low-Level Chemical Warfare Agents Exposure Research Master Plan, which addresses research on potential operationally relevant performance decrements and delayed adverse health effects associated with low-level exposures to chemical warfare agents. It builds upon, refines, and updates the May 1999 Strategy and provides more detail on research.

The objective of DoD's low-level CWA research program is to fully characterize the toxicity of CWAs in order to enable rational decision-making regarding Doctrine, Organization,

Training, Materiel, Leadership, Personnel and Facilities (DOTMLPF). The purpose of the Plan is not to outline a research program to investigate Gulf War Illnesses. The Master Plan describes the planned research, from FY02 to FY07, to fill gaps in the toxicological data for CWA at low levels of exposure. The research plan, which is being reviewed by the National Academy of Sciences Committee on Toxicology, is structured along three major thrusts:

- Characterize concentration-time (Ct) relationships for low-level/longer time CWA vapor exposures
- Identify alternative, but physiologically significant, toxicological endpoints
- Conduct appropriate integration studies linking experimental data sets with predictive human health effect assessments.

In FY03, continuing research efforts to understand the effects of low level chemical toxicity on the human body and to develop medical countermeasures, if warranted, to minimize effects of low level chemical exposure were underway at or were sponsored by USAMRMC's U.S. Army Medical Research Institute for Chemical Defense and Edgewood Chemical and Biological Center (ECBC).. Accomplishments are found in Annex E. A consolidated joint medical and non-medical defense research DTO (CB.51) entitled Low Level CW Agent Exposure: Effects and Countermeasures was initiated in FY03.

ISSUE: **An inadequate amount of agent fate data exists to support the fundamental understanding of post attack environment. Nearly all of the pertinent data was collected during a time when test programs were focused on offensive war strategies. Little attention was given to the wider spectrum of data that pertains to post attack recovery, restoration of operations, effects at non-lethal (*e.g.*, low level) exposures, and for advanced model development and validation.**

SOLUTION: The primary objective of DTO CB.42 Environmental Fate of Agents is to provide decision-makers information to accurately predict agent persistence and the resulting hazard from chemical agent attacks. This can be achieved through lab, field and wind tunnel testing so that different variables, such as meteorological and vapor measurements can be validated. The collection of agent fate data will support the development of a validated hazard prediction model.

***ISSUE*: The cost for implementing new biosurety and biosecurity requirements will have an as yet undetermined impact on CBRNDP S&T Programs.**

Since the anthrax letter attacks of October 2001, the handling and security of anthrax and other hazardous pathogens at DoD facilities has received intense attention and scrutiny. While issues of biological safety had been addressed with an Army regulation and pamphlet over ten years ago, the concepts of surety and security in the context of biological research are relatively new, even though these areas have been well developed for chemical warfare agents and nuclear materials. The fundamental property of bacteria and viruses – their ability to reproduce themselves – leads to numerous complexities and hurdles in the development of regulations and policies for the surety and security for these materials.

SOLUTION: DoD-wide working groups of scientists, surety and security experts have been called upon to assist in the development of Army and DoD policy and regulations for Biological Surety and Biological Security. However, because most facilities that conduct CBRNDP research with biological materials have never had to implement surety or enhanced security programs, the costs of implementation of the new requirements in these areas are still under review.

***ISSUE*: The classified GAO Report *Chemical and Biological Defense: Sustained Leadership Attention Needed to Resolve Operational and System Survivability Concerns,* May 30, 2003 (GAO-03-325C), identified several issues related to the ability of key systems to survive after being contaminated by NBC agents and being decontaminated.**

SOLUTION: The Program Analysis and Integration (PAI) Office has been addressing the nuclear, biological, and chemical contamination survivability (NBCCS) concerns raised in the GAO Report. In response to a request by ATSD(NCB), the PAI Office developed an NBCCS implementation plan that is responsive to GAO concerns about the NBC contamination survivability of major defense acquisition programs, and the need for increased management oversight to ensure their survivability. The PAI Office convened an NBCCS Integrated Product Team (IPT) that, over the course of three meetings and through correspondence, developed an NBCCS roadmap and a program plan for its implementation. By relying on resident NBCCS expertise among the organizations currently responsible for NBCCS policy and implementation, and then encouraging participation of all the Services in the IPT process, the PAI Office ensured that the resulting program plan and roadmap had broad acceptability to the Services. The NBCCS IPT process and resulting NBCCS Program Plan are under review by senior CBRNDP leadership.

Chapter 3

Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Logistics Status

3.1 INTRODUCTION

The overall logistical readiness of the Department of Defense's CBRN defense equipment continues to improve. The Services have increased stock of most CBRN defense equipment, and the overall Service requirements have decreased as a result of a smaller force. Both factors have improved the overall DoD readiness and sustainment status. Automated inventory management and asset visibility initiatives continue to increase the ability to manage what is becoming an increasingly joint collection of CBRN defense end items and consumables. A number of items continue to pose a moderate to high risk challenge due to low inventories and continued modernization efforts.

The DoD CBRN Defense Program jointly manages the research, development, and procurement of major end items of CBRN defense equipment. These items are funded through defense-wide funding accounts. Replenishment of consumable (Class II) CBRN defense items are managed by the Services and the Defense Logistics Agency (DLA).[1] The existence of defense-wide (rather than Service-specific) research, development, and acquisition funding accounts has ensured the joint integration of CBRN defense programs. However, no defense-wide (that is, joint) operations and maintenance funding mechanism exists for the sustainment of CBRN defense items, including replenishment and replacement of consumables. Because of this, the *joint* CBRN defense community is limited to tracking the status of the DoD CBRN defense logistics readiness and sustainment program and making recommendations on funding issues.

The Joint Program Executive Office for CB Defense (JPEO-CBD) coordinates CBRN defense logistics issues. The JPEO-CBD works to ensure a smooth transition through the phases of CBRN defense equipment life cycles. It is also charged with developing and maintaining an annual Joint Service CBRN Defense Logistics Support Plan (LSP). This LSP forms the basis for the analysis found later in this chapter.

This chapter reflects logistics data to support FY04 logistics planning needs. In September 2001, the Quadrennial Defense Review presented a new force sizing construct that supersedes the requirement for supporting two nearly simultaneous Major Theater Wars (MTW). Logistics requirements to support the new force sizing construct, termed the "1-4-2-1 construct"

[1] Not included in the category of CBRN defense equipment is equipment maintained by emergency responders typically for HazMat response that may have a CBRN capability but is not intended for deployment or use in warfare theaters. Most, if not all of this equipment, is considered consumable and is procured either locally (installation level), through higher headquarters, or through special programs, such as the Defense Emergency Response Fund (DERF) and the Joint Service Installation Pilot Project (JSIPP). Interoperability with local communities is key to the procurement of these capabilities.

are being developed. During the past year, increased focus by all Services and DLA on CBRN defense logistics has visibly improved the overall program. Readiness shortfalls have been identified and addressed to the degree that full sustainment to win decisively in one major combat operation (MCO) is reasonably assured. The ability to support military operations to swiftly defeat the efforts in a second nearly simultaneous MCO is in question, due to the evolution of the new requirements and potential critical shortfalls of specific program areas. In addition, Homeland Security CBRN defense requirements must be met during the execution of these missions. These requirements have not yet been identified. Contingent upon implementation of the 1-4-2-1 construct derived from recommendations contained in the Secretary of Defense's Quadrennial Defense Review, the Services have programmed funds to specifically address these problem areas. Additionally, the services are formulating doctrine, tactics, techniques, and procedures for domestic response to terrorist incidents involving weapons of mass destruction.

As of the publication of this report the Services are also reacting to the demands of the current military actions not modeled by previous requirements studies such as the Joint Chemical Defense Equipment Consumption Rates (JCHEMRATES) study (published April 1999). To address these shortcomings and to include biological defense, the Joint Requirements Office for Chemical, Biological, Radiological and Nuclear (JRO-CBRN) Defense is managing the *Joint Chemical and Biological Defense Expendable Equipment Combat Consumption* (E^2C^2) study. The E^2C^2 study will provide projected consumption rates for consumable equipment in battlefield scenarios consistent with the 1-4-2-1 force planning construct. The Services will then evaluate the results of the study and develop their consumables requirements based on those rates. Service requirements for end items (non-consumables) will be based on Service concepts of the 1-4-2-1 construct. The E^2C^2 study began in FY02 with an identification of user needs and concerns and continued in FY03 with the development of a campaign combat data base for the initial study scenario. A Study Advisory Group consisting of representatives from each Service has been convened to establish the consumption rules for each scenario. The Services are drawing on the lessons learned during these current actions to refine the consumption rules which the E^2C^2 Study will use as the basis for its consumption models. The Services are also re-assessing their total needs beyond those of active forces.

The E^2C^2 study is proceeding at a measured pace to ensure that the Services can collectively assess the scenarios being modeled and that they achieve consensus on the consumption rules that dictate how equipment is used on the battlefield. At the time of publication of this report, the E^2C^2 study had successfully built the first of the two scenarios to be modeled, and had accounted for the CBRN defense items of equipment to be included in the study. The Services are in the process of defining the consumption rules. Once that is done, preliminary results will be produced and validated. Final results from two scenarios are expected to be available by January 2005.

Until the E^2C^2 study is complete, the Services do not have a current analytical basis for requirements modeling. Previous requirements based on JCHEMRATES results have become outdated and are not consistent with the 1-4-2-1 construct. During this interim period while new requirements are being modeled and validated, numerical requirements are not yet available to be listed in Annex G, thus the risks normally calculated against those requirements are not presented. The previous requirements are no longer meaningful in light of the new force structure.

Rather, readiness risks are discussed in terms of general inventory trends, historical patterns, and the health of the industrial base. Once the Services and JRO-CBRN have had adequate opportunity to validate the impact of the 1-4-2-1 construct on their new requirements, the 1 Win Decisively (1 WD) Requirement accompanied by the 2 Swiftly Defeat (2 SD) Requirement, which together cover the majority force requirements of the 1-4-2-1 construct, will be presented.

The Services continue to have issues regarding the accountability and management of CBRN defense item inventories. Limited asset visibility of consumable CBRN defense items below the wholesale level remains a problem due to the lack of automated tracking systems at that level (the exceptions being the Air Force and Marine Corps automated inventory management initiatives). This has the full attention of the senior CBRN defense managers. The Joint Total Asset Visibility (JTAV) project is also progressing toward addressing these problems in the long term.

The Services still replace and replenish consumable CBRN defense items through multiple, separate, and distinct funding authorizations, as discussed in Section 3.6 of this chapter. Each Service addresses secondary item procurement policies independently. There continue to be shortfalls of specific CBRN defense items when measured against the interim requirements.

The process by which the Services and DLA fund and store war reserve materiel has been hampered by differing definitions, and deployment strategies, and a lack of validated requirements for jointly managed items. The E^2C^2 study is being tailored to address these concerns and thus will create a solid foundation for providing a basis for the common planning of future requirements.

The JPEO-CBD initiated the seventh Joint Service CBRN Defense Logistics Support Plan (LSP) in October 2003. This report focuses on identifying the current on-hand stores of the Services' and DLA's CBRN defense equipment, and matching these numbers against the interim MCO requirements. The aim of the LSP is to identify the Services' readiness and sustainment capability, maintenance requirements, and industrial base issues in the area of CBRN defense. The data call conducted for the FY04 LSP was used to develop the findings in this chapter.

3.2 CBRN DEFENSE LOGISTICS MANAGEMENT

CBRN defense logistics management remains in transition. The Program Analysis and Integration Office (PAIO) had been charged with coordinating and integrating logistics readiness. They initiated a process to collect data and define requirements for this report and to ensure consistency across all planning efforts by convening, with the JPEO-CBD, a Joint Service CBRN Defense Logistics Integrated Product Team (LIPT). The JRO-CBRN, in coordination with the Services and the JPEO-CBD, provides coordination and integration of joint CBRN defense logistics. The JPEO-CBD will identify current readiness and sustainment quantities in the logistics area, with respect to current Defense Planning Guidance. Developmental CBRN defense programs that will be fielded within the POM time period are addressed to identify modernization efforts that are underway.

As currently envisioned (see **Figure 3-1**) the Services retain "starter stocks" of CBRN defense equipment to support immediate deployments and initial operations. The length of time

that these stocks will last each unit depends on the Service. Air Force units deploy with 30 days of CBRN defense consumables. Army divisions use a planning figure of 45 days, while Marine Corps forces and Navy shore units use 60 days as the basis for their plans. Navy ships stock 45 days or 90 days of consumable materiel based on the unit's mission. However, Navy ship values are notional in that they are based on peacetime demand and/or projections of wartime demand as contained in pertinent allowance documentation.

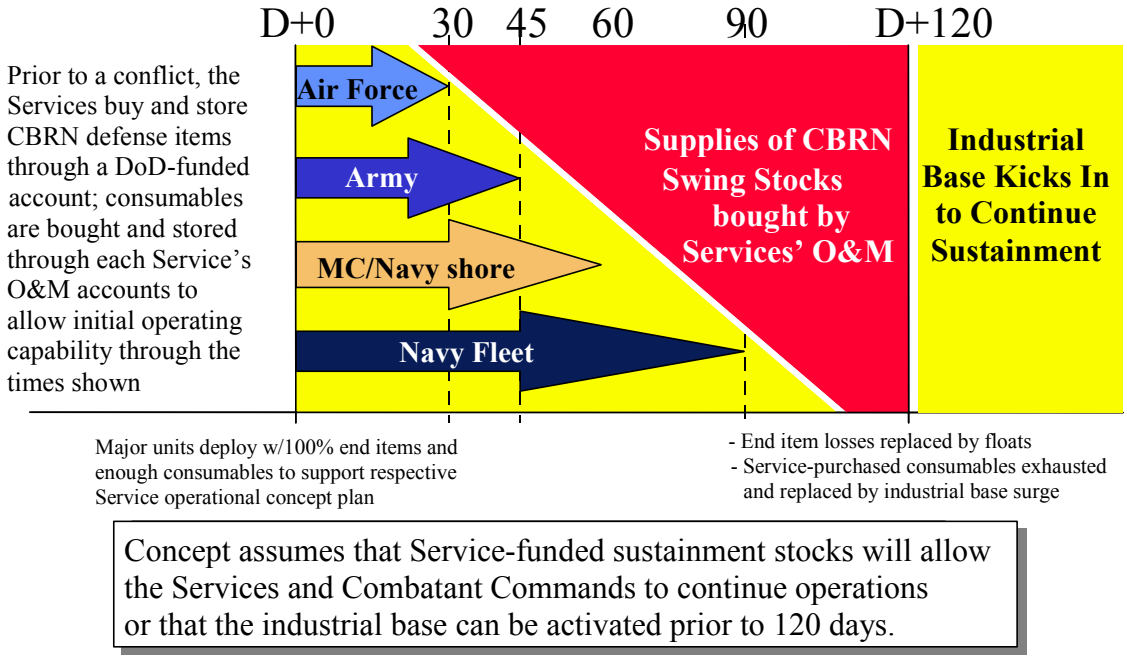

Figure 3-1. War Reserve Requirements and Planning

For CBRN defensive materiel, and particularly in the case of individual protective equipment (IPE), the days of supply represent a minimum stockage position based on current investment guidelines for such materiel. In most cases, the Services will first redistribute any available uncommitted assets to provide sustainment before sourcing elsewhere. Once these starter stocks are depleted, the military force turns to the DoD CBRN defense item managers for "swing stocks," also known as "sustainment stocks." The industrial base is also relied upon to surge production for sustainment. In general this assumption is valid, however, certain items may have long lead-time components, such as fabric for suits, which may delay the industrial base contribution to sustainment.

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. They are responsible for industrial base development, and storage of wholesale peacetime and sustainment wartime stocks. They buy (process procurement actions) and, if requested, store CBRN defense materiel (swing stocks) for the Services. However, the Services must provide funding to DLA and AMC for the procurements.

DLA and AMC depots primarily store Army-owned sustainment stocks, although the Air Force, Marine Corps, and Navy may provide funds to DLA and AMC to store their sustainment stocks. All Services are responsible for individually programming and funding sustainment stocks to provide the required support to their supporting force structure. Because of a

lack of visibility of CBRN defense items, unclear wartime requirements, scarce Operations and Maintenance funds, and low priorities given to CBRN defense stocks, the current quantity of DLA and AMC CBRN defense war reserves have been reduced and may not support sustainment requirements for the entire DoD force during a full 2 MCO scenario. These numbers are reflected in the tables of Annex G.

Service inventories of CBRN defense items maintained at unit level use either manual records or a semi-automated tracking system. Stocks held at wholesale level are maintained using a separate automated system. Currently, there is little connectivity between the two systems. As a result, there is limited Service level asset visibility for CBRN defense items. The Services are addressing this deficiency under the auspices of Joint Total Asset Visibility (JTAV), a long-term initiative that will link existing DoD logistics automated systems.

The Army has improved its visibility through an initiative to standardize individual issue of eleven critical CBRN defense items across all major commands. Unit Status Reporting was implemented for units to report on-hand stocks vs. requirements on a monthly basis. In addition, plans are in place for consumable chemical defense equipment for all forces other than Force Package I and other early deploying units to be consolidated and centrally stored at Bluegrass Army Depot. This seven-year execution plan is managed by HQ AMC and will enable better visibility and rotation of CBRN defense consumable items. The Air Force has a similar program that consolidates stocks of CBRN defense items for deployment in support of contingency operations. These initiatives have also reduced surveillance costs and improved overall management of CBRN defense stocks. The Marine Corps has been leading a Joint IPE Surveillance Technical Working Group, whose initiatives have been increasing cooperative efforts in surveillance and shelf life programs. The Marine Corps has also begun a CBRN stocks consolidation program and is implementing a CBRN Defense Equipment Management Program (DEMP) database to track the inventory, shelf life, and maintenance histories of CBRN defense items. The Air Force has also deployed the Mobility Inventory Control and Accounting System (MICAS) and is similarly realizing the benefits of its comprehensive shelf life management system. MICAS is being adopted by the Army. The Navy recently began a reconstitution of all Navy IPE under the Readiness Improvement Program (RIP). RIP is designed to enhance CBR-D asset management and unit readiness at afloat and ashore sites. CBR-D IPE falls under the cognizance of the Damage Control Assistant (DCA) shipboard. An existing system called Damage Control-Operating Space Items Management System (DC-OSIMS) is used to manage all DC equipment. To more effectively manage CBR-D IPE, the CBR module of DC-OSIMS is being upgraded to a web-enhanced browser-based system. Each item is barcoded and individual kits are provided to each sailor. To enhance CBR-D total asset visibility throughout the Navy, a new web-based system is being developed for tracking of all Navy CBRN assets, called the CBRD Total Asset Visibility Management System, or CBRD TAVMS.

Both DLA and AMC will remain key players in the future CBRN defense logistics management system. The Joint NBC Defense Board, through the JPEO-CBD, provides coordination and integration based upon the input of all Services and Combatant Commands. DLA and AMC will continue to provide services such as raw data collection, inventory control, and a distribution infrastructure. With the results of the E^2C^2study, the Services and DLA can immediately begin plans to improve their readiness and sustainment status based on a common understanding of modern conflict scenario requirements.

3.3 QUANTITIES, CHARACTERISTICS, AND CAPABILITIES

The results of the data collection efforts are compiled in Tables G-1 through G-5 in Annex G, CBRN Defense Logistics Readiness Data. Tables are included for each of the four Services and the DLA.

3.4 LOGISTICS STATUS

During collection of FY03 data, information on the inventory status of 135 fielded CBRN defense equipment items was compiled. The supply needs of deploying troops have caused inventory numbers to fluctuate during the data collection process, so the quantities discussed here and provided in Annex G should be viewed as a snapshot of inventory as of 30 September 2003. Inventory data are also complicated because once certain equipment items are issued, although in possession of a deployed warfighter, they are considered expended and are not counted as on-hand inventory. At the same time, these fluctuations have provided valuable lessons for the sustainment of the industrial base (*see Section* 3.7 **INDUSTRIAL BASE**).

While RADIACs were not traditionally a part of this chapter, they have been retained in an effort towards continuity with other chapters and annexes of this report. CBRN defense items such as spare parts and sub-components were considered a subset of the primary item for risk assessments, and were not reviewed separately. Batteries for critical systems are listed for informational purposes. Inventory tracking for batteries is difficult because of a lack of visibility and because they typically have other applications. Trainers were not included, since they do not reflect wartime service requirements. Characteristics and capabilities of selected fielded CBRN defense items are discussed in detail in Annexes A–F of this report.

Among medical consumables, sodium nitrite and sodium thiosulfate were combined in a single Cyanide Antidote Treatment Kit. The Chemical Agent Patient Treatment Medical Equipment Set and Medical Aerosolized Nerve Agent Antidote (MANAA) Atropine Sulfate Inhalation Aerosol were added.

Beginning with the 2000 report, the 2 MCO requirement for consumables was adjusted to include the initial issue along with the consumption provided by JCHEMRATES. This decision was made to provide for some inventory to remain after 120 days, thus enhancing our readiness if another conflict ensues. This more closely aligned the requirements calculations with those of other commodities such as ammunition. By 2005, consumable requirements will be guided by the E^2C^2 study and will be consistent with the 1-4-2-1 construct.

The current report omits requirements while new guidance is being developed that is consistent with the combination of MCOs and lesser contingencies put forward in the QDR, and subsequently detailed in the *Secretary of Defense Annual Report to the President and the Congress (2002)*, Chapter 5, pages 49-64.

Once the new requirements are validated, the risk assessments associated with on-hand inventory of critical items compared with their requirements will be resumed according to the accepted methodology defined in the “RISK ASSESSMENT” box, below. In the interim, some general observations are highlighted as follows:

RISK ASSESSMENT

Low –	Services have at least 85 percent of wartime requirement on-hand to support requirements
Moderate –	Services have between 70 to 84 percent of wartime requirement on-hand to support requirements
High –	Services have less than 70 percent of wartime requirement on-hand to support requirements

- The Air Force developed a mitigation plan in concert with procurement of the JSLIST ensembles to minimize risk in individual protection. Increased procurement funds for protective suits has aided in plans to transition to the JSLIST program. DLA provided an offset to the Services based on the value of defective BDOs that were removed from inventory, that is being applied toward purchase of additional JSLIST suits. Other BDOs will remain in inventory until they reach maximum shelf life.
- The Air Force is relying on the CWU 66/77P to provide a protective aircrew ensemble. It replaces the now obsolete Chemical Protective Undercoverall. Continued planned procurements should mitigate risks in the short term. The Joint Protective Aircrew Ensemble (JPACE), being procured in FY06, will replace this suit.
- The collective protection area continues to be assessed as high risk, in part due to the continued emphasis on contamination avoidance and individual protection, which overshadows this area. As the procurement cycle in these two latter areas matures, the risk assessment of collective protection systems will lessen slightly.
- JCHEMRATES IV indicated a significant increase in DS2 requirements as compared to JCHEMRATES III and current on-hand stocks. Because of the magnitude of this change, DS2 is omitted from the risk assessments pending the results of the E^2C^2study.
- With the expiration of M258A1 decontamination kits in FY99, the status of M291 kits becomes more critical. Present inventory and planned procurements along with improved organic manufacturing capability should keep this risk low. Production of M295 kits has improved.
- Medical chemical defense materiel remains generally in low risk. Shortages of 2-PAM autoinjectors can be supplemented with existing supplies of atropine and Nerve Agent Antidote Kits (NAAK), reducing its risk. These items are gradually being replaced by the Antidote Treatment Nerve Agent Autoinjector.
- To meet JVAP requirements, the prime systems contractor (DynPort Vaccine Company) and its subcontractors have retrieved data, files, microbial stocks, and experimental lots of biological defense vaccines produced over the last 10–30 years from government laboratories and contractors in order to conduct an assessment of the suitability of these products for contingency/emergency use. A thorough and ongoing review of this information in the light of current FDA requirements for use under a contingency/ emergency use scenario has been completed. Recommended expanded testing and maintenance requirements are now being evaluated for implementation in order to make these products available for contingency/emergency use to reduce the risk of not meeting wartime requirements. This risk of not meeting wartime requirements is still high but with expanded testing and maintenance over the next year could be reduced to a low to moderate risk.

In general, the Services continue to exhibit shortages in certain critical areas. Shortages exist for chemical and biological agent detection systems, collective protection shelters and their respective filters, and biological warfare vaccines. These shortages may have a serious impact on the joint force's ability to survive and sustain combat operations under CBRN hazard conditions in all of the operational scenarios of the 1-4-2-1 construct. The extent of the operational impact of CBRN defense equipment shortages is under review in several classified studies.

3.5 PEACETIME REQUIREMENTS

In peacetime, quantities of CBRN defense equipment are necessary to train personnel in CBRN defense and to build confidence among our warfighters that CBRN equipment will provide the necessary protection when used correctly. The two most critical areas of peacetime stocks are individual protective equipment and medical chemical defense materiel. The Services have indicated that adequate CBRN defense equipment is on-hand to conduct training.

Generally, items used in peacetime for training are drawn from retail stocks, requiring units to maintain both training and contingency stocks. For selected items, such as protective clothing, contingency utility is lost when the item is used (or consumed) for training. Because peacetime training requirements are met in this manner, major commands are inconsistent in their accountability and tracking of training equipment and in their estimates of on-hand assets. The Joint Service NBCD Equipment Assessment Program (JSNBCDEAP) has established a Memorandum of Agreement (MOA) with the Defense Reutilization and Marketing Service (DRMS) to segregate CBRN items turned in to Defense Reutilization and Marketing Offices (DRMO) suitable for issue as "Training Only". The JSNBCEAP indelibly marks them and fills requests for training items submitted by various authorized DoD agencies. Requirements or applicability for use in homeland security have not yet been determined or validated. Currently, each of the services has a mixed approach to the use of CBRN defense equipment intended for warfighters during peacetime. Until such time as requirements are defined these types of assets will not be a part of the logistics status report.

3.6 FUNDING

In accordance with statutory requirements (50 USC 1522), funding of RDT&E and procurement was centralized in a DoD defense-wide account beginning in FY96. Operations and maintenance (O&M) funding for CBRN defense materiel is not consolidated at the DoD level. Therefore, for secondary items (*e.g.*, consumables such as decontamination kits, detection kits, and filters), each Service continues to separately fund replenishment and sustainment of CBRN defense equipment. Depot maintenance and contractor logistics support for some low density major items are also O&M funded. These appropriations are not included in the joint CBRN defense program. Additionally, the Army is the only Service that currently earmarks funds solely for the purchase of CBRN defense medical consumable items.

Funding of CBRN defense items classified as war reserves secondary items (WRSI) remains a significant issue. The Services are responsible for developing the requirements and funding items in war reserve stocks. Funding of WRSI comes from Congressional appropriations made into the Working Capital Fund from the transfer of Services' O&M funds. For example, replenishment of CBRN defense items in Army war reserves will require substantial funding through 2006 as some items reach their maximum extended shelf lives and require

replacement. The recent plus-up of funds for protective suits is assisting in building an initial stockage and minimum sustainment (war reserve) stock to meet the current guidance.

Under current acquisition procedures and DoD guidance to minimize wholesale stockpiles, procurements are based only on funded Service requisitions. The Services remain responsible for program funding to replace CBRN defense equipment wartime stocks. Procurement is usually based on economic buy quantities (a consolidation of all Service requisitions) to provide the best value to the government. Some procurements, however, suffer significant delays in delivery because of the time required to accumulate sufficient requisitions to produce economic buy quantities. This situation occurs when item managers try to plan purchases of consumable items that have a low peacetime consumption but high wartime consumption (such as decontamination kits, large collective protection filters and M256A1 detector kits). The result is a low purchasing history with a small industry production capability, which in turn causes a very low war reserve status with minimal industry surge capability.

3.7 INDUSTRIAL BASE

The smaller DoD force coupled with mergers and acquisitions have generally reduced the number of firms participating in current defense production. But demand is growing for these products. The demand increase is a function of ongoing operations in Afghanistan and Operation Iraqi Freedom, DoD's increased emphasis on homeland defense for DoD installations and units, and of the growing threat to homeland security. Many of the smaller firms in the sector have merged with or have been acquired by larger, more traditional defense firms. The decreased number of firms has reduced competition in the sector, but the remaining firms appear to have stabilized. While the current sector is stable, vulnerabilities still exist, particularly in collective protection and medical vaccines.

The current global political climate coupled with the threat to homeland security is affecting the CBRN industrial base. Some firms, with only commercial experience in producing "CBRN-like" products are now attempting to enter the DoD market. Other firms with a long history of producing CBRN items for DoD are now attempting to market products to local and state governments, foreign military, the Department of Homeland Security, as well as to the commercial sector. As noted above, many of the traditional smaller firms in the sector have merged with larger, more stable, traditional defense firms. The potential markets for DoD, foreign military, the Department of Homeland Security, state and local governments and direct sales to concerned citizens have attracted many firms. With the lure of increased demand, some firms without any history or expertise are making inquiries into how they can enter this market. The result is an industrial base in transition.

The industrial base currently ranges from small to large firms but is adjusting to new buyers and increased demand. The sub-sectors of detection and individual protection should benefit in the long term from a more robust industrial base as new firms enter the market and older firms expand sales to civil agencies. These two sub-sectors are aligned with new demands from the new markets. The challenge to DoD is to work with the testing community to validate commercial product performance so that fielding decisions can be based on high-confidence government test data rather than on manufacturer-provided data. While not yet reflected in the current assessments, we anticipate an improvement in the industrial base that supports the Detection and IP sub-sectors. The other sub-sectors have not been affected by the new demands

of homeland security. Many of the firms in these other sub-sectors are still dependent on Service demands and sales for their financial survival. Collective protection systems (filters in particular) continue to be the most critical sub-sector in the CBRN defense area. Additionally, protective clothing procurement continues to receive intense scrutiny due to the possibility of industrial base shortfalls in satisfying requirements during a contingency. The limited pharmaceutical industrial base to support DoD CB defense medical programs, coupled with a lack of government vaccine production, represents a serious medical industrial base shortcoming.

Ongoing operations in Afghanistan and Operation Iraqi Freedom are testing the capacity of the CBRN industrial base. In recognition of the potential effect on preparedness, an Annual Report to Congress CBRN Defense Industrial Base Working Group has convened to review recent industrial base studies and reports, and to identify ongoing and emerging industrial base issues that can be presented in this and subsequent reports. Examples of some of the industrial base management issues identified and discussed by the Working Group follow:

Sole Single Sources and Diminishing Manufacturing Sources: Diminishing sources and sole sources of manufacturing impact the supply of several important CB defense items. The Diminishing Manufacturing Sources and Material Shortages Program identified numerous Single Point Failures that put readiness at risk for certain equipment because critical components are available from only one qualified source. For example, the M256A1 Chemical Agent Detector Kit uses a filter paper that is provided by a single manufacturer that planned to discontinue this production line. As demand was expected to exceed the level of stockage of this paper, the manufacturer was persuaded to resume this production line for a specific time period while another manufacturer can be identified.

Maintenance of a Warm Industrial Base: Commercial industry, and particularly small businesses, cannot handle the fluctuations in production necessitated by wartime. The problem is that once production has surged because of a period of high demand, DoD is challenged to maintain the industrial capability after production resumes normal peacetime levels. Conversely, the small business has difficulty surging production to meet wartime demand because of a small labor force or inadequate production facilities. In many cases, stockpiling of War Reserve Materiel during peacetime is impractical because of shelf life considerations. Tank-Automotive and Armaments Command - Soldier Biological Chemical (TACOM-SBC) maintains a Critical Items list, established after September 11, 2001, that tracks on-hand quantities, production, deliveries, demand and requirements for major CB defense items and secondary items Item managers add remarks and status updates to the list, which is also forwarded to the JPEO-CBD. This list allows the managers to be proactive in asset management and production forecasting, and facilitates action when JPEO-CBD assistance is needed to resolve issues. The Industrial Base Working Group is exploring ways to establish a similar Joint Industrial Preparedness Planning List that would focus attention on items with critical production issues.

The Working Group also recognized the importance of preserving essential manufacturing capabilities through programs such as the Warstoppers program. Selected CBRN defense items (JSLIST program, chemical gloves, and nerve agent auto-injectors) have been designated as critical to combat operations because of low peacetime demand, high wartime use, and the fragile supporting industrial base. As a result, DLA established, with OSD approval, the Warstoppers program to sustain key industrial base capabilities, using industrial preparedness funding. The Warstoppers program preserves essential production capability and provides the

means to invest in improving industry responsiveness. This includes the funding of Industrial Preparedness Measures (IPMs) that allow industry to surge production of battle-critical materiel. Industrial Base Maintenance Contracts currently preserve critical production capabilities for nerve agent antidote autoinjectors and chemical protective gloves with minimal annual investment.

Establishment of Organic Capabilities: In instances where it is impractical to resume commercial manufacturing due to the uniqueness of a component or cost, an in-house capability to manufacture or repair a critical item may be developed. Ongoing examples include the continued sole production of M291 Skin Decontaminating Kits at Pine Bluff Arsenal following the discontinuation of production by the commercial manufacturer, and the upgrade of the M12A1 Decontaminating Apparatus by replacing old components and retrofitting with diesel engines at Pine Bluff Arsenal. Pine Bluff Arsenal is also the sole producer of M49 Filters. Shortages exacerbated by Operation Iraqi Freedom have been alleviated to a degree by production lines established at Pine Bluff Arsenal for the M295 Decontamination Kit, M100 Sorbent Decon System, and 200 CFM and M48 Filters, that complement existing commercial manufacturing. In total, the *Army Transformation Industrial Base Study (Interim and Legacy Forces)* found that there are 83 defense items manufactured at Pine Bluff Arsenal; 39 are considered critical warfighter issues, and 9 of those39 items are CBRN defense items. In addition, the Pine Bluff Arsenal is currently constructing an $18m, 33,000 square foot Quality Evaluation Facility (QEF). Slated to be operational in the first quarter of FY05, the QEF will significantly expand Pine Bluff's laboratory capabilities with 70 hoods for both toxic and non-toxic testing of chemical and biological defense equipment used by the armed forces to assure it is adequate to provide protection against weapons of mass destruction. The QEF will expand the capability to perform a Protective Clothing Surveillance program currently performed by contractor support in an existing facility. The QEF will also provide surveillance, first article and production support testing of chemical protective filters of all sizes from C2A1s for protective masks, M48s for armored vehicles to large volume filters for installations and naval vessels. The QEF will give Pine Bluff the capability to provide the Joint Services and the manufacturing community a full service facility to perform a wide range of toxic and non-toxic quality assurance testing and evaluation.

Lessons learned and specific impacts of recent military actions including Operation Iraqi Freedom:

C2A1 Filter Canisters: The peacetime production rate of C2A1 Filter Canisters by the commercial manufacturer was 30,000 canisters per month. Pine Bluff Arsenal instituted a material change to the packaging of the canister that saved about one dollar per canister, and allowed Pine Bluff to surge production to over 200,000 canisters per month. As a result, Pine Bluff is being considered as a second source producer for the C2A1 Canister.

M291 Skin Decontaminating Kits: Normal peacetime production at Pine Bluff Arsenal would alternate production between two production lines, with one line running while the other undergoes maintenance. During wartime, PBA has been running both lines simultaneously. With the addition of extra shifts, production is being increased from 2,800 boxes per month (peacetime) to 12,000 per month to alleviate backorders.

Gas Particulate Filters: During wartime the manufacturer of the M48 and M18 filters surged production from 500 to 1,200 per month and from 400 to 1,425 per month for the M48 and M18 Filters, respectively. Pine Bluff Arsenal is currently in First Article Test phase for manufacturing small quantities of M48 Filters, to augment commercial production.

Storage of Bioassay Products: Following September 11, 2001, the demand for bioassay products exceeded the capacity of the Critical Reagents Program (CRP) to manage. The CRP turned to SBCCOM-Rock Island to manage storage of Biological Sampling Kits (BSK). Pine Bluff Arsenal was selected as the storage facility and provided interim storage while a new 25,000 cubic foot cold storage facility was constructed. Since that time, in addition to the BSKs, the facility is also managed as the storage facility for Joint Portal Shield caddies, Hand Held Assay panels and Joint Biological Point Detection System (JBPDS) assay strip carriers. Congressional funding has been provided to double the storage volume of the facility to 50,000 cubic feet and to add a 28,000 cubic foot clean room production area. The target date to be operational is August, 2004.

Included in the mission of the Joint Service Logistics Integrated Product Team (LIPT) for the Annual Report to Congress and Logistics Support Plan (LSP) is an assessment of the Industrial Base which is presented in detail in the LSP. This assessment is designed to assist the Services in identifying problems and issues related to production capabilities of consumable and end item Chemical and Biological Defense Equipment (CBDE). It identifies CBDE not able to fully support 1-4-2-1 construct requirements due to asset shortfalls, and documents maximum production capabilities, as well as warm and cold base for each item. These assessments provide DoD decision-makers with accurate industrial base information and analysis.

The LIPT is addressing issues from across the Services for more than 135 items/systems and spare parts critical to readiness. The LIPT is conducting analyses to include industrial and technology capabilities, alternative sources of supply, and a financial and economic analysis. These analyses will provide the CBRN management structure with alternatives and recommendations within the sub-sectors of CBRN defense. Last year, all systems were evaluated with 78 systems given in-depth analysis. Industrial preparedness measures were recommended for some of those items while others were identified as having a need for re-programming to fund buy-outs that would make up the shortfalls.

The LIPT will continue to monitor the industrial base and the Industrial Base Working Group will address the industrial base issues as new demands and new markets affect decisions by the commercial firms within this sector. While the many changes may make the sector more robust, added demands for equipment may induce firms to shift their priorities from military sales to the civilian sector and to the Department of Homeland Security. The Joint Materiel, Priorities, and Allocation Board (JMPAB) is one mechanism for helping resolve such conflicts in procurement priority for overlapping DoD and other government agency requirements. Also, the Joint Service NBCD Equipment Assessment Program (JSNBCDEAP) led by the Marine Corps is exercising authority over the release of assets to Federal Agencies, DoD activities, and the private sector.

3.8 INDIVIDUAL PROTECTION

Recognizing that the risk to individual protection of the warfighter is contingent on the availability of a complete protective ensemble, an alternative risk calculation has been provided

in past reports that compared the aggregate quantities of all available fielded items that fulfill a particular protective function with the sum of their requirements. The overall risk is then determined by the component in shortest supply. In the interim until the requirements are updated, **Table 3-1** presents the aggregate inventory totals only.

It is acknowledged that historically the risk for individual protection has been higher when the entire protective ensemble (suits, gloves, boots, *etc.*) is assessed on the sum of its individual components within each Service. However, accelerated procurement of all JSLIST components is expected to rapidly mitigate this risk, and in the course of any military operations, the Services will take appropriate risk-reduction measures.

Table 3-1. Protective Ensemble Inventory Summary

ARMY		
Component	**FY03 On-Hand**	**FY04 (projected)**
Suits	800,383	863,458
Masks	845,318	1,177,100
Filters	601,385	603,450
Gloves	827,929	886,451
Boots	912,326	941,438
Hoods	620,253	620,253

AIR FORCE		
Component	**FY03 On-Hand**	**FY04 (projected)**
Suits	737,152	737,152
Masks	289,710	289,710
Filters	1,399,234	1,399,234
Gloves	1,393,335	1,393,335
Boots	1,258,407	1,258,407
Hoods	1,002,365	1,002,365

NAVY		
Component	**FY03 On-Hand**	**FY04 (projected)**
Suits	202,397	202,397
Masks	149,141	150,211
Filters	348,971	348,971
Gloves	323,561	323,561
Boots	158,452	158,452
Hoods	1,211	1,211

MARINE CORPS		
Component	**FY03 On-Hand**	**FY04 (projected)**
Suits	405,433	440,578
Masks	132,317	156,867
Filters	425,163	449,163
Gloves	307,610	426,108
Boots	891,415	1,015,728
Hoods	51,749	51,749

COMBINED SERVICES		
Component	**FY03 On-Hand**	**FY04 (projected)**
Suits	2,083,531	2,181,751
Masks	704,542	786,153
Filters	2,774,753	2,800,818
Gloves	2,832,774	3,009,794
Boots	3,157,588	3,311,013
Hoods	2,289,860	2,289,860

3.9 CBRN DEFENSE LOGISTICS SUPPORT ASSESSMENT

ISSUE: **Department of Defense CB Defense Program readiness shortfalls that would preclude full support of the entire 1-4-2-1 force planning construct have been identified in past reports. The Services' modernization efforts and common war reserve requirements are lessening the overall risk over the near term.**

SOLUTION: The Services continue to increase their readiness and sustainment status by consolidating common stocks and increasing visibility of their wholesale (war reserve) stocks. In most cases, accelerated procurement of critical items into war reserves will increase readiness against the potential use of weapons of mass destruction.

During 1998, all four Services participated in the development of the JCHEMRATES IV study, which was finalized in 1999. JCHEMRATES IV provided a more accurate prediction of the initial issue and sustainment quantities required for each Service. A follow-on study,

the *Expendable Equipment Combat Consumption* (E^2C^2) Study is being conducted in FY03 and FY04 under the auspices of the JRO-CBRN. The use of this common methodology will allow the presentation of joint service requirements in future reports and facilitate improved joint logistics management.

ISSUE: **DoD has lacked a joint, integrated system to maintain asset visibility of CBRN defense equipment below wholesale level, and lacks a standardized war reserve program for CBRN defense equipment. Resourcing the procurement and sustainment of wartime stocks of consumables such as individual protective equipment, decontamination kits, and detector kits remains the responsibility of the Services.**

***SOLUTION*:** DoD established the requirement for asset visibility and reviewed existing systems and procedures, both for peacetime reporting and wartime reporting. The Services and DLA are addressing the CBRN defense asset visibility deficiency under the auspices of the Joint Total Asset Visibility initiative. Additionally, DLA is actively involved in a Business System Modernization (BSM) Program to replace the current legacy inventory management system by FY05. The resulting fully integrated system will interface with the individual Services. The Marine Corps have continued to improve and implement the automated CBRN Defense Equipment Management Program (DEMP) which standardizes accountability by tracking inventory by NSNs, contract numbers, lot numbers, shelf lives, and related personnel data (issues, sizes, *etc*.). The Air Force has implemented the Mobility Inventory Control and Accounting System (MICAS) for inventory management and has demonstrated the system to the other Services. The MICAS is under consideration for adoption by the Army. The Navy is pursuing CBRD TAVMS, which is a web-enabled asset management solution. This system is designed to manage CBRD assets from acquisition through disposal, support shelf-life management, and provide total asset visibility resulting in improved readiness. In addition, the recently enacted DoD acquisition policy mandating the use of unique item identifiers (UID) on critical items and all new acquisitions after January 1, 2004, will facilitate these efforts through better item tracking in these business systems.

ISSUE: **CBRN defense industries have a limited ability to augment specific shortfalls during any future contingency, in part due to lowered DoD procurements and the inability to retain warm production lines in critical areas. Without the introduction of significant plus ups or the use of innovative business practices (such as the use of performance specifications), many of the small firms that make up this sector may choose to re-focus on the commercial market place.**

SOLUTION: DoD continues to pursue innovative strategies to maintain a responsive industrial base, especially those strategies that decrease industry reliance on DoD procurement for industrial base survival. Strategies may include tapping into independent research and development (IR&D) conducted by universities and corporations, increasing reliance on dual-use technologies, and pursuing strategies that will encourage companies to decrease dependency on DoD requirements for their survival.

ISSUE: **Recent world events have focused concern on providing total protection for all deploying warfighters. The Services must have mechanisms in place to ensure that all warfighters are issued complete and functional protective ensembles when deployed.**

SOLUTION: The Services have the following processes in place:

NAVY

a. Issuance. All deployable Navy units have established allowances for IPE. The basic allowance document is the Allowance Equipage List (AEL) crafted for each ship class and deployable unit type. The AEL identifies a numeric allowance for each element of IPE, and if the item, say for example a protective suit or gas mask, is issued in multiple sizes, then the size distribution oriented to the population of the unit in question is provided. The basis of issue for all clothing items is 2.15 per person for amphibious and mine warfare ships and 1.15 per person for the other surface ships; the basis of issue for the expeditionary warfare forces for all clothing items is 2.5 per person and 1.05 for naval installation commands; masks are issued at a rate of 1.05 masks per person. The excess quantities generated cover training needs, size anomalies, and surge assignments that may exist at the unit level. Each ship currently maintains this material centrally under control of the Damage Control Assistant. Those units having completed the RIP Program have one clothing set and barcode etched mask issued in a carrying bag to each crewmember. The material will be returned to ship's custody prior to transfer of the individual. Aviator IPE is issued to the aviator squadron directly prior to deploying aboard ship

b. Inventory Management. Inventory managers issue bulletins regarding imminent expiration and/or extension of shelf life material. Although these are typically issued via naval message, timely distribution of information is occasionally problematic given the number of operating units and the number of local management echelons. Accordingly, the Navy will utilize CBRD TAVMS to automate shelf life data updates via the Internet throughout the equipment's life cycle. Outdated material is discarded or reserved for training and replacement material ordered using unit operational funds.

c. Preparation for Deployment. On a monthly basis or whenever mission readiness changes, each ship reports its operational readiness through the chain of command via the SORTS reporting system. Any projected deficiencies in readiness that are noted in pre-deployment workups are reported to the Immediate Superior in Command and Type Commander. If material shortfalls, such as a deficiency of IPE, cannot be remedied by requisitioning needed material from the supply system, the Type Commander takes action to fill the shortfall using assets "crossdecked" from non-deploying activities under its control. It is important to note that the delivery of a fully equipped, mission-capable unit to the operational commander is a Type Commander responsibility.

ARMY

a. Issuance. Army policy varies regarding authorization of contingency stocks to various units:

Force Package 1 (FP1) and supporting units - Army authorizes these early deployer units to maintain two complete sets on hand per individual authorized on the unit Modified Table of Organization & Equipment, plus a small overage to accommodate

sizing. These units conduct periodic command inspections to ensure that proper maintenance of contingency IPE, and Army training requirements include an annual evaluation of each soldier to ensure proper fit and employment of the protective ensemble components.

FP2 and above and supporting units - Army authorizes follow-on deployer units to draw IPE requirements from contingency stocks maintained at Blue Grass Army Depot (BGAD) through the auto-mated Army Electronic Product Support (AEPS) network. Units determine requirements, to include sizing tariff, and submit them via secure email to the AEPS website. Submitted requirements are validated and approved by the parent MACOM, item manager, and ADC G-4, and then release by BGAD to the requesting unit.

Sustainment stocks for all units are maintained in pre-positioned accounts at various theater-specific support locations.

b. Inventory Management. Protective masks are unit property and receive PMCS inspection as prescribed by the appropriate item technical manual.

The Army's Natick Test Activity routinely tests, by lot number, each of the expendable ensemble components to validate shelf life. Deficient lots are identified to the appropriate item manager and the Army ADC G-4 for publication to Army units via appropriate notification message.

Army regulation and periodic technical bulletins direct owning units to survey on-hand stocks annually, unless sooner notified, of potential shelf life problems by the Army ADC G-4. Upon identification of expiring shelf life for specific commodity lots, deficient stocks are issued as training items and replacement stocks appropriately requisitioned.

c. Preparation for Deployment. At in processing at the unit, each soldier is evaluated by the unit CBRN defense staff for proper size and fit of each protective ensemble item. The unit CBRN staff records the information for each individual and maintains in unit battle book.

When in receipt of deployment orders, each soldier is inspected by unit supervisors for possession of all required IPE. All shortages (FP2+ units) are immediately requisitioned from BGAD via AEPS for issue upon receipt prior to deployment from home station or at the port of embarkation.

AIR FORCE

a. Issuance. Air Force Instruction (AFI) 10-2501, *Full Spectrum Threat Response Planning and Operations* establishes standard basis of issue (BOI) Air Force member stationed in or deployable to nuclear, biological, chemical and conventional (NBCC) medium and high threat areas. Installations within the CONUS and US Air Forces Europe procure and maintain 50% of the NBC IPE for each Air Force military member and emergency-essential civilian in, or deployable to, NBCC medium and high threat areas. The remaining 50% of the NBC IPE is maintained on site for Air Force installation in the Pacific Air Forces; for all other Air Force units, IPE is configured for rapid deployment on unit type code equipment packages at two CONUS locations. Emergency-essential civilians and foreign national citizens and contractors designated

as emergency essential are equipped according to theater directives or host nation agreements. People on temporary duty (TDY) to these areas are equipped before they depart to a NBCC medium or high threat area. The Base Supply organization sustains the wartime contingency mission by maintaining a 10% backup stock for IPE items. Units and training organization are authorized a smaller stock for use during training operations.

b. Threat Areas

Low Threat Areas (LTA). Within LTAs, only military or emergency-essential personnel filling mobility positions are authorized individual protective equipment. C-1 (one half of the BOI) authorizations will be stored at the host installation. Sustainment assets for CONUS units are stored at the Consolidated Mobility Bag Control Center(s) according to AFI 23-226. For OCONUS units, sustainment assets will be stored using MAJCOM guidance.

Medium Threat Areas (MTA). Within MTAs, all military and emergency-essential civilian personnel are authorized a C-1 bag. Only personnel assigned to mobility positions are authorized sustainment equipment. Both C-1 and sustainment equipment are stored and deployed using MAJCOM guidance.

High Threat Areas (HTA). Within HTAs, all military and emergency-essential civilians are authorized the full issue of both C-1 and sustainment assets. Storage, issue and deployment of these assets will be according to MAJCOM guidance.

c. Inventory Management. Some individual units maintain a portion of their IPE (normally Security Forces), i.e. protective masks (minus operational filters), protective vests, etc.) and are responsible for maintenance and inspection in accordance with tech manuals. Most IPE is centrally stored at Base Logistics Readiness and all required inspections and inventories take place there. Management of assets is accomplished through the Mobility Inventory Control and Accountability System (MICAS). HQ Air Force Civil Engineer Support Agency (AFCESA) and HQ Air Force Installations & Logistics monitor IPE issues such as shelf life expiration or extension and lot testing. Upon any changes in regard to stocked items, they send bulletins, information letters, and message traffic to each MAJCOM for distribution to their respective units.

d. Preparation for Deployment. Squadron or Group commanders identify deployable Air Force members and emergency-essential civilians at unit-level. Once identified, personnel are sized and information is maintained at the base Logistics Readiness function. Upon receipt of deployment orders, each individual is issued IPE and given a quantitative fit test in their protective mask. The test is conducted to ensure each mask will provide its wearer optimum respiratory protection. IPE shortages are reported in Status of Resources and Training System-Chemical (SORTS-C) and worked through MAJCOM to overcome.

MARINE CORPS

a. Issuance. Each command has a designated table of equipment that lays out the asset requirements for that unit. It is the command's responsibility to ensure that proper replacement and replenishment has been conducted as to provide unimpeded support to

its service members. In addition, the Marine Corps maintains War Reserve Assets to meet initial operational requirements as outlined by DoD policy.

b. Inventory Management. The Commandant Marine Corps' (CMC) decision to constitute and consolidate the Marine Corps' NBCDE best supports equipment readiness, asset visibility, unit responsiveness, and level funding. This effort is comproised of a two-block initiative under the Strategic Logistics Asset Management (SLAM) umbrella. SLAM Block I consists of the consolidation and constitution of all designated NBCDE. SLAM Block II consists of follow-on support and consolidated planning.

c. Preparation for Deployment. Units have options in the event immediate assets are required to fill shortages prior to a deployment. Commands distribute excess inventories between themselves, place expiring assets on order and submit samples of expiring assets to the Joint Service NBCD Equipment Assessment Program for shelf life extension testing (*see next **ISSUE***).

***ISSUE*: Increasing demands for CBRN equipment dictates that an integrated program of supply and maintenance activities to include shelf life surveillance be conducted to optimize utilization of CBRN assets below the wholesale level.**

***SOLUTION*:** The Marine Corps Logistics Command, Albany, Georgia, leads the Joint Service Nuclear, Biological and Chemical Defense Equipment Assessment Program (JSNBCDEAP). It has expanded its capabilities in shelf life management in support of the Defense Logistics Agency (DLA), Defense Supply Center Philadelphia (DSCP), Defense Reutilization and Marketing Service (DRMS), Navy, Air Force, and Army. Specifically, the JSNBCDEAP functions now include:

- Chair, Joint NBCD Equipment Surveillance Technical Working Group.
- Manage and execute toxic agent shelf life extension testing of CBRN Defense Assets.
- Maintain and manage set-asides for shelf life extension testing, as well as samples for each lot produced during acquisition or follow on contractual buys, and pull samples from each wholesale DLA Defense Distribution Center (DDC) warehouse, worldwide.
- Maintain a Joint Services CBRN defense clothing and textiles web page containing shelf life data, item descriptions, stock numbers, and lab reports for first article testing.
- Conduct random cyclic evaluations of CBRN defense assets at selected DLA depots annually.
- Support operational requirements for the Navy's CBRN defense assets Readiness Improvement Program (RIP).
- Co-chair for CBRN defense assets for DoD shelf life committee.
- Manage accountability of CBRN clothing assets turned in to DRMS Worldwide.
- Oversight of Joint NBCD IPE assessment programs.

The JSNBCDEAP has responsibility for shelf life management, assessment/surveillance and notification of all items identified as clothing used for the protection from nuclear, biological and chemical warfare agents within DoD. The JSNBCDEAP Web Site at http://shelflife.pmnbc.com/ currently posts all IPE shelf life extension information and can be accessed by an individual with a user name and password. Samples of each manufactured lot are received and those assets are stored for future follow on surveillance

testing. The clothing and textile web site has streamlined the dissemination of information on a DoD level, assuring all chemical protective items that have been tested for shelf life extension are listed and available to all users. A Joint Service CBRN Defense Equipment Surveillance Working Group has been established. A Memorandum of Agreement (MOA) has been signed by the services, DLA and the JSNBCDEAP. The MOA will be updated annually. As a joint venture, the JSNBCDEAP will continue to request funding support for the surveillance program. The services as well as DLA will continue to provide funding previously allocated for surveillance testing to the JSNBCDEAP until the program office is budgeted and funded. In FY03 DSCP, Navy, Air Force and Marine Corps along with Congressional Plus-Up provided available funding to support this effort, however, the funding, was insufficient to accomplish the entire testing requirement. This centrally managed program that commenced in November 2002 has extended DoD CBRN defense assets' shelf life, avoiding the requirement of procurement prior to whole life expiration. This action has identified a significant cost avoidance for DoD. Additionally, by all service agencies consolidating the management of shelf life testing, the JSNBCDEAP has eliminated excess or duplicative test efforts and provided a single historical base providing a more efficient process within DoD.

The JSNBCDEAP has continued to randomly assess specified Army, Navy, Air Force checks and services. The result of this effort is published separately in a Joint Service Mask Assessment Report, published quarterly, commencing in 2003.

The JSNBCDEAP has also established a Memorandum of Agreement (MOA) with the Defense Reutilization and Marketing Service (DRMS) to provide expert technical assistance with the sorting, assessment and proper disposal instructions for excess CBRN clothing and textiles turned in to Defense Reutilization and Marketing Offices (DRMO) throughout the world. Additionally, the JSNBCDEAP is segregating CBRN items suitable for issue as "Training Only", from these turn-ins, marking them accordingly and filling requests submitted by various authorized DoD agencies. This MOA was established in March 2003 and establishes the JSNBCDEAP as the only authorized recipient of excess CBRN clothing and textiles turned in to DRMO. An added bonus to this process has been the recovery of condition code "A" items turned in to various DRMOs. These items have either been returned to the service that turned them in or placed back in stock for reissue.

Note: The negative impact of asset expiration on operational readiness and force protection continues to result in Congressional interest (*i.e.*, Congressional Hearings, GAO audits, DODIG Investigations). Without testing and extension of these type II, NBCD clothing and textiles assets they will be placed in a non-issueable status. This could result in the unnecessary disposal of hundreds of millions of dollars in assets and the requirement to fund for replacements. Cost avoidance, as displayed below in ***Figure 3-2***, saves millions of dollars for all end-users of type II, NBCD clothing and textiles. Surveillance testing conducted by JSNBCDEAP can continue to be a great asset for the DoD community, but greater funding for this program can enable proactive scheduling of testing instead of reactive testing when items are identified expired and commands are under short timelines to get serviceable gear, which usually means they have replace the item.

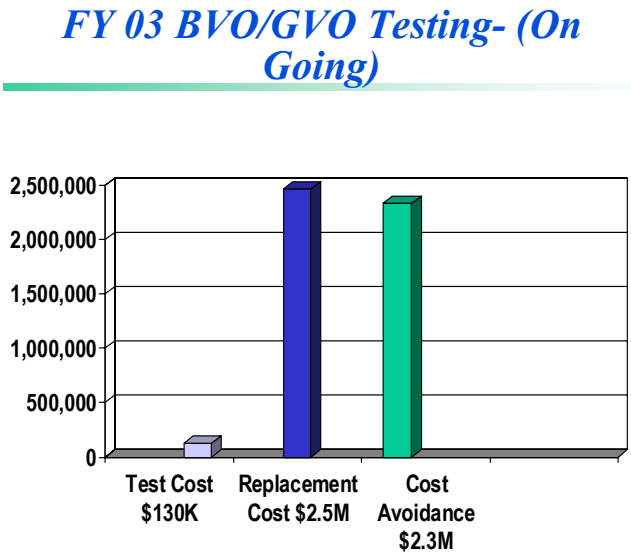

Figure 3-2. Example of Cost Avoidance versus Cost of Item Replacement

Chapter 4

Chemical, Biological, Radiological and Nuclear (CBRN) Defense Doctrine, Readiness and Training

4.1 INTRODUCTION

The DoD CBRN Defense Program (CBRNDP) builds on the success of each Service into effective joint CBRN defense capabilities by leveraging efforts and applying joint requirements documents, joint doctrine and Tactics, Techniques, and Procedures (TTPs), joint modeling, simulation, and wargaming; and joint professional training to service CBRN defense programs.

4.2 CBRN DEFENSE DOCTRINE

CBRN Defense doctrine exists at the Joint, Multi-service and Service levels. Various initiatives have continued through 2003 that have supported efforts to make CBRN defense doctrine more integrated, relevant and current. Each Service (to include the National Guard Bureau and Reserve Component) has CBRN defense doctrine that supports or is integrated into the multi-Service doctrine/TTP manuals developed by the four Services. The core Joint and Multi-Service, and Service unique CBRN Defense doctrine publications are listed in **Table 4-1.**

Table 4-1 Core CBRN Defense Doctrine

Publication	Status/Comment	Army	Air Force	Navy	Marine Corps
Joint Publication 3-11, *Joint Operations in a Nuclear, Biological, and Chemical Environment*, 11 July 2000	Joint Doctrine	●	●	●	●
Joint Publication 3-26, Joint Doctrine for Homeland Security	Joint Doctrine (Under development)	●	●	●	●
Joint Publication 4-02, *Doctrine for Health Service in Joint Operations*, July 2001	Joint Doctrine (Under revision)	●	●	●	●
Joint Publication 3-40, *Joint Doctrine for Combating Weapons of Mass Destruction*	Joint Doctrine (Under revision)	●	●	●	●
Joint Publication 3-41, *Joint Tactics, Techniques and Procedures for CBRN Consequence Management*	Joint Doctrine (Under development)	●	●	●	●
Multi-Service Tactics, Techniques, and Procedures (MTTP) for NBC Defense of Theater Fixed Sites, Ports and Airfields	Multi-Service Doctrine	FM 3-11.34	AFTTP (I)3-2.33	NTTP 3-11.23	MCWP 3-37.5
Chemical and Biological Contamination Avoidance	Multi-Service Doctrine	FM 3-11.3	AFTTP (I)3-2.43		MCRP 3-37.2A
Nuclear Contamination Avoidance	Multi-Service Doctrine	Part of 3-11.3	Part of 3-11.3		MCRP 3-37.2B
NBC Aspects of Consequence Management	Multi-Service Doctrine	FM 3-11.21	AFTTP (I)3-2.37	NTTP 3-11.24	MCRP 3-37.2C
NBC Defense Operations	Multi-Service Doctrine	FM 3-11	AFTTYP(I) 3-2.42	NWP 3-11	MCWP 3-37.1

Publication	Status/Comment	Army	Air Force	Navy	Marine Corps
NBC Decontamination (Restoration) MTTP	Multi-Service Doctrine	FM 3-11.5			MCWP 3-37.3
NBC Protection MTTP	Multi-Service Doctrine	FM 3-11.4	AFTTP (I) 3-2.46	NTTP 3-11.27	MCWP 3-37.2
Field Behavior of NBC Agents	Multi-Service Doctrine	FM 3-6			MCRP 3-37.B
NBC Field Handbook	Army Doctrine	FM 3-7			
Potential Military Chemical/Biological Agents and Compounds	Multi-Service Doctrine	FM 3-9			MCRP 3-37.1B
NBC Vulnerability Analysis	Multi-Service Doctrine	FM 3-11.14		NTTP 3-11.28 Draft	MCRP 3-37.1A
MTTP for NBC Reconnaissance and Surveillance	Multi-Service Doctrine	FM 3-11.19	AFTTP (I) 3-2.44	NTTP 3-11.29 Draft	MCWP 3-37.4
Weapons of Mass Destruction Civil Support Teams TTPs	Army Doctrine	FM 3-11.22			
Digital Corps and Divisions	Army Doctrine	FM 3-11.85			
Chemical Staffs and Units	Army Doctrine	FM 3-11.100			
MTTP for Biological Defense	Multi-Service Doctrine	FM 3-11.86		NTTP 3-11.31 Draft	MCRP 3-37.1C
CBRN Responder Operations Handbook	Army Doctrine	FM 3-11.xx			
Health Service Support in a Nuclear, Biological, and Chemical Environment	Multi-Service Doctrine	FM 4-02.7 (FM 8-10-7)	AFTTP 3-42.3 AFTTP 3-47.3	NTTP 4-02.7 Draft	MCRP 4-02.1E
Treatment of Nuclear and Radiological Casualties	Multi-Service Doctrine	FM 4-02.283	AFMAN 44-161 (I)	NTRP 4-02.21	MCRP 4-11.1B
Treatment of Biological Warfare Agent Casualties	Multi-Service Doctrine	FM 8-284	AFMAN (I) 44-156	NTRP 4-02.23 (NAVMED P-5042)	MCRP 4-11.1C
Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries	Multi-Service Doctrine	FM 8-285	AFJMAN 44-149	NAVMED P-5041	FMFM 11-11
NATO Handbook on the Medical Aspects of NBC Defensive Operations (AMedP-6[B])	Multi-Service Doctrine	FM 8-9	AFJMAN 44-151	NAVMED P-5059	

4.2.1 Joint/Coalition Medical Doctrine Initiatives

The Army's Office of The Surgeon General, Directorate of Health Care Operations (DASG-HCF) is the Executive Agent for DoD on medical international issues, to include CBRN medical operational issues. DASG-HCF is responsible for coordinating and developing U.S. positions within their respective medical functional area in accordance with the policies and direction established by ASD (HA). DASG-HCF is the U.S. Head of Delegation of the NATO General Medical Working Group and the NATO NBC Medical Working Group (NBC MED WG). The NBC MED WG initiated new editions of several key standardization agreements (STANAGs), to include:

- STANAG 2873, Allied Medical Publication (AMedP) 7, Ed. 2 – Concepts of Operations in an NBC Environment (US custodian).

- STANAGs 2475-77, AMedP 8s – Planning Guides for the Estimation of NBC Casualties (US custodian).

The US has also been instrumental or the custodian of several STANAGs to address doctrinal medical CBRN defense capability gaps:

- STUDY 2276- Development of a NATO BT Defense Laboratory Network (IT custodian).
- STUDY 2277 – Health Surveillance System for Data Collection, Analysis, Identification and Dissemination of Info Related to a Bio Outbreak (US custodian).
- STANAG 2491 – BW Immunization Programme, Smallpox Annex.
- STANAG 2242 – Chemoprophylaxis and Immunotherapy in BW Defense (US custodian).

The DASG-HCF also oversees doctrine development to support CBRNE hazards in domestic applications for the support of the Federal Response Plan and the National Response Plan. The Army Medical Department Center and School (AMEDDC&S) leads in doctrine and development for military medical support for Military Support to Civilian Authorities (MSCA). The focus is on Homeland Defense and Homeland Security issues for the AMEDD in environments under CBRNE conditions for consequence management.

4.2.2 Marine Corps and Navy Doctrine.

The Marine Corps fully participates in all multi-Service doctrine working groups to produce and update the joint and multi-Service CBRN Defense doctrinal publications listed in Table 4-1. The Marine Corps Capstone Doctrinal publication for Marine Air Ground Task Force (MAGTF) NBC Defense Operations is being rewritten to address Marine Corps Expeditionary Maneuver Warfare (EMW) concepts. Marine Corps Warfighting Publication (MCWP) 3-37 will be completed during FY04.

During FY03, Navy and Marine Corps representatives met and identified doctrinal deficiencies in the area of chemical and biological defense during amphibious operations that current multi-Service and individual service (Marine Corps/Navy) doctrine did not address. In October 2003, the coordinating draft of NTTP 3-02.1.1, dual designated by the Marine Corps as MCWP 3-37.6, *Retrograde Operations in a CBRN Environment* was disseminated to the services for review and comment. With the emerging/evolving concepts of Sea Basing, Ship to Objective Maneuver (STOM), Operational Maneuver From the Sea (OMFTS), and Maritime Prepositioning Forces (MPF) 2010, the Naval Warfare Doctrine Center (NWDC) and MCCDC will address the deficiencies through this collaborative doctrinal effort. MCWP 3-37.6 will be promulgated during FY04.

During June 2003, the Marine Corps and Air Force signed a memorandum of agreement (MOA) establishing a joint working group (JWG) designed to enhance both services' efforts in the area counter CBRN warfare concepts of operation (CONOPS). A few of the initial tenets of this organization are as follows:

- Establish processes, procedures, and milestones for promoting Service interoperability through the development of Joint Operational guidance for C-CBRN that focuses on fixed site passive defense.

- Establish processes, procedures, and milestones within the JWG covering the development of common C-CBRN knowledge and skill sets to influence Joint Education, Training, and Exercises (JETE).
- Establish formal partner relationship between appropriate USAF-USMC C-CBRN organizations at the earliest practical date.

The Marine Corps will leverage the Air Force's experience from fixed site (airfield) Counter-Chemical Warfare Concept of Operations (C-CW CONOPS), RESTOPS ACTD studies and analysis, and agent fate testing, to create a dual designated publication that defines the tactics, techniques and procedures for USAF and USMC Air Field Operations in a CW environment. The proposed publication is to be completed during FY04. Possible efforts with respect to counter biological and counter nuclear/radiological CONOPS are currently underway.

4.3 CBRN DEFENSE READINESS AND TRAINING

Each service establishes standards of proficiency and currency for CBRN defense training. The following sections describe each Service's activities for CBRN defense training.

4.3.1 Army

Individual Training. Each year the Army tests all soldiers on common tasks required for warfighting and survivability. The following CBRN Defense tasks were tested in FY03. A summary of army-sponsored unit training is provided in **Table 4-2**.

Table 4-2. Summary of Army Unit Training in FY03

Task	Description
031-503-1013	Decontaminate Yourself and Individual Equipment Using Chemical Decontamination Kits
031-503-1015	Protect Yourself From NBC Injury / Contamination With the Appropriate Mission Oriented Protective Posture (MOPP) Gear
031-503-1019	React to Chemical or Biological Hazard or Attack
031-503-1035	Protect Yourself From Chemical/Biological Contamination Using Your Assigned Protective Mask
031-503-1036	Maintain your assigned protective mask

Medical Training. The Army funds medical CBRN training in support of patient care, leader development and medical force health protection. Patient care training provides medical professionals with the clinical skills necessary to diagnose and treat individuals exposed to CBRN agents. Leader development prepares Army medical leaders to plan for and manage CBRN casualties on the battlefield or in the Continental United States. Medical force health protection training provides preventive medicine personnel with the skills necessary to support Force Health Protection programs across the full spectrum of military operations. Training is conducted at the U.S. Army Medical Department Center and School (AMEDDC&S), the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the Armed Forces Radiobiology Research Institute (AFRRI), and the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). Training modalities include in residence training, training conducted at the requesting unit's site (On Site training), and through Distance Learning programs. Each training modality offers unique advantages. In residence training enables students to use labora-

tory and field training facilities while maximizing student-instructor interactions. On site training, *i.e.*, courses taken "on the road" and presented at military installations worldwide, minimizes student travel costs while preserving direct student-instructor interactions. Distance learning programs minimize training costs and support increased audience sizes, without direct student-instructor interactions. A summary of Army-sponsored medical CBRN training is provided in **Table 4-3**.

Table 4-3. Summary of Army Medical CBRN Training in FY03 (as of 30 Sep 03)

Type of Training	Total Number Trained	Army Trained
AMEDDC&S		
Leader Development (NBC)	4,963	4,963
CBRNE	16,217	16,217
AFRRI		
Medical Effects of Ionizing Radiation (MEIR)	864	452
USAMRIID/USAMRICD		
Medical Management of Chemical and Biological Casualties Course (MCBC) in residence	612	303
Field Management of Chemical and Biological Casualties Course (FCBC) in residence	406	233
On-site to active military	1,530	1,392
On-site training – non-military	417	
MCBC Video	42	41
MCBC Computer Based Training	1,176	142
Medical Response to Chemical Warfare and Terrorism 2000 Satellite Broadcasting/Video Course	51	2
Biological and Chemical Warfare and Terrorism: Medical Issues and Response 2001 Satellite Broadcast/Video Course	3	1
Satellite: Biological & Chemical Warfare and Terrorism: Advanced Topics on Medical Defense Against Biological and Chemical Agents	42,453	3,612

Table 4-4. Summary of contact Hours Awarded to Physicians/Nurses for MCBC (FY03)

Type of Training	Physician Hours	Nurse Hours
USAMRIID/USAMRICD		
MCBC in residence	11,921	5,624
MCBC Offsite course	4,966	8,973

Approximately 41% of Army Medical Department (AMEDD) officers (clinicians and non-clinicians) and 39% of the AMEDD enlisted received CBRN training. See **Table 4-5**.

Table 4-5. Total AMEDD Personnel Trained (as of Sep 03)

	Medical Personnel Trained		Percent Trained	
	Clinicians	**Non-clinicians**	**Clinicians**	**Non-clinicians**
Officers	3,570	2,189	41%	41%
Enlisted	6,175	4,283	33%	45%
Total	**9,745**	**6,472**	35%	44%

The AMEDD has aggressively incorporated CBRN into all Army medical training programs in support of our nation's homeland security efforts and in response to Congressional concerns regarding DoD's failure to establish CBRN readiness as a medical priority in Defense Planning

Guidance (GAO-02-38, "DoD Needs to Clarify Expectations for Medical Readiness, October 2001). OTSG provided the vision ("Plan for Enhancing Medical NBC Readiness," December 2001) and the Commander, AMEDDC&S developed and executed the comprehensive strategy to strengthen NBC/CBRNE medical readiness and improve training for health care personnel (AMEDD CBRNE Training Strategy) by incorporating CBRNE training into the life training cycle of all AMEDD soldiers. The strategy is comprised of the following elements.

AMEDD Common Skills. The AMEDDC&S trains all U.S. AMEDD personnel and selected personnel from all armed services, including the active, reserve and National Guard components. The strategy requires the basic NBC soldier skills with additional orientation to CBRNE to include early detection, identification, initial treatment, and hands-on instruction in patient decontamination for all AMEDD soldiers be added.

Advanced Individual Training and Functional Courses. Proponents of AMEDD advanced individual (military specialty) training courses and functional (specialized skill) courses incorporate specialty-specific CBRNE instruction including tailored CBRNE training for each specialty.

Leadership Courses. AMEDD leadership courses incorporate targeted instruction in NBC/CBRNE and Homeland Security. The instruction addresses Antiterrorism/Force Protection, Military Support to Civilian Authorities, Consequence Management, Hospital Emergency Incident Command System, DoD Smallpox Response Plan and leader skills required by the audience. Course materials were specifically developed by the Leader Training Center of the AMEDDC&S and integrated into the 70 H Course, the BDE/DIV Surgeons Course, the Executive Skills Course and Pre-command Course. An elective course under the Army's Baylor Program is offered to future Hospital Administrators and addresses what the hospitals must do to meet the demands of today's environment utilizing an "All-Hazards" approach.

AMEDDC&S medical NBC leader development training begins with 27 hours of NBC/CBRNE classroom instruction and 4 hours of NBC field training during the Officer Basic Course (OBC). OBC teaches new AMEDD officer's basic soldier skills and the fundamental knowledge necessary to conduct medical operations in NBC environments, control CBRNE contamination in medical units, and understand the medical implication of CBRNE exposures. In FY03, 2443 students completed OBC.

The AMEDDC&S Officer Advanced Course (OAC) includes 10 hours of medical NBC correspondence courses. The foreign officers attending the AMEDD OAC received an additional 40 hours of Medical NBC/CBRNE training. In FY03, 567 students completed OAC.

Prior to promotion to the rank of staff sergeant, Army combat medics attend the AMEDDC&S Basic NCO Course (BNCOC). BNCOC incorporates classes and practical exercises in battlefield medical operations in an NBC environment, decontaminating, managing and treating contaminated casualties, and training non-medical soldiers in casualty decontamination procedures. In FY03, 597 NCOs completed the BNCOC.

The Principles of Military Preventive Medicine Course prepares future preventive medicine officers to support medical force health protection programs in NBC/CBRNE environments. In FY03, 64 students completed the Principles of Military Preventive Medicine Course.

The Preventive Medicine Specialist Course was revised to incorporate Low Level Radiological (LLR) training. LLR training has been expanded in the Health Physics Specialists' course and in training provided the Nuclear Medical Science Officers (NMSOs) during the OBC, OAC and Principles of Military Preventive Medicine Courses. LLR training enables NMSOs and Health Physics Specialists, with the support of Preventive Medicine Specialists, to provide medical force health protection to deployed forces supporting incidents involving potential radiation exposures, including Radiological Dispersal Device attacks or releases of radioactive materials from nuclear facilities. In FY03, 69 students completed the training.

Training for Medical Care Providers. Medical care provider courses include CBRNE-specific instruction that includes identification, surveillance, reporting, and treatment. Army medics are learning CBRNE first responder skills, while CBRNE training for physicians, nurses, physician assistants, and dentists is provided during the respective "track" phases of officer basic training. "Gold standard" courses such as the Medical Management of Chemical and Biological Casualties Course and the Medical Effects of Ionizing Radiation Course are being incorporated into the physician/PA lifecycle training plan.

Postgraduate Professional Short Course Program (PPSCP). Effective 31 March 2002 enrollment in PPSCP courses required completion of a web-based CBRNE review module. Completion of the Intro to CBRNE at SwankHealth.com started Mar/Apr 2002 and has registered some 9000 participants to date. There is no available breakout for FY03. ATRRS lists 2052 personnel attending all PPSCPs in FY03. PPSCP proponents also incorporate course-specific CBRNE instruction into their curricula.

Support o US Army Medical Command (MEDCOM) Homeland Security Initiatives. The AMEDDC&S was directed to plan, prepare and execute a CBRNE Sustainment Training Program by the 2001 OTSG Message. It is a two-phase program and will require support from various AMEDDC&S departments and outside agencies. **Phase 1** consists of seven long distance modules, which will be distributed through VTT, VTC or satellite. The first module aired 5 October 2003 and the next six modules will be in FY04. **Phase II** consists of a 15-20-man contract training team to go to Army Medical Treatment Facilities (23 in 04), and train and evaluate CBRNE response. AMMEDC&S will be the overseer of this team.

4.3.2 Air Force

Air Force policy is to provide initial Nuclear, Biological, Chemical, and Conventional (NBCC) defense training to military personnel and emergency essential civilians in or deployable to NBCC medium and high threat areas (**Table 4-6**) and refresher training every 15 months. NBCC Defense training instructors at base level receive their professional training through Air Force Apprentice, Craftsman and Advanced courses at the Air Force Civil Engineer Readiness School, Fort Leonard Wood, Missouri. Selected command, control, and response personnel receive additional home station and/or in-residence to meet requirements for hazardous material emergency response, weapons of mass destruction emergency response, exercise evaluation team duty. The designation of NBCC threat areas is used for both deliberate and execution level planning. Airbases within these geographical locations are categorized as NBCC high, medium, or low threat areas. Assessments use open source publications, MAJCOM and theater guidance, and unclassified intelligence information and are updated annually, or as needed.

Table 4-6. NBCC Threat Areas.

NBCC Threat	Geographical Location
High Threat Area[1]	Bahrain, Balkans Region, Diego Garcia, Egypt, Greece, India, Israel, Jordan, Kingdom of Saudi Arabia, Kuwait, Pakistan, Qatar, Republic of China (Taiwan), Republic of Korea, Somalia, Singapore, Sudan, Thailand, Turkey, United Arab Emirates
Medium Threat Area[2]	Germany, Italy, Japan, and Yemen
Low Threat Area[3]	All locations not listed as a high or medium threat area

Individual and Team (Collective) Training.

There are two types of individual training. The first is general theory, equipment and procedures training, which enables personnel to recognize and protect themselves and others from NBCC hazards. This training is both knowledge and performance based. The second is individual proficiency training, which enables personnel to perform their wartime tasks in a NBCC environment. Individual proficiency training is conducted at the unit level. More, detailed, location specific training comes with assignment to a threat area or to a deployable unit. NBCC Defense training is required for military personnel and emergency essential civilians who are in or identified as "tasked to deploy" or "identified to deploy" to a NBCC medium or high threat area. Individuals graduating from Air Force Basic Military Training will receive credit for NBCC Defense Initial training.

Personnel also receive NBCC defense training in accordance with AFI 10-2501, *Full Spectrum Threat Response Planning and Operations*, as shown in **Tables 4-7** and **4-8**. Individual NBCC defense task proficiency training occurs through on the job training and exercise participation. Specialized team members and personnel in senior or key leadership positions also receive additional information that will help them decisions to be better lead their personnel while insuring air base survivability. In addition, aircrews are required to conduct a one-time flight while wearing chemical defensive equipment.

Air Force medical personnel receive NBCC Defense training at their technical schools during Basic Expeditionary Medical Readiness Training or Expeditionary Medical Readiness Course.

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[1] *NBCC High Threat Area (HTA).* Forces in these areas are at risk from attack with NBCC weapons and subject to terrorist use of weapons of mass destruction (WMD). Potential adversaries within the region either possess or are likely to possess a substantial stockpile of NBCC weapons and weapons systems and may have special operations forces capable of conducting sustained attacks on airbases. Actual or potential terrorist threats exist during peacetime or wartime. Air Force personnel and units in or deployed to these locations will be organized, trained, and equipped to survive NBCC attacks and conduct sustained combat operations in NBC environments.

[2] *NBCC Medium Threat Area (MTA).* Forces in these areas are at risk to attack with NBCC weapons and subject to terrorist use of WMD. Potential adversaries within the region either possess or are likely to possess NBCC weapons and have weapons systems and may also have special operations forces capable of conducting limited attacks on airbases. Actual or potential terrorist threats exist during peacetime or wartime. Air Force personnel and units in or deployed to these locations will be organized, trained, and equipped to survive NBCC attacks and conduct combat operations in NBC environments.

[3] *NBCC Low Threat Area (LTA).* Forces in these areas are not considered at risk from attack with NBCC weapons, but are subject to attack by terrorists using WMD. Actual or potential terrorist threats exist during peacetime or wartime. Air Force personnel and weapons systems in or deployed to these locations will be organized, trained, and equipped to survive attacks by terrorists using WMD and restore primary mission capability. CONUS installations will comply with applicable Continuity of Operations Plans and nuclear fallout shelter requirements in AFI 10-2501 and AFMAN 32-4005, *Personal Protection and Attack Actions*.

Table 4-7. Air Force Individual and Team Training Courses and Requirements.

Course	Target Audience	Initial Training Frequency	Refresher Training Frequency	Duration for Initial/Refresher Training
Base Emergency Preparedness Orientation	All military and civilian personnel assigned to the installation	Within 60 days of arrival to the installation	Quarterly	30 minutes
NBCC Defense	All stationed in an NBCC LTA	Within 60 days once identified	Not to exceed (NTE) 15 months after initial	8 hours/4 hours
	All stationed in an NBCC MTA	Within 60 days of arrival in MTA	NTE 15 months after initial	8 hours/4 hours
	All stationed in an NBCC HTA	Within 30 days prior to arrival in HTA	NTE 30 days after arrival, train theater specific procedures, annually thereafter	8 hours/4 hours
NBCC Defense Task Qualification Training	Same audience as NBCC Defense Course	Within 60 days of assignment	NTE 15 months after initial	Determined locally
Disaster Control Group	Designated OSC and DCG members.	Within 60 days of team assignment	NTE 15 months after initial	4 hours
Key Leadership NBCC Defense Course	Installation/Group Commanders and other key personnel	Within 60 days of assignment	Annually in HTAs, NTE 15 months for LTA/MTAs	2 hours/2 hours
Readiness Support Team	Members assigned by Unit Commander	Within 60 days of assignment to team	Quarterly in HTAs, NTE 15 months in LTA/MTAs	12 hours/4 hours
Shelter Management Team	Members assigned by Unit Commander	Within 60 days of assignment to team	Annually in HTAs, NTE 15 months in LTA/MTAs	7 hours/4 hours 8 hours/2 hours
Contamination Control Team	Members assigned by Unit Commander	Within 60 days of team assignment	Annually in HTAs, NTE 15 months in LTA/MTAs	4 hours/2 hours
Exercise Evaluation Team	Members assigned by Unit Commander	Within 60 days of team assignment	Annually, NTE 15 months after initial	2 hours/2 hours
Unit Control Center and Survival Recovery Center	Assigned members	Within 60 days of appointment	Annually in HTAs, NTE 15 months in LTA/MTAs	2 hours/2 hours
Explosive Ordnance Reconnaissance	All personnel attending NBCC Defense Course	Same as NBCC Defense Course	Same as NBCC Defense Course	30 minutes

Table 4-8. Major Accident and WMD In-Residence Training Requirements.

Target Audience	Rank (or Civilian Equivalent)	Assigned To:	In-Residence Training (In Addition to Local Training)
On-Scene Commander	0-7 through 0-10	Response Task Force	Commander and Staff Radiological Accident Response Course Response Workshop (DNWS)
			Air Force On-Scene Commander Course (AU)
On-Scene Command and Alternates	0-5 through 0-6	Initial Response Base or Disaster Control Group	Radiological Accident Command, Control and Coordination Course (DNWS)
			Air Force On-Scene Commander Course (AU)
Officer or Civilian		Response Task Force	Radiological Accident Command, Control and Coordination Course (DNWS)
			Air Force On-Scene Commander Course (AU)
Officer/Enlisted or Civilian	E-7 through 0-5	Response Task Force or Disaster Control Group	Radiological Accident Command, Control and Coordination Course (DNWS) or Radiological Emergency Teams Operations Course (DNWS)
Disaster Response Force	Any Rank	Contingency Support Staff, Contamination Control Team, or EOD	Radiological Emergency Team Operations Course (DNWS)
Exercise Evaluation Team Chief or Inspector General Evaluator		Response evaluation duties	Air Force On-Scene Commander Course (AU)

DNWS - Defense Nuclear Weapons School, Kirtland AFB, NM
AU – Air University, Maxwell AFB, AL

Federal regulations (29 CFR 1910.120(q)) contain specific training requirements based on the duties an individual or team is assigned. Air Force hazardous waste and emergency response training levels and courses are in **Table 4-9**. Personnel responding to a hazardous materials or WMD incidents must be able to demonstrate to the incident commander that they are trained to the level specified.

The Air Force provides the opportunity for WMD emergency response training and certification for all DoD personnel through the DoD Fire and Emergency Services Certification Program. This program is administered by the Air Force Civil Engineer Support Agency (HQ AFCESA/CEX) and program guidelines are outlined in DoD Manual 6055.6, *Fire and Emergency Services Certification Program*. This program adopts the professional qualification standards published by the National Fire Protection Association (NFPA) and has over 19,000 participants (Army, Navy, Air Force, Marine Corps, Defense Logistics Agency, Coast Guard, Veterans Administration, Department of Energy, and contractors who work for the federal government). Training and certification for DoD Hazardous Materials Emergency Response Instructors is conducted at the DoD Fire Academy, Goodfellow AFB, Texas. The program uses self-study career development course (CDCs), interactive CD-ROMs and instructor-led training courses. Specific courses allow personnel to obtain Federal Emergency Management Agency (FEMA)/Department of Justice (DOJ) certificates for Emergency Response to Terrorism at various levels. Additional information on this program and available WMD courses can be found at www.afcesa.af.mil/Directorate/CEX/fire/default.html.

Table 4-9. Air Force Hazardous Material Emergency Response Training Courses.

Target Audience	Training Level					
	1	2	3	4	5	6
Designated OSC and Alternates	X				O	X
Base Civil Engineer	X				O	O
Senior Fire Officials*	X	X	O		X	X
HAZMAT Emergency Response Team*	X	X	X		O	
Contamination Control Team members	O	O				
Fire Protection*	X	X	O		O	O
Civil Engineer Readiness *	X	X	O		O	
Explosive Ordnance Disposal	X	X	O			
Ambulance Service/Field Response Teams*	X	X				
Acute Care/Emergency Room Staff	X					
In-Place Patient Decontamination	X	O				
Bioenvironmental Engineering	X	X		X		
Security Forces*	X					
Disaster Control Group Representatives	O					

X - Designates Mandatory Training Level O – Designates Optional Training Level
* - Designates Mandatory Use of DoD HAZMAT Certification Program
1 – First Responder Awareness Level 4 – Hazardous Materials Specialist Level
2 – First Responder Operations Level 5 – Hazardous Materials Incident Commander
3 – Hazardous Materials Technician Level 6 – On Scene Commander

Unit Training Exercises. **Table 4-10** summarizes training requirements for Air Force units. Units in or deployable to NBCC threat areas conduct the following training exercises:

Table 4-10. Air Force Unit Training Exercise Requirements.

Type of Exercise	Category	Frequency	Remarks
Major Accidents	Radioactive material	Annually	Applies only if the installation is an Air Force fixed nuclear facility.
	Nuclear weapons	Annually	
	Off-base response	Annually	
	Mass casualties	Annually	
	HAZMAT Team	Annually	
Terrorist Use of WMD	Chemical, radiological, nuclear or high-yield explosive incident	Biannually	Execute cross-functionally according to the local WMD threat; incorporate all local response elements; Alternate annually between the two categories of Terrorist Use of WMD exercises
	Biological Attack incident	Biannually	
Enemy Attack	NBCC Low Threat Area	Not to Exceed 15 Months	Implement Full Spectrum Threat Response Plan 10-2 and other contingency plans.
		Not to Exceed 15 Months	Exercise unit's mobility commitments
	NBCC Medium Threat Area	Not to Exceed 7.5 Months	Implement Full Spectrum Threat Response Plan 10-2, Base Support Plan, and other contingency plans; Integrate exercise requirements for units with mobility commitments
	NBCC High Threat Area	Quarterly	Implement Full Spectrum Threat Response Plan 10-2, Base Support Plan, and other contingency plans

4.3.3 Navy

Navy Chemical, Biological and Radiological Defense (CBR-D) training is conducted in two phases: individual and unit training. Individual training consists of attendance at formal school courses and completion of basic and advanced CBR-D Personnel Qualification Standard (PQS) training. Navy personnel also conduct periodic unit CBR-D training and pre-deployment unit training exercises. The Naval Aviation Maintenance Program, OPNAV 4790.2 has been modified to reflect CBRD requirements for personnel protection and for equipment cleaning. This doctrinal change institutionalizes CBRD in Naval Aviation.

Individual Training. The Navy provides initial entry-level CBR-D training to all officers and enlisted personnel in the accession programs. Enlisted personnel receive three hours of training (two hours in the classroom; one hour in the lab) focused on the use of personal protection equipment and survival skills, including an exercise designed to increase individual confidence in the protective equipment. Officers receive two hours of class time focused on personal protection equipment and survival skills.

Officer and Enlisted Personnel assigned to ship and shore billets requiring CBR-D expertise receive additional CBR-D related instruction. This includes the Disaster Preparedness Specialist Course and the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Additional CBR-D training is covered in the Repair Party Leader Courses conducted at various Fleet Training Centers. Officers receive additional CBR-D–related training at the Damage Control Assistant Course, the Shipboard Department Head Course, the Prospective Executive Officer Course, and the Prospective Commanding Officer Course held at the Surface Warfare Officer School, Newport, Rhode Island. Officer and Enlisted personnel assigned to Ashore Expeditionary Forces (including Naval Construction Forces) also receive follow-on CBR-D instruction. This training includes the SEABEE Personal Protection and Decontamination and Command Center Staff CBR-D Operations courses of instruction at Naval Construction Training Center Gulfport, MS and Port Hueneme, CA. Information on selected individual CBR-D training standards is provided in **Table 4-11**.

Table 4-11. Navy Basic CBR-D Standards (FY03)

- Complete CBR-D Fundamentals Personnel Qualification Standard
- Locate and transit Decontamination station/ CCA stations
- Locate Casualty Collection stations and Deep Shelter Stations
- Don and doff Chemical Protective Ensemble
- Change protective mask canister
- Use the M-291 skin decontamination kit
- Demonstrate self and buddy aid for nerve agent exposure
- Identify CBR markers
- Use M8 and M9 paper
- Pass through CPS air lock/pressure lock
- Decontaminate internal and external areas
- Satisfactorily perform or simulate immediate actions for the following emergencies: nuclear attack, chemical attack, biological attack, nuclear radiation exposure, chemical agent exposure, and biological agent exposure.

Unit Training. Proficiency training is conducted at the unit level by Navy instructors, who are graduates of the CBR-D Operations and Training Specialist Course conducted at the U.S. Army Chemical School. Navy units conduct Basic, Intermediate, and Advanced training

exercises as part of the Inter-Deployment Training Cycle. During the basic training phase, CBR-D training exercises may involve additional unit training by CBR-D specialists from an Afloat Training Group (ATG) or Naval Construction Training Center.

After reporting to designated units, Navy personnel are required to complete basic and advanced CBR-D PQS training. PQS is a compilation of the minimum knowledge and skills that an individual must demonstrate to qualify to stand watch or perform other specific duties necessary for the safety, security, or proper operation of a ship, aircraft or support system.

The Naval Air Training and Operational Procedures Standardization (NATOPS) Manual, OPNAV 3710.7S, has been modified to include requirements for CHEM/BIO training for aircrew personnel. Further, a preliminary CBD NATOPS, NAVAIR-00-80T-121, which addresses specific CBRND procedures and requirements, has been released for review, comment, and implementation.

Medical Training. Information on the status Navy CBRN defense medical training as of the end of FY03 is provided in **Table 4-12**.

Table 4-12. Navy Medical CBRN Defense Training Status

	Clinicians[1]			Non-clinicians[2]		
	Trained	**Total**	**% Trained**	**Trained**	**Total**	**% Trained**
Officers	3, 238	4,214	77%	4, 988	7,435	67%
Enlisted	226	289	78%	8,273	14,499	57%
Total	3,464	4,503	77%	13,261	21,934	60%

[1] All primary care clinicians, specifically; emergency physicians, family physicians, internal medicine physicians, pediatricians, general medical officers, undersea medical officers, flight surgeons as well as family practice, pediatric and adult nurse practitioners, physician assistants and independent duty corpsmen received at least 12 hours of training in the identification and management of chemical and biological casualties. The following courses were acceptable alternatives to meet the above requirement for 12 hours of training;
- USAMRIID and USAMRICD 12 hour satellite/video training program on CB warfare and terrorism,
- USAMRIID and USAMRICD 7 day residential course on CB warfare and terrorism, and
- Navy Environmental Health Center (NEHC) 3 day course on CB warfare and terrorism.
- Navy Online Casualty Care Management Course (Added Feb 03)

All other credentialed providers (to include dental officers), and house staff (interns/residents) received at least two hours of training in the identification and initial management of CB casualties. Acceptable alternatives for this training include:
- either of the two training options described,
- Naval School Of Health Sciences (NSHS) self-paced course titled "Differentiation among Chemical, Biological and Radiological Casualties" and
- Naval Medical Center San Diego (NMCSD) self-paced web-enabled course titled "Bioterrorism provider and Healthcare System Response".

[2] Non-clinician medical department personnel were not required to participate in CBRN training. Opportunities were afforded for them to participate in any of the above training. Only two hours or more of direct medical CBRN training is reported here.

Navy medical providers attend the Management of Chemical and Biological Casualties Course at the U.S. Army Medical Research Institute for Chemical Defense (USAMRICD) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). The Navy Environmental Health Center (NEHC) sponsors a three-day course for providers, and a one-day familiarization/awareness course. Additionally, NEHC has developed and deployed a “distance-learning,” CNET web-based, provider course. Two Medical Service Corps officers are selected annually to complete a one-year fellowship at the US Army Soldier Biological and Chemical Command, Aberdeen Proving Ground, MD. Advanced training in the entire Medical Defense spectrum against chemical, biological and radiological agents including environmental contaminants encountered during deployment is provided. Specific focus on the planning and execution of military response and support to CBRN related events both domestically and during conflict is also emphasized.

The Naval Air Training and Operational Procedures Standardization (NATOPS) Manual, OPNAV 3710.7S, has been modified to include requirements for CBRN defense training for aircrew personnel. Further, a preliminary CBD NATOPS, NAVAIR-00-80T-121, which addresses specific CBRND procedures and requirements, has been released for review, comment and implementation.

4.3.4 Marine Corps

The Marine Corps conducts training in two categories: Individual Training based on Individual Training Standards, and Collective (unit) Training based on Mission Performance Standards (MPS). **Figure 4-1** shows the individual CBRN training provided to all Marines.

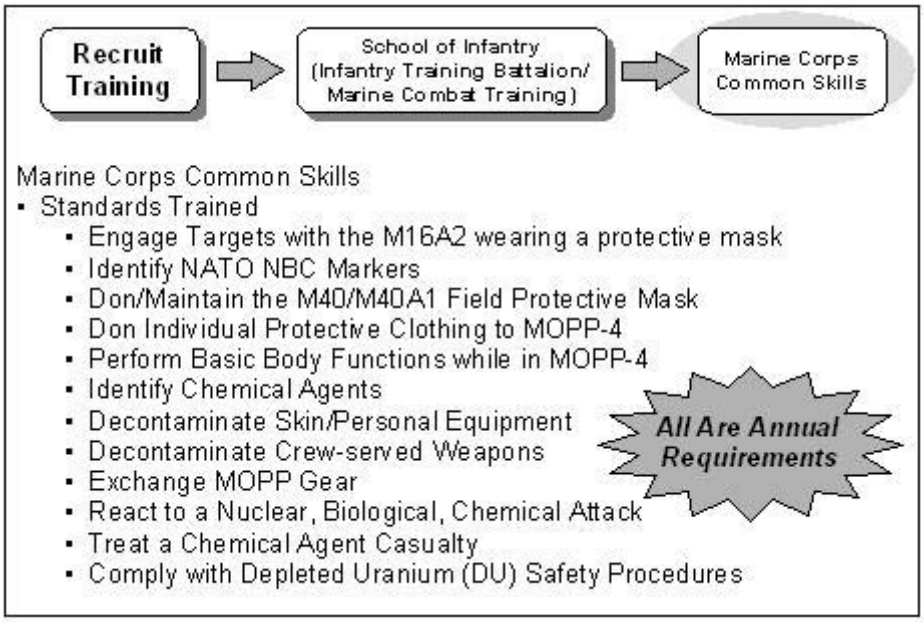


Figure 4-1. USMC Individual CBRN Training

Individual Training. Marine entry-level training begins at recruit training or at Officers Candidate School (OCS) where Marines are introduced to the field protective mask and the CS chamber exercise. All enlisted Marines then proceed either to Marine Combat Training or the School of Infantry, and upon completion of OCS, all Officers proceed to The Basic School. The CBRN portion of this training focus is surviving and functioning in a CBRN environment. Training transitions from a classroom/academic environment to practical application/field environment in order to provide students more hands-on experience.

Once Marines reach their units they begin the Marine Corps Common Skills (MCCS) and Marine Battle Skills Training (MBST) program. MCCS and MBST tasks are individual training standards that all Marines are required to be proficient in and are evaluated on annually. Marine Battle Skills CBRN training focuses on providing Marines with the capability to survive as well as function in a CBRN environment. Senior Field grade General Grade Officers and CWO4/CWO5s attend the "United States Army Chemical School Joint Senior Leaders Course." These courses will round out the phases that the Marine Corps go through in the development of Marines and Leaders to operate in a CBRN environment. Distance learning will also be available beginning in FY03 for all Marines via the Marine Corps Institute Course

5702, Nuclear, Biological, and Chemical Individual Survival Measures. Additionally, MOS 5702 Officers attend the U.S. Army's Chemical Captains Career Course.

Unit Training. Unit level (or collective) training includes classroom and field training identified in unit training exercises and plans. (See **Figure 4-2**.) Many units are also required to meet specific training standards. These requirements take the form of Mission Performance Standards (MPSs) for specific types of units such as infantry, artillery or tank units. These MPSs are published in the 3500 Series of Marine Corps Orders.

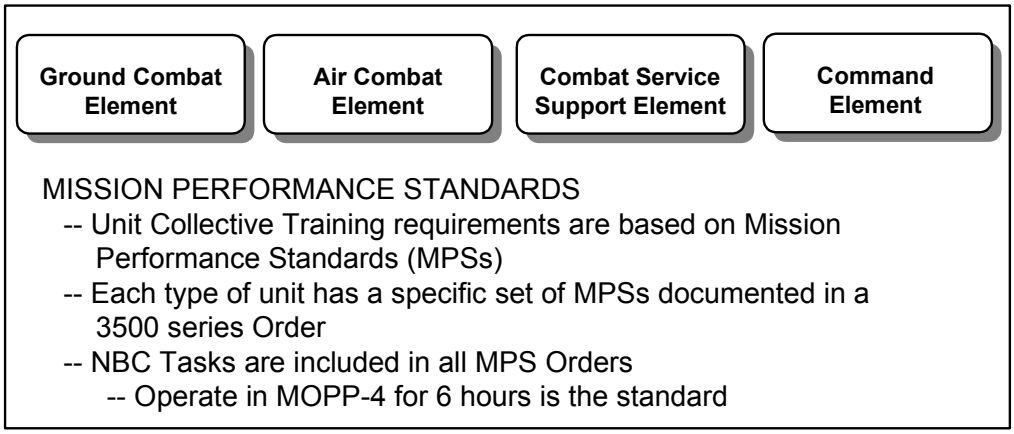


Figure 4-2. USMC Collective Training, CBRN Requirements

Each MPS Order includes CBRN Tasks that the unit must accomplish. However, each set of requirements varies from unit to unit. For example, a Tank Battalion must be able to utilize the vehicle's CBRN filtration system, decontaminate tanks, and operate tanks under CBRN conditions. An Infantry Battalion on the other hand has no requirement to decontaminate tanks, but does have to decontaminate crew served weapons. CBRN training is validated through the Marine Corps' inspection program. Those units that are part of the Marine Corps' Unit Deployment Program (UDP) and designated Marine Expeditionary Units (MEUs) are required to undergo a CBRN evaluation prior to deployment. Units that do not have specific CBRN defense MPSs are evaluated in CBRN defense as part of routine Commanding Generals' Inspection Programs, normally conducted at least biennially.

4.4 CBRN DEFENSE SPECIALIST TRAINING

Public Law 103-160 requires all Services to conduct CBRN defense professional training at the same location. Currently, all Service training, except for medical CBRN courses (as described in sections 4.3.1 and 4.3.2 above), is co-located at the United States Army Chemical School (USACMLS). Each Service conducts their training with their own Service instructors. The experts who graduate from the Service's technical training and the Army's Chemical Defense Training Facility become instructors for their Service's unit training. The Defense Nuclear Weapons School (DNWS), as part of the Defense Threat Reduction Agency (DTRA) Albuquerque Operations Office at Kirtland AFB, New Mexico, conducts a Radiological Emergency Team Operations Course; Radiological Emergency Medical Response Course; Radiological Accident Command, Control and Coordination Course; and Weapons of Mass Destruction Command, Control, and Coordination Course.

4.4.1 CBRN Defense Professional Military Education

Joint Professional Military Education, Phases I and II, currently contains limited CBRN defense considerations and does not adequately address CBRN threat or U.S. response capability in their curricula, and associated wargames and workshops. It is essential that officers of all Services assigned to joint staffs understand the CBRN threat, are familiar with U.S. capabilities to detect and mitigate the threat, and comprehend their staff roles and responsibilities in dealing with CBRN issues. JRO support is critical at the Joint Forces Staff College (JFSC). At the JFSC, the Joint & Combined Warfighting School for Intermediate level (JCWS-I) provides Joint Specialty Officers with teaching for three-year joint duty assignments—from Joint Staff to a Joint Task Force and Service Component Staff. The Senior-level counterpart of that course is the JCWS-S, designed to educate senior officers and other government leaders in joint operational-level planning and warfighting, in order to instill a primary commitment to joint, multinational, and interagency teamwork, attitudes, problem-solving and perspectives. Section 4.6.1 details an ongoing JRO initiative that addresses these shortfalls.

The JRO also sponsors the Joint Senior Leaders Course, which is conducted at the USACMLS three times per year. This course is designed to offer critical elements of CBRN subject matter expertise, with an operational to strategic-level focus, to senior leaders who wish to augment their understanding of current CBRN issues. During the three JSLCs in FY03, there were 106 U.S. Joint Service and allied/Coalition Military personnel with the rank of E-9 (enlisted) and O5 and above (officer) and their civilian equivalents who completed the course. The JSLC prepares attendees to integrate CBRN Defense considerations into their commands, staffs or organizations. It also provides a forum for senior leaders to exchange ideas and gain a familiarization with the most current CBRN defense issues.

The military Senior Service Schools are infusing CBRN core and elective CBRN courses into curriculums to increase exposure to weapons of mass destruction (WMD) issues. The USAF Counterproliferation Center sponsors a three hour core presentation for all students who attend Air War College at Air University, Maxwell AFB, Montgomery, Alabama, entitled DFW 6530, *Emerging CONOPS for Counter-Chemical, Biological and Radiological Warfare*, that is offered by the Warfighting Department. The Center also teaches three elective courses containing homeland security, chemical and biological warfare, and nation state adversarial issues. Additionally, the Center conducts three workshops each year on counterproliferation and WMD topics and hosts an annual USAF Counterproliferation Conference.

4.4.2 Army CBRN Defense Specialists Training

U.S. Army CBRN Defense Professional Training presently takes place at Fort Leonard Wood, Missouri. Training consists of three enlisted/non-commissioned officer courses two officer courses, and two Re-Classification Classes. At initial entry level (See **Table 4-13**), enlisted soldiers and officers receive training in chemical, biological, and radiological agents, plus HAZMAT characteristics, smoke and decontamination operations, chemical and radiological survey procedures, HAZMAT awareness operations, and individual protective clothing and equipment. This program provides 19 weeks of intensive training, culminating in live/toxic agent training in the Chemical Defense Training Facility. Toxic agent training is an integral, mandatory component of all Chemical Corps initial entry and professional courses.

Table 4-13. U.S. Army Professional and Initial Entry Training (FY03)

Training Command	Type of Training	Training Method	Number of Graduates[4]
USACMLS	Chemical Officer Basic	Initial Entry - Resident	183
USACMLS	Chemical Captain's Career Course	Initial Entry - Resident	52
USACMLS	Chemical Officer Advanced -RC	Resident	65
USACMLS	Chemical Operations Specialist One Station Unit Training (OSUT/OSUT2/AIT)	Initial Entry - Resident	1735
USACMLS	Chemical BNCOC	Resident	131
USACMLS	Chemical BNCOC (RECLASS)	Resident	29
USACMLS	Chemical ANCOC	Resident	200

- Chemical Corps enlisted soldiers attend a two phase (Phase 1: 9-week Basic Training; Phase 2: 10-week Advanced Individual Training MOS specific) Chemical One-Station Unit Training (OSUT), where they are trained to be a soldier, a CBRN company squad member and a CBRN Specialist in a non-chemical company.
- Chemical Corps sergeants attend a two-phase training program, Chemical Basic Non-Commissioned Officer Course (BNCOC): Phase 1: Two-week common core; Phase 2: a nine-week, 3-day MOS specific). During the program they receive training on chemical company squad leader skills and non-chemical company or battalion chemical operations skills NCO.
- Chemical Corps staff sergeants and sergeants first class attend a two-phase training program, Chemical Advanced NCO Course (ANCOC): Phase 1: Two week, 2-day common core; Phase 2: a six-week, two-day MOS specific. During the program they receive training on chemical company platoon sergeant skills, NCO at brigade level, and a CBRN NCO in a division or Corps level chemical section skills.
- Chemical Corps lieutenants attend a 19-week, 1-day officer basic course, 10 weeks during mobilization, where they are trained to be a leader, a CBRN platoon leader and a CBRN officer in a non-chemical battalion. Chemical lieutenants receive basic leadership training, and develop skills to serve as a chemical platoon leader and a chemical officer in a non-chemical battalion. Reserve Component officers must attend the full-time resident course.
- Chemical Corps captains attend the Captain's Career Course, an 18-week officer advanced course, where they are trained to be a chemical company commander, a branch immaterial company commander, a chemical officer in a non-chemical brigade, and a chemical officer in a division or higher chemical section. Extensive use is made of computer simulations to reinforce the application of CBRN defense assets in support of tactical operations. In the Maneuver Support Center (MANSCEN) configuration, the Chemical Officer shares training with Military Police and Engineer Officers in Common Training, Shared Tactical Training, and Brigade Battle Simulation Exercise (BBS).

[4] Graduates included from all services and foreign military. (Data source ATRRS for period FY03)

Specialized functional training is conducted in standalone courses attended by DoD, Allied, and international students, as shown in **Table 4-14**. All courses use a resident training method and are conducted at USACMLS.

Table 4-14. U.S. Army Specialized Professional Training (FY03)

Type of Training	Training Duration	Number of Graduates[5]
Nuclear, Biological, Chemical Reconnaissance	6 weeks	98
Master Fox Scout	3 weeks	0
Biological Integrated Detection SYS (BIDS) SP	4-weeks, 3 days	266
Decontamination Procedures (Non-US)	1 week	173
Radiological Safety (Installation Level)	3 weeks	46
Operational Radiation Safety	1 week	110
WMD Installation Emergency Responder	1 week	55
WMD-CBRN Installation Planner's Course	1 week	TBD
Civil Support Skills Course	8 weeks	60
Chemical Pre-Command & Div/Corps	1 week	19
US Coast Guard Strike Force	1 week	TBD

4.4.3 Air Force CBRN Defense Specialist Training

The Air Force training detachment at Fort Leonard Wood, Missouri offers five separate in-residence courses designed to enhance the CBRN proficiency of primary-duty Air Force Civil Engineer Readiness Flight personnel. These courses fulfill the differing needs of the total force, including Active Duty, Air National Guard, and Air Force Reserve. The School of Aerospace Medicine at Brooks AFB trains over 7,000 students per year in a variety of AFMS readiness specialties. These courses are tailored to the approved and registered medical deployable CBRN related unit type code assemblages. Each course contains a wide range of materials covering critical aspects of Readiness Flight operations in situations ranging from peacetime, military operations other than war, through wartime.

4.4.4 Navy CBR-D Specialist Training

The Navy Construction Training Center Detachment at USACMLS, Fort Leonard Wood, Missouri, offers two courses of instruction for Navy CBR-D specialists. The courses are open to Navy, Coast Guard, Military Sealift Command, and select foreign military personnel, E-5 and above. Courses are designed to provide both afloat and ashore commands with individuals who can successfully perform their requisite duties in a CBR contaminated environment. In addition, the training enables CBR-D specialists to act as the primary CBR-D trainers for their respective commands. For fiscal year 2003, 327 students graduated from the Navy courses conducted at Fort Leonard Wood, MO

In addition to CBR-D Specialist courses conducted at the US Army Chemical School, the Navy has incorporated CBR-D readiness training into courses that are attended by personnel at all levels of professional development. (See **Table 4-15**).

[5] Graduates included from all services and foreign military. (Data source ATRRS for period FY03)

Table 4-15. US Navy CBR-D Courses

Course Name	Course Location
Shipboard CBR-D Specialist Course	Fort Leonard Wood, MO
Disaster Preparedness Officer Course	
Recruit Training CBR-D	Naval Training Center Great Lakes, IL
Damage Control "A" School	
Senior Enlisted Damage Control	Fleet Training Center San Diego, CA
Hospital Corpsman "A" School	Naval Training Center Great Lakes, IL
Independent Duty Corpsman	Naval School of Health Sciences San Diego, CA and Naval School of Health Sciences Portsmouth, VA
Preventive Medicine Technician "C" School	Naval School of Health Sciences, San Diego, CA
Confirmatory Lab Operator	Naval Medical Research Center, Silver Spring, MD
Management of Chemical Casualties	U.S. Army Medical Research Institute for Chemical Defense, Aberdeen Proving Ground, MD
Medical Affects of Ionizing Radiation	Armed Forces Radiobiology Research Institute Bethesda, MD
Radiation Health Indoctrination	Naval Undersea Medical Institute Groton, CT
Radiation Health Officer	
CBR-D Command Center	Naval Construction Training Center Gulfport, MS and Naval Construction Training Center Port Hueneme, CA
CBR-D Personnel Protection	
CBR-D Team Training	Naval Construction Training Center Gulfport, MS and Naval Construction Training Center Port Hueneme, CA
MSC CBR-D Course	Military Sealift Command Training Center Earle, NJ
Repair Party Leader	Fleet Training Center San Diego, CA Norfolk, VA; Mayport, FL Ingleside, TX Pearl Harbor HI; Yokosuka, Japan
Repair Party Officer Short Course	Surface Warfare Officers School Newport, RI
Division Officer	
Damage Control Assistant	
Department Head	
Executive Officer	
Commanding Officer	

4.4.5 Marine Corps CBRN Defense Specialist Training

The Marine Corps NBC Defense School is a formal school collocated at Fort Leonard Wood with the other services' equivalent schools. The programs of instruction consist of an Enlisted Basic NBC Defense Course and an Officer Basic NBC Defense Course. In addition to courses conducted by the Marine Corps NBC Defense School, Marines attend four other functional courses (Chemical Captain's Career Course, Radiological Safety Officer Course, CBRN Reconnaissance Course, and the Master FOX Scout) conducted by the USACMLS at Fort Leonard Wood. In addition to specialist CBRN defense training conducted by the Marine Corps or attended by Marines at Fort Leonard Wood, MO, the Chemical Biological Incident Response Force (CBIRF) located at Indian Head, MD conducts specialized training courses for unit members. CBIRF training courses concentrate on the more technical and specialized skills employed by unit members in support of consequence management operations.

The USMC Enlisted Basic NBC Defense Course trains NBC Defense Specialists in a comprehensive 11-week program covering all the Individual Training Standards specified in MCO 1510.71. All Marine NBC Officers are Warrant Officers. As Warrant Officers, they focus entirely on technical expertise, CBRN defense operations, training, and supervision of enlisted NBC defense specialists. Many of the Marine Corps' NBC Defense Officers also attend the

U.S. Army's Chemical Captain's Career Course and other joint CBRN courses as part of advanced Military Occupational Specialist (MOS) training.

4.5 EXERCISES

4.5.1 Joint, Combined, and Service CBRN Exercises

Chairman of the Joint Chiefs of Staff (CJCS) Exercise Program. Joint Vision (JV) 2020 provides the operational based templates for the evolution of our Armed Forces to meet challenges posed by an adversary's use of weapons of mass destruction. JV 2020 serves as the Doctrine, Training, Leader-development, Organization, and Material (DTLOM) requirements benchmark for Service and Unified Command visions. The CBRN defense cornerstone resource for this vision of future warfighting embodies three required operational imperatives:

First, and most importantly, CJCS and Service leaders should recognize that CBRN strategic and operational level of war expertise is an essential resource requirement in the Joint Warfighter Center (JWFC) and U.S. Joint Forces Command (USJFCOM) Joint Training and Analysis Center (JTASC). Success for JV 2020, a strategy centered on capabilities-based forces, requires these organizations to successfully accomplish their respective joint CBRN defense doctrine, training, and leader development roles, and for USJFCOM to accomplish its CBRN defense mission as force provider, force trainer, and force integrator. CBRN expertise at all levels and from all Services is paramount.

Second, Unified Commands should staff their organization appropriately with the right expertise to meet current and future requirements to shape and respond to CBRN challenges.

Third, doctrine, training, and leader-development training strategies should facilitate sophisticated battlefield visualization and situational awareness proficiency, allowing commanders and staffs to conduct service, joint, and combined operations in a CBRN environment.

The CJCS published Master Plan Exercise Guidance in May 1998. This guidance provides exercise objectives to the Combatant Commanders. This guidance provided specific counterproliferation objectives. CBRN Defense and Force Protection were identified as the Chairman's top training issues.

Air Force. CBRN warfare defense preparedness is an integral part of periodic Operational Readiness Inspections conducted by MAJCOM Inspectors General. Realism is injected into these scenarios using a simulated wartime environment including the use of bomb simulators, smoke, attacking aircraft, and missile attack. Personnel are tasked to perform war skills while in their full complement of IPE. Additionally, Air Force units participate in major joint and combined exercises that incorporate realistic CBRN situations.

Navy. Due to the unique nature of naval force deployments, CBR-D training may be conducted whether platforms are operating independently or in a group. During scheduled CBR-D training periods, realism is stressed and CBR-D equipment is used extensively.

Naval units conduct basic, intermediate, and advanced training CBR-D exercises prior to deployment. During the basic training phase, CBR-D training exercises may involve additional unit training by CBR-D specialists from Afloat Training Groups (ATG) or Naval Construction Training Centers.

The exercises conducted by deploying Battle Groups and Amphibious Ready Groups during pre-deployment Composite Training Unit Exercises and Fleet Exercises are designed to meet Combatant Commanders' training requirements for forces in the deployment area of responsibility. These Combatant Commanders' requirements are also tested during exercises with deployed forces. Chemical – Biological Defense scenarios have been incorporated into major joint/Combined Exercises and Fleet Exercises for deployed units. In addition the Navy expanded the scope of Navy Region and Installation CBRN exercises with major regions conducting CBRN exercises in FY03.

Marine Corps. The Marine Corps provides the opportunity for units to incorporate CBRN training into combined arms exercises (CAX) at the Marine Corps Air Ground Combat Center in Twenty Nine Palms, California. Battalion level unit exercises are also conducted during Korea and Thailand Incremental Training Programs where units deploy and exercise various tasks. Like the Air Force and Army, the Marine Corps also participated in major joint/combined exercises. The mission, threat, and task organization determines the level of training allowed.

All Marine Corps units conduct annual CBRN evaluations. Evaluations include operational, administrative, and logistical functional areas. These evaluations incorporate realistic CBRN defense training into an operational scenario that supports the unit's combat mission.

Army. **AMEDD CBRN Defense Exercise Program Initiatives.** OTSG/USAMEDCOM sponsors between three to five exercises each year. OTSG began sponsoring and funding medical NBC defense exercises in 1995 when OTSG and the Center for Army Analysis (CAA) sponsored three games that examined Army biological warfare defense capabilities. In 1997, OTSG initiated the "Chemical Biological Awareness Training" (CBAT) program sponsoring five exercises for combatant commands (PACOM, USFK, EUCOM, and CENTCOM) and a Joint Medical Planner's Workshop (CRIMSON SHIELD, Feb 98). In 2000, the CBAT program was expanded to six medical NBC defense exercises for 3rd MEDCOM, I Corps, XVIII ABN Corps, and MEDCOM. The "Command and Staff Awareness Training" (CSAT) exercises became a new vehicle for the commanders and their staffs to use for exploring contemporary issues, concepts, doctrine and policies relating to the medical aspects of CBRN defense and thus the program was renamed

In FY03, OTSG and USAMEDCOM combined their exercise initiatives and co-sponsored an exercise for the AMEDD Homeland Security (HLS) Conference (Feb 03). Under the new combined exercise program, OTSG and USAMEDCOM successfully sponsored Exercise Orbit Comet 04 (Oct 03), in collaboration with XVIII Airborne Corps, Ft Bragg, Pope Air Force Base, and the local communities. Future exercises include an I Corps Medical CBRN Defense Tabletop Exercise (Mar 04), a tabletop exercise at the AMEDD HLS Conference (Jun 04), and the NATO BW Defense Tabletop Exercise (May 04). Currently, the purpose of these exercises is to support the testing and refinement of medical CBRN defense operational concepts, capabilities, and command and control relationships through a series of unit/ installation/medical treatment facility exercises. These exercises will be utilized to evaluate and enhance concepts and processes developed as part of the AMEDD CBRN Defense Program.

Throughout this process, information, plans, training techniques and materials, and subject matter expertise have been shared freely among Services, agencies, and educational

institutions. By working in collaboration with others, the AMEDD has been able to leverage its efforts and increase its productivity. This ensures that the most current information, training, and expertise are available at all times and the changes to curriculum can be made rapidly. This collaboration benefits both the Army and the nation.

4.6 CBRN DEFENSE TRAINING AND READINESS INITIATIVES

This section provides details on a variety of joint and Service-unique initiative in support of CBRN defense training and readiness. During 2003, JRO sponsored the development of an NBC Defense Medical Training and Doctrine Analysis. The initial focus of this Analysis was to establish a baseline of the current status of individual Services and Joint NBC defense medical training and included a detailed assessment of the capabilities of the training; common and unique properties in training programs and doctrinal materials, areas of duplication and areas that warrant additional effort. The final phase of the Analysis will define a set of recommendations to eliminate duplication and deficiencies that cover the full spectrum of NBC defense medical training programs, materials, and doctrine within each Service.

4.6.1 Joint CBRN Defense Training

Available training includes the Joint Senior Leader NBC Course at the Army Chemical School in Fort Leonard Wood and the Weapons of Mass Destruction Staff Support Seminar at the Defense Nuclear Weapons School, Kirkland AFB.

Doctrine/Training. In response to a number of assessments and reports, the JRO continued implementation of a multi-year strategy to enhance the CBRN Defense-related awareness across the Joint Service community. This strategy includes providing CBRN Defense training, education and awareness at Service and Joint Professional Military Education (PME) institutions/colleges and at Combatant Commander staffs. The JRO initiative also supports the review of joint doctrine, ensuring that the foundation, upon which education, training and operations is established, properly reflects CBRN conditions and issues.

As previously stated, the initiative emphasizes providing of direct support to the Service and Joint PME institutions/colleges. This was accomplished by providing: review of curriculum to ensure CBRN is properly addressed, instructors and speakers who are experts in the CBRN arena, review and Subject Matter Expert (SME) support to college wargames, awareness training of faculty, workshops to stimulate CBRN synergy among the colleges, and by developing course curricula and other related support. During the year, the JRO provided the following support:

- Coordinated/facilitated the JRO-CBRN Defense SME Guest Speaker Program at Joint/Service PME institutions. This support involved 12 different SMEs providing lectures at Joint Forces Staff College (JFSC), Naval War College, Navy Senior Enlisted Academy, Army Command and General Staff College (AC&GSC) and Marine Corps Command and Staff College's (MCC&SC) to a total of 650 officers and Senior Non-Commissioned Officers. The information exchange and resulting discussions directly impacted students who are now serving in vital joint billets/positions.
- Assisted with the development of wargaming at Joint/Service PME institutions. The JRO provided assistance to the Army War College's Strategic Crisis Exercise, Air Force Wargaming Institute's Solo Challenge-03, Office of the Secretary of Defense's

Transformation Wargame, Marine Corps Command and Staff College's (MCC&SC) Exercise Open Access, and to the Joint and Service Colleges as they were linked to the Joint Land, Air, and See Simulation (JLASS) wargame at the Air Force Wargaming Institute (AFWI). This support affected over 400 officers and ensured that the appropriate levels and types of CBRN events were inserted into these wargames.

- Coordinated/provided CBRN Defense SME technical assistance at Joint/Service PME institutions in the review and improvement of existing core and/or elective curriculum. The JRO reviewed and provided improvements to the CBRN Annex to the OPLAN used at JFSC, the curriculum at the Joint and Combined Warfighting School-Intermediate and the Asymmetric Warfare Exercise (Purple Rogue) scenario at JFSC. These products are used by all students attending the JFSC and these enhancements will help ensure that proper consideration is afforded to CBRN Defense planning and mitigation efforts.

Simultaneously, the JRO initiative addresses the training provided to the combatant commands, through the Joint Training System (JTS). This is accomplished by providing: CBRN familiarization training to staffs, SME support to the planning, execution and assessment of exercises, and other related support. During the year, the JRO provided the following support:

- Coordinated/conducted Mobile Training Team (MTT) sessions of the Joint Nuclear Biological Chemical Familiarization Course (JNBCFC) at United States Northern Command, United States Transportation Command, United States Special Operations Command, and Marine Corps War College with total audience of 70 students. The JNBCFC is designed to familiarize Joint Staff Officers with the threat of CBRN weapons, joint force NBC defense, and joint staff officer NBC roles and responsibilities. This one-day, 8 hour curriculum reinforced participants' awareness of the CBRN proliferation threat, and of their potential roles in countering this threat while serving in the billets they are assigned to.
- Planned, coordinated and conducted a Biological Senior Level Seminar (SLS) at United States NORTHCOM. Seminar objectives were a) to provide NORTHCOM Senior Leaders with a baseline knowledge of how to respond to an extremis Biological Terrorist event, b) to establish an understanding of the challenges that must be met by NORTHCOM to effectively coordinate the DOD response in case of a biological agent attack and c) to prepare NORTHCOM Senior Leaders for the Top Officials-2 (TOPOFF-2) exercise that took place 12–16 May 2003. Seminar participants included NORTHCOM Commander and Deputy, numerous NORTHCOM Senior Staff Officers, General Officers from NORTHCOM subordinate components, General Officers/senior officials from NORAD, USJFCOM, Department of Justice, Homeland Security Department, Federal Bureau of Investigation, Department of Health and Human Services, DTRA, SBCCOM and representatives from various state Army National Guard units, with over 100 total conference attendees including 35 General/Flag/SES Officers and civilians. NORTHCOM and its components gleaned valuable insight and knowledge regarding command and control of DOD assets while responding to a major biological event. Their main takeaway was obtaining a greater understanding of the coordination requirements with non-DOD entities as they react to this type of scenario.

- During October 2003, the Joint CBRN Defense Capabilities Improvement Initiative Team (JCBRN CIIT) was established to integrate new JCBRN processes and development into the Joint National Training Capability and Joint Training System in order to provide and improve CBRN Defense capability to the warfighter in the shortest time possible. This organization codified a formal working relationship between the JRO and Joint Forces Command (JFCOM) to improve current and emerging Joint Force Warfighting and supporting capability in a CBRN environment. Under the JRO lead, the JCBRN CIIT will assist Combatant Commanders (COCOM) with CBRN-related tasks/missions in each of the four phases of the JTS- Requirements, Plans, Execution and Assessment. One of the CIIT's main objectives is to develop a capability to train the force from the tactical, through operational, to the strategic level to perform mission essential CBRN tasks and to perform other tasks under CBRN conditions to require standards. The JCBRN CIIT has already initiated planning and coordination of FY04 support with three COCOMs-United States Pacific Command, United States Northern Command, and United States European Command.
- The JRO completed a review of the Universal Joint Task List (UJTL) version 4.2 for adequacy in addressing CBRN-related tasks and to ensure training requirements were derived from a universally recognized baseline. This linkage ensures the currency and relevancy of JSLC as the UJTL serves as the common language and common reference system for the joint force commanders, combat support agencies, operational planners and trainers to communicate mission requirements. During the review, the UJTL's were crossed checked against the latest definitions of SENSE, SHAPE, SHIELD, SUSTAIN, and format was made consistent with the JFCOM guidelines of how to write UJTL tasks. While participating in the official JFCOM sponsored review in FY04, the UJTLs will be linked to appropriate CBRN related doctrine, i.e., JP 3-11 and JP 3-40. UJTLs properly grounded in CBRN considerations will assist COCOMs in preparation and validation of their Joint Mission Essential Tasks List items during future exercises and training events.

4.6.2 Marine Corps CBRN Defense Training.

Following is a summary of Marine Corps CBRN Defense Training accomplishments for FY03.

- Completed CBRN Tier II training for all 17 Marine Corps installations including MCAS Iwakuni and Camp Butler, Japan.
- Initiated inventory assessments of Marine Corps installations to begin Tier III CBRN response training, including enhancements to medical response training.
- Began planning and preparations to address CBRN response training for major Marine Corps Reserve (MARFORRES) installations/sites.
- Completed preparations for installation CBRN detection equipment First Responder training at the completion of the radiological safety licensing process.

MARFORPAC Participated in the following Joint Training during FY03:

- Jan 03 Exercise Yama Sakura.
- Mar 03 Exercise RSO&I.
- Aug 03 Exercise Ulchi Focus Lens.

- Exercise Internal Look 02(IL02).
- Dec 02 Exercises Lucky Warrior 02 and 03(LW02/03).
- Feb 03 CENTCOM/CFLCC reporting exercise.

The Marine Corps conducted or participated in a number of other CBRN related training exercises:

- Exercise Tayoreau Partner.
- Exercise Ryukyu Express.
- NBCD Readiness Deployment Exercise.
- Exercise RSO&I.
- Exercise Cobra Gold.

Marine Corps FY03 Initiatives:

- Completed installation equipment upgrades to minimum Tier II response capabilities, emphasizing compatibility with local community response agencies.
- Initiated installation Tier III CBRN response equipment assessments, with completion scheduled for mid-December 2003. These assessments will provide accurate lists of the types and numbers of CBRN response equipment for all Marine Corps installations to upgrade response capabilities to the next higher level.
- Individual Military Police Chemical-Biological protection kits were acquired and issued to Marine Corps installation MPs. These kits will allow MPs to protect themselves and carry out their security duties during a known or suspected CBRN attack.
- Increased support for the Marine Corps Military Working Dog program to develop greater capabilities for Marine Corps installation CBRN security.
- Completed the acquisition of security equipment to enhance Marine Corps installation protection against CBRN attack, including new barrier systems.
- Conducted exercises to test Marine Corps security preparations.
- Designed a logistic and training support software system to track and account for response equipment and to track and monitor individual responder training level and currency.
- In a support role, Marine Force Pacific (MARFORPAC) continued its participation in RestOps. The RestOps ACTD is a USPACOM-USCENTCOM co-sponsored experiment designed to improve actions before, during and after a CBRN attack.

4.6.3 Army Medical Initiatives.

NBC Sciences Branch Joint Civilian CBRNE Training Initiative. The AMEDDC&S gave support to a partnership with the Associated Medical Schools of NY (AMSNY) and NY State Academic Dental Centers (NYSADC) for the purpose of developing a well-trained civilian reserve medical corps to meet surges in healthcare demands resulting from catastrophic events. This partnership will:

- Train future civilian medical and dental leaders in WMD and CBRNE response and crisis management;
- Adapt military CBRNE education and training materials to civilian needs, with emphasis on curriculum for physicians, dentists and other health professionals;

- Create a civilian-military academic fellowship program for WMD training and policy formation.

This was evidenced by the two projects AMEDDC&S, NYSADC, AMSNY co-sponsored with the US Army Recruiting Command. The first was a five man AMEDDC&S CBRNE training team presented 2.5 days of lectures and hands on training in New York City to 80 physicians, medical and dental students, and first responders. The second project had 14 New York medical/dental students and advisors travel to Fort Sam Houston, Texas and received 40 hrs of CBRNE lectures and hands on training in a field environment.

NBC Sciences Branch Oversight Training Initiative. The Army Medical Command's advanced training in management of chemical and biological threat agent incidents is conducted through two subordinate commands of the Medical Research and Materiel Command. Together, USAMRICD and USAMRIID conduct the Medical Management of Chemical and Biological Casualties (MCBC) and the Field Management of Chemical and Biological Casualties (FCBC) courses. These courses train all members of the health care team, including emergency responders and public health officers, in the medical preparation for, and treatment of, chemical and biological warfare agents. Although they have a military focus these courses have become increasingly important in the national and international anti-terrorism effort.

USAMRICD and USAMRIID successfully met their mission to train every Army medical unit deploying into Theatre in support of both Operations Enduring Freedom and Operation Iraqi Freedom.

USAMRIID and USAMRICD cooperated this past year to produce a six part satellite program on advanced topics in the medical management of biological and chemical warfare agents. These were explicitly constructed to meet both deployed military and urban/homeland defense needs. The data (table 4-3) demonstrate the utility of the programming and also the outreach capability of this educational medium.

EMERGENCY RESPONSE: ARMY MEDICAL RESPONSE

The Army Medical Department (AMEDD) continues to support DoD and federal counter-terrorism initiatives and contingency operations related to CBRN threat agents, with elements of the U.S. Army Medical Command (USAMEDCOM). The AMEDD has provided assistance to the following offices and agencies: DoD SO/LIC, J4 Medical Readiness, U.S. Army Technical Escort Unit, US Department of State, Federal Bureau of Investigation, Department of Health and Human Services, Office of Emergency Preparedness, and the U.S. Marine Corps CBIRF. The U.S. Army published AR 525-13, *Antiterrorism (AT): Security of Personnel, Information, and Critical Resources from Asymmetric Attacks*, September 10 1998. From this regulation it is assumed that U.S. Army medical treatment facilities (MTFs) and clinics will be called upon to provide assistant to civilian first responders if a WMD terrorist act occurs and to provide emergency room and inpatient treatment for both eligible DoD beneficiaries and civilian casualties. This regulation specifically states that the Surgeon General will:

- Establish policy and guidance on the management and treatment of conventional and CBRN casualties.
- Coordinate emergency medical CBRN response capabilities worldwide with other DoD, joint, Federal, state, local and host nation agencies.

- Maintain medical CBRN response teams to address nuclear, biological/emerging infection, chemical accidents/incidents worldwide.
- Provide chemical and biological analysis of biomedical samples from patients/deceased to assist in the identification of agent(s) used against U.S. personnel.
- Provide guidance on the vaccination and prophylaxis against biological warfare agents.

By the end of 2003, USAMEDCOM published Regulation 525-4 and USAMEDCOM Pam 525-1 (*Emergency Medical Management Planning)*, which includes all medical teams and systems that could potentially be available to support civil authorities in the event of a CNBRE event or a terrorist attack with WMD. The regulation also includes the Army policy for fixed facility MTFs in support of local domestic First Responders.

The AMEDD has formed Special Medical Augmentation Response Teams (SMARTs). SMARTs provide a rapidly available asset to complement the need to cover the full spectrum of military medical response—locally, nationally, and internationally. These teams are organized by the, USAMEDCOM subordinate commands; they are not intended supplant TOE units assigned to Forces Command or other major commands. The regional medical commands (RMCs), the United States Army Center for Health Promotion and Preventive Medicine (USACHPPM), and the US Army Medical Research and Materiel Command (USAMRMC) commanders organize SMARTs using their table of distribution and allowances (TDA) assets. These teams enable the commander to field standardized modules to meet the requirements of the mission. The two SMARTs that can most likely to support CBRN are the SMART– Preventive Medicine (SMART-PM) and the SMART– Nuclear/Biological/Chemical (SMART-NBC). The following paragraphs describe activities/programs within the USAMEDCOM that support civil authorities, consequence management, and domestic preparedness.

Army Medical Department Fusion Network. The OTSG/USAMEDCOM is developing an AMEDD CBRNE Defense Program that includes the AMEDD Medical Fusion Network (AMFN) concept. The AMFN concept is to better serve as the integration/fusion framework for collecting and assimilating information from a myriad of sources and fusing those into time critical knowledge for the commander. The AMFN serves as the nexus for enabling the CBRN defense framework and effectively applying the four key operational elements: Sense, Shape, Shield, and Sustain. The AMFN will employ CBRNE incident assessment tools, applying the staff process to make timely and appropriate medical threat predictions and response recommendations to the commander. It will also tie in the SMARTs and RMC's into the reach-back technical research commands. Exercises and operational experience suggest that conventional organizational structures are not well suited for the response to and management of a major CBRNE incident. Decision-making processes must be real-time; based upon a synthesis of all available and relevant technical expertise; coordinated among multiple agencies at the local, regional and national levels; and effective, in that required actions are executed rapidly and appropriately. The broad geographic dispersion of Army installations, deployed forces, and MTFs within MEDCOM increases the complexity of a coordinated Army (and likely Joint) medical response to any CBRN attack. MEDCOM must be able to coordinate support for Army medical resources to meet the passive defense, active defense, consequence management/civil support, force protection, and Homeland Security mission requirements of the Headquarters Department of the Army (HQDA) and the DOD in multiple geographical locations. The AMFN construct will thus require a multi-level, hierarchical structure with coordination between

individual cells and cell groupings, and the ability to coordinate seamlessly with external services and agencies at each level. Coordinated response and management of CBRN incident will require a real-time, coordinated, common relevant operational picture (CROP). The CBRNE incident CROP involves more than the geo-position of forces and responders. It includes: Display of all of the relevant information required to understand status and progress of the CBRN incident response, Visualization of CBRN response elements in the context of the larger operational or incident response and an understanding of existing CBRNE capabilities and how to effectively apply them. This requires a clear understanding of the definitions of data, information, knowledge, and expertise. The AMEDD continues to develop the AMFN concept and evaluate it in future exercises.

Medical Capabilities. The USAMEDCOM has organized, trained and equipped SMARTs. Designated USAMEDCOM Subordinate Commands will deploy SMARTs in CONUS or OCONUS to provide short duration, medical augmentation to Local, State, Federal and Defense Agencies or Medical Teams responding to disasters, civil-military cooperative actions, humanitarian assistance, WMD and emergencies within 12 hours of notification. Reaction time to and length of OCONUS missions will vary based on the situation.

SMART Areas. There are a total of 38 SMARTs in ten functional areas that are capable of responding.

1. Trauma/Critical Care (SMART-TCC).
2. Nuclear/Biological/Chemical (SMART-NBC).
3. Stress Management (SMART-SM).
4. Medical Command, Control, Communications, Tele-medicine (SMART-MC3T).
5. Pastoral Care (clinical) (SMART-PC).
6. Preventive Medicine (SMART-PM).
7. Burn (SMART-B).
8. Veterinary (SMART-V).
9. Health Systems Assessment and Assistance (SMART-HS).
10. Aero-Medical Isolation (SMART-AIT).

SMART Composition. The teams are composed of military officers, warrant officers, enlisted soldiers, civilian employees and appropriate DoD contractors assigned to MEDCOM by name and capable of deploying to augment local, state and federal response assets in domestic support, civil-military cooperative assistance, disaster relief and humanitarian assistance operations in CONUS. Approximately 265 USAMEDCOM Personnel designated to respond as SMART members. These teams are trained and equipped and can be alerted and sent out within 12 hours of notification.

The National Medical Chemical and Biological Advisory Team (MCBAT) is comprised of USAMRMC elements from USAMRIID and USAMRICD. These assets are Tier 1 elements of the DoD Chemical Biological Rapid Response Team (CB-RRT) and are ready to deploy worldwide within 4 hours after receiving their orders. The regional CB SMARTs are trained medical teams located at the RMCs that can deploy in response to a CBRN incident. Examples of incidents that may require a rapid response include:

- An accident involving the transport or storage of CBRN weapons,
- The release of CW or BW agents or radiological material,

- A leak of an industrial chemical, infectious material, or radioactive material.

The MCBAT is the principal DoD medical advisor to the Commander, CB-RRT and the Interagency Response Task Force. Both the MCBAT and regional CB SMARTs can provide medical advice and consultation to commanders or local medical and political authorities for preparation of a response to a threat or actual incident. They can also provide medical advice to commanders or local authorities on protection of first responders and other health care personnel, casualty decontamination procedures, first aid (for non-medical personnel) and initial medical treatment, and casualty handling. The initial advice includes identifying signs and symptoms of CBRN exposure, first aid (self-aid, buddy aid, and combat lifesaver aid for military personnel), and initial treatment when an incident has occurred. The MCBAT also assists in facilitating the procurement of needed resources. The regional CB SMART may, after initial assessment of the situation, elect to use telemedicine reach back.

USAMRICD has developed a Chemical Casualty Site Team (CSST) with the capability of rapid deployment in support of DoD or the MCBAT as part of the Foreign Emergency Response Team (FEST), or the Domestic Emergency Response Team (DEST). The CSST is tasked to support each specific mission. Personnel available for deployment consist of physicians, a nurse, toxicologists, veterinarians, and laboratory specialists. These personnel are knowledgeable in the medical effects of specific chemical warfare agents, identification of chemical agents or their metabolites in biological samples, determination of blood cholinesterase levels, technical and biomedical expertise required to enable protection of personnel responding to chemical incidents or to guide decontamination of personnel and causalities, and technical expertise to accomplish mission planning.

USAMRIID developed and is responsible for deploying the SMART-AIT consisting of physicians, nurses, medical assistants, and laboratory technicians, who are specially trained to provide care to and transport patients with disease caused by biological warfare agents or by infectious diseases requiring high containment. The SMART-AIT is a highly specialized medical evacuation asset for the evacuation of limited numbers of contagious casualties, with lethal infectious diseases, or for consultation on appropriate management of such casualties in the event of a mass casualty situation. USAMRIID's teams are deployable worldwide on a 12-hour notice using USAF transportation assets.

Another USAMRIID asset, the Biological Threat Response Cell, (BTRC) is designed to respond to any CONUS or OCONUS biological warfare or biological terrorist event. The cell is composed of the Deputy Commander/OIC, Operational Medicine physicians, SMART-AIT, selected scientists and clinicians, a Biological Safety Officer, a logistician and an engineer. USAMRIID also provides consultants to the CBRRT as members of the MCBAT.

USAMRIID has a 16-bed ward capable of isolating Biosafety Level 3 patients with infectious diseases in a contingency situation. USAMRIID also has a special Biosafety Level 4 (highest level of containment) patient care area designed for a maximum of 4 patients. These patient care areas are capable of providing intensive care for critically ill patients with specialized personnel and equipment augmentation from Walter Reed Army Medical Center. USAMRIID can perform medical diagnostic assays for recognized biological agents.

MEDCOM has also taken the initiative to provide standardized decontamination equipment, documentation, and personnel training for the command's fixed MTFs. This

equipment and training provides a decontamination capability at all Army fixed MTFs for a CBRNE event.

4.6.3 Air Force CBRN Defense Training and Readiness Initiatives

Because CBRN defense is an urgent need, Air Force efforts have been focused on expanding and improving readiness in several ways, as described below.

The USAF Counter-Chemical Biological Radiological Nuclear and High-Yield Explosive (C-CBRNE) Concept of Operations. Throughout 2003, the Air Force continued work on its concept of operations for addressing the C-CBRNE threat. Because each element of CBRNE poses different operational concerns and responses, they are treated distinctly. The elements are in varying stages of implementation, from counter-chemical warfare's (C-CW) Air Force-wide implementation, to the counter-high-yield explosive's definition/pre-implementation stage.

The C-CW Element of the CBRNE Concept of Operations. For years, the Air Force operated under the assumption that a single chemical-armed theater ballistic missile could produce base-wide contamination, requiring personnel to conduct all operations in full Mission-Oriented Protective Posture (MOPP) gear for extended periods of time (days to weeks). As a result, the Air Force expected a significant sortie generation and cargo throughput degradation following a chemical attack, with no viable alternatives other than shifting operations to a clean base—provided one was available and the transfer feasible. However, after five years of analysis and testing, the Air Force has a much better understanding of the chemical effects on airbase operations. With this understanding, the Air Force implemented the counter-chemical warfare element of the C-CBRNE CONOPS. Analysis indicates that adopting these procedures will help reduce the length of time personnel will remain in full MOPP attire and consequently will significantly reduce degradation so that operations can be sustained on current airfields.

When the C-CW element was implemented in 2003, the goal was full operational capability by 2004. The primary tools for accomplishing this implementation are functional training and the Air Force's Nuclear, Biological, Chemical, and Conventional Defense Course. Inspector General criteria were also updated to more adequately evaluate how well units operate in a CW environment.

Operational Effectiveness Assistance (OEA) visits are used to help tailor C-CW procedures at some high/medium threat USAF installations. OEAs use installation-level analyses to assist unit-level integration and implementation of critical C-CW tactics, techniques, and procedures. OEAs comprise evaluation of the installation's threat, mission, and infrastructure and modeling that installation's processes to identify high-leverage actions for improving mission capability in a contaminated environment. The OEA provides quantifiable recommendations and tools to tailor the C-CW element to the installation's unique requirements through a hands-on, unit-level approach.

The C-BW Element of the C-CBRNE Concept of Operations. In 2002, the Air Force formed the Bio-Defense Task Force (BDTF) to enhance awareness of biological threats. In March 2003, it completed a status report containing more than fifty detailed recommendations to improve operational capability; doctrine and guidance; education, training, and exercises; joint and OSD matters, funding, and organization. The BDTF also produced an Interim Base

Bio-Defense Plan to enhance base-level bio-defense planning and preparation. With Operation IRAQI FREEDOM pending and limited counter-biological warfare guidance readily available, the plan was released to the field for use. As directed by the Chief of Staff of the Air Force, this plan is being refined; it will eventually serve as the basis of the C-BW element of the C-CBRNE CONOPS.

In 2004, the Air Force will focus its C-BW CONOPS development effort on three activities. The first is a series of exercises designed to develop C-BW policy and guidance for fixed-site operations in an outside the continental US (OCONUS), wartime operations environment. The second is to improve bio-defense guidance in CONUS/peacetime environments through the Weapons of Mass Destruction Installation First Responder Preparedness Pilot Program (see below) and the Joint Service Installation Protection Plan. The third activity is the ongoing research initiated by the BDTF into the operational impacts of biological warfare. Soon, the BDTF plans to transition its responsibilities to the newly formed USAF C-CBRNE Council. The C-CBRNE Council will become the single coordinating body for C-CBRNE activities within the Air Staff.

The Counter-Radiological Warfare (C-RW), Counter-Nuclear Warfare (C-NW), and Counter-High-Yield Explosive Warfare (C-EW) Elements of the C-CBRNE Concept of Operations. The other elements of the concept of operations are still under development. Work on the counter-radiological element began in 2003. A draft concept will be available for operational test and evaluation beginning in spring 2004. The requirements for C-NW and C-EW elements are being scoped.

Medical Countermeasures. The Air Force is continuing several medical initiatives to support force protection and mission sustainability. It has established expeditionary and modular medical teams with specific purposes that can be deployed in anticipation of, or in response to, a CBRNE contingency. These teams include the Prevention and Aerospace Medicine Team, Patient Decontamination Team, Bioenvironmental Engineering, Biological Augmentation Team, Global Reach Laydown Team, NBC Patient Support Package, Theater Epidemiology Team, and Radiological Assessment Team. Other C-CBRNE medical assets include Expeditionary Medical Support, the Air Force's deployable airbase hospital, and the Global Expeditionary Medical System, which provides near real-time medical surveillance.

Weapons of Mass Destruction (WMD) Installation First Responder Preparedness Pilot Program. This Air Force program is designed to enhance first responder (Firefighters, Medical staff, Security Forces, Explosive Ordnance Disposal, and CE Readiness) planning, training, and equipment capabilities to enable an installation to detect, assess, contain, and perform limited recovery from a peacetime CBRNE terrorist incident.

Organizational Activities. In 2003, the USAF undertook several initiatives to improve the organization and management of its C-CBRNE activities. As a result of the Vice Chief of Staff Forum topic on C-CBRNE operations, the Air Force decided to assign an operational lead for C-CBRNE activities, in close association with key functional communities. To implement this organizational structure, the Air Force established the C-CBRNE Council to coordinate on C-CBRNE activities and began revising its C-CBRNE Master Plan.

The USAF C-CBRNE Council. At the direction of the Assistant Vice Chief of Staff, in 2003 the Air Staff reorganized its Counterproliferation Integrated Process Team and re-

chartered it as the USAF C-CBRNE Council. Chaired by AF/XON, the C-CBRNE Council is charged with disseminating and tracking the implementation of decisions on C-CBRNE issues across the Air Force; monitoring USAF C-CBRNE activities to ensure that they support C-CBRNE operational capabilities and strategic vision; advocating for resources, systems, and programs that support USAF C-CBRNE operational capabilities (including defense); coordinating the development and implementation of C-CBRNE-related actions underway within the Joint Staff, the Office of the Secretary of Defense, and the Interagency; and improving communication and awareness on C-CBRNE operational issues across the Air Force.

The USAF C-CBRNE Master Plan. The original USAF Counterproliferation Master Plan was promulgated in 1997. Although it was a landmark document that put forward the initial organizing principles of the Air Force's counterproliferation program, due to the radically different threat environment we now face, this original plan has reached the end of its useful life. To correct this, the Air Force has initiated an effort to revise the plan to reflect the changed threat environment and a capabilities-based approach. The new Master Plan will be published in early 2004.

The Master Plan outlines the operational capabilities the Air Force needs to counter the CBRNE threat, lays out a methodology and approach for developing and enhancing those capabilities, and organizes these efforts into four sub-plans or "roadmaps." Three of these roadmaps parallel the service's Title X responsibilities to organize, train, and equip, with the fourth covering fundamental research and definition of the problem and potential solutions.

The *organize* roadmap covers those tasks dealing with doctrine and organization, to include personnel requirements and resources. The *train* roadmap focuses on developing a life-cycle approach that integrates C-CBRNE into the education, training, and exercises that USAF personnel receive throughout their careers. The *equip* roadmap deals with developing Air Force requirements for and contributions to joint research and development and procurement. A fourth roadmap, *Define*, includes those tasks that help the USAF better: 1) understand the threat and the hazard environments, 2) define/scope the problem and, 3) develop potential operational solution sets. Together, these roadmaps combine materiel and non-materiel solutions to meet the threat posed by CBRNE weapons.

C-CBRN Capabilities Investment Strategy. The Air Force developed and is implementing a C-CBRN Investment Strategy—a tool that enables the Air Staff and MAJCOMs to effectively advocate for C-CBRN capabilities, requirements, and high-leverage materiel solutions in future Air Force and Joint research and funding processes. The Investment Strategy began in 2002 as a stand-alone effort, but is being incorporated into the C-CBRNE Master Plan as part of the Equip roadmap.

USAF/USMC C-CBRN Joint Working Group. In 2003 the Air Force and Marine Corps established a joint working group to address common C-CBRN issues. The working group is charged with facilitating the exchange of information on operational doctrine and joint programs, development of joint operational guidance with a focus on passive defense for fixed sites, developing a common approach for joint exercises, promoting operational standards in agent testing, and cooperation in requirements development for improved passive defense equipment.

4.7 READINESS REPORTING SYSTEM

In order to improve the picture of logistics and unit readiness, the Joint Staff increased the visibility of operational standards and readiness reporting for CBRN defense within the Global Status of Resources and Training System (GSORTS). The Joint Staff directed units that report in GSORTS to report CBRN defense readiness beginning in July 2001. GSORTS is in place and operational at the Joint level. GSORTS provides information from Unit Commanders on CBRN defense equipment and training. The operationally ready (serviceable) quantity of equipment provides a unit's S-level, and a unit's training status provides a unit's T-level. The S- and T-levels of specific units are classified data. Each individual Service still has the primary responsibility to analyze CBRN defense unit readiness within that Service. The Services individually monitor their GSORTS data to determine the type of equipment and training needing attention. Units routinely report their equipment on hand and training status for operations in a chemical or biological environment. Commanders combine this information with other factors, including wartime mission, to provide an overall assessment of a unit's readiness to go to war.

Additionally, combatant commands, Services and Combat Support Agencies submit readiness assessments quarterly as required by the CJCS Readiness System following the Joint Quarterly Readiness Review (JQRR) process. In the JQRR, the combatant commands, Services and Combat Support Agencies provide DoD leadership a current, macro level assessment of their ability to support the execution of the National Military Strategy. As needed, they will also address CBRN defense readiness and deficiencies as part of the JQRR.

Navy CBRD Readiness Reporting. In FY02 the Navy issued new requirements for unit CBRD readiness reports. As a result of changes in NTTP 1-03.3 (REV A) "Status of Resources and Training System Joint Report-Navy," Fleet Forces Command issued requirements for more detailed unit CBR equipment, supply and training status to be reported via the Navy TYCOM Readiness Management System (TRMS). Software changes were made to TRMS to allow the Navy data to be provided to the Joint readiness system G-SORTS. These actions resulted in improved Navy CBRD readiness reporting and provided a more efficient process for rapidly identifying and correcting reported shortfalls in equipment or training.

USMC CBD Readiness Reporting. The Marine Corps has developed the Chemical and Biological Defense (CBD) Calculator (automated program) that can be used by Commanders to assist in assessing their unit's CBD readiness. The CBD Calculator provides a measurable standard that commanders can use to base their assessment on. Unit CBRN personnel enter training and equipment data into the calculator and automatically generate a recommended CBD readiness status formatted for input to the SORTS report. The Marine Corps SORTS order is being revised to recommend that all Commanders use the CBD Calculator when determining their CBD status for SORTS reporting.

Army CBD Readiness Reporting. Army commanders at all levels assess their unit's ability to execute wartime missions by assessing the demonstrated proficiency of subordinate units, leaders, and individual soldiers in or during the exercises and events. A CBRN environment is an assumed training condition associated with the unit's Mission Essential Task List. Where applicable, Army training doctrine establishes that NBC is a condition under which a unit must operate and be able to perform its mission. Army unit commanders are directed to

integrate NBC training into their unit's overall training program, and CBRN training requirement is not treated as a separate and distinct task. Army units report the NBC training status monthly. If needed, commanders report the number of CBRN training days required to meet the proficiency standard.

4.8 CBRN DEFENSE READINESS AND TRAINING ASSESSMENT

In response to the General Accounting Office (GAO) Report 02-38, Chemical and Biological Defense, "DoD Needs to Clarify Expectations for Medical Readiness", the Defense Medical Readiness Training Institute (DMRTI) was tasked by Deputy Assistant Secretary of Defense (Force Health Protection and Readiness) (DASD/FHP&R) to review the Services current CBRNE medical training and develop a standardized Tri-Service CBRNE Training Program. On 22 September 2003, the Force Health Protection Council of DASD/FHP&R, approved the Tri-Service Training Program designed by DMRTI that contains the Standards of Proficiency that are necessary to support Medical CBRNE readiness. These Standards of Proficiency were developed to provide standardized training to all medical military, civil service, and contract personnel. **The specific GAO recommendations are summarized below and the progress made on each:**

(a) Services and Joint Staff support completion of the Common User Database (CUD) by defining common personnel requirements and treatments. OASD(HA) funded CUD's definition and initial development; the Joint Research Clinical Advisory Board (JRCAB) is developing common treatments and requirements.

(b) Services and Joint Staff develop joint models and tools. The Army developed analysis tools—the Casualty and Requirements Estimation Tool (CREST) and the CBRN Analytic Framework—to be considered by DoD for joint use.

(c) Services develop CBRN medical training requirements and assess the effectiveness of the training with rigorous proficiency metrics and standards. The Services and the Defense Medical Readiness Training Institute (DMRTI) have taken measures to improve training and are assessing mechanisms to institutionalize improved CBRN training.

(d) DoD develops and maintains information management systems to monitor completion of required CBRN training and track the proficiency of medical personnel. Each Service is capturing the training and is actively seeking more rapid and standardized methodology.

(e) The Joint Staff, Combatant Commanders, and Services increase the realistic exercise of medical support and explore scenarios that overwhelm them. There has been increased medical play at the Combatant Command and Service level. Examples are SOUTHCOM's "Blue Advance" (September 2002) and PACOM's BW Executive Seminar (October 2002).

(f) In addition, the GAO-IPT focused on the overarching need to address the gap between the stated CBRN threat and the current level of medical readiness by conducting a hazard analysis. The Army's Office of The Surgeon General provided a draft hazard analysis to estimate medical workload and material requirements. This draft report will be reviewed by the Joint Staff and Services. The effort builds on the methodology that underpins NATO Allied Medical Publication 8 (AMedP-8), *Medical Planning Guide of NBC Battle Casualties*, and is captured in the CREST computer model.

Chapter 5

Status of DoD Efforts to Implement the Chemical Weapons Convention

5.1 INTRODUCTION

The Chemical Weapons Convention (CWC) was opened for signature on January 13, 1993. The Convention entered into force on April 29, 1997. As of January 1, 2004 there are 158 States Parties to the CWC, including the United States. In 2003, 11 countries ratified or acceded to the CWC.

5.2 DEPARTMENT OF DEFENSE IMPLEMENTATION OF THE CWC

In 2003, DoD hosted 69 inspections and visits at chemical weapons (CW) storage, former production, and destruction facilities. The Army (the Service most directly affected by CWC implementation activities) and DoD's Defense Threat Reduction Agency (DTRA) continue to host and escort inspectors from the Organisation for the Prohibition of Chemical Weapons (OPCW) Technical Secretariat (TS). The OPCW is charged with overseeing world-wide implementation of the CWC. TS inspectors conduct both continuous and non-continuous monitoring at DoD CW destruction facilities and systematic inspections at DoD CW storage, former production and Schedule 1 facilities. DTRA provides CWC Orientation Training and associated Mission-Support Training—Treaty Escort Training, Hazardous Materials (HAZMAT), and Hazardous Waste Operations and Emergency Response (HAZWOPER)—to United States Government (USG) National Escorts and other treaty compliance personnel. In 2003, 128 USG personnel completed orientation training. DTRA insures all escorts are trained and ready to receive OPCW TS Inspection Teams.

In addition to supporting inspections at DoD facilities, DTRA assists the Department of Commerce (DOC) with CWC inspections at U.S. chemical industry sites pursuant to a Memorandum of Agreement. The DOC is the lead agency for chemical industry inspections. DTRA supports DOC with training, escort, and logistic support on a non-interference, cost reimbursable basis. U.S. chemical industry inspections began in May 2000. The OPCW conducted 7 chemical industry inspections in 2004.

DoD conducts a Chemical Weapons Agreements Implementation Working Group (CWIWG), chaired by the Office of the Secretary of Defense (OSD) Treaty Manager—the Deputy Assistant to the Secretary of Defense (Chemical Demilitarization and Threat Reduction), to implement the CWC. Through regularly recurring meetings, representatives of OSD, the Joint Staff, the Military Departments, the Military Services, and DoD agencies and activities coordinate planning efforts to ensure proper implementation of the CWC. Formal meetings of the CWIWG are scheduled approximately monthly and small group meetings are held as needed to address specific requirements in support of the CWIWG. A Compliance Review Group (CRG) was established within DoD to address, as needed, CWC compliance

concerns. OSD, the Joint Staff, the Military Services, and DTRA provide technical experts to support activity at the U.S. Delegation to the OPCW in The Hague, The Netherlands.

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

5.3 SAFETY ORIENTATION FOR INSPECTORS

All OPCW inspectors who conduct continuous monitoring at U.S. chemical weapons demilitarization facilities are required to attend a 32-hour safety orientation, which is broken down into two sections and is presented by the Army. One section is 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. The second section is an 8-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. Approximately 146 currently assigned OPCW TS inspectors have attended HSO training; eight inspectors have taken the 48-hour DPE class. The orientation is conducted at the Chemical Demilitarization Training Facility in Edgewood, Maryland. Annual 8-hour HSO refresher courses are also required and are being accomplished by the Army in The Hague. DTRA provides USG national escorts for OPCW inspectors while attending required training at U.S. facilities. DTRA ensures that all inspectors receive required training.

5.4 PREPARATION OF DEFENSE INSTALLATIONS

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

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

All of the Military 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. Commonly, the lead Service responsible for developing an exercise also produces a comprehensive Lessons Learned report to ensure DoD readiness for possible challenge inspections. 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 USAF, DoD sponsored a mock challenge inspection exercise in 2003, using Charleston Air Force Base, South Carolina as the challenged site. DoD's overall objective was to practice using existing CWC compliance guidance and improve the processes by which the DoD would demonstrate compliance with the Chemical Weapons Convention.

5.5 DEFENSE TREATY INSPECTION READINESS PROGRAM

The Defense Treaty Inspection Readiness Program (DTIRP), for which DTRA is the executive agent, has implemented an extensive outreach program to provide information about the CWC, security countermeasures, and facility preparation to both government and government contractors. In 2003, DTIRP distributed over 25,000 arms control and security educational products (electronic and print media). DTIRP supported all seven OPCW industry inspections by providing a Security Countermeasures Officer to assist DOC with protecting proprietary information and hosting inspections. The program also provided the Army's Chemical Material Agency with tailored training to three of its chemical depots and trained over 200 site personnel. The Chemical Technology Security Course, the only 5-day course within the USG that specifically discusses security concerns and site preparations for facilities subject to CWC inspections, was presented twice. 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, United States industry and research institutions. Three vulnerability assessments were conducted in 2003 as well as five DOC site assistance visits. Program personnel also participated and presented at nine arms control and security conferences.

5.6 TECHNICAL EQUIPMENT INSPECTION PROGRAM

The Technical Equipment Inspection (TEI) Program ensures OPCW TS verification equipment meets U.S safety, environmental and security requirements through a familiarization process authorized by OPCW Conference of States Parties. Familiarization results are documented in the U.S. "Certification Report of Chemical Weapons Convention Organisation 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 OPCW equipment for all OPCW inspection teams at the Point of Entry. The chemical agent monitoring is conducted to protect both U.S. and OPCW personnel and to prevent inaccurate findings as a result of pre-existing contaminants on the OPCW verification equipment.

5.7 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 Advise 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 not provided any chemical weapons detection equipment or assistance in the safe transportation, storage, and destruction of chemical weapons to other States Parties. Such assistance, however, is being provided to Russia under DoD's Cooperative Threat Reduction (CTR) program.

5.8 ARMS CONTROL TECHNOLOGY

In 2003 the Arms Control Technology Program completed two significant Defense Technology Objectives (DTOs). Each effort was conducted in response to requirements from the DoD Arms Control Community with the primary goal of protecting DoD equities and minimizing the threat to national security interests posed by U.S. involvement in CW arms control activities. Both Arms Control DTOs are identified in the Protection Area of the Joint Warfighter Science and Technology Plan (JWSTP). The CW objectives of JD.18: Chemical Biological Weapons Agent Screening and Analysis was to complete and publish Volume 2 of the US/Finnish Joint Method for Field Sample Preparation and Analysis (Joint Method) and to complete phase one of an investigation into capabilities for confirming CW alleged use by analyzing biological samples, to include blood, urine and saliva. The first of these objectives, Volume 2 of the Joint Method, defines procedures for the detection of trace chemicals in complex environmental matrices and is a continuation of work completed and efforts documented in Volume 1. The second objective, biological sample methods development, was conducted collaboratively between the US Army Medical Research Institute for Chemical Defense (MRICD) and labs in both the UK and the Netherlands. Volume 2 of the Joint Method was approved for public release in September 2003. The work has been received by the OPCW and has also been provided to offices and agencies in DoD, DOS and DOC. The results of the biological sample methods included data on a method that significantly extends the time after a CW event that agents can be positively identified.

The objective of DTO JD.19: Portable Isotopic Neutron Spectroscopy (PINS) was to complete an upgrade of the mini-PINS (formerly PINS) system, by providing an electrical neutron generator as an energized neutron source option. The PINS unit was initially fielded from the Arms Control Technology R&D program to function with a Californium^{252} source. The development of an electrical neutron generator significantly decrease the logistics burden of handling, transporting and storing this radioactive isotope. Under DTO JD.19, several options were evaluated, followed by a down select. The selected neutron generator then underwent operational field testing on simulants and live agents. It will now be available as a mini-PINS system option.

Annex A

Contamination Avoidance Programs

Table A-1. Contamination Avoidance Research, Development, & Acquisition (RDA) Efforts

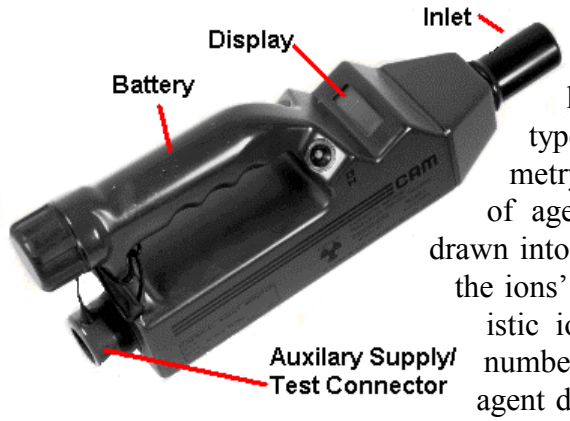
Category		Nomenclature	Status	USA	USAF	USMC	USN
Automatic Detectors and Monitors	Chemical	- M22 Automatic Chem Agent Detector Alarm (ACADA)	Production	Joint	Joint	Joint	Rqmt
		- MK27 Shipboard ACADA	Production				Rqmt
		- Improved Point Detection System (IPDS)	Production				Rqmt
		- Improved CAM (ICAM)	Production	Rqmt	Interest	Rqmt	Rqmt
		- Joint Chemical Biological Agent Water Monitor (JCBAWM)	RDTE	Joint*	Joint*	Joint*	Interest
		- Joint Chemical Agent Detector (JCAD)	RDTE	Joint*	Joint*	Joint*	Joint*
	Biological	- Interim Biological Agent Detector (IBAD)	Fielded				*Rqmt*
		- Biological Integrated Detection System (BIDS NDI)	Fielded	*Rqmt*			
		- BIDS P3I	Fielded	*Rqmt*			
		- DoD Biological Sampling Kit	Fielded	Joint	Joint	Joint	Joint
		- Detection System, Biological Agent: Joint Portal Shield	Production	Joint	Joint		Joint
		- Joint Bio Point Detection System (JBPDS) -- Block I	Production	Joint	Joint	Joint	
		- Dry Filter Unit (DFU)	Production	Rqmt			Rqmt
		- Hand Held Assays (HHA)	Production	Rqmt			Rqmt
		- Critical Reagents Program (CRP)	RDTE	Joint	Joint	Joint	
		- CB.20 Automated Genetic Identification	DTO				
		- CB.37 Chemical/Biological Agent Water Monitor	DTO				
		- CB.50 Lightweight Integrated CB Detection	DTO				
		- CB.52 Detection of CB Contamination on Surfaces	DTO				
		- CB.38 Activity-Based Detection and Diagnostics (DARPA)	DTO				
		- CB.41 Biological Warfare Defense Sensor Program (DARPA)	DTO				
Stand-Off Detection and Remote/ Early Warning		- Joint Service Lightweight Stand-off Chemical Agent Detector (JSLSCAD)	RDTE	Joint	Joint	Joint	Joint
		- Artemis (Chemical Agent Standoff Detection System)	RDTE		Joint*	Joint*	Joint*
		- Joint Bio Stand-off Detection System (JBSDS)	RDTE	Joint	Joint	Joint	Joint
		- CB.35 Standoff Biological Aerosol Detection	DTO				
NBC Reconnaissance		- Joint Service NBC Reconnaissance System (JSNBCRS)	RDTE				
		--NBCRS/CB Mass spectrometer	*	*Rqmt*		*Rqmt*	
		--Joint Service Light NBC Reconnaissance System (JSLNBCRS)	*	Rqmt	Rqmt	Joint	*Interest*
		- NBC Recon Vehicle (NBCRV)	RDTE	Joint			
		- CB.53 Wide-Area Aerial Reconnaissance for Chemical Agents	DTO				
Radiation Detection		- AN/UDR-13 Pocket Radiac	Fielded	Rqmt	Interest		
		- AN/PDR-75 Radiac	Fielded	Rqmt		Rqmt	
		- AN/PDR-77 Radiac	Fielded	Rqmt			
		- AN/VDR-2 Radiac	Fielded	Rqmt		Rqmt	
		- Multi-Function Radiac	Fielded	Rqmt	Rqmt		
		- ADM-300A	Fielded	Rqmt			

Joint = Joint Service requirement
Joint* = Draft Joint Service requirement
Rqmt = Service requirement
Interest = Service interest, no imminent requirement
Rqmt Interest = requirement or interest in sub-product
* = Sub-product(s) of a Joint project
LRIP = Low Rate Initial Production
DTO = Defense Technology Objective (Science & Technology Base Program)
Fielded = Fielded Capability (Sustained by Services)
RDTE = Research, Development, Test & Evaluation (Advanced Development program)

AUTOMATIC DETECTORS AND MONITORS

FIELDED AND PRODUCTION ITEMS

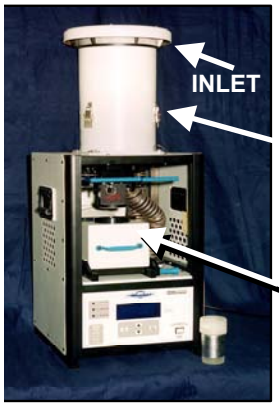
Chemical Agent Monitor (CAM) and Improved Chemical Agent Monitor (ICAM)



The CAM is a hand held instrument capable of detecting, identifying, and providing relative vapor hazard readouts for G and V type nerve agents and H type blister agents. The CAM uses ion mobility spectrometry (IMS) to detect and identify agents within one minute of agent exposure. A weak radioactive source ionizes air drawn into the system, and the CAM then measures the speed of the ions' movement. Agent identification is based on characteristic ion mobility and relative concentrations based on the number of ions detected. The ICAM has the same chemical agent detection capability as the CAM; improvements are that it is 300% more reliable, starts up 10 times faster, and the modular design is much less expensive to repair. The ICAM has the additional features of an RS-232 data communications interface, and the ability to be programmed for new/different threat agents. The four pound, 15" long ICAM can be powered either by an internal battery or by an external source through the ICAM's combination power/fault diagnosis/RS-232 plug. The ICAM may be used for a variety of missions, to include area reconnaissance and area surveillance, monitoring of decontamination operations, and medical triage operations. The ICAM significantly reduces the level and frequency of maintenance *vs*. CAM without affecting performance. The ICAM sieve pack has double the capacity of the two CAM sieve packs, which results in twice the operational life of the ICAM over the CAM. When fielded, the ICAM will significantly reduce operating and sustainment costs associated with the CAM by $135 million over its life cycle in FY02 constant dollars. ICAM production is scheduled to continue through 2QFY04, at that time transitioning to management at the Integrated Materiel Management Center (IMMC).

M31 Biological Integrated Detection System (BIDS) Non-Developmental Item (NDI) & Pre-Planned Product Improvement (P3I)

BIDS uses a multiple technology approach, both developmental and off-the-shelf materiel, to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully integrated biological detection system. The system is a collectively-protected, HMMWV-mounted S788 shelter and is modular to allow component replacement and exploitation of "leap ahead" technologies. The NDI variant (M31) (*shown*) is capable of detecting and presumptively identifying four BW agents simultaneously in less



than 45 minutes. The P3I BIDS is capable of detecting and presumptively identifying eight BW agents simultaneously in 30 minutes. The suite is semi-automated and contains several technologies, including the Ultraviolet Aerosol Particle Sizer (UVAPS), Chemical Biological Mass Spectrometer (CBMS), Mini-Flow Cytometer, and the Biological Detector (BD). Thirty-eight BIDS NDIs were fielded to the 310th Chemical Company (U.S. Reserve) during FY96. This gave DoD its first credible, rapidly deployable biological detection capability. The BIDS is a Corps level asset. Fielding of 38 systems to the 7th Chemical Company was completed in October 1999. In 4QFY03, the third BIDS Company, 13th Chemical (P3I), began fielding at Ft. Hood, Texas and will be completed by 3QFY04. As full-rate production becomes complete by 3QFY04, program emphasis will continue on planned upgrades and sustainment. Future fieldings of the BIDS in FY04 and beyond will utilize the upgrade capability of the Joint Biological Detection System (JBPDS) Block I. The BIDS is a Corps level asset.

Interim Biological Agent Detector (IBAD)

IBAD provides shipboard detection of biological warfare agents. IBAD consists of a particle sizer/counter, wet wall cyclone particle sampler, and hand held assays (HHAs) for the presumptive identification of suspect aerosol particles. IBAD is capable of detecting an increase in the particulate background, which may indicate a man-made biological attack is underway, and sampling the air for identification analysis. IBAD can detect a change in background within 15 minutes and can identify biological agents within an additional 30 minutes, utilizing the HHAs. It is an interim rapid prototype system that started service with the fleet in FY96. Twenty IBAD systems have been fielded. These systems will be among ship platforms as dictated by fleet priorities.

Joint Portal Shield (Biological Agent Detection System)

Joint Portal Shield (JPS) is an interim Joint Service biological detection system used to protect high value fixed assets. The system uses an innovative network of sensors to increase probability of detecting a biological warfare attack while decreasing false alarms and consumables. The JPS system consists of a variable number of biological sensors forming a network under the command and control of a centralized command post computer (CPC). The CPC communicates with and monitors the operation of each sensor. The sensor is modular in design and can detect and presumptively identify up to eight BW agents simultaneously in less than 25 minutes. In addition the systems has a chemical sensor interface (M22, M21, M90), which provides an integrated chemical and biological sensor network capability. The system successfully attained MSIII and systems were provided to support a Joint Staff "Directed Buy". The JPS has been deployed to a total of nine sites in Northeast Asia and 12 sites in the Middle East.

In June FY03 CENTAF consolidated efforts and shutdown operations at four sites resulting in a total 17 JPS sites. Contractor Logistics Support personnel are on-site at fielded locations in the CENTCOM and PACOM theaters of operation to maintain and sustain equipment. In FY03/04 JPS was provided to four Joint Service Installation Protection Program (JSIPP) sites. In FY03 the JPS System was upgraded with the JBPDS collector, BAWS, and a new identifier. Independent

Developmental and operational testing has been completed. Based on favorable evaluation and Milestone Decision Authority (MDA) decision, the fleet will be upgraded worldwide in FY04. JPEO-CBD provides lifecycle management of the system. System consumables were transitioned to Rock Island Arsenal in FY03, while maintenance is lifecycle Contractor Logistic Support upgrades enable JPS to have similar performance to JBPDS characteristics.

Joint Biological Point Detection System (JBPDS)

JBPDS provides point biological detection capabilities for all four services throughout the battlespace. The system, which at end state will replace all "current force" detection systems (*i.e.*, JPS, BIDS, IBADS), is more affordable and effective. The sensor's highly maintainable and modular design detects and presumptively identifies ten BW agents simultaneously in less than 20 minutes. This program has developed a standard biological detection suite that will be integrated on Service designated platforms. Its detection suite 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 & JLNBCRS, and marine expeditionary applications). The system may be operated locally or remotely, and fully automates the functions of: *collection* (capturing samples of the suspect aerosol for systems and confirmatory analysis), *detection* (interrogating and broadly categorizing the contents of the aerosol), *identification* (providing presumptive identification of the suspect BW agent), and *warning* (providing visual and audible alert to local and remote control units). This acquisition strategy allows for significant economies throughout the RDA process, eliminating duplicative efforts among the Services, and greater logistic supportability in joint operations. The current strategy also offers the fastest possible fielding of these urgently required systems, as well as the flexibility needed to continuously improve the system with the latest advances in the biological detection/identification, information processing and engineering sciences.

JBPDS Shipboard variant

Fielding of JBPDS began in FY03. In response to the national emergency, a network of eight JBPDS systems was deployed in the National Capital Region. These systems, referred to as the Homeland Defense Trailer (HDTR), were deployed November 28, 2001 and were fully operational on December 3, 2001. These HDTR systems are deployed in a commercial trailer configuration that was jointly developed and produced. The system was also deployed to a critical site during Operation Iraqi Freedom.

JBPDS - HDTR

Fielding of 35 M31E2 JBPDS Biological Integrated Detection Systems to the 375th Chemical Company began in June 2003 and was completed in November 2003. In support of the Joint Service Installation Pilot Program, five JBPDS were also deployed at a

CONUS site, which was completed in November 2003. Army fieldings planned in FY04-05 include additional BIDS Companies.

Dry Filter Unit (DFU)

The Dry Filter Unit is a stand-alone collector that can be used to collect internal and external ambient sample for subsequent analysis using Hand Held Assays (HHA) and Polymerase Chain Reaction (PCR) assays. It is simple, has an exceptional concentration factor, is inexpensive, and extremely flexible. When mated with a detection technology, these characteristics allow the detection of low concentrations of biological agents. The DFU can be used for both internal monitoring, and external monitoring. It is complementary to and does not replace the role or need for more robust detection systems such as JBPDS, JPS and BIDS. The system was developed in response to critical needs identified after the conventional and anthrax terrorist attacks in 2001. System development was originally funded with DERF. In FY 2003 it was further procured and fielded based on an Umbrella Urgent Need Statement by the Joint Requirement Organization to support Combatant Commander's urgent needs in support of OIF and other initiatives. To date over 1700 DFUs have been fielded to units, sites (including six JSIPP sites), ships, and select U.S. cities to provide for BW attack monitoring. The system has been tested technically and operationally and is undergoing preparations to obtain MS C in FY04 in order to support potential future needs such as installation protection, Navy ship requirements, and other initiatives.

Hand Held Immunochromatographic Assay (HHA)

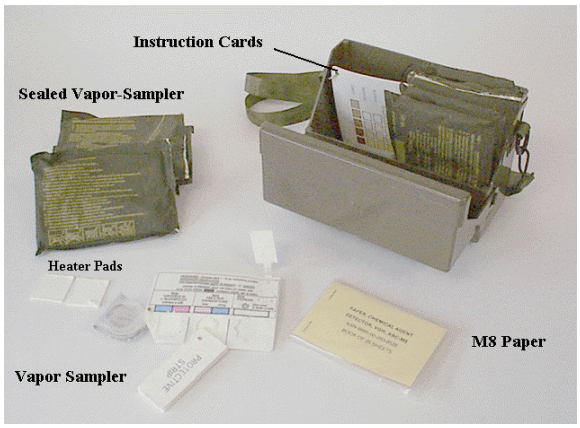
The HHA is a simple, antibody-based test used as a quick screen to presumptively identify BW agents from environmental samples. HHAs are inexpensive, easy to use, very reliable, and provide presumptive identification in 15 minutes. HHAs are designed to presumptively identify one agent per HHA and can currently identify ten different BW threat and four simulant agents. Training HHAs are also available. HHAs are read at 15 minutes and can either be read by eye or incorporated into automated detection device (*e.g.*, XM-99 Joint Portal Shield, Joint Biological Point Detection System (JBPDS), *etc*.). HHAs should not be used for the analysis of soil samples and are not for diagnostic use. HHAs must be stored at 4°C, but cannot be frozen. Shelf life at refrigeration temperatures (4°C) is 2 years. The HHA has a one-time use only capability, and cannot be reused once fluid is applied. HHAs are considered presumptive identification and must be confirmed by testing of the sample with other technologies for confirmation of identification results.

DoD Biological Sampling Kit

The DoD Biological Sampling Kit (*shown left*), with its associated HHAs, provides a presumptive identification capability for BW agents in environmental samples and are employed for: field screening suspect

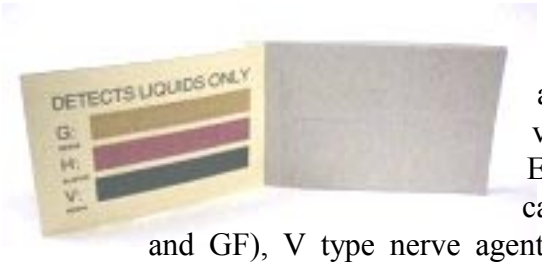
munitions or munitions fragments for presence of BW agents; screening envelopes or packages that display suspicious liquids, powders or suspensions; screening suspect terrorist laboratory or weapons materials that might be associated with the manufacture or delivery of BW agents; or as a contamination identification kit for indoor areas where it is suspected a BW agent has been released in fairly high concentrations. The DoD Biological Sampling Kit contains a panel of 8 HHAs, a blue-capped tube containing a bottle of buffer solution and cotton tipped swabs, and a basic instruction card. Training DoD Biological Sampling Kits are also available as well as an interactive, multimedia training CD-ROM. The DoD Biological Sampling Kit must be stored at 4ºC, has a one-time use only capability, and is not for diagnostic use.

M256A1 Chemical Agent Detector Kit



The M256A1 kit can detect and identify field concentrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustard, phosgene oxime, mustard-lewisite, and lewisite), and blood agents (hydrogen cyanide and cyanogen chloride) in both vapor and liquid form in about 15–20 minutes. The kit consists of a carrying case containing twelve chemistry sets individually sealed in a plastic laminated foil envelope, a book of M8 chemical agent detector paper, and a set of instructions. Each detector ticket has pretreated test spots and glass ampoules containing chemical reagents. In use, the glass ampoules are crushed to release a reagent, which runs down pre-formed channels to the appropriate test spots. The presence or absence of chemical agents is indicated through specific color changes on the test spots. The kit may be used to determine when it is safe to unmask, to locate and identify chemical hazards (reconnaissance), and to monitor decontamination effectiveness.

ABC-M8 VGH, and M9 Chemical Agent Detector Paper



M8 and M9 paper are dye impregnated papers that change color when exposed to liquid chemical agents or aerosols. These papers cannot detect chemical agents in vapor form. M8 paper (*left*) comes in 4" x $2^1/_2$" booklets. Each booklet contains 25 sheets of detector paper that are capable of detecting G series nerve agents (GA, GB, GD, and GF), V type nerve agents, and H (mustard) type blister agents. M8 paper can identify agents through distinctive color changes from its original off-white: yellow-orange for G, blue-green for V, and red for H. M8 paper is typically used to identify unknown liquid droplets during chemical reconnaissance/surveillance missions.

M9 (SR119) detector paper (*right*) is rolled into 2-inch wide by 30-feet long rolls on a 1.25-inch diameter core. M9 paper can detect G and V nerve agents, H agents, and L agents but it cannot distinguish the identity of agents. It turns pink or a shade of red when in contact with liquid

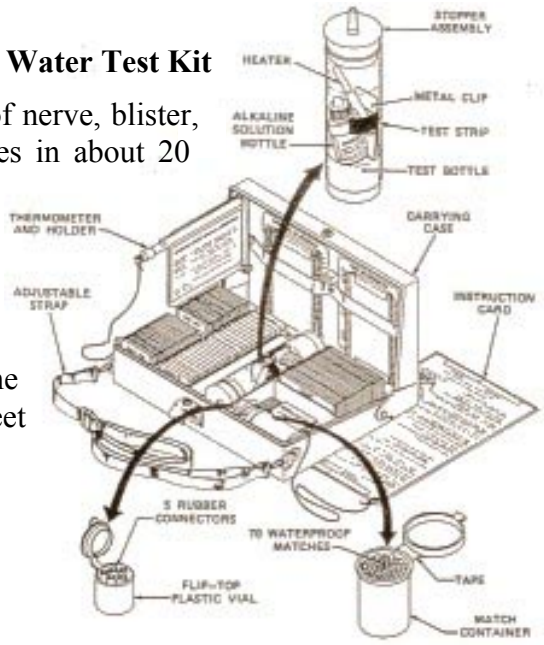
chemical nerve and blister agents. M9 paper is typically placed on the BDO, equipment, and vehicle exteriors to warn personnel of the presence of a liquid chemical agent.

M18A3 Chemical Agent Detector Kit

The M18A3 can detect and identify dangerous concentrations of nerve agents (sarin, tabun, soman, GF, and VX), blister agents (mustards, phosgene oxime, mustard-lewisite mixture, phenyl dichloroarsine (PD), ethyl dichloroarsine (ED), and methyl dichloroarsine (MD)), blood agents (hydrogen cyanide and cyanogen chloride), and choking agents (phosgene) in about 1–4 minutes. The kit is also used to confirm results of the M256A1 kit. The M18A3 kit contains a squeeze bulb and enough detector tubes, detector tickets, and chemical reagents needed to conduct 25 tests for each agent vapor. The kit also contains a booklet of M8 chemical agent detector paper to detect liquid agents. Agent vapor detection is indicated by the production of a specific color change in the detector tubes. The M18A3 kit is only used by special teams such as surety teams or technical escort personnel.

M272 Water Test Kit

The M272 kit can detect and identify hazardous levels of nerve, blister, and blood agents in treated or untreated water resources in about 20 minutes. The kit contains enough detector tubes, detector tickets, a test bottle, and pre-packed, pre-measured test reagents to conduct 25 tests for each agent. The kit also contains simulants used for training. Agent detection in water is indicated by the production of a specific color change in the detector tubes or in the ticket. The M272 was fielded in 1984 and does not meet current lower level detection requirements.



M8A1 Automatic Chemical Agent Alarm (ACAA)

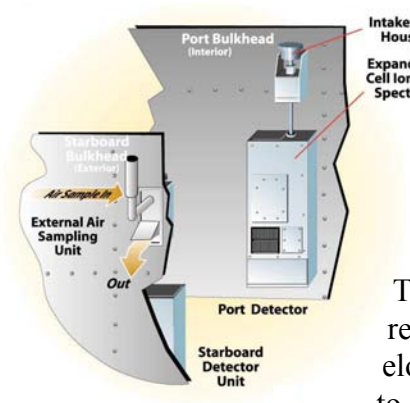
The M8A1 ACAA is a system that continuously samples the air to detect the presence of dangerous concentrations of G and V type nerve agent vapors. This system is currently being replaced by the ACADA in many Army units. Displaced M8A1 systems are being cascaded to lower priority units throughout the Army. The M8A1 ACAA may be employed in a number of configurations, but all configurations are built around the M43A1 detector unit and the M42 alarm unit. The configurations differ primarily in their mountings and power supplies: ground mounted and battery operated, or mounted on a vehicle and powered by the vehicle's electrical system. The M43A1 detector unit measures $7^{1}/_{2}$" x $5^{1}/_{2}$" x 11". Using the battery in ground mounted operations adds another $7^{3}/_{4}$" to the height. The M43A1 detector unit uses a radioisotope to ionize molecules in the air that is pumped through the system, then detects electrical current changes that occur in the presence of nerve agents. The M43A1 detector unit will alarm within about 1–2 minutes from exposure to agent. The M42 alarm unit is a remote visual and audible alarm that measures 7" x 4" x $2^{1}/_{3}$". The M42 alarm unit may be placed up to 400 meters from the M43A1 detector unit to give users warning of an approaching agent cloud.

M90 Automatic Mustard Agent Detector (AMAD)

The AMAD is an automatic nerve and mustard agent detector that detects agents in vapor form. This system is currently in use by the Air Force. It transmits an alarm by radio to a central alarm unit.

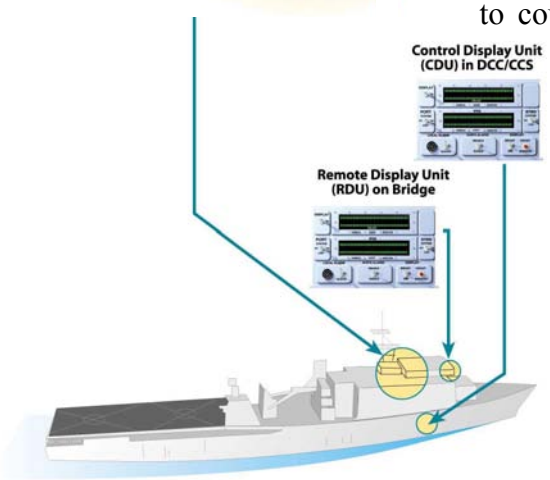
Chemical Agent Point Detection System (CAPDS), MK21, MOD1

CAPDS is a fixed system capable of detecting nerve agents in vapor form, using a simple baffle tube ionization spectrometer. Installed in a ship's upper superstructure level, CAPDS obtains a sample of external air, ionizes airborne vapor molecules, and collects them on a charged plate after eliminating lighter molecules via the baffle structure. When a sufficient mass of ions is collected, a pre-set potential is achieved, and an alarm signal is generated and sent to both Damage Control Central and the bridge. The CAPDS system is being replaced by the MK 26 Mod 0 Improved (Chemical Agent) Point Detection System



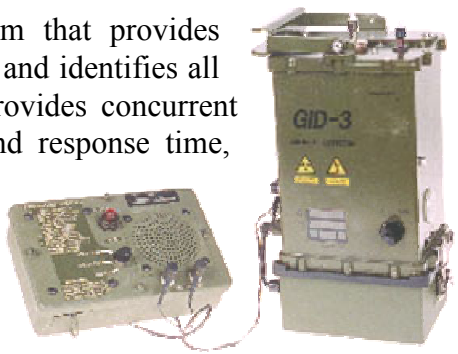
Improved (Chemical Agent) Point Detection System (IPDS)

The IPDS is a new shipboard point detector and alarm that replaces the existing shipboard CAPDS. IPDS uses special elongated ion mobility cells to achieve the resolution necessary to counter false alarms caused by interfering vapors. IPDS can detect nerve and blister agent vapors at low levels, and automatically provide an alarm to the ship. The unit is built to survive the harsh sea environment and the extreme electromagnetic effects found on Navy ships.



M22 Automatic Chemical Agent Detection Alarm (ACADA)

ACADA is a man-portable, point sampling alarm system that provides significant improvement over current capabilities; it detects and identifies all nerve agents, mustard, and lewisite, by class. ACADA provides concurrent nerve and blister agent detection, improved sensitivity and response time, agent identification capability, improved interference rejection, extensive built-in test, a data communications interface, and the capability to be programmed for new threat agents. It replaces the M8A1 Alarm as an automatic



point detector and augments the CAM as a survey instrument. The ACADA consists of an off-the-shelf non-developmental item (NDI)—the GID-3 chemical agent alarm. A shipboard version of the ACADA has been fielded to address the unique interferents found aboard Navy ships that cause false alarms on the NDI ACADA. The shipboard version of ACADA will serve to cover the Navy's emergency requirements until the Joint Chemical Agent Detector can be fielded. In FY04, enhancements were made to the ACADA to decrease maintenance and increase life expectancy of systems that are operating 24 hours a day, 7 days a week. The ACADA 24/7 version has been fielded within the Joint Service Installation Pilot Program in FY03 and early FY04. Additional improvements will be the addition of the ACADA 24/7 to detect and identify Toxic Industrial Chemicals that pose a threat to DoD Installations. This variant of the ACADA will be fielded in FY04 in support of JPM Guardian programs.

Shipboard ACADA

AUTOMATIC DETECTORS AND MONITORS

RDTE ITEMS

Agent Water Monitors

The Joint Service Chemical Biological Agent Water Monitor is a cooperative RDTE effort, chartered to develop a detection system that will detect chemical and biological agents in water. The detector will feature multi-agent capabilities, and operate automatically, improving both ease and response time of existing system. The project will accommodate the four services' requirements.

Rationale:

- Joint Army (materiel development lead), Air Force (requirements lead), and Marine Corps requirement. Navy interest.

Key Requirements:

- Detect and identify chemical agents and agents of biological origin in water
- Perform monitoring automatically with continuous and batch sampling capabilities
- Easy to operate and support in forward areas, austere environments, and limited lighting

Description:

The Agent Water system will improve current water monitoring and purifying capabilities. It will automatically detect CB agents at or below harmful levels in water and not false alarm to common interferents. The system will be compact, man-portable and easy to use, and be decontaminated to a negligible risk level.

Defense Technology Objective (DTO) CB. 37 Chemical/Biological Agent Water Monitor

Objectives. This effort will develop system concepts and technologies to meet the service requirement for a Joint Chemical/Biological Agent Water Monitor (JCBAWM). The desired capability is for the detection and identification of hazardous chemical and biological agents in potable water. The system will be capable of processing source (pretreatment, ponds, lakes, rivers, etc.,) and product waters (post

Defense Technology Objective (DTO) CB. 37 Chemical/Biological Agent Water Monitor

treatment verification and distribution quality assurance). It is unlikely that a single technology will be able meet this objective; therefore, the system will most likely consist of two or more integrated technologies that have been optimized to meet a specific challenge.

Payoffs. This DTO address Joint Future Operational Capability of Contamination Avoidance: Medical and Environmental Surveillance. The only system currently fielded for the detection of agents in water is the M272 Water Test Kit. This kit has several drawbacks, including an inability to detect biological agents and a relatively long response time. This kit is difficult to use when in a protective posture and is incapable of autonomous operation, requiring a user to interpret the results. The water monitor developed in this effort will be capable of detecting both chemical and biological agents. In addition, it will be capable of real-time, autonomous operation, which will allow the system to be used as a true water monitor. In FY01, development of standardized test evaluation protocols was completed and the testing of technologies was initiated. Transition criteria were established based on JCBAWM Operational Requirements Document (ORD). A first-generation design for a water monitor system was completed and the breadboard build was initiated. In FY02, the breadboard was completed and surety testing was initiated. In FY03, receiver operator curves (ROC) were established on the breadboard to predict technology performance.

Challenges. The challenges associated with this DTO are numerous. The system will be required to operate under a variety of environmental conditions, ranging from extremely turbid source water to chemically treated ”clean” water. Experience shows that this will pose a significant challenge in terms of both agent sensitivity and specificity. The system will also be required to operate in near real time. Work conducted in FY03 based on ROC curve analysis predicts chemical agent will be more difficult than previously assumed. The bio-detection is within 4-5 minutes time to detection. Sensitivity requirements also pose a significant challenge. The current requirement is in the parts-per-trillion to parts-per-billion range for chemical agents. Chemical agents, for instance, undergo chemical changes in water much more quickly than in air. Factor such as hydrolysis will be significant. Biological agents will no doubt undergo changes as well, making the detection problem somewhat dynamic.

Milestones/Metrics.

FY2004: Initiate a limited utility assessment to demonstrate technology. Develop assessment criteria and initiate a prototype design and build for the assessment.

FY2005: Complete prototype build and assessment methodology.

FY2006: Conduct utility assessment.

Joint Chemical Agent Detector (JCAD)

The JCAD is a fully cooperative RDTE effort, chartered to develop a chemical agent detector for a variety of mission requirements and service platforms. The detector will provide warfighters near-real time information on the presence of chemical agents so that miosis or more severe effects can be avoided and not subvert the mission. The project will accommodate the four services' requirements.

Rationale:

- Joint Army, Navy, Air Force and Marine Corps requirement

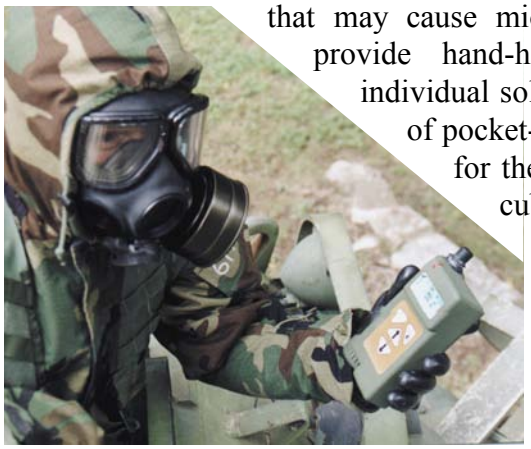
Key Requirements:

- Small, lightweight detector capable of detecting presence of chemical agent vapors

- Capable of de-warning, allowing for rapid reduction of protective postures
- Detect, identify, quantify, and warn of presence of even low levels of nerve, blister, and blood agents in vapor form in aircraft and shipboard interiors
- Operated/maintained by ship's force; operate in a shipboard environment

Description:

JCAD (*handheld prototype shown*) will provide a detector or a network of detectors capable of automatically detecting, identifying, and quantifying chemical agents (nerve, blister, and blood) inside aircraft and shipboard interiors. The device must be sufficiently sensitive to warn aircrews before accumulation, over the entire mission, of levels of agent that may cause miosis or more severe effects. JCAD will also provide hand-held monitoring capabilities, protecting the individual soldier, sailor, airman, and marine through the use of pocket-sized detection and alarm. The requirements are for the detector to be considerably smaller (within 40 cubic inches) and lighter (2 lbs. or less) than the ACADA and to be configurable for a variety of applications, such as individual soldier detectors, post-attack monitoring, shipboard chemical agent monitoring, special operations forces applications, and aircraft interior detection.



Critical Reagents Program (CRP)

Rationale:

- Supports requirements of all Services, as well as biological detection programs of DoD first responders, other Federal Agency's, and NATO countries'.

Key Requirements:

- Provide Total Life Cycle Management for the critical reagents (antibodies, antigens, and gene probes and primers), Electrochemilluminescense Assays (ECLAs), Polymerase Chain Reaction Assays (PCRAs), Hand Held Assays (HHAs), and DoD Biological Sampling Kits necessary to the operation of all DoD biological detection systems.
- Ensure best quality reagents and immuno assays are available in time and in adequate quantities.
- Ensure adequate security and surge capability of critical reagents, ECLAs, HHAs and PCRAs.
- Produce HHAs and DoD Biological Sampling Kits that are critical to all DoD biological detection programs.

Description:

The CRP ensures the quality, availability, and security of BW reagents, ECLAs, PCRAs, HHAs, and DoD Biological Sampling Kits, which are critical to the successful development, test, and operation of DoD biological warfare detection systems and medical biological products. The program maintains an R&D effort to ensure the best

possible reagents are available for use against both current and emerging threats and to include analysis of commercially available reagents and technologies. The CRP has instituted a program-wide quality assurance program and addresses relevant security issues. The CRP consolidates all DoD antibody, antigen, gene probe/primer, ECLA, PCRA, HHA, and DoD Biological Sampling Kit developments and requirements. The CRP currently has reagents and HHAs to detect 10 BW threat agents from the ITF-6A threat list. The CRP provides required reagents and HHAs to support fielded DoD BW detection systems (BIDS NDI and P3I, XM-99 Joint Portal Shield, IBAD, and DoD Biological Sampling Kits) and developmental systems (JBPDS), as well as other Federal Agencies and NATO allies. The near future requires the development of environmental and diagnostic molecular reagents for the JBAIDS. Outlying years will focus on the development of reagents to identify new and emerging threats and the procurement of improved reagents to replace older stocks.

Joint Biological Tactical Detection System (JBTDS)

Rationale:

- Draft Joint Operational Requirements Document (US Marine Corps Lead Service).

Key Requirements:

- Lightweight biological detection system
- Capable of being integrated into warning and reporting network

Description:

The JBTDS (concept shown) will be developed to provide warfighters a lightweight sensor with biological agent detection, warning and sample isolation capabilities. The detector will be networked to provide a cooperative detection capability to increase the probability of warning personnel and reduce the probability of false alarm. Each JBTDS will be capable of acting in two modes: a biological agent detector mode and/or a command module. The command module will be capable of receiving data from the arrayed detectors (three or more) while being able to control the detectors and track information generated within the network. Control capability will consist of remotely resetting, enabling and disabling the detectors on the network and tracking information generated within the network. The network capabilities of the network will include both hardwire and wireless interfaces to provide maximum flexibility in fixed site and remote application. The required throughput of the system will be consistent with the alert data exchange and archiving requirements. The sample isolation feature will collect and preserve a sample for evacuation and analysis. JBTDS will have the flexibility to warn automatically or to permit for manual

intervention in the detection-to-alarm process. JBTDS will be employed remotely or in an unattended configuration, on platforms to include vehicles, aircraft, and by foot-mobile forces.

Joint Modular Chemical and Biological Detection System (JMCBDS)

Rationale:

- Joint Operational Requirement Document.

Key Requirements:

- Point chemical and biological detection in a single system
- Capable of being integrated into warning and reporting network.

Description:

In the far-term, chemical and biological detection will be integrated into a single system. The JMCBDS is envisioned to be modular, miniaturized, multi-technology, automated system capable of detecting all CW/BW agents. The JMCBDS is envisioned to integrate advanced chemical detection with miniaturized biological point detection capabilities into a single system. It will automatically warn troops and provide fused sensor data to JWARN.

Defense Technology Objective (DTO) CB.20 Automated Genetic Identification
Objectives. This DTO will develop and demonstrate technology to reduce the logistics burden associated with biological identification through an advanced, automated Biological Identification System based upon genetic detection and identification technology. The primary objective to reduce the logistics burden is only partially handled by an automated sample preparation system. Consumables continue to be the major logistics impact for biological warfare agent detection and identification systems. The extended work will focus on the reduction of the total number of required assays through multiplexing/multiagent analysis within a single sample.
Payoffs. This DTO addresses the Joint Future Operational Capability of Contamination Avoidance, Biological Detection/Identification When this DTO is completed, the technology will expand the scope of detectable and identifiable biological agents, shorten the time required for sample analysis, ensure that a maximum and properly prepared sample load is analyzed, and reduce the associated logistics burden as well as overall footprint associated with these detection technologies. To date, automated sample processing and preparation have been demonstrated for feasibility without impacting on standard PCR methodology. Multiplexing/multiagent analysis within a single sample/assay will result in a significantly reduced logistics footprint and lower operational and maintenance costs.
Challenges. Major technical challenges include the development of new chemistry to reduce the total number of assays needed through multiplexing/multi-agent concepts for a single sample analysis; the number of practical analyses that can be conducted on a sample within a single reaction tube; the removal of environmental/biological materials that may diminish performance of these platforms, rapid preconcentration of samples, rapid and efficient extraction of nucleic materials, automation of the entire sample treatment process to permit fully unattended operation.
Milestones/Metrics.
FY2004: Demonstrate the feasibility of a cost-effective MMA PCR assay. Complete the design of a prototype system to use MMA PCR assays that is compatible to the Joint Bio Point Detection System requirements.

Defense Technology Objective (DTO) CB.20 Automated Genetic Identification
FY2005: Build and demonstrate an automated prototype for the MMA PCR assays to include automated sample preparation.

DTO CB. 50 Lightweight Integrated CB Detection
Objectives. This DTO will develop technology to meet the requirements of the Joint Modular CB Detection (JMCBD) System. The critical path is to demonstrate an overall size of two cu ft and weight of 35 lb with biological sensitivity of 15 agent containing particles per liter of air (ACPLA) and chemical identification equal to that of the Joint Chemical Agent Detector. This will demonstrate the potential to meet the JMCBD operational requirements. **Payoffs.** This effort addresses the Joint Future Operational Capabilities for Contamination Avoidance in Biological Early warning Detection/Discrimination, Chemical Early Warning Identification, and Chemical Detection and Identification. This effort will provide the next generation of smaller, lighter CB detection capabilities and will be the first to provide an integrated system for CB capabilities. This DTO addresses the overarching need to reduce the total number of systems out in the battlefield for better logistics. **Challenges.** The major technological challenges are in the biological detection and discrimination to reduce the overall size, weight, and power requirements, integration of chemical and biological capabilities, and integration of the next generation of aerosol collection/sampling technology. The primary focus will be a cost to benefit analysis on the level of discriminate for biological detection and the size and weight of the overall system. Current philosophy is that the higher level of biological discrimination will require a bigger and heavier system. Integration of chemical and biological capabilities will be a challenge due to the fundamental differences in the nature of the materials. Integration of aerosol collection/sampling will be dependent on the availability of technology. **Milestones/Metrics.** **FY2004:** Conduct tradeoff analysis to identify best two or three approaches. Complete information for the downselection database. Downselect to two or three technologies. **FY2005:** Downselect technologies to the best two or three approaches. Prepare preliminary design concepts based on these approaches. **FY2006:** Assess ability of technology to meet JMCBDS requirements. Design brassboard. Initiate fabrication of brassboards. **FY2007:** Complete fabrication of brassboards. Test and evaluate.

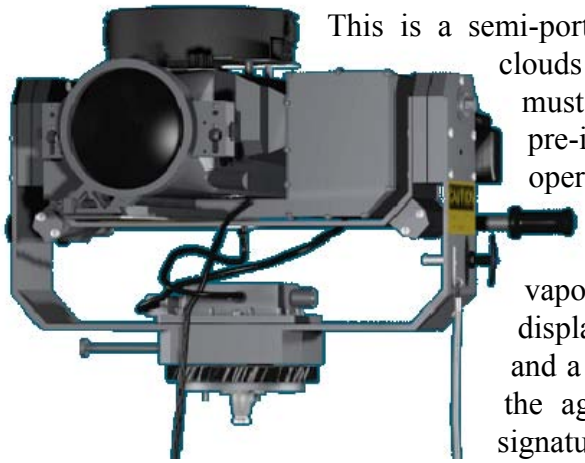
DTO CB.52 Detection of CB Contamination on Surfaces
Objectives. This DTO will develop a capability for the detection of operationally significant concentrations of chemical and biological agents on surfaces. **Payoffs.** This DTO addresses the Joint Future Operational Capability of Contamination Avoidance, Point Detection: Biological and Chemical detection and Identification The successful completion will provide a capability for affordable, rapid, short-range standoff reconnaissance and contamination avoidance of CB agents on surfaces. **Challenges.** Significant progress has been made in both the biological and chemical standoff detection arenas. Despite this, significant challenges remain in terms of developing a cost-effective approach for surface detection. The challenges of standoff detection of CB agents on surfaces include changing albedo due to background, fill-factor mitigation, and real-time detection algorithms.

DTO CB.52 Detection of CB Contamination on Surfaces
Milestones/Metrics. **FY2003:** Perform data collection on three surfaces (glass, sand, and concrete/asphalt) with four surety agents (GA, GD, VX, and HD) using laser enhanced RAMAN spectroscopy. The data is to be incorporated into a database for use to develop algorithms to address the detection of contaminants on surfaces. **FY2004:** Construct initial characterization of breadboard(s) to demonstrate the capability to detect chemical agents at a deposition of 0.5 g/m^2 and operationally significant biological agent contamination levels. **FY2005:** Optimize breadboard(s) based on results and assess the capability to detect chemical agents at a deposition of 0.01 g/m^2 and operationally significant biological agent contamination levels.

STAND-OFF DETECTION AND REMOTE/EARLY WARNING

FIELDED AND PRODUCTION ITEMS

AN/KAS-1/1A Chemical Warfare Directional Detector (CWDD)



This is a semi-portable system designed to detect nerve agent vapor clouds at ranges up to five kilometers. The AN/KAS-1/1A must be removed from its stowage case and set up on a pre-installed pedestal for operation. A trained, diligent operator must manually aim the detector at the suspect cloud and interpret its infrared images to determine whether or not the cloud contains nerve agent vapors. The AN/KAS-1A provides a remote video display, an enhanced capability for vapor cloud analysis, and a remote relative bearing indicator useful for avoiding the agent cloud or other surface target with a thermal signature.

M21 Remote Sensing Chemical Agent Alarm (RSCAAL)

The M21 RSCAAL is an automatic scanning, passive infrared sensor that detects nerve (GA, GB, and GD) and blister (H and L) agent vapor clouds based on changes on the infrared spectrum caused by the agent cloud. It is effective at line-of-sight distances of up to five kilometers. The alarm is used for surveillance and reconnaissance missions in both vehicle-mounted and tripod-mounted modes.

STAND-OFF DETECTION AND REMOTE/EARLY WARNING

RDTE ITEMS

Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD)

Rationale:

- Joint Army Navy, Air Force, and Marine Corps requirement.

Key Requirements:

- Automatically detect nerve, blister, and blood agents at a distance up to 5 km
- Lightweight and employed from manned and unmanned systems
- Capable of being data-linked with centralized hazard information data collection center
- Capable of remote operations; aerial and on-the-move operation

Description:

JSLSCAD will be capable of scanning 360° x 60°, and automatically detecting nerve or blister agents at a distance up to 5 km. The system will be light, compact and operate from a stationary position or on-the-move. The JSLSCAD Michelson interferometer employs a passive infrared system that will detect presence of chemical agents by completing a spectral analysis of target vapor agent chemical clouds. JSLSCAD is envisioned for employment on various platforms and in various roles, including fixed site defense, unmanned aerial vehicles, tanks and other vehicles, and on board ships. Among the vehicle platforms will be the JSLNBCRS (both HMMWV and LAV variants). During FY03, DoD continued development and test and evaluation of the JSLSCAD. In addition, a side-by-side test between the JSLSCAD and the Mobile Chemical Agent Detector (MCAD) was conducted as part of an effort to examine all available technologies capable of meeting military requirements, including those specified in the JSLSCAD ORD.

Artemis (Chemical Agent Standoff Detection System)

Artemis is a joint effort chartered to develop a standoff chemical agent warning and identification system for each of the Services. Artemis will utilize an active LIDAR sensor to perform rapid chemical agent identification and ranging to satisfy requirements for all four services.

Rationale:

- Draft Joint Navy, Marine Corps, and Air Force requirement

Key Requirements:

- Automatically detect/identify, range, and track CW agents at distances of up to 20 km
- Scan atmosphere and terrain to detect chemical vapors, airborne rains and liquid and solid aerosols

- Provide a long range stand-off capability for both fixed site and mobile reconnaissance
- Provide for CW agent threat cloud mapping

Description:

Artemis will initially be a fixed site (*concept shown*), contamination monitoring system, which detects/identifies and quantifies all types of chemical agent contamination (including agent rain, vapors, and aerosols) in a stand-off mode to a distance of 20 kilometers (km). Artemis will operate initially from fixed sites only and later be ground vehicle, shipboard, and rotary and fixed wing aircraft mounted. The system has distance-ranging and provides for contamination-mapping capabilities and transmits this information to a battlefield information network.

Biological Remote/Early Warning

The Joint Biological Remote Standoff Detection System (JBSDS) program is intended to give the warfighting commander a significantly shortened decision cycle regarding biological attacks; that is, the commander will see and be able to react to a biological attack much faster, thereby allowing many more personnel to take protective measures before they become exposed to the biological warfare agents. This means that fewer people will become casualties, and fewer people will have to take post-attack medical treatments.

Joint Biological Standoff Detection System (JBSDS)

Rationale:

- Joint Requirement (Army materiel development lead, Air Force requirement lead)

Key Requirements:

- Detect and track aerosol clouds out to 15km
- Discriminate biological clouds from non-biological clouds out to 3km
- Operationally eye and skin safe

Description:

The JBSDS uses an IR and UV laser to detect (15km) and discriminate (3km) aerosol clouds at operationally significant concentrations. The Interim JBSDS is being developed in response to an urgent demand identified in a Joint Staff Statement of Urgency and will be fielded to the U.S. Army and the U.S. Air Force. The Interim JBSDS provides 120 degree scanning while operating from fixed sites or mobile platforms in a stationary mode. The next generation system will provide 360 degree scanning while operating on-the-move and will be fielded to all four Services. The Interim JBSDS underwent a combined Production Qualification Test during FY03 and a Milestone B FY03. A

Milestone C is scheduled for FY04, an IOT&E FY05 and FUE FY06. A MS B for the next generation system is planned for FY05.

DTO CB. 35 Standoff Biological Aerosol Detection
Objectives. This DTO will develop and demonstrate technology for an advanced, standoff biological detection capability to both detect and discriminate biological aerosol clouds at operationally significant concentrations. **Payoffs.** This DTO addresses Joint Future Operational Capability Contamination Avoidance: Biological Early Warning Detection/Discrimination and Identification. The development of this technology would permit the rapid detection, discrimination, and location of biological aerosol clouds. This technology would also be capable of being used on various platforms for the purpose of air or ground biological reconnaissance and contamination avoidance. Technology developed under this effort is intended to address operational requirements of the Joint Biological Standoff Detection System. In FY02, system performance parameters were established through coordination with users, and downselection of candidate technologies based on weighted criteria including performance, logistics, platform, operational concerns, maturity, and cost was conducted. Experimental data were generated to support downselect. Downselected technologies include long-wave and mid-wave infrared (LWIR and MWIR), Differential Scattering/ Differential Absorption Lidar (DISC/DIAL), and Passive LWIR Spectroscopy. **Challenges.** Significant progress has been made recently in both active and passive standoff detection arenas with respect to biological detection. Despite this, significant challenges remain. In addition to size, weight, and power, challenges exist with respect to both sensitivity and specificity, possibly leading to cost-effective hybrid technology concepts (use of two or more technologies) for the final system design. **Milestones/Metrics.** **FY2004:** Complete construction and characterization of breadboards to demonstrate the capability to detect and discriminate (bio vs. non-bio) biological agents at a concentration of 1,000 agent containing particles per liter of air (ACPLA). Evaluate breadboards via field test. **FY2005:** Evaluate breadboard(s) via field test and demonstrate the capability to detect and discriminate (bio vs. non-bio) biological agents at a concentration of 1,000 agent containing ACPLA at a range of 1 km. Initiate feasibility studies to integrate chem and bio capabilities with the objective of maintaining demonstrated capabilities. **FY2006:** Complete feasibility studies on the integration of chem. And bio capabilities to include a design approach/concept.

NBC RECONNAISSANCE

FIELDED AND PRODUCTION ITEMS

M93 NBC Reconnaissance System (NBCRS)

The M93 NBC Reconnaissance System, known as the FOX, is a high mobility armored vehicle capable of performing NBC reconnaissance on primary, secondary, and cross country routes throughout the battlefield. The NBCRS was procured as a Non-Developmental Item and is capable of detection, warning and sampling the effects of NBC weapons and is used as a reconnaissance

vehicle to locate, identify and mark chemical and nuclear contamination on the battlefield. The M93 FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission. The NBCRS has an overpressure filtration system that permits the crew to operate the system in a shirt sleeve environment, which is fully protected from the effects of NBC agents and contamination. It utilizes a secure communications system to warn follow-on forces. Samples gathered are forwarded to the Theater Area Medical Laboratory for further analysis and verification. The mobility platform is a six wheeled all wheel drive, armored combat vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is fully amphibious and is capable of swimming speeds up to 6 MPH. The M93 NBCRS has been fielded worldwide to the Army and Marine Corps forces.

M93A1 – FOX NBC Reconnaissance System (NBCRS)

The Block I Modification—M93A1 NBCRS contains an enhanced and fully integrated NBC sensor suite consisting of the M21 RSCAAL, MM1 Mobile Mass Spectrometer, CAM/ICAM, AN/VDR-2, and M22 ACADA. The NBC sensor suite has been digitally linked together with the communications and navigation subsystems by a dual-purpose central processor system known as MICAD. The MICAD processor fully automates NBC Warning and Reporting functions and provides the crew commander full situational awareness of the Fox's NBC sensors, navigation, and communications systems. The M93A1 FOX is also equipped with an advanced position navigation system (GPS & ANAV) that enables the system to accurately locate and report agent contamination. The NDI mobility platform is a six wheeled, all wheel drive armored vehicle capable of cross-country operation at speeds up to 65 MPH. The Fox System is also fully amphibious and is capable of swimming at speeds up to 6 MPH. It is used as a reconnaissance vehicle to locate, identify, and mark chemical and biological agents on the battlefield. The FOX usually accompanies the scouts or motorized reconnaissance forces when performing its NBC mission.

NBC RECONNAISSANCE

RDTE ITEMS

Stryker NBC Reconnaissance Vehicle (NBCRV)

Rationale:

- U.S. Army and U.S. Marine Corps Requirements

Description:

The Stryker NBCRV will incorporate enhanced chemical and biological detectors that will allow on-the-move standoff chemical agent vapor detection (*i.e.*, JSLSCAD). Biological agent detection capability is added for the first time through the Chemical Biological Mass Spectrometer (CBMS). The CBMS also improves the detection and identification of liquid agents. Integration of common NBC technical architecture will facilitate low-cost expansion/upgrading of on-board computers. Stryker NBCRVs Program with enhanced CB Sensor Suites will be used to equip the Army's future Brigade Combat Teams.

Joint Service Light NBC Reconnaissance System (JSLNBCRS)

Rationale:

- Joint U.S. Army, U.S. Air Force, and Marine Corps Requirements

Key Requirements:

- Stand-off and point detection from vehicle mounted or dismounted operations
- Chemical standoff detection
- Detection while on-the-move capability from speeds of 0–45 kph
- Biological point detection and identification
- A dismountable, handheld, self-contained chemical point detection capability
- Radiological detection capability (vehicle mounted or dismounted operations)
- Collective protection
- Environmental Conditioning Unit capable of providing climate conditioning for the crew and equipment
- Overpressure protection from all known agents

Description:

The JSLNBCRS will provide a premiere vehicle for accurate, rapid NBC combat hazard information by verifying the absence of, finding, mapping, and marking radiological, biological, and chemical hazards. The JSLNBCRS will be an integration of advanced NBC

detection and analysis equipment suited for Marine Air-Ground Task Forces (MAGTFs), U.S. Air Force tactical forces, and U.S. Army Light Contingency Forces. Two variants, the HMMWV (*variant shown*) and the Light Armored Vehicle (LAV) are planned and will house the same equipment.

DTO CB.53 Wide-Area Aerial Reconnaissance for Chemical Agents

Objectives. This DTO will: (1) develop and demonstrate a lightweight, wide-area passive standoff imaging detection system for airborne reconnaissance of chemical warfare (CW) agents for the purpose of contamination avoidance and facilities evaluation; (2) utilize existing hyperspectral imaging sensors to do phenomenology studies to determine the optimal tradeoffs between spatial and spectral resolution for mapping of CW threats; and (3) design and demonstrate a passive CW imaging detection system based on commercial off-the-shelf (COTS) focal plane array (FPA) and digital signal processing (DSP) technology. This DTO will have a strong focus on measurement and analysis of airborne detection phenomenology, real-time signal processing requirements, and algorithm development.

Payoffs. This DTO addresses Joint Future Operational Capability of Contamination Avoidance: Chemical Early Warning. The Wide Area Aerial Reconnaissance System (WAARS) will allow rapid evaluation of large areas for chemical warfare (CW) contamination, and provide detailed information as to the position of a CW agent cloud. Current single-pixel designs have an extremely limited field of view (typically 26 m at a distance of 1 km). In addition, they cannot scan at sufficient speeds for proposed high-speed applications (i.e., tactical helicopter, high-speed aircraft, and hemispherical scanning applications). The WAARS will be capable of operating at fields of view 8 to 100 times greater than current systems. In addition, scan speeds must be increased significantly to allow for high-speed applications and more sophisticated signal processing techniques. The potential deployments include fixed sites, ground vehicles, unmanned aerial vehicles, helicopters, and high and low aircraft.

Challenges. Airborne deployment of a passive standoff system requires a detailed understanding of the measurement phenomenology. Wide-area detection using imaging focal plane array (FPA) technology demands higher speed operation and more sophisticated signal processing techniques than current systems. A significant effort is required to perform the necessary measurements and determine the tradeoffs between wide-area spatial resolution and the spectral resolution required to detect and map a CW threat. Knowledge of these tradeoffs will enable the design of practical detection algorithms that can be implemented using existing digital signal processing technology. The most significant current challenge is posed by the high frame rate required to do imaging interferometry. Novel solutions must be developed to efficiently acquire and process this high-speed data and implement algorithms that can execute in real time.

Milestones/Metrics.

FY2004: Develop a 30-Hz frame rate, 64-pixel Fourier transform infrared (FTIR) hyperspectral imager (TurboFT). Perform sensor characterization tests. Develop off-line algorithms and signal processing techniques.

FY2005: Develop a 3-Hz, 128x128 tunable hyperspectral imager. Perform sensor characterization tests. Develop off-line algorithms and signal processing techniques.

FY2006: Conduct demonstration of enhanced FTIR and tunable IR systems with real-time data processing. Determine optimum spectrometer performance specifications in terms of scan speed, spatial resolution, and spectral resolution.

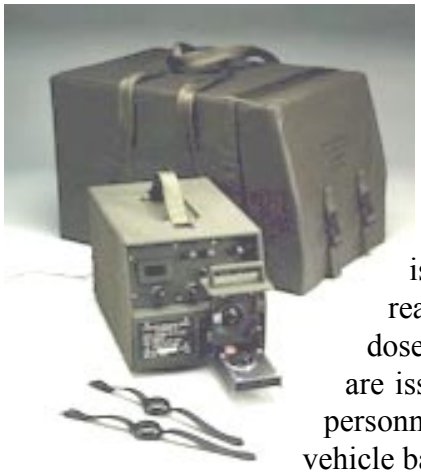
RADIATION DETECTION (RADIACS)

FIELDED AND PRODUCTION ITEMS

AN/VDR-2

The AN/VDR-2 measures gamma dose rates from 0.01 µGy/hr (micro-Grays per hour) to 100 Gy/hr and beta dose rates from 0.01 µGy/hr to 5 cGy/hr. The unit functions simultaneously as a dose rate meter and dose meter with independent adjustable alarms that can be set at any level over the entire range. Dosage data is independently stored in non-destructive memory for display on command and may be retained when the unit is turned off. The unit is powered by three 9 volt batteries.

AN/PDR-75 Radiac Set



The AN/PDR-75 measures dose from 0 to 999 cGy (centi-Gray). The Radiac Set consists of a dosimeter and a reader. It provides the capability to monitor and record the exposure of individual personnel to gamma and neutron radiation. Each individual will be issued a DT-236/PDR-75 dosimeter. This device, worn on the wrist, contains a neutron diode and a phosphate glass gamma detector. When a determination of exposure is required, the dosimeter is inserted into a CP-696/PDR-75 reader, which then displays the cumulative neutron and gamma dose. The reader is issued at the company level and the dosimeters are issued to all combat, combat support, and combat service support personnel. The reader can be powered by a BA-5590 lithium battery, vehicle battery, or external power supply via adapter cables provided.

AN/PDR-77 Radiac Set

The AN/PDR-77 Radiac Set is a set of portable radiation detection equipment for detecting alpha, beta, gamma, and x-ray radiation. The set consists of a radiacmeter to which one of three radiation probes can be attached for measuring particular types of radiation. The probes are part of the set. The set includes accessories and basic test and repair parts for unit maintenance including a carrying pouch with shoulder straps capable of holding the radiacmeter, alpha probe, and beta/gamma probe for field use. The entire set is contained in a carrying case (large briefcase) for easy portability and storage.

AN/UDR-13 Pocket RADIAC

The AN/UDR-13 Pocket RADIAC is a compact, hand-held, tactical device capable of measuring the gamma dose-rate and gamma and neutron cumulative dose in a battlefield environment. Its pocket size permits convenient use by troops on foot. Alarm pre-sets are provided for both the dose-rate and total dose modes. A push-button pad enables mode selection and functional control. Data readout is by liquid crystal display. It will replace the obsolete IM-93 quartz fiber dosimeter and the PP-1578 Dosimeter Charger.

Multi-Function Radiation (MFR) Detector

This program improves radiation detection equipment by replacing the current suite of logistically unsupportable assets. Present detectors (PAC-1S, AN/PDR-43 and AN/PDR-56F) have exceeded maintainability standards. Original manufacturers have either discontinued production or are no longer in business. The MFR provides an improved capability to support both wartime and peacetime nuclear accident response operations. The MFR alone detects gamma radiation but in combination with the OA-9449/PDQ probe it can measure gamma and detect beta radiation. A production contract was awarded in March 1995. First deliveries were made in 1997.

ADM-300A Multifunction Survey Meter

The ADM-300A is a battery-operated, self-diagnostic, multiple functional instrument. It is used alone to locate and measure low and high intensity radioactivity in the form of gamma rays or beta particles. It is used with external probes to locate and measure alpha, beta, gamma, and x-rays, and neutron radiation.

DARPA Programs

DTO CB. 38 Activity-Based Detection and Diagnostics

Objectives. The ADT program objectives will provide innovative detection platforms in support of the QDR Operational Goals for Protecting Bases of Operation: Biological and Chemical Defense. It will demonstrate engineering of cells and tissues that is directed toward the development of activity detection systems for biological and chemical threats, and develop metrics for system performance in detection applications to include environmental sensing and advanced diagnostics for critical defense needs.

Payoffs. The successful demonstration of cell and tissue activity detection systems could provide dramatic new capabilities for sensing the activity of existing, emerging, and engineered biological and chemical warfare threats or hazards. These detection systems could also be used as monitors for toxins related to operational exposures in deployment toxicology and could provide rapid surveillance tools

DTO CB. 38 Activity-Based Detection and Diagnostics
for epidemiologic surveillance of environmental or medical samples. Successful demonstration of cell- and tissue-based detection systems could also be used as high-throughput information against chemical and biological agents. In FY02, cell and tissue based assays against at least 20 chemical and biological agents were demonstrated in high-density formats. Early progress on freeze-drying B-cells suggests that significant logistical improvements will be made in delivering these detection platforms to the field. **Challenges.** The program approach is based on robust extraction of cell and tissue signatures of agent response. The first task will focus on the generation of these signatures and the use of pattern recognition tools to robustly extract signatures of activity and response. This task will also include the reduction of critical risk parameters associated with the design and fabrication of working prototype cell- or tissue-based activity detectors. These include sample collection and preparation, extended cell and tissue performance and shelf life, optimized fluidics, and data acquisition and analysis tools. The second task is dedicated to testing and validating the system prototypes that include hand-held and small footprint benchtop systems. The most significant issues that must be addressed are: (1) Cell/Tissue Response and System Prototype Development--populate library of key cell and tissue responses to chemical and biological agents of interest to DoD that could be monitored in environmental and diagnostic samples; demonstrate extended performance of cells and tissues to enable the recording of agent response for an operationally relevant timeframe (21 days); and develop a sample collection and preparation module suitable for cell and tissue detector systems threats; (2) System Testing and Validation--incorporate cell/tissue signatures into prototype systems; test and validate prototype detection systems; and develop metrics for specific operational use. **Milestones/Metrics.** **FY2004:** A prototype B-cell sensor will be evaluated as a fast BW trigger under field conditions at a military facility. The objectives of these tests are to determine sensitivity, specificity and time of response using actual aerosol samples.

Microfluidic Molecular Systems Program

Accomplishments:

- Demonstrated discrimination of 0.4% differences in cell impedance using micromachined dielectrophoreses system.
- Demonstrated on-chip circulation—controlled transport of target liquids through combination of integrated fluidic channels and reaction components.
- Demonstrated microscale enabled immunoassay with enzyme labelers to replace conventional optical label.
- Demonstrated microfan and filter system to capture airborne particulates into liquid for input to detection system.
- Demonstrated efficient transport of DNA over cm distances using electrophoretic confinement and transport through electrophoretic vias.
- Demonstrated a multi-channel device that is able to carry out six independent assays simultaneously using a single point detector.

Description:

This program recently concluded with the goal of developing micro total analysis systems through focused research on microfluidic, chip-scale technologies. Automated sample collection and sample preparation are key front-end processes for early biological agent detection, whether it is by immunoassays, DNA assays, or tissue-based assays. To scale

down these processes into miniaturized, multiplexed detection systems, microfluidic chip-scale components was the aim of this program. Microfluidic components/devices that were investigated include chip-scale micropumps/valves, particle separation filters, fluidic interconnects, fluidic manipulation of hybridized microbeads, controlled mixing/ dosing, etc. Several demonstrable handheld prototypes, such as a programmable microfluidic system for remote sensors, were tested.

Pathogen Genome Sequencing Program

Accomplishments:

Organism	**Status**	**Notes**
Brucella suis	Completed (8/2002)	Strain 1330
Coxiella burnetti	Completed (4/2003)	Strain Rsa493
Bacillus cereus	Completed (4/2003)	Strain Atcc 14579
Franciscella tularensis	Completed (10/2003)	Unpublished
Burkholderia mallei	Completed (9/2002)	Unpublished
Rickettsia typhi	Completed (9/2003)	Not In Genbank

- Random phase sequencing via low-level coverage of Ochrobactrum anthrop, a near neighbor of *Brucella suis* was completed.
- Random phase sequencing with high level coverage of *Bacillus thuringiensis*, near neighbor of *Bacillus anthracis* was completed.
- Sequence information will be available for all organisms via National Library Of Medicine (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=Genome).
- Rickettsia typhi sequence can currently be found at the baylor college of medicine genome sequencing center website (ftp://ftp.hgsc.bcm.tmc.edu/pub/data/rtyphi).

Description:

DARPA has made a commitment to sequencing the genomes of one representative strain for each of the high threat biowarfare agents identified by the Chairman of the Joint Chief of Staff threat list. This effort, undertaken with broad community interaction, supports Biological Warfare Defense research activities sponsored by DARPA and is intended to satisfy the needs of Department of Defense components, the Intelligence Community, and other governmental organizations. Interest is focused on BWD pathogens, and non-pathogenic near neighbors thought to be important to establish a basis for low false alarm detection and identification via genotype analysis. The work also contributes to the development of advanced unconventional pathogen countermeasures.

Protection Program

Accomplishments:

- Built first prototype of water disinfection pen (size of a thick fountain pen) based on an eletrochemical cell. The pen is able to create a mixed oxidant solution that is more potent than tablets used nowadays by the forces: the mixed oxidant pen was able to destroy many waterborne pathogens to at least 3 to 4 log removal. The Marine Corps

Systems Command is now overseeing fabrication of the first 10,000 mass-produced versions of these pens.

- Demonstrated that harmonic pulsing of a reverse osmosis membrane increases water flux through the membrane and decreases the total dissolved solids. This concept has been translated into the first prototype of a hand-held desalination handpump, with which the individual soldier can make 1 liter of water from brackish or salt-water sources in 5 minutes.
- Built first generation air purification unit to destroy airborne pathogens by thermocatalytic destruction. The destruction efficiencies for various air pathogens and simulants in the high 90% range. The goal is to get towards at least 99.999% removal rates.
- Began work on advanced carbon surface treatments to improve adsorption capacity and kinetics.

Description:

There are two related programs currently ongoing within DARPA that further enable the individual warfighter by providing significantly more mobile and flexible water purification and desalinization systems and better air filtration media. The intent is to demonstrate highly efficient, smaller, lighter, high water through-put technologies for water purification and desalinization, and to explore pioneering air filtration schemes that have an acutely high utility for the DoD enabling new mission scenarios that are critical to the changing battlefield environment. The water desalinization and purification systems would meet Army Operational Requirements (*i.e.*, effectively treat salt/brackish water and nuclear, biological and chemical contaminated water, purify 0.2 liter water per minute, weigh less than 2 lbs., *etc*.) New soldier-portable equipment is being developed to harvest water from unconventional sources such as atmospheric moisture condensed into canteens at 15 Whr/liter of energy expenditure, and collecting/purifying water from engine exhaust at the rate of 1 liter of water recovered from 1 liter of diesel fuel burned. Work in air purification develops simple air filtration and purification systems for the individual that provide significant improvements over the current charcoal filter gas mask technology (which have remained virtually unchanged for over 20 years). The intention is to develop air purification systems for collective protection that will require much less maintenance and greater personal safety than current based-carbon recirculating filters.

Annex B

Battlespace Management Programs

Table B-1. Battlespace Management RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Warning and Reporting	- Joint Warning and Reporting Network (JWARN)	RDTE/Prod	Joint	Joint	Joint	Joint
	- Multipurpose Integrated Chemical Agent Detector (MICAD)	Fielded*	*Rqmt*		*Rqmt*	*Rqmt*
Hazards Analysis	- Vapor, Liquid and Solid Tracking (VLSTRACK)	RDTE/Fielded	Joint*	Joint*	Joint*	Joint*
	- Chemical Warfare Naval Simulation (CWNAVSIM)	RDTE				Rqmt
	- MESO	RDTE	Joint*	Joint*	Joint*	Joint*
	- CB Warfare Computational Fluid Effects (CBW-CFX)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Hazard Prediction and Analysis Capability (HPAC)	Fielded	Joint*	Joint*	Joint*	Joint*
	- Joint Effects Model (JEM)	RDTE	Joint*	Joint*	Joint*	Joint*
	- CB.42 Environmental Fate of Agents	DTO				
	- CB.62 Hazard Prediction with Nowcasting	DTO				
	- CB.55 Chemical and Biological Hazard Environment Prediction	DTO				
Operational Effects Analysis	- Simulation Training and Analysis For Fixed Sites (STAFFS)	RDTE	Joint*	*Rqmt*	Joint*	Joint*
	- Joint Operational Effects Federation (JOEF)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Joint Medical NBC Decision Support Tool (JMNBCDST)	RDTE	Joint*	Joint*	Joint*	Joint*
	- CB.43 Chemical and Biological Warfare Effects on Operations	DTO				
Simulation Based Acquisition	- NCBR Simulator	RDTE	Joint*	Joint*	Joint*	Joint*
	- Virtual Prototyping System (VPS)	RDTE	Joint*	Joint*	Joint*	Joint*
Training Simulation	- Virtual Emergency Response Training System (VERTS)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Training Simulation Capability (TSC)	RDTE	Joint*	Joint*	Joint*	Joint*

Joint= Joint Service requirement
Rqmt= Service requirement
Fielded = Fielded Capability (Sustained by Services)
Joint*=Draft Joint Service requirement
Rqmt = sub-product requirement or interest
RDTE = Research, Development, Test & Evaluation (Advanced Development program)
DTO=Defense Technology Objective (Science & Technology Base Program)

WARNING AND REPORTING

FIELDED AND PRODUCTION ITEMS

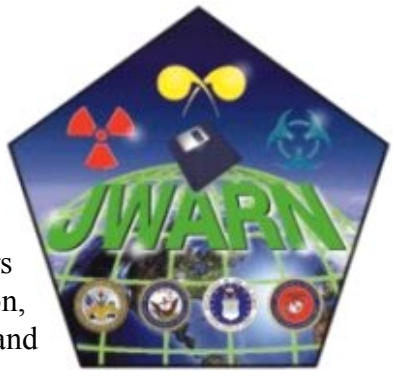
Joint Service Warning and Reporting Network (JWARN) Block I (FUE FY 99)

Rationale:

- Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Capable of generating NBC reports
- Capable of automatic transmission of NBC alarm and data



Description:

JWARN Block I is an automated Nuclear, Biological, and Chemical (NBC) Information System. JWARN Block I is essential for integrating the data from NBC detectors and sensors into the Joint Service Command, Control, Communication, Computers, Information and Intelligence (C^4I^2) systems and

networks in the digitized battlefield. JWARN Block 1 provides the Joint Force an analysis and response capability to predict the hazards of hostile NBC attacks or accidents/incidents. JWARN Block I will also provide the Joint Forces with the operational capability to employ NBC warning technology that will collect, analyze, identify, locate, report and disseminate NBC threat and hazard information. JWARN Block I is located in command and control centers at the appropriate level defined in Service-specific annexes and employed by NBC defense specialists and other designated personnel. It allows operators to transfer data from and to the actual detector/sensor/network and automatically provide commanders with analyzed data for decisions for disseminating warnings to the lowest echelons on the battlefield. It provides additional data processing, production of plans and reports, and access to specific NBC information to improve the efficiency of NBC personnel assets. Blocks II and III are planned to integrate this capability into Command and Control centers so that it will be a segment on existing and future C4ISR systems, and to integrate the sensor outputs directly and automatically with the NBC warning and reporting tools so that sensor data automatically feeds the information system and so that the C4ISR operator may have direct control of the CBRN sensors.

Multipurpose Integrated Chemical Agent Detector (MICAD) Embedded Common Technical Architecture (ECTA) Pre-Planned Product Improvement (P3I)

Rationale:

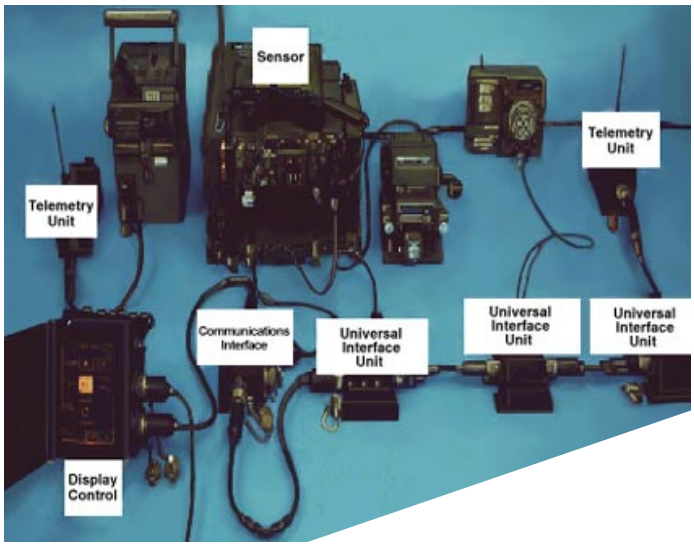
- Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Capable of interfacing with all NBC detectors and sensors
- Capable of interoperability with all service command and control systems
- Capable of generating NBC reports
- Capable of automatic transmission of NBC alarm and data
- Capable of vehicle (Fox, M93A1) operation

Description:

ECTA completely meets the JWARN ORD requirements for a fully automated CBRN Information System for vehicles, shelters and ships where data is taken directly from the CBRN sensors to generate warning and reporting information directly to and on the host C4ISR system. ECTA provides the Joint Force a legacy analysis and response capability to predict the hazards associated with any CBRN event. ECTA is a P3I to the MICAD system deployed on the Army's Fox vehicles. As such, the ECTA will take MICAD functions such as control of NBC sensors



which is performed through direct, hard wire connections, operator initiated analysis using legacy tools such as the Vapor Liquid Solid Tracking (VLSTRACK) and Hazard Prediction and Analysis Capability (HPAC), and automatic generation of NATO Standard warning reports using JWARN Block 1 software, and imbed the control functionality within the host C4ISR system. Initial target C4ISR systems are the Maneuver Control System (MCS) used by the Army for Fox vehicles, the GCCS-M system used on Navy ships, and the Theater Battle Management Core Systems (TBMCS) used by the Air Force.

WARNING AND REPORTING

RDT&E ITEMS

Joint Service Warning and Reporting Network (JWARN) Blocks II & III (FUE FY 06)

Rationale:

- Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Capable of interfacing with all NBC detectors and sensors
- Capable of interoperability with all service command and control systems
- Capable of generating NBC reports
- Capable of automatic transmission of NBC alarm and data

Description:

JWARN Blocks II & III completely meet the JWARN ORD requirements for a fully automated CBRN Information System for stationary, vehicular, mobile and dispersed sensor applications that takes data directly from the CBRN sensors and generates warning and reporting information directly to the host C4ISR system. JWARN Blocks II & III will provide the Joint Force a comprehensive analysis capability with the use of the Joint Effects Model (JEM) which is currently under development to replace legacy analysis tools. JWARN will also be capable of utilizing the suite of capabilities to analyze operational consequences and perform alternative course of action analyses using the suite of tools to be provided by the Joint Operational Effects Federation (JOEF). JWARN will also provide the Joint Forces with the operational capability to employ evolving warning technology that will collect, analyze, identify, locate, report and disseminate NBC threat and hazard information. JWARN will be located in command and control centers and hosted as a segment on C4ISR systems at the appropriate level defined in Service-specific annexes and employed by NBC defense specialists and other designated personnel. The JWARN system will transfer data automatically via hard wire or other means from and to the actual detector/sensor/ network nodes and provide commanders with analyzed data for decisions for disseminating warnings to the lowest echelons on the battlefield. It will provide additional data processing, production of plans and reports, and access to specific NBC information to improve the efficiency of NBC personnel assets.

HAZARDS ANALYSIS

FIELDED AND PRODUCTION

Vapor, Liquid and Solid Tracking (VLSTRACK)

VLSTRACK is a chemical and biological agent hazard assessment model *that predicts the behavior of agents and the resulting hazards from a chemical or biological weapons attack*. This model has been specifically verified and validated against all known data concerning passive defense against biological and chemical weapons and is the only model accredited by the Department of Defense for this purpose. As such, it supports operational decisions, operational contingency planning, hazard assessment doctrine, acquisition program studies, and requirements generation. VLSTRACK Version 3.1 is currently available and fielded directly from the science and technology program. Limited training is also available from the developer. This technology is being transitioned to the Joint Effects Model (JEM) Acquisition Program.

Hazard Prediction and Assessment Capability (HPAC)

HPAC is a nuclear, chemical and biological hazard prediction system *that predicts hazards resulting from the use of force on opposition facilities or assets*. It is the only model accredited by the Department of Defense for this purpose. HPAC Version 4.0 is a modular system of capabilities using a Gaussian puff methodology transport and dispersion engine called SCIPUFF to drive specific nuclear, biological or chemical event applications. It has a broad data base system and is able to use various weather data inputs. HPAC supports operational decisions, operational contingency planning, hazard assessment doctrine, acquisition program studies, and requirements generation. HPAC Version 4.0 is currently available and fielded directly from the Technology development program conducted by the Defense Threat Reduction Agency (DTRA). Training is also available from the developer. This technology is being transitioned to the Joint Effects Model (JEM) Acquisition Program.

HAZARDS ANALYSIS

RDTE ITEMS

CWNAVSIM (Chemical Warfare Naval Simulation)

Rationale:

- Navy requirement

Key Requirements:

- Predict ship system degradation resulting from a chemical attack
- Predict Mission Oriented Protective Posture (MOPP) resulting from a chemical attack
- Predict shipboard chemical agent detection system effectiveness

Description:

CWNAVSIM was developed to address specific Naval acquisition program decisions regarding chemical weapons defensive systems, specifically the Tactics, Techniques and Procedures (TTP) needed to defend the ship and the placement of detection devices. The CWNAVSIM model is comprised of three modules: Deposition and Weathering of a Chemical Attack on a Naval Vessel (DAWN), Ship Chemical Warfare Ventilation

Model (VENM) and the Naval Unit Resiliency Analysis (NURA). DAWN simulates Gaussian puff vapor and liquid clouds (primary cloud) interacting with the ship surfaces using potential flow equations. The DAWN module allows deposition and off gassing (secondary cloud) of the contaminant from the ship's external surfaces. The primary and secondary clouds are then entrained into the ship and transported throughout by the ship's HVAC system. VENM traces the vapor movement internally keeping track of concentrations and dosages in each compartment using a zonal model. VENM can simulate attack scenarios without input from the DAWN module. NURA provides casualty assessments and ship's mission degradation. NURA was developed primarily from the Army's AURA code. Currently the DAWN module is being replaced with CBW-CFX Computational Fluid Dynamic (CFD) code.

MESO (3D mesoscale meteorological model)

Rationale:

- Joint requirement

Key Requirements:

- Advance the state-of-the-art in use of Lagrangian particle transport and diffusion (T&D)
- Advance the state-of-the-art in characterization of the planetary boundary layer
- Address physical processes and hazard assessment capabilities of current standard models for CBD

Description:

MESO is developed to provide a T&D capability that is more accurate and more theoretically sound than Gaussian puff methodology but does not require the time and computer resources of a full Navier-Stokes Computational Fluid Dynamics (CFD) code. The development effort for the Department of Defense is also intended to provide advances in modeling important physical processes relevant to hazard assessment. MESO is currently not in distribution.

Chemical and Biological Warfare Computational Fluid Effects (CBW-CFX)

Rationale:

- Joint requirement

Key Requirements:

- Track threat from vapor, liquid, and solid CB agents around or within complex structures, *e.g.*, ships and buildings

Description:

CBW-CFX uses CFD code to model the transport, diffusion, deposition, and surface evaporation of chemical and biological agents in and around 3-D structures. CFX is a commercial code, which allows licensed users to develop subroutines that can be used within the code. CBW-CFX adds methodology for physical processes unique to chemical and biological agents. CBW-CFX is intended for use by researchers. To extend its utility it has been interfaced with other models, *e.g.*, VLSTRACK and the Ventilation Model (VENM).

Defense Technology Objective (DTO) CB. 42 Environmental Fate of Agents

Objectives. This DTO will measure and understand the physicochemical processes of chemical agents on surfaces in order to predict their persistence and residual agent concentration in operational scenarios via an agent fate model. Such data will be incorporated with CB environment models to enhance description of the CB Battlespace environment and its evolution in time.

Payoffs. This DTO addresses the Joint Future Operational Capability of Battle Management: Battlespace Analysis and Planning. This DTO establishes challenge levels and protection factors necessary for multi-service operating environments based on validated datasets and consistent analytical methodology, and develops a science-based understanding of the chemistry and physics of chemical warfare agents on surfaces. A surface evaporation module will be produced - validated against laboratory studies, wind tunnel tests, and field trials to reduce uncertainty for predicting chemical threat agent fate and persistence. Such a model, when addressing physical processes relevant to environment fate of agents on surfaces, serves as a key component -for addressing persistence analysis for future novel chemical and biological threat agents. Data developed by this effort, when incorporated with CB environment models, will decrease risk to operational commanders when faced with critical decisions in the CB battlespace. Such decisions have impact not only on the survivability of the warfighter, but also on the integrity of the mission in the face of disruptions due to chemical agent hazards. Results of this program will directly support numerous decision tools such as the Joint Effects Model (JEM) and Joint Operational Effects Federation (JOEF). During FY03, phase II of a literature search produced a bibliographic report and an on line reference tool containing experimental data of chemical agents on surfaces. The definition of a test matrix and thickened agent formulation was completed. VX fate on/within concrete was determined in lab experiments and a scale up methodology for HD was established. A baseline model analysis incorporating HD/VX lab wind tunnel/ field results was initiated. A phase I version of the Chemical Hazard Estimation Method and Risk Assessment Tool (CHEMRAT) was produced and provided to the user community.

Challenges. Formulation, standardization, and dispersing techniques for thickened agents as well as understanding the chemistry and physics of agents on complex matrices such as concrete and asphalt are major technical hurdles. Scale up parameters need to be defined and verified to correlate various size wind-tunnel test conditions to outdoor conditions that would exist on a fixed site.

Milestones/Metrics.

FY2004: Complete development, documentation and validation of laboratory scale wind tunnels. Perform and document testing for neat -HD and GD on concrete under lab wind tunnel conditions and begin testing on asphalt. Develop methodology to determine absorbance and reactivity of agents on live grass. Develop methodology for correlating data from wind tunnel scale to field trial scale. Refine model structure to include humidity, temperature, contact hazard, droplet spread, and droplet absorption data. Continue level of effort literature review focusing on agent evaporation rate studies. Demonstrate ability to calibrate and disseminate thickened agents. Update CHEMRAT and the surface evaporation module of VLSTRAK by incorporating agent fate data measured to date.

FY2005: Perform and document testing of neat HD and VX on soil and asphalt. Perform and document testing of neat GD on asphalt. Perform and document neat and thickened GD and VX on soil laboratory studies. Validate test methodology for agents on live grass. Complete Agent/concrete model and conduct predictions of field test experiments; conduct validation experiments. Complete and document methodology development.

Agent Fate, Model Validation, and Source Characterization Databases

Rationale:

- Joint requirement

Key Requirements:

- Provide the Joint Service with field trial data assembled within databases in spreadsheet format
- The spreadsheets will contain information needed to develop or validate any open terrain contaminant transport and fate model
- Evaluate the validity of source characterization parameters
- The databases will initially directly support the Joint Effects Model (JEM) program
- The databases will be used to validate M&S tools developed under the M&S CA and the Information Systems Technology Business Area (BA)

Description:

Agent Fate Database: Currently CB Modeling and Simulation capabilities do not adequately address the fate of chemical agents deposited onto various surfaces and the resulting vapor and liquid hazards. The ability to assess these risks is key to post attack recovery planning, developing new equipment performance specifications, and the general planning for operational performance degradation expected due to the presence of persistent chemical agents. The goal of the Agent Fate Database is to translate detailed laboratory and field acquired data to improve the behavior characterization of chemical agent liquid deposited onto materials sufficiently well that computer models can be developed to simulate the behavior and accurately predict the resulting contact and vapor hazards. Results from modeling studies and analyses can then be used to develop decontamination and restoration of operations doctrine and training and influence the acquisition of materiel needed to meet associated requirements.

Model Validation Database: Each of the three DoD standard models (VLSTRACK, HPAC, and D2PC) has been validated against field trial data. The source terms, meteorological conditions, and contamination levels will be collected from the field trial reports and the files used for model validation. All relevant information will be put into an Oracle database. Additional literature search of DTIC and Technical Libraries will be performed for field trial reports contain data for contaminant releases in open areas that can be used for model validation. The data will be extracted from these reports and added to the validation database in the same fashion as the original set of reports. Further literature searches will be done to locate reports containing data on the flow of contaminants around buildings and to collect data characterizing the behavior of chemical or biological agents under conditions representative of high altitudes. This additional data will be added to the validation database for use in validating the complex flow and missile intercept capabilities of JEM Blocks 2 and 3.

Source Characterization Database: The overall objective is to develop a source characterization database of CB agent delivery systems as part of M&S tools available to the operational CB community and in direct support to the HPAC program. A tool called CARREM has been developed to estimate a delivery system's initial source, in parameters needed by transport and diffusion models. Subject matter experts will

evaluate the validity of these estimated parameters. When there is no consensus in the validity of the parameters or the experimental methods used to obtain them, a community accepted value would be determined. In cases where there is a significant disagreement in a value and there is no clear indicator which is the more valid, the parameters will be identified as an estimate used pending further experimentation or investigation.

DTO CB.62 Hazard Prediction with Nowcasting

Objectives. The overall objective is to develop a high –resolution local, regional, and global atmospheric prediction system that describes and forecasts/nowcasts battlespace environment (BSE) parameters to support prediction of the fate of chemical and biological agents, smoke, toxic industrial materials, and other agents in the environment for all DoD applications; and incorporate these BSE parameters into improved chemical/biological (CB) dispersion models to more accurately describe dispersion under a wider range of atmospheric conditions (night time, stable, in complex terrain, at high altitudes, etc.), than current capabilities. This DTO matures emerging basic research (6.1) for direct applications to the Service (6.4) users. The work necessary to integrate the Joint Effects Model with mesoscale nowcasts constitutes the technical effort that will be done under this DTO.

Payoffs. CB dispersion models will be improved by investigating methodologies that more accurately represent turbulent fluctuations, and will be coupled to atmospheric models in a physically realistic (thermally and dynamically) manner, as developed in the other DTO effort (BE.10).

Challenges. As time-critical decisions are necessitated, the forecast capability to support dispersion modeling should be tied to real-time observational nowcast and battlefield management systems such as JWARN (currently in development) for executing and managing prudent operations in the battlespace. Improved modeling of high-altitude and near-surface atmospheric physics and agent behavior, especially in environments containing interferents such as smoke, fog, and dust, will require significant effort to validate. Considerable effort is required for the operational test and evaluation of the capability, exercise support, and development of concepts of operations, tactics, techniques, and procedures.

Milestones/Metrics.

FY2004: Demonstrate improvement (approximately two-fold) of hazard predictions when driven by turbulence parameters obtained from the mesoscale model.

FY2005: Incorporate improved high-altitude physics from the Navy Global Atmospheric Prediction System (extended from 30 km to 150 km altitude) into the Joint Effects Model, the next-generation CB hazard model.

DTO CB.55 Chemical and Biological Hazard Environment Prediction

Objectives. The objective of this effort is to develop an improved capability to predict the behavior of chemical and biological agents in the environment. It will address the physical and biological processes that effect chemical and biological agents after they have been released into the environment. These processes include transport, diffusion, deposition, evaporation, biological decay, and reaerosolization and will incorporate new methodology developed under DTO CB.42 (Environmental Fate of Agents) that describes agent fate and persistence. This DTO directly supports the Joint Effects Model (JEM) ORD.

DTO CB.55 Chemical and Biological Hazard Environment Prediction
Payoffs. This capability will allow the warfighter to assess potential hazards from the use of chemical or biological weapons on the battlefield. This information is an important consideration when evaluating possible courses of action and their associated risks. Since the Joint Operational Effects Federation (JOEF) makes use of the chemical and biological hazard environment predictions, improvements in the capabilities to make those predictions will likewise improve the results of the operational analyses performed by JOEF. **Challenges.** The primary challenge to developing this capability is the scale of the problem domain (meters to many kilometers). There are a wide range of interacting processes involved and a variety of operational environments that must be addressed. Each of the modeled processes of transport, diffusion, deposition, surface adsorption, surface desorption, evaporation, and biological decay is addressed through mathematical calculations that are valid over a specific range of conditions but may be unsuitable outside that range. For example a fast-running Gaussian model (designed for flat terrain) might be applied to transport and diffusion in an urban environment for rapid analysis, but the results will be very inaccurate compared to a full computational fluid dynamics analysis that requires greater computing resources. Computer code implementation also represents a continuing challenge. The need for faster codes that execute on available and affordable computer platforms will be an ongoing issue for the foreseeable future. New methodology on agent persistence, surface evaporation, reaerosolization (produced under DTO CB.42) will need to be integrated into this broader modeling framework of hazard prediction tools. **Milestones/Metrics.** **FY2004:** Select and transition an urban dispersion model to JEM Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging. **FY2005:** Further enhance the complex terrain and flow around structures modeling capability to address variable surface characterization and solar effects on agent evaporation (shading of areas as a function of time of day). Perform code optimization and validation of the complex terrain and flow around structures tools. Improve integration of hazard environment prediction tools to allow automated data transfer between various models. Incorporate methodologies for agent fate and persistence developed under DTO CB.42. **FY2006:** Transition the complex terrain and flow around structures modeling capabilities to JEM Block III program.

Joint Effects Model (JEM) (FUE FY 06)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Predict hazard areas and contamination effects from nuclear, chemical or biological attack
- Predict hazard areas and contamination effects from nuclear, chemical or biological agent releases and releases of toxic industrial materials

Description:

JEM is the acquisition program that will transition the science and technology capabilities of VLSTRACK, HPAC, and D2PC. Once fielded, JEM will be the standard

DoD NBC hazard prediction model. JEM will be capable of modeling hazards in a variety of scenarios including: counterforce, passive defense, accident or incidents, high altitude releases, urban NBC environments, building interiors, and human performance degradation; some of these capabilities will be included following release of Block 1. JEM will support defense against NBC and Toxic Industrial Chemical (TIC)/Toxic Industrial Material (TIM) weapons, devices, and incidents. JEM will be verified, validated, and accredited (VV&A) in accordance with the applicable DoD VV&A directives. When used operationally, JEM will reside on and interface with command, control, communications, computers, and intelligence (C4I) systems. Warning systems on those C4I systems will use JEM to predict hazard areas and provide warning to U.S. forces within those areas. When used analytically, JEM will assist DoD components to train jointly, develop doctrine and tactics, and assess warfighting, technology, and materiel development proposals, and force structuring. JEM (unclassified version) will also support homeland defense through use by Civil Authorities and Allies.

OPERATIONAL EFFECTS ANALYSIS

RDTE ITEMS

Simulation Training and Analysis For Fixed Sites (STAFFS)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Determines operational effects of CB warfare environment on military fixed site operations
- Interfaces with key NBC models, simulations, and data bases

Description:

STAFFS is a general-purpose simulation model which represents the operations of large fixed-site facilities such as air bases, aerial ports of debarkation (APODs) and seaports of debarkation (SPODs), with the capability to represent chemical and biological warfare (CBW) attacks and their effects on operations. No other capability currently exists within DoD to assess the operational impact of CBW attacks on critical fixed-site targets. Due to their fixed location and essential combat support roles to forces in the theater of operation, these rear-area facilities can be expected to be high priority targets to aggressor forces and thus one of the most likely targets to encounter CB weapons and their effects. These sites may be particularly susceptible to repeated CBW attacks, which could significantly degrade logistical throughput and hamper combat operations. STAFFS is currently in use and being further developed in two major functional areas: 1) support of wargaming and operational exercises including distributed interactive environments, and 2) support of operational and requirements analysis. Wargame applications run interactively with STAFFS accepting input and providing output to other model applications running as a system. Man-in-the-loop games and simulations may be performed. Analysis applications typically involve the examination of many

different simulation/analysis cases (a case matrix) often involving parametric representation of unknown system data. Different user interfaces are provided specific to the application. STAFFS wargaming applications utilize an interactive graphic user/system interface while analysis applications typically utilize file base batch processing.

STAFFS utilizes spatial and temporal CB challenge data calculated by other standard CB hazard assessment models including VLSTRACK and HPAC. CB equipment and agent effects represented in high resolution include detectors, protective gear, decontamination, toxic and infective agent effects, collective protection, medical treatment, equipment induced thermal effects, equipment induced encumbrance, and doctrinal procedures such as work-rest cycles. These effects are represented by engineering level sub-models, which can be easily changed to represent different equipment capabilities and levels of availability. Basic operational tasks are modeled using a task-network approach that is adaptable to any desired level of resolution. STAFFS is developed by AFRL. Limited training is available.

Joint Operational Effects Federation (JOEF) (FUE FY 06)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Analyzes operational issues and doctrine through the interrelation and effects of various elements within the overall system.
- Evaluates the performance of particular equipment based on material characteristics.
- Assesses individual Warfighter ability to perform mission essential tasks.
- Aggregates individual performance parameters into unit effectiveness.
- Integrates existing transport/diffusion models for CB agent hazards.

Description:

The JOEF will provide the operational community with the federated models and simulations specific to their operational environment required to predict or immediately respond to the need for operational effects information relative to any nuclear, radiological, chemical, or biological event. JOEF will include both fixed site and mobile forces simulation capabilities that, when married to specific data bases, will completely simulate all nuclear, radiological, chemical and biological defense processes, forces, and battlespace environments. In addition, the Federation will address both personnel degradation and medical processes and resources. JOEF will be used by both the operational commander and operational analyst to make rapid course of action analysis effects-based operational decisions, logistics decisions, CBD asset location decisions, and develop TTPs for CBD operations. The JOEF will be utilized by: 1) operational planners and decision makers in support of course of action assessment and plan evaluation; 2) the analysis community in support of high level concept assessments and system effectiveness studies and 3) Joint exercises and experiments in support of planning, execution, and analysis. The JOEF vision is of a set of validated low-to-medium fidelity

warfare entity models, certified data, appropriate simulation services, and related user support tools in a framework suitable for modeling multi-warfare scenarios.

Joint Medical NBC Decision Support Tool (JMNBCDST)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Provide the capability to support deliberate planning, crisis action planning, exercises/training, and execution of medical support for operational missions, both on the battlefield and in urban environments.
- Interface with current and co-developmental medical planning tools such as the Medical Analysis Tool (MAT), Command and Control systems, medical informatics including the Defense Medical Surveillance System (DMSS) database, and Joint Warning and Reporting Network (JWARN) for discretionary transmission of data.

Description:

The Joint Medical NBC Decision Support Tool will enable the Service/medical planner/operator to model and analyze the NBC battlefield both to identify Service/Joint Force agent exposures on military and civilian populations and to estimate NBC casualties. It will also relate treatment protocols (time, task, treater files) to these casualties to determine: medical materiel requirements, medical personnel requirements, medical evacuation requirements and for hospital bed requirements at Levels 3-5. As such, it supports operational decisions, operational contingency planning, threat assessment doctrine, acquisition program studies, and requirements generation.

DTO CB. 43 Chemical and Biological Warfare Effects on Operations

Objectives. This DTO will develop a general-purpose model of the operations of large fixed-site facilities (air bases, aerial ports of debarkation (APODS), and seaports of debarkation (SPODS)), with the capability to represent chemical and biological warfare (CBW) attacks and their operational impacts (i.e., sortie generation rate, cargo throughput).

Payoffs. This DTO addresses Joint Future Operational Capability of Battle Management Analysis, with secondary modeling and simulation support to Contamination Avoidance. The model will assess the operational impact of CBW attacks on fixed-site targets, which are particularly susceptible to CBW attacks, significantly degrading their output, and hampering combat operations. It is intended as both an interactive and distributed tool, filling an important gap in the DoD modeling and simulation toolset. In wargaming simulations, the model will receive tasking inputs from its operators or the other simulations, and will generate corresponding degrades after an attack. It will alert the theater wargame model of the mission results and determine the disposition of assets on the mission, track surviving assets, and model asset turnaround for other missions. The model will provide wargaming support for APODs, SPODs, depots, and other fixed-site facilities. In studies, it can be used to assess the feasibility of base operations in a given CBW scenario, responding to the postulated threat and the defensive capabilities of a selected fixed-site facility. Operational planners can determine best trade-offs for base assets, work degradation, and relocation options. Newly fielded hardware/defensive capabilities (equipment procurement, detector deployment or modified CONOPS) can be assessed in terms of increased sortie rate, cargo throughput, or reduced casualties. The model will help determine the best

DTO CB. 43 Chemical and Biological Warfare Effects on Operations
mix of CBW defense capabilities and the most effective acquisition strategy. **Challenges.** Obtaining datasets that are complete, accurate, and representative for each contemplated use of the model is the most significant challenge. Validating model results with real-world results of CBW operational exercises is difficult because data are extremely limited. Data collection is time consuming and costly. Support of controlling organizations is frequently necessary, not only in making the data available, but also in its reduction, interpretation, and conversion to usable formats. In some cases the data will have to be obtained through experimentation, such as the effect of wearing next-generation CBW protective equipment and performing typical tasks. Other challenges include developing methodology for APODs/SPODS and increasing model execution speed sufficiently for wargaming environments. **Milestones/Metrics.** **FY2004:** Test and finalize APOD and SPOD representation. Define CASPOD data requirements. Populate SPOD representation. Support JOEF Block 1 Demonstration. Perform independent validation and verification on core model. Begin module definition and design for Marine Expeditionary Force HQ, depot, and railroad modules. **FY2005:** Test and finalize toward JOEF transition Block 2. Develop Marine Expeditionary Force HQ, depot, and railhead modules. Perform internal V&V.

SIMULATION BASED ACQUISITION SYSTEMS

RDTE ITEMS

Nuclear, Chemical, Biological and Radiological (NCBR) Simulator

Rationale:

- Army requirement, and Navy, Air Force and Marine Corps interest.

Key Requirements:

- Simulation of fielded and developmental CB defense systems to evaluate performance in operational situations.
- Integration of a CB environment into a distributed simulation environment involving mobile forces.

Description:

The NCBR Simulator provides the capability to utilize existing hazard transport and dispersion codes within the context of detailed materiel evaluations. The NCBR Simulator enables high fidelity simulations of CB defense equipment (CBDE) such as detectors and protective gear to "see" and react to CB hazards within a detailed synthetic environment. In real time, the NCBR Simulator calculates a high fidelity, three-dimensional (3D) hazard environment as a function of hazard delivery system (source term), meteorological conditions and complex (3D) terrain. The DTRA SCIPUFF and the Naval Surface Warfare Center's VLSTRACK Gaussian puff models provide the means for the NCBR Simulator to calculate CBR hazard environments. The NCBR Simulator makes the data available to other simulations via full 3D

representations of the environments (instantaneous air concentration), 2D grids (dose, deposition, and air concentration contours), and at a point via a subscription process. SBCCOM serves as the proponent for configuration control and release of the NCBR Simulator, and DTRA WMD Analysis and Assessment Center supported the migration of the tool to the DoD's High Level Architecture (HLA) standard for distributed simulation. The NCBR Simulator is a key enabling technology for the more inclusive Virtual Prototyping System and will provide the mobile forces capability to JOEF.

To address nuclear environments, the NCBR Simulator uses DTRA's External Blast (XBLAST) and Version 6 of Atmospheric Transport of Radiation (ATRv6) as the means for calculating the blast and prompt radiation environments resulting from tactical nuclear warheads. The NCBR Simulator publishes axis-symmetric 2D grids and 1D (line) arrays that the receiving simulation rotates about the origin of symmetry to obtain a full 2D or 3D environment.

Virtual Prototyping System (VPS)

Rationale:

- Army requirement, and Navy, Air Force and Marine Corps interest

Key Requirements:

- Simulation of fielded and developmental CB defense systems to evaluate performance in operational situations.
- Integration of a CB environment into a distributed simulation environment involving mobile forces.

Description:

The NCBR Environment Server provides the capability to utilize existing hazard transport and dispersion codes within the context of detailed materiel evaluations. The NCBR serves an environment for high-fidelity simulations of CB defense equipment (CBDE) by other distributed simulations (Distributed Interactive Simulation; High Level Architecture) such as CB Dial-a-Sensor and the Exposure Toxicity Server, enabling analyses of detectors and protective gear within a detailed synthetic environment. In real time, the NCBR Simulator calculates a time varying high-fidelity, three-dimensional (3D) hazard environment as a function of hazard delivery system (source term), meteorological conditions and complex (3D) terrain. The Naval Surface Warfare Center's VLSTRACK Gaussian puff models provide the means for the NCBR Simulator to calculate CBR hazard environments. The NCBR's modular, scalable architecture supports integration of other hazard models (an earlier-generation NCBR included DTRA's SCIPUFF, External Blast (XBLAST) and Version 6 of Atmospheric Transport of Radiation (ATRv6) codes). A proof-of-principle integration of a particle code has been completed. The NCBR makes the data available to other simulations via a time resolvable full 3D representations of the environments (instantaneous air concentration) and 2D grids (dose, deposition, and air concentration contours).

The Edgewood Chemical Biological Center (ECBC) leads a consortium of organizations including Defense Modeling and Simulation Office, Defense Threat

Reduction Agency, US Army Test and Evaluation Command, and the Joint Program Executive Office for Chemical and Biological Defense in the development and implementation of this tool. ECBC also serves as the lead proponent for configuration control and release of the NCBR. The NCBR is a key enabling technology for both the more inclusive Virtual Prototyping System and the mobile forces capability within JOEF.

TRAINING SIMULATION SYSTEMS

RDTE ITEMS

Virtual Emergency Response Training System (VERTS)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement.

Key Requirements:

- Visually immersive training environment for specialized missions of the US Army National Guard Weapons of Mass Destruction Civil Support Teams—WMD CST.
- Must represent not only the deploying military units' personnel and equipment, but also the civil first responders and their equipment with which the CSTs will work.
- Detailed visual and structural databases required for each city/site.

Description:

The VERTS is being developed to enhance the training of WMD CSTs. WMD response requires significant training demands for individual and collective tasks. Soldiers and airmen must be proficient on a wide array of government and commercial equipment for NBC protection, detection and medical response. The WMD CSTs, in particular, are required to master a variety of equipment and procedures. The VERTS is required to support both individual and collective training. VERTS supports training in all tasks for the CST. It allows training on procedures for response to dangerous NBC agents, procedures that are difficult if not impossible to recreate in a live training environment. VERTS also allows mission rehearsals in actual and realistic urban settings. Training in the virtual cities of VERTS allows these teams to learn to navigate in actual cities, in actual buildings and to do so without the threat of being observed by adversaries, criminals and terrorists. VERTS, by being distributable over a network, allows teams to train together without having to travel long distances. Once validated for CSTs, VERTS offers the promise to train other DoD response elements and first responders as well.

The simulation system will consist of a network of PC-based modules that will serve as Survey Team Stations (Desk-Top), a Chief Trainer/Battlemaster Station, Immersive Station, Medical Station, Network Server Station, AAR Station, and Data Logger Station.

Training Simulation Capability (TSC)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Provide an integrated and consistent training tool for warfighters to prepare for operations in a NBC environment
- Integration with and have access to current and planned individual service C^4I^2RS systems
- Provide ability to gather and store lessons learned and identified failure/error incidents in order to provide after action review
- Provide capability to use NBC effects models and mission data to perform mission rehearsals using a simulation federation.

Description:

The TSC will provide the ability to simulate NBC attacks using NBC defense assets and Command, Control, Communications, Computers, Intelligence, Information, Reconnaissance, and Surveillance (C^4I^2RS) systems for training and exercises. It will allow for exercise planning, execution, and capturing lessons learned for after action review (AAR). It will provide the capability to use or simulate the use of NBC sensors, Tactical Engagement Simulation (TES) gear, and simulators for training and exercises. The TSC will provide the capability to simulate NBC environments and effects under live, virtual, and constructive simulations. It will provide the capability to use training and simulations in both Command Post Exercise (CPX) and Field Training Exercise (FTX) environments. It will operate in conjunction with the Joint Warning and Reporting Network (JWARN), future Joint NBC Battlespace Management systems, and the other Modeling and Simulation capabilities developed to support NBC defense requirements.

The TSC will be used at all levels of NBC defense decision-making to train for and simulate NBC attacks against friendly forces. It will provide for the training and use of simulation capability by all NBC defense personnel and commanders related to NBC threats and scenarios. When fully fielded the TSC will run the gamut from individual/team trainers up through large unit battle staff training capabilities.

Annex C

Non-Medical Protection Programs

Table C-1. Protection RDA Efforts

	Category	Nomenclature	Status	USA	USAF	USMC	USN
INDIVIDUAL PROTECTION	Aviation/ Surface Respiratory Protection	- MBU-19/P Aircrew Eye/Respiratory Protection (AERP)	Production	Interest	Rqmt	Interest	
		- M48 Aircraft Mask	Production	Rqmt			
		- CB Respiratory System (A/P22P-14(V))	Production			Rqmt	Rqmt
		- M45 Aircrew Protective Mask (ACPM)	Production	Rqmt		Interest	
		- M45 Land Warrior Mask	Production	Rqmt	Rqmt		
		- M40A1/M42A2	Fielded	Rqmt		Rqmt	Rqmt
		- MCU-2A/P	Fielded		Rqmt		Rqmt
		- Joint Service Aircrew Mask (JSAM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
		- Joint Service General Purpose Mask (JSGPM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
		- Joint Service Chemical Environment Survivability Mask	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	Universal Common Individual Protective Equipment	- Protection Assessment Test System (PATS)	Production	Rqmt	Rqmt	Rqmt	Interest
		- Voice Communication Adapter	Production	Rqmt	Rqmt	Rqmt	Rqmt
		- Joint Service Mask Leakage Tester	RDTE	Interest	Rqmt	Rqmt	Rqmt
		- CB.36 End-of-Service-Life Indicator for NBC Mask Filters	DTO				
	Aviation/ Surface Protection Ensembles	- CB Protective Overgarment Saratoga	Fielded	Interest		Rqmt	Interest
		- Chemical Protective Undergarment (CPU)	Fielded	Interest		Int-NIR	Interest
		- Modified CPU (mCPU)	Production	Rqmt			
		- CMU-34P and CMU-35P (USN modified CPU)	RDTE	Rqmt		Rqmt	Rqmt
		- Joint Service Lightweight Integrated Suit Technology -- Overgarment -- Boots (MULO)	 Prod.* Prod.*	 Rqmt Interest	 Rqmt Rqmt	 Rqmt Rqmt	Rqmt
		-Battledress Overgarment (BDO)	Fielded	Rqmt	Rqmt	Rqmt	Rqmt
		Joint Protective Aircrew Ensemble (JPACE)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
		- CB.45 Self-Detoxifying Materials for Chemical/Biological Protective Clothing	DTO				
	Specialty Suits	- STEPO	Fielding	Rqmt			
		- EOD Ensemble	Production		Rqmt		
		- Improved Toxicological Agent Protective (ITAP)	Production	Rqmt			
		- Joint Firefighter Integrated Response Ensemble (JFIRE)	Fielded	Rqmt	Rqmt		
		- Suit Contamination Avoidance Liquid Protective (SCALP)	Fielded	Rqmt			
COLLECTIVE PROTECTION	Tentage and Shelter Systems	- M20A1 Simplified CP Equipment (SPE)	Fielded	Rqmt	Rqmt		Rqmt
		- M28 CP Equipment (CPE)	Fielded	Rqmt	Rqmt		Rqmt
		- CB Protective Shelter (CBPS) (Medical)	Production	Rqmt	Interest	Interest	
		- CP Deployable Medical System–Chemically/ Biologically Hardened Air Transportable Hospital (DEPMEDS/CHATH)	Production	Rqmt	Rqmt	Interest	
		- CP Expeditionary Medical Shelter System (CP EMEDS)	Production	Interest	Rqmt	Interest	Interest
	Collective Protection (CP) Systems	- Shipboard Collective Protection System (CPS)	Production	Interest	Interest		Rqmt
		- Modular Collective Protection System (MCPE)	Fielded	Rqmt	Interest		Interest
		- M8A3 Gas-Particulate Filter Unit (GPFU)	Fielded	Rqmt			
		- M13A1 GPFU	Fielded	Rqmt	Rqmt		Rqmt
		- Joint Collective Protection Equipment (JCPE)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
		- CB.08 Advanced Adsorbents for Protection Applications	DTO				
		- CB.40 Immune Building Program (DARPA)	DTO				
	Generic Filters	- M48/M48A1 (100 cfm) Gas-Particulate Filter	Fielded	Rqmt		Rqmt	Rqmt
		- M98 (200 cfm) Gas-Particulate Filter Set	Fielded	Rqmt	Rqmt	Interest	Rqmt
		- Fixed Installation Filters	Fielded	Rqmt	Rqmt		Interest

Rqmt = Product requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement
* - Sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product requirement or Interest
DTO = Defense Technology Objective (Science & Technology Base Program)

INDIVIDUAL PROTECTION EQUIPMENT

SURFACE RESPIRATORY PROTECTION FIELDED AND PRODUCTION ITEMS

MCU-2A/P Protective Mask

The MCU-2A/P provides eye and respiratory protection from all chemical and biological agents as well as radioactive particulate material. The mask uses a replaceable, standard NATO filter canister, which is mounted on either side of a wide-view optical quality visor. The mask provides improved fit, comfort, and visibility relative to earlier masks, and includes a drinking tube for attachment to the standard canteen, and electronic voicemitter connections for improved communications. The MCU-2A/P designed to meet needs of the Air Force ground crews and the Navy Shipboard and shore-based support units.

M40/42 Series Protective Mask

The M40/42 series protective masks provide eye-respiratory face protection from tactical concentrations of CB warfare agents, toxins and radioactive fallout particles. Each mask consists of a silicone rubber face piece with an in-turned peripheral face seal and binocular rigid lens system. The facepiece is covered with a chlorobutyl/EPDM second skin to provide optimum liquid agent protection for the masks. It accommodates NATO standard canisters, which can be worn on either cheek of the mask. The M40 series (*left*) is designed for the individual dismounted ground warrior, while the M42 series (*right*) is designed for combat vehicle crewmen. Recent improvements include a universal second skin, making the mask compatible with JSLIST and Saratoga overgarments, and ballistic/laser protective eye lens outserts. The mask facepiece has been made a spare part, which has resulted in a significant operation and support cost savings. Use of modular parts permits the M40 series facepiece to be used in both the M40 and M42 configuration. This has resulted in significant operational and support cost savings.

Voice Communication Adapter

The Voice Communication Adapter (VCA) is a low risk program providing additional capability to the M40/42 mask. The VCA provides effective voice communication between masked personnel enhancing Command and Control on the NBC contaminated battlefield. The VCA is a joint program between the USMC and U.S. Army.

Universal Second Skin

The Universal Second Skin is one of the components of a pre-planned product improvement (P3I) in the M40/M42 series mask. The Universal second skin provides liquid agent protection for the mask faceblank material. This program is a Joint U.S. Army/U.S. Marine Corps effort. The Air Force is fielding a second skin for the MCU 2A/P.

SURFACE RESPIRATORY PROTECTION R&D ITEMS

Joint Service General Purpose Mask (JSGPM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- 24-hour CB protection
- Lower breathing resistance
- Reduced weight and bulk

Description:

The JSGPM (*prototype shown*) will be a lightweight protective mask system—consisting of mask, carrier, and accessories—incorporating state-of-the-art technology to protect U.S. forces from all anticipated threats. The mask components will be designed to minimize the impact on the wearer's performance and to maximize the ability to interface with current and co-developmental Service equipment and protective clothing.

Joint Service Chemical Environment Survivability Mask (JSCESM)

Rationale:

- Joint Army (SOCOM), Navy, Air Force, and Marine Corps requirement

Key Requirements:

- One size fits all
- For low threat area usage
- Limited protection
  (6 hours, limited agent concentrations)
- Small, lightweight
- Drinking capability (Block II)

Description:

The JSCESM will be a lightweight complement to the JSGPM. It will provide commanders at all levels with greater options for protection, especially in Operations Other Than War (OOTW). The JSCESM will provide an inexpensive/disposable, emergency mask for use in NBC situations confronting the Services operating in low NBC

threat conditions and military medical care providers and patients in certain instances when using the standard service mask is not practical. Warfighters in special operations or other combat/non-combat roles will carry JSCESM (in the uniform cargo pocket) or while in civilian clothing (concealable) during deployment when an NBC threat is possible, but unlikely. Additionally, other missions exist for the JSCESM such as use in collective protection shelters (CPS) if the shelter filtration system fails or emergency evacuation of a shelter is required when contamination is present.

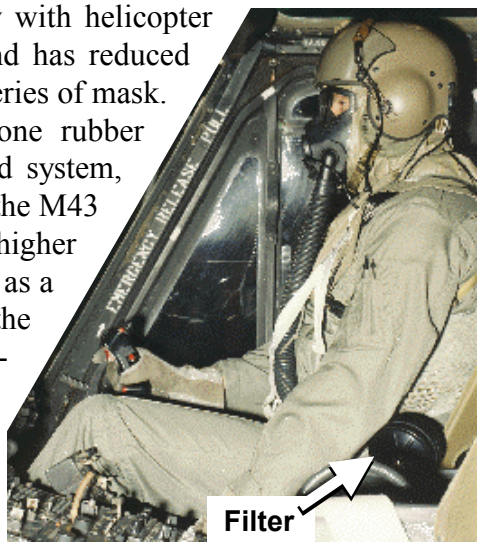
AVIATION RESPIRATORY PROTECTION FIELDED AND PRODUCTION ITEMS

M43 Protective Mask

The M43 Aviator Mask consists of a form-fitting face piece with lenses mounted close to the eyes; an integral CB hood and skull-type suspension system; an inhalation air distribution assembly for air flow regulation, lenses and hood; and a portable motor/blower filter assembly that operates on either battery or aircraft power. The M43 Type I (Apache version) was developed for the AH-64 aviator and is compatible with the AH-64 Integrated Helmet and Display Sight System and the Optical Relay Tube. The M43 Type I will be replaced by the M48. The M43 Type II is intended for the general aviator. The M43 Type II general aviation version is being replaced by the M45.

M45 Aircrew Protective Mask (ACPM)

The M45 Air Crew Protective Mask is specially designed to meet the requirements of Army helicopter pilots and crews (except for the Apache helicopter). It does not require power or forced air to provide CB protection; it provides compatibility with helicopter optical systems, aircraft displays and night vision devices; and has reduced weight, cost and logistical burden when compared to the M43 series of mask. The ACPM has close fitting eyelenses mounted in a silicone rubber facepiece with an in-turned peripheral seal, a detachable hood system, and utilizes the standard NATO canister. The M45 will replace the M43 (Type II) and the M24 aviator's mask. The M45 fits a higher percentage of the extra-small and -large population, and is used as a mask for personnel who do not get an adequate face seal in the M40 or MCU-2A/P masks. It will be used to phase out the extra-small M17 masks currently being used for some hard-to-fit personnel. The M45 is also used for specific ground force applications where close eye compatibility is required for unique equipment such as for the Land Warrior system.



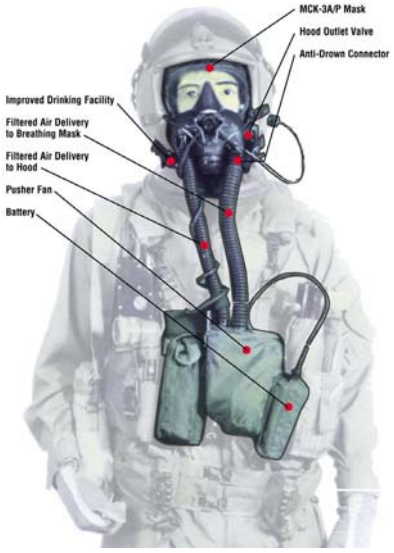
M48 Protective Mask - Production

The M48 is the third generation M43 series masks. The M48 mask replaces the M43 Type I mask and will be the only mask for the Apache aviator until the Joint Service Aviator Mask – Apache Variant is produced. The M48 mask consist of a lightweight motor blower, a new hose assembly, a web belt, the mask carrier, facepiece carrier, eyelens cushions, and facepiece. The motor blower is aircraft mounted with a quick disconnect bracket on the pilot's seat during flight operations.

Aircrew Eye/Respiratory Protection (AERP)

The AERP, MBU-19/P (replaces the MBU-13/P system for aircrews) is a protective mask that enables aircrews to conduct mission operations in a chemical-biological environment. The AERP system includes a protective hood assembly with a standard MBU-12/P mask, an intercom for ground communication, and a blower assembly that provides de-misting. The blower is stowed during flight operations on a bracket that is mounted inside the aircraft.

CB Respiratory Assemblies (A/P22P-14(V) 1, 2, 3, & 4) NDI



The CB Respiratory Assembly is a self-contained protective ensemble designed for all forward deployed rotary-wing and fixed-wing aircrew members. Respirator assemblies are provided in the following configurations: A/P22P-14(V)1 Helo (self contained), A/P22P-14(V)2 LOX, A/P22P-14(V)3 OBOGS, and A/P22P-14(V)4 Panel Mounted Regulator. The design incorporates a CB filter, dual air/oxygen supply and a cross-over manifold with ground flight selector switch to provide filtered air for hood ventilation, and filtered air for oxygen for breathing. The system provides enhanced protection and offer anti-drown features.

AVIATION RESPIRATORY PROTECTION R&D ITEMS

Joint Service Aircrew Mask (JSAM)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Continuous CB protection
- Improved anti-G protection

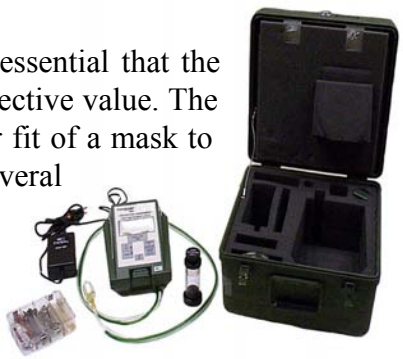
Description:

JSAM will be a lightweight CB protective mask that can be worn as CB protection for all aircrew. With the addition of anti-G features, it can be worn as combined CB and anti-G protection for aircrews in high performance aircraft. It will be compatible with existing CB ensembles, provide flame and thermal protection, provide hypoxia protection to 60,000 feet, and the CB portion will be capable of being donned in flight. JSAM will also be compatible with existing aircrew life support equipment.

UNIVERSAL COMMON INDIVIDUAL PROTECTIVE EQUIPMENT

FIELDED AND PRODUCTION ITEMS

M41 Protection Assessment Test System



During the issuing process for Protective Masks it is absolutely essential that the mask be properly fitted to the individual to ensure the highest protective value. The M41 Protection Assessment Test System (PATS) validates proper fit of a mask to the face of the individual. It tests all current military and several commercial masks. The system provides a visual display of the fit achieved by the mask when worn by the individual and requires calibration every 18 to 24 months. The M41 PATS is currently in use by the Army, Air Force, and Marines.

MQ1A Mask Tester

The MQ1A mask tester also validates proper fit of a mask to the face of the individual. It tests currently fielded AF MBU-5/P and MBU-12/P aviator masks and the MBU-13/P and MBU-19/P aviator NBC protective masks. The system provides a visual display of the fit achieved by the mask when worn by the individual. The MQA1 Mask Tester is currently in use by the Air Force at units supporting the MBU-5/P, MBU-12/P, MBU-13/P and MBU-19/P.

UNIVERSAL COMMON INDIVIDUAL PROTECTIVE EQUIPMENT

RDTE ITEMS

Joint Service Mask Leakage Tester

The Joint Service Mask Leakage Tester (JSMLT) will be a man portable test system capable of testing the serviceability of a protective mask in the field and in acquisition. It will have expanded capability compared to the M41 PATS by allowing component level testing of the mask as well as system level testing with added components. It will provide a capability for an overall mask serviceability and fit factor validation of protective masks in the field.

Defense Technology Objective (DTO) CB.36 End-of-Service-Life Indicator for NBC Mask Filters

Objectives. A low-cost, qualitative, end-of-service-life indicator (ESLI) will be developed for use in NBC protective mask filters that will indicate the presence of a broad range of chemical warfare agents and toxic industrial chemical vapors/gases. This will be achieved through an extensive technology survey, identifying best candidate solutions, developing an ESLI design concept, and demonstrating the efficacy of ESLI filter prototypes with target challenge agents.

Payoffs. This effort addresses the Respiratory Individual Protection /Unlimited Respiratory Protection (OC/EC) JFOC by alerting the user that his/her mask filter has been exposed to chemical agents and/or battlespace contaminants and has a limited remaining service life. Presently there are no means to determine the residual life of fielded filters. Development of a chemical agent ESLI will greatly enhance serviceman safety by alerting the user to replace the filter before its gas life capacity has expired. Other benefits include reduced cost and logistical burden since current change-out doctrine is conservative and results in the premature replacement and excess stockpiling of filters in the field. This DTO addresses a desired requirement for the Joint Service General-Purpose Mask. The ESLI technology developed in this effort will also have direct application to commercial respirator filters used by first responder personnel responding to chemical terrorist events, as well as other dual-use applications such as residual life indicators for collective protection filters and chemical protective clothing. In FY03, completed second level screening evaluations of lead candidate colorimetric indicator technologies to assess range of sensitivity against target chemical warfare agents. Also completed initial environment stability assessment and characterized the performance of ESLI films in carbon test beds.

Challenges. Development of an ESLI to detect such a wide range of chemical warfare agents is considered moderate risk. Although state-of-the-art passive (non-powered) technologies such as colorimetric indicators exist for detecting specific contaminants, most rely on specific reaction chemistry and, thus, are not suitable as broad-spectrum vapor/gas indicators. Realistically no single indicator is expected to achieve such nonspecificity; however, it is feasible that a combination of different indicator technologies could be used to target key organic vapor and acid gas agents. This DTO will focus on low-cost passive indicator technologies capable of detecting major chemical warfare agents of concern.

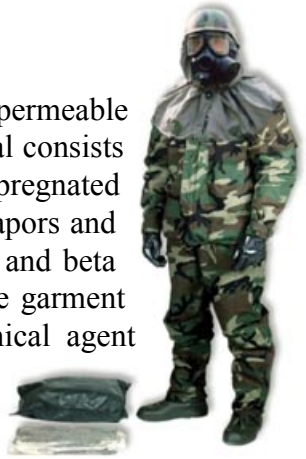
Milestones/Metrics.

FY2004: Fabricate and conduct demonstration testing of ESLI filter concept models to verify ESLI is a reliable indicator of gas-life depletion for key target agents (i.e., GB, HD, CK, AC and CG). Assessments will include determining the effects of environmental factors (e.g. heat and humidity) that may impact ESLI performance and evaluating the effects of long-term storage.

FY2005: Assess the effects of common battlespace interferents on ESLI performance. Optimize ESLI design and complete demonstration testing on ESLI filter prototype (s). Investigate new indicators (or optimize existing indicators as required) to detect sorbent-depleting battlefield contaminants, or optimize existing indicators as required, to detect sorbent-depleting battlefield contaminants.

SURFACE PROTECTIVE ENSEMBLE FIELDED AND PRODUCTION ITEMS

Battle Dress Overgarment (BDO)



The BDO is a camouflage patterned (desert or woodland), two-piece, air permeable overgarment typically worn over the duty uniform. The overgarment material consists of an outer layer of nylon cotton, and an inner layer of activated charcoal impregnated polyurethane foam. The BDO provides protection against chemical agent vapors and liquid droplets, biological agents (to include toxins), and radioactive alpha and beta particles. The BDO is issued in a sealed vapor-barrier bag that protects the garment from rain, moisture and sunlight. The BDO provides 24 hours of chemical agent protection once contaminated and has a field durability of 22 days (extendable).

Joint Service Lightweight Integrated Suit Technology (JSLIST) Overgarment

The JSLIST Overgarment will provide 24-hour protection with up to 45 days of wear and 6 launderings. The 24-hour protection and 45 days of wear applies for a period of up to 120 days after the garment is removed from its vacuum packaging. The liner currently is based upon activated carbon bead technology, replacing the bulky activated carbon foam technology in previous garments. The JSLIST Overgarment is a two-piece jacket and trouser design with an integrated hood compatible with respective Service masks and second skins. It will be worn as an overgarment for the duty uniform or as a primary garment over underwear depending upon the environment and mission.

CP Suit, Saratoga (USMC)

Like the JSLIST, the SARATOGA CP Suit is an air permeable, camouflage patterned overgarment. The SARATOGA uses spherical, activated carbon adsorbers immobilized in the liner fabric. This system allows for a lighter, cooler garment, which is launderable. The Saratoga provides a 24-hour protection period and has a durability of 45 days of wear.

SURFACE PROTECTIVE ENSEMBLE RDTE ITEMS

CWU-66/P Aircrew Ensemble

The CWU-66/P, a one-piece flightsuit configuration, provides 16-hour protection against standard NATO threats. It is made with Von Blucher carbon

spheres, and is less bulky than prior ensembles. It offers a reduced thermal load burden and is compatible with aircrew life support equipment.

Chemical Protective Undergarment (CPU)

The CPU is a one-time launderable two-piece lightweight undergarment made of a non-woven fabric containing activated charcoal. When worn under a combat vehicle crewman coverall, battle dress uniform, or aviation battle dress uniform, the CPU provides 12 hours of both vapor and liquid protection and is durable for 15 days.

SURFACE PROTECTIVE ENSEMBLES
RDTE ITEMS

Joint Service Lightweight Integrated Suit Technology (JSLIST)

The JSLIST program is a fully cooperative Joint Service RDTE and procurement effort chartered to develop and field new CB protective clothing for all Services. The program will yield a family of garments and ensembles, developed for Joint Service mission needs and tested to Joint Service standards. The JSLIST will provide enhanced CB protective ensembles with reduced physiological heat burden and will be generally lightweight and launderable. There are six JSLIST clothing item components: 1) overgarment, 2) lightweight garment, 3) undergarment, 4) socks, 5) boots and 6) gloves. Each of the Services' requirements are incorporated by these six JSLIST components.

In April 1997, the JSLIST program type classified and began fielding the JSLIST Overgarment and Multi-purpose Overboot (MULO). Current JSLIST RDT&E includes programs intended to field a chemical protective glove to meet U.S. SOCOM requirements (JSLIST Block 1 Glove Upgrade), a follow-on chemical protective glove program (JSLIST Block 2 Glove Upgrade) intended to field a chemical protective glove to meet Joint Service requirements found in both the JSLIST and Joint Protective Air Crew Ensemble Operational Requirements Documents (ORD) and Multipurpose Protective Sock program, which will field a sock to meet the requirements found in the JSLIST ORD.

The JSLIST Additional Source Qualification (JASQ) was initiated to qualify additional sources of JSLIST materials and to conduct field wear tests and laboratory chemical tests on commercial JSLIST suit candidates. The JASQ candidates that perform as well as, or better than the current JSLIST garment will be considered for placement on a JSLIST qualified products list and may be authorized as additional JSLIST material sources.

Joint Protective Aircrew Ensemble (JPACE)

Rationale:

- Joint Army, Navy, Air Force, and Marine Corps Requirement

Key Requirements:

- Provides below-the-neck protection for rotary and fixed wing aircrew
- 30 day wear time
- Launderable
- Compatible with aircrew mounted aviation life support systems
- Ejection safe and water survivable

Description:

JPACE (*concept shown*) will be a CB protective ensemble for all services' aviation communities. It will be a replacement for the Navy/Marine Corps MK-1 undergarment, Army Aviation Battle-dress Uniform (ABDU)-BDO and/or CPU system and AF CWU-66/P overgarment. JPACE will provide aviators with improvements in protection, reduced heat stress in CB environments, extended wear, and service life. In addition, it will be compatible with legacy aviation mask systems and co-developmental masks, such as the Joint Service Aircrew Mask (JSAM). This ensemble will be jointly tested with JSAM and will be used as a technical insertion to the Army Air Warrior program. JPACE will provide the fixed and rotary wing aviator with below-the-neck protection against CB threats.

Modified Chemical Protective Undergarment (mCPU)

A modified CPU (mCPU) is being developed to include a pass-through for microclimate cooling unit tubing. The mCPU worn with the ABDU will be used as interim chemical protection for Army aviators until the development and fielding of JPACE.

DTO CB.45 Self-Detoxifying Materials for Chemical/Biological Protective Clothing
Objectives. Agent reactive catalysts and biocides will be directly incorporated into CB protective clothing and their capability to self-detoxify agents in a cost effective clothing system will be demonstrated.
Payoffs. This DTO addresses the Joint Future Operational Capability of Individual Protection (Respiratory and Percutaneous) by reducing reduces the probability of skin, eye, or respiratory contact with CB agent hazards. This effort will simplify personal decontamination and provide an increased level of protection to CB protective clothing through the added capability of self-detoxification. The most efficient and cost effective agent reactive catalysts and biocides that neutralize chemical/biological warfare (CW/BW) agents will be incorporated into fibers, coatings, and membranes, resulting in increased protection and a substantially reduced hazard when donning and doffing as well as disposing of contaminated clothing. Reactive nanoparticles in fibers were shown to break down VX simulant and mustard. Hyperbranched compounds that float to surfaces were synthesized to increase the effectiveness of reactive compounds by concentrating reactive nanoparticles and other decontaminating catalysts near protective fabric surfaces. Surface enrichment of

DTO CB.45 Self-Detoxifying Materials for Chemical/Biological Protective Clothing

hyperbranched materials was demonstrated in coatings. Undergarments were treated with N-chloramine and other new antimicrobial agents to kill biological warfare agents, and N-halamine chemistry has been shown to work for antimicrobially treated electrospun fibers. New test methods have been developed to measure the degree of decontamination of aerosolized spores and airborne biological pathogens within the fabrics and on clothing surfaces.

A domestic manufacturing capability has been identified that meet the required production speeds of 1,000 m^2/day for ultrafine fiber liner material that will contain the detoxifying compounds. This process for reactive membrane manufacturing with ultrafine fibers will exceed the original target costs of $20/yard – realistic production costs could range from $30-$100/yard. DTO investigators have identified formulations that improve the physical strength and the chemical binding of detoxifying additives for the manufactured ultrafine fiber liner material. N-halamine chemistry has been tailored to further include nylon/cotton fabrics, polyesters, and polyurethane coatings to broaden the materials selection for biologically self-detoxifying fabric treatments. A postulated "catch and kill" mechanism of aerosol threats for antimicrobially treated electrospun fibers in the ultrafine fiber liner layer within CB clothing has not been demonstrated – it has been found that significant surface contamination by biological agents must be remediated by fabric surface treatments. It has been demonstrated that good dispersion of reactive nanoparticles can be achieved through numerous fabric coating methods – these methods will be optimized in FY04.

Challenges. The addition of agent reactive catalysts and biocides to advanced CB clothing systems must strike a balance between the added capabilities provided and the potential increased cost and extra weight added to the garments. Increasing the reactivity and effectiveness of decontaminating additives after bonding to fabrics is the key to cost reduction. Since CB clothing is burdensome to wear, any extra weight must result in additional benefit to the warfighter. In this case, the additional benefit is increased protection. Agent reactive catalysts are specific in their behavior. Catalysts have been developed that are effective against mustard, for example, while other catalysts have been shown to be effective against nerve agents. It is not practical at this time to expect universal agent neutralization by a single reagent, but combinations of additives will decontaminate the most important threats. In general, biocides are more universal in their activity, but must be effective after UV exposure, long-term storage and laundering. Durability of all detoxifying additives will require continued and long term testing with sequential adjustments to chemistry and formulations..

Milestones/Metrics.

FY2004: Transition self-detoxification chemistries for G-agents, VX, and HD to commercial electrospinning. Demonstrate improved reactivities for hyperbranched surface migrating compounds. Demonstrate agent deactivation chemistry of fiber-bound catalysts through solution and vapor challenge testing for a target reactivity level of 2mg agent/1cm^2/day. Demonstrate effectiveness of scaled-up N-halamine treated materials against significant biological challenges including airborne spore and virus challenges. Demonstrate nanoparticle reactivities in excess of 2mg agent/1cm^2/day in both fiber and coating form. Down-select most reactive, cost-effective nanoparticle compositions and optimize.

FY2005: Demonstrate reactivity stability to realistic time, temperature, and use conditions. Optimize materials and processing conditions for reactive fibers/membranes. Improve durability and overall cost effectiveness of scaled-up electrospun self-detoxifying membranes, N-halamine treated textiles, and materials containing reactive nanoparticles. Down-select reactive particles and processing approach for fibers/membranes. Select materials from DTO and related projects (DARPA SBIR, Congressional Program) for the development of prototype garments. Measure chemical/aerosol breakthrough of candidate fabrics. Measure durability and effectiveness of candidate fabrics from all sources. Conduct

DTO CB.45 Self-Detoxifying Materials for Chemical/Biological Protective Clothing
toxicology and live agent testing of manufactured fabrics. Optimize/down select fabric design from agent and durability testing. **FY2006:** Fabricate prototype garments. Demonstrate activity of treated fabric systems. Measure chemical/aerosol breakthrough of garments. Conduct field-testing of chemically self-detoxifying fabric systems. Collect user assessments. Field test biocidal treated ensemble for durability and persistence of reactivity. Conduct CWA simulant and live CWA testing on worn garments to assess durability. Develop transition plan. **FY2007:** Optimize garment designs, and manufacture optimized prototype garments. Demonstrate, durability and overall cost effectiveness of scaled-up electrospun self-detoxifying membranes, N-halamine treated textiles, and materials containing reactive nanoparticles. Measure chemical/aerosol breakthrough of optimized garments. Conduct field testing and assessments. Down-select candidates. Transition to JSLIST Upgrade.

PROTECTIVE ACCESSORIES FIELDED AND PRODUCTION ITEMS

Chemical Protective Footwear Covers

The CPFC are unsupported, impermeable, butyl rubber overshoes that can be stored flat. They are a loose fitting butyl rubber upper vulcanized to a non-slip molded butyl rubber sole with five holes to allow lacing around the foot. They are worn over the combat boot. They have the ability to resist acid, jet fuel, oil and fire. They were manufactured in two sizes, small and large, but are no longer being procured.

Chemical Protective Sock

This sock is the first generation Air Crew Chemical Defense Equipment. It is plastic and disposable. The sock comes in one size as 500 ea per roll, 21 inch long, 4 mils thick and 8 in wide flat extruded tubing with 1/8 in wide heat-seal closure. This sock is to be worn over regular sock.

Disposable Footwear Cover

Plastic over-boots are worn over the flyer's boot. They protect the user from chemical contamination en-route from the shelter and the aircraft. They come in one size and are removed before entering the aircraft or shelter.

Green Vinyl Overboots /Black Vinyl Overboots (GVO/BVO)

The GVO/BVO are fitted vinyl overshoes that are worn over the combat boots to provide chemical agent protection and/or moisture vapor protection during wet weather. The impermeable GVO/BVO provide protection against chemical agents for 24 hours and are durable for up to 60 days.

Multipurpose Overboot (MULO) *(JSLIST Boots)*

The MULO is a joint service program under the auspices of the JSLIST program and will replace the GVO/BVO. It is made of an elastomer blend and will be produced by injection molding. It is designed for wear over the combat boot, jungle boot, and intermediate cold/wet boot, and provides 24 hours of protection from chemical agents with a wear life of up to 60 days. The MULO provides more durability, improved traction, resistance to POLs, flame protection, decontaminability, and has better donning and doffing characteristics over standard footwear.

Chemical Protective (CP) Gloves

The CP butyl glove set consists of a butyl-rubber outer glove for protection from chemical agents, and a cotton inner glove (25 mil glove only) for perspiration absorption. CP outer gloves come in three thicknesses: 7, 14, and 25 mil. The 7 mil glove is used by personnel who require a high degree of tactility, such as medical and personnel engaged in electronic equipment repair, and aircrews. The 14 mil glove is used by personnel such as aviators and mechanics, in cases when good tactility is necessary and stress to the glove is not too harsh. The 25 mil glove is used by personnel who require a durable glove to perform close combat tasks and heavy labor. The 14 and 25 mil glove sets provide protection for at least 24 hours. The 7 mil glove set should be replaced within 6 hours of exposure to a chemical agent.

Glove Inserts

These gauntlet cotton inserts are worn under the chemical protective (CP) butyl rubber gloves. They provide perspiration absorption. They can be worn in either hand and are available in three sizes (small, medium and large).

Chemical Protective Helmet Cover

The Chemical Protective Helmet Cover is intended to provide any standard helmet with protection from chemical and biological contamination. It is a one-piece configuration made of butyl coated nylon cloth and gathered at the opening by elastic webbing enclosed in the hem. The covers come in one size and are of olive green color.

Aircrewman Cape

This disposable cape is a one size fits all plastic bag (74 in x 23 in) worn over the entire body to provide additional protection against liquid contamination. The cape should be worn if aircrews have to walk around liquid contaminated areas and if aircraft are not sheltered. If worn, the cape is removed before entering the aircraft.

SPECIALTY SUITS

FIELDED AND PRODUCTION ITEMS

Joint Firefighter Integrated Response Ensemble (JFIRE)

JFIRE is a joint effort between the Air Force (lead agency) and the Army. The JFIRE Program has developed an ensemble that will protect military firefighters in accordance with National Fire Protection Association (NFPA) standards and provide CB protection during firefighting operations in a CB environment. JFIRE leverages the JSLIST overgarment for chemical protection, to be worn under aluminized proximity firefighting outergear and with a switchable filtered/supplied air mask with chemical warfare kit. A commercial off-the-shelf glove that can be used for both fire and CB protection has replaced the need for CB gloves to be worn under standard proximity gloves. JFIRE meets several key requirements, including (1) providing 24 hours of CB agent protection against 10 g/m^2 liquid agent, (2) providing firefighters CB protection in both structural and crash fire fighting/rescue operation, (3) allowing firefighters to use mission essential tools and equipment in a CB environment, (4) providing resistance to water and all standard fire fighting chemicals (foam, CO_2, aircraft POL), and (5) is capable of being donned in 8 minutes.

Suit Contamination Avoidance Liquid Protection (SCALP)

The SCALP (*shown* right) can be worn over standard chemical protective garments to provide one hour of protection from gross liquid contamination. The SCALP, which consists of a jacket with hood, trouser and booties, is made from a polyethylene-coated Tyvek™ impermeable material.

Self-Contained Toxic Environment Protective Outfit (STEPO)

STEPO (*shown left*) provides OSHA level A protection for Army Chemical Activity/Depot (CA/D), Explosive Ordnance Disposal (EOD) and Technical Escort Unit (TEU) personnel. The STEPO is currently being fielded to CA/D, TEU and EOD. The STEPO is a totally encapsulating protective ensemble for protection against CB agents, missile/rocket fuels, POL, and industrial chemicals for periods up to four hours. The ensemble incorporates two types of NIOSH approved self-contained breathing systems (one hour and four hour configurations) and a tether/emergency breathing apparatus option, a battery powered Personal Ice Cooling System (PICS) (*shown right*), a hands-free communications system, and standard M3 Toxicological Agent Protective (TAP) boots and gloves. The suit is capable of being

decontaminated for reuse up to 5 times after chemical vapor exposures. STEPO shares common, modular components with the ITAP and JFIRE ensembles simplifying logistics and reducing costs.

EOD M3 Toxicological Agent Protective (TAP) Ensemble

One-piece coverall for the protection of personnel engaged in extreme hazardous decontamination work or other special operations involving danger from spillage or splashing of chemical agents including toxic industrial material. The coverall is constructed from butyl rubber coated plain weave nylon cloth and comes in four sizes (small, medium, large and extra large). The design consists of snap-type button front and protective flap. This is a special purpose Life Support Clothing and Equipment item.

Improved Toxicological Agent Protective (ITAP)

ITAP replaces the M3 TAP ensemble. ITAP enhances existing capabilities by increasing personal protection and reducing the thermal burden on the wearer. ITAP also provides skin and respiratory protection both during peacetime and wartime for short term operations in Immediately Dangerous to Life and Health (IDLH) toxic chemical environments (up to 1 hour), emergency life saving response, routine Chemical Activity operations and initial entry and monitoring. ITAP shares common, modular components with the STEPO and JFIRE ensembles, simplifying logistics and reducing costs.

ITAP provides splash and vapor protection against potential exposure to liquid agent when worn as a system—requirements: 10g/m^2 HD, VX, GB, L agent challenge for 1 hour. It provides an optional Personal Ice Cooling System (PICS), and is functional as a system where temperatures range from 0° to 100°F when used with the cooling system. The ITAP suit and overhood are capable of being decontaminated for a minimum of 5 reuses, 2 hours per use (1 hour at IDLH), after vapor and particulate contamination. After liquid contamination ITAP suit will be decontaminated and held for disposal.

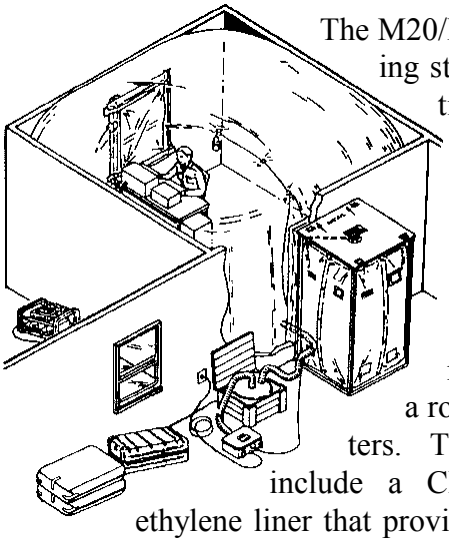
The ITAP fabric is self-extinguishing meeting NFPA 1991. The fabric is also static dissipative and does not hold a charge sufficient to set off munitions and explosives in accordance with current Explosive Safety Board requirements. The fabric is light in color to reduce operator solar heat load, and is capable of being stored within the temperature range of 0° to 120°F. ITAP has a minimum shelf life of 5 years.

COLLECTIVE PROTECTION EQUIPMENT

TENTAGE AND SHELTERS

FIELDED AND PRODUCTION ITEMS

M20/M20A1 Simplified Collective Protection Equipment (SCPE)



The M20/M20A1 SCPE is used to convert an interior room of an existing structure into a positive overpressure, NBC collective protection shelter where individuals can perform assigned missions without wearing the protective mask and overgarment. The M20 SCPE system consists of a liner, protective entrance, filter canister, and support kit. The SCPE is a low cost method of transforming a room in an existing structure into an NBC collective protection shelter for command, control and communication (C^3), medical treatment, and soldier relief functions. M20A1 is a room liner for existing shelters. The M20A1 components include a CB vapor resistant polyethylene liner that provides a protected area in an existing structure; a collapsible, protective entrance that allows entry to/exit from the protected area; a hermetically sealed filter canister, which provides filtered air to both the liner and the protective entrance; and a support kit, which contains ducting, lighting, sealing and repair material and an electronically powered blower.

M28 CPE (SCPE)

The M28 CPE is a low cost method of transforming existing tentage into an NBC collective protection shelter for command, control and communication (C^3), medical treatment, and soldier relief functions. M28 is a liner for the TEMPER tent. M28 CPE components include a CB vapor resistant polyethylene liner that provides a protected area in an existing structure; a collapsible, protective entrance that allows entry to/exit from the protected area; a hermetically sealed filter canister, which provides filtered air to both the liner and the protective entrance; and a support kit, which contains ducting, lighting, sealing and repair material and an electronically powered blower. A pre-planned product improvement (P^3I) program building upon the M20 SCPE design, resulted in the improved M20A1 SCPE and the M28 CPE models which, in addition to a vapor agent resistance capability, they also provide a liquid agent

resistance capability, protective liners for tents, interconnections, and an interface with environmental control units. These improved models also remove the restriction imposed on the M20 SCPE with respect to exit/entry procedures therefore, meeting the mission requirement as outlined in the M20 SCPE Letter Requirement by allowing 150 or more people to enter and exit the shelter over a 24 hour period.

Chemically Protected Deployable Medical System (CP DEPMEDS)

The Army's CP DEPMEDS program is a Joint effort with the Air Force to insert environmentally controlled collective protection into currently fielded hospital shelters. The requirement is to be able to sustain medical operations for 72 hours in a chemical contaminated environment. Environmentally-controlled collective protection is provided through the integration of M28 CPE, chemically protected air conditioners, heaters, water distribution and latrines, and alarms systems. M28 CPE provides protection to existing TEMPER tents and passageways within the hospital. DEPMEDS ISO shelters are protected through the replacement of existing shelter seals with those that are CB protected. The Field Deployable Environmental Control Unit provides CB protective air conditioning and the Army Space Heater provides CB protective heating. Both environmental control units are chemically protected through the addition of a CB kit. To sustain approximately 500 patients and staff, chemically protected latrines and water distribution systems have been developed.

Collective Protection for Expeditionary Medical Support (CP EMEDS)

The Air Force's CP EMEDS program is an effort to insert environmentally controlled collective protection into currently fielded hospital shelters. The role of CP EMEDS, as part of the Air Force Theater Hospital (AFTH), is to provide individual bed-down and theater-level medical services for deployed forces or select population groups within the entire spectrum of military operations. CP EMEDS Small Portable Expeditionary Aeromedical Rapid Response (SPEARR), +10, and +25 configurations are modular packages, tailored to meet theater requirements, by providing a flexible hospitalization capability. The CP EMEDS +25 has the capability to provide 24-hour sick call, 25 inpatient beds, & emergency medical care to a population at risk of 3,000–5,000. The following capabilities are also available: medical command and control, preventive medicine, trauma resuscitation and stabilization, general and orthopedic surgery, critical, urgent, & primary care, aeromedical evacuation coordination, aerospace medicine, dental, and limited ancillary services. The CP EMEDS is used in a CB threat area and permits operation in CB active environments while minimizing impact to the AFTH mission. The CP EMEDS provides a contamination free environment where medical treatment can be rendered to personnel without the encumbrance of individual protective equipment.

Chemically/Biologically Hardened Air Transportable Hospital (CHATH) – Fielded

The Air Force's CHATH program is a Joint effort with the Army to enable medical personnel to deploy and setup in chemical and biological threat areas and operate in chemically and biologically active environments. CHATH allows personnel to perform their hospital duties in a

Toxic Free Area. CHATH upgrades TEMPER-based Air Transportable Hospitals (ATHs) retaining the same medical equipment and personnel. CHATH uses existing and modified U.S. Army equipment to line the current ATH tents providing an airtight shelter. The Human Systems Program Office (HSC/YA) developed a Chemically/biologically Hardened Air Management Plant (CHAMP). The CHAMP filters chemically and biologically contaminated air, and recirculates and filters interior air to maintain a clean hospital standard, provides heating, cooling, and over-pressurization to the hospital. The CHAMP can be operated from standard electrical sources or from its own internal generator. The CHAMP comes equipped with an Automatic Transfer Switch (ATS) to maintain power after Base power is shut off. The ATS starts the Diesel generator after three seconds of power interruption. The CHAMP allows the CHATH to be staged near warfighters in the field in a bare base environment. The CHATH can be deployed in increments of 10, 25, and 50 beds. This flexibility of the CHATH system helps ensure the best medical care is as near to the crisis area as possible.

CB Protected 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 forward surgical teams. CBPS also replaces the M51. The system is self-contained and self-sustaining. The CBPS consists of a dedicated M1113 Expanded Capacity Vehicle (ECV), a Lightweight Multi-purpose Shelter (LMS) mounted onto the vehicle, a 300 square foot airbeam supported CB protected shelter, and a High Mobility Trailer with a towed 10kw tactical Quiet Generator Set. The ECV and LMS transports a crew of four and their gear. All medical equipment required for the shelter is transported in the LMS or on the trailer. The CB shelter is rolled and carried on the rear of the LMS during transport. The CBPS is operational within 20 minutes with a crew of four. All power required to support operations is provided by the ECV engine or with the 10kw generator for limited power. The system is environmentally conditioned by a hydraulically powered environmental support system, which provides filtered air, heating, air conditioning, and electrical power. The system is presently in full rate production.

COLLECTIVE PROTECTION SYSTEMS

FIELDED AND PRODUCTION ITEMS

Shipboard Collective Protection System

Shipboard CPS is an integral part of the HVAC systems on new construction ships. CPS provides each protected zone on the ship with filtered air at an overpressure of 2.0 inches water gauge. CPS is modular and is based on the 200 cfm M98 Gas-Particulate Filter Set. CPS includes filters, filter housings, high pressure fans, airlocks, pressure control valves, low pressure alarm system, and personnel decontamination stations. These systems are being installed through both new ship construction and the CPS Backfit program.

COLLECTIVE PROTECTION SYSTEMS

RDTE ITEMS

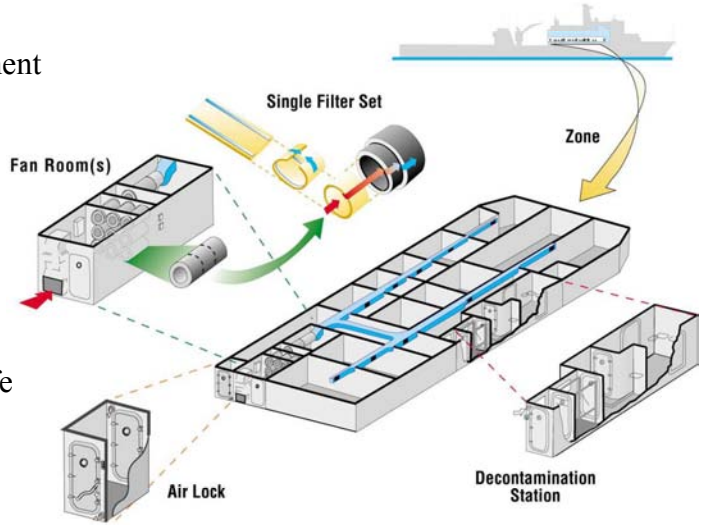
Shipboard Collective Protection Equipment (CPE)

Rationale:

- Navy Service-Unique requirement

Key Requirements:

- Provide protection against chemical and biological threat agents
- Provide a minimum of three year continuous operational life
- Provide more efficient, long life filters
- Provide quieter, more efficient supply fans
- Develop methods to counter new and novel threat agents



Description:

Shipboard CPE provides a contamination-free environment within specified zone boundaries such that mission essential operations and life sustaining functions can be performed during or after a CB attack. The objective of this program is to provide Pre-Planned Product Improvements (P3I) to the current Shipboard CPS to decrease logistic costs by extending particulate filter life, reducing shipboard maintenance requirements, and providing energy-efficient fans. The program develops improvements to existing shipboard HEPA and gas adsorber filters, supports long term shipboard testing of filter improvements to develop filter life database, and provides plans for backfitting existing non-CPS ships. Shipboard CPE is being installed on selected new construction ships. The Shipboard CPE program transitioned to the JCPE program in FY03.

Joint Collective Protection Equipment (JCPE)

Rationale:

- Joint Service requirement

Key Requirements:

- Rapid insertion of technology improvements to existing equipment
- Increased number of shelters for command/control, medical, and rest/relief areas
- Improved shipboard systems
- Standardization of equipment

Description:

JCPE provides needed improvements and cost saving standardization to currently fielded collective protection systems by using the latest technologies in filtration, shelter materials, and environmental controls to provide affordable, lightweight, easy to operate and maintain equipment. Inserting improved technology into currently fielded systems will result in improved performance with reduced operating costs. Standardization of individual system components across Joint Service mission areas will reduce logistics burden while maintaining the industrial base. Taken both individually and collectively, these tasks will improve NBC defense readiness for Joint Services by providing state-of-the-art, off-the-shelf solutions for currently fielded equipment deficiencies.

DTO CB.08 Advanced Adsorbents for Protection Applications
Objectives. This effort will develop advanced adsorbent bed materials and compositions (e.g., layered adsorbents) to enhance the chemical agent and toxic industrial chemicals (TICs) removal. Result will be superior air filtration protection capabilities of current single-pass filters and regenerative filtration systems under development; and reduce the size, weight, encumbrance, and capital and O&M cost of existing purification systems.
Payoffs. This DTO addresses multiple Joint Future Operational Capabilities for Individual and Collective Protection. Advanced adsorbent bed compositions for use in NBC filters will achieve smaller, lighter-weight filtration systems with reduced logistical requirements, improved protection against toxic industrial materials, and reduced combustibility. In FY00, families of adsorbents having characteristics for retention of low- to high-volatility chemicals (including water) were identified. In FY01, about 200 novel carbon and non-carbonaceous porous materials were evaluated. In FY02, development of modified ASZM-TEDA adsorbents were initiated and optimized for shallow bed and deep bed filters. This modified material will provide enhanced TIC protection against ammonia and formaldehyde. The material to date has been shown to perform well for high volume collective protection filters. In FY02 work for regenerative filtration (TSA), we characterized several non-carbonaceous adsorbents for removal of light TICs. This work demonstrated the initial capacity and purge characteristics and provided the basic design information for sizing an adsorbent bed for a regenerative filter. For electric swing adsorption (ESA), activated carbon fiber cloth was identified as a candidate material for removal of a binary mixture of a weakly adsorbed chemical agent and ambient water.
Challenges. For single-pass filters, adsorbent beds that improve kinetics of agent removal are needed to meet the goal of smaller, lighter-weight filters; also, specific impregnant formulations are needed owing to the diversity of the TICs. The expanding number of TICs requires novel technologies to provide the broad reactivity needed. Respirator filter needs for low breathing resistance is an important challenge being addressed through identification of adsorbent structures that exhibit reduced airflow resistance.

DTO CB.08 Advanced Adsorbents for Protection Applications
For regenerable filters, adsorbent beds that readily release adsorbed agent during the purge cycle are needed to minimize size and energy requirements. The identification of noncombustible adsorbents with high levels of agent removal at all humidity conditions has proven to be an especially difficult challenge. Adsorbent bed compositions need to address recently approved requirements for NBC protection systems (e.g., Joint Service General Purpose Mask (JSGPM)), including capability for protection against TICs, which is not adequately provided by current NBC filters. **Milestones/Metrics.** **FY2004:** Evaluate impregnation formulations as intercalated adsorbent preparations. Further modify ASZM-TEDA carbon to remove at least one additional (total of two) hard-to-remove TIC compounds. Construct composite vapor-aerosol media for reduced pressure drop with a target pressure drop of that of the adsorbent alone. Develop adsorbents for improved temperature performance under cyclic conditions by increasing high-temperature performance duty by 50%.

DTO CB. 40 Immune Building Program (DARPA Program)
Objectives. This DTO will develop and demonstrate technologies and systems to allow military buildings to actively respond to attack by agents of chemical or biological warfare so as to protect the human occupants from the lethal effects of the agent, restore the building to function quickly after the attack, and preserve forensic evidence about the attack. **Payoffs.** Enabling buildings to respond actively and in real time to the presence of threat agents will not only greatly reduce the effectiveness of such attacks, but will also make the buildings less attractive as targets. **Challenges.** These objectives will be achieved through a mix of passive and active modifications and augmentations to building infrastructure. "Passive" modifications are those in use continually and include, for example, highly efficient filtration; "active" augmentations are those used only in the presence of the threat and include real-time control of airflow or real-time neutralization of aerosolized agent. Active response requires networked surveillance systems. Such systems require the development of a number of component technologies in areas such as filtration, neutralization, and decontamination. In addition, the implementation of a complex system of this type requires that a number of systems-level issues be resolved, including the design, implementation, and optimization of systems architectures. As proof that all issues have been appropriately addressed, the program will conclude with a full-scale demonstration of a functioning system at a military installation. **Milestones/Metrics.** **FY2004:** Design and optimize system for demonstration at a military installation. **FY2005:** Conduct full-scale demonstration at military installation.

GENERIC NBC FILTERS AND COLLECTIVE PROTECTION FILTRATION SYSTEMS

FIELDED AND PRODUCTION ITEMS

Generic, high volume air flow NBC filters, and CP filtration systems exist that are currently installed on a wide variety of applications. These CP systems are modular and have been applied to numerous vehicles, vans, mobile shelters, and fixed sites.

GENERIC NBC FILTERS

NBC filters are used to remove Nuclear and Biological particulates and Chemical aerosols and vapors from the air supplied to collective protection systems.

M48/M48A1 Gas-Particulate Filter

The 100 cubic foot per minute (cfm) filter (*shown right*) is used in the M1A1/A2 Abrams tank, M93 Gas Particulate Filter Unit (GPFU), CB Protected Shelter, and Paladin Self Propelled Howitzer.

M98 Gas-Particulate Filter Set

The 200 cfm filter (*shown left*) is used as the basic filter set in the MCPE and in Naval applications. It can be stacked to obtain filtration of higher airflow rates.

600 cfm and 1200 cfm Stainless Steel Fixed Installation Gas Filters

These filters are used in fixed site applications where high volumes of airflow are required. They can be stacked to provide higher NBC filtered airflow rates. Particulate filter would be procured separately.

GENERIC NBC CP FILTRATION SYSTEMS

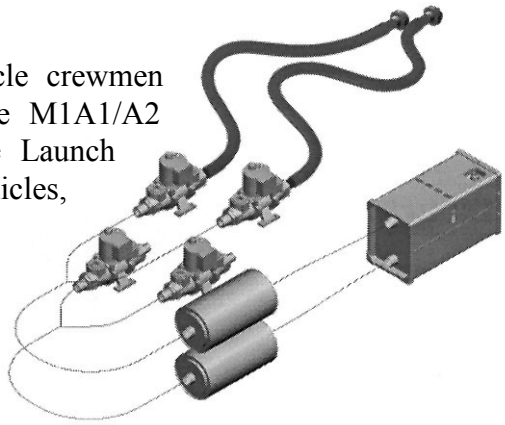
The following are NBC CP filtration systems, which are applied to a wide variety of applications. They consist of an NBC filter, motor/blower unit, housings, and integration housings/ductwork. Some can be integrated into environmental control equipment.

M8A3 Gas Particulate Filter Unit (GPFU)

The 12 cfm system provides air to armored vehicle crewman ventilated facemasks, *i.e.*, M42A1/A2. Used in M113 Armored Personnel Carrier variants and USMC AAVP7A1 amphibious vehicle.

M13A1 GPFU

The 20 cfm system provides air to armored vehicle crewmen ventilated facemasks, *i.e.*, M42A1/A2. Used on the M1A1/A2 Abrams tanks, Bradley Fighting Vehicles, Multiple Launch Rocket System (MLRS), tank transporter, Stryker vehicles, and other vehicles.



Modular Collective Protection Equipment (100, 200, 400, 600 cfm Systems)

Modular Collective Protection Equipment (MCPE) consists of a family of related end items from which modules can be chosen and combined to meet the unique demands of individual systems. These end items employ common parts and mountings and interchangeable connections and accessories to the greatest extent possible. MCPE provides collective overpressure to a wide variety of mobile shelters and vans. It uses the M48A1 Gas-Particulate Filter in the 100 cfm system and the M98 Gas-Particulate Filter Set in the others.

DTO CB. 61 Advanced Air Purification System Model
Objectives. The effort will develop a model, database, and design concepts for Advanced Air Purification systems that incorporate emerging and mature technologies for the purpose of providing: 1) broader protection against an expanding chemical and biological threat that is more universally adaptable and 2) reduced logistical burden as compared to current single pass filter technology. This will be accomplished by developing a model for Advanced Air Purification systems that can address wide application requirements by providing the optimal mix of technologies. Enhanced protection capabilities will result as well as improvements in weight, cube, logistics and cost.
Payoffs. This DTO addresses three Joint Future Operational Capabilities for Transportable, Mobile, and Fixed Site Collective Protection. Advanced Air Purification systems for improved protection against chemical, biological, radiological, and nuclear (CBRN) agents and toxic industrial materials (TIM) will provide smaller, lighter weight systems with reduced power and logistical requirements. The Advanced Air Purification Systems Model will be employed as a tool by the platform development community to configure an optimized air purification system (air conditioning, aerosol/particulate, and chemical removal processes) for the application. The model will permit the rapid, confident, tradeoff of competing characteristics (weight, volume, power, consumables, threat, performance, unit cost, life cycle cost, etc.) to ensure the best possible system configuration to meet user requirements. The Advanced Air Purification Systems Model will also be useful to the procurement community to assess proposed systems and for identification of technological gaps by the S&T community to focus R&D. Applications include Deployable Medical System (CP DEPMEDS), and Chemical Biologically Protected Shelter (CBPS), mobile systems [e.g., Advanced Amphibious Assault Vehicle (AAAV), Comanche helicopter, C-17 transport, Future Combat Systems (FCS), and Ship Collective Protection Equipment (SCPE) Program], and for fixed sites. Benefit to the warfighter is an air purification system optimized to meet user need (threat protection, size, weight, power requirements, etc.).
Challenges. Currently, there is no known system of technologies that offers near universal protection

DTO CB. 61 Advanced Air Purification System Model
against all threats. The goal of this effort is to identify the air purification technology or combination of technologies (hybrid) that most optimally meets the needs of the application. Many of these technologies when considered as stand alone systems are capable of removing CBRN agents and TIMs. However, each technology may have limitations that need to be overcome. For example, single-pass filters cannot effectively remove some of the TIC vapors, regenerative filtration systems produce toxic levels of agent in the purge gas for extended periods of time and catalytic systems require consumable acid-gas scrubbers. The objective of this effort is to utilize the advantages of each of these approaches to develop a system that maximizes chemical/biological protection while minimizing size, weight, energy, and logistics burden. A considerable challenge will be development of appropriate standard test and evaluation methodology. Incorporating all of the parameters into a single, validated model will also be a significant challenge. **Milestones/Metrics.** **FY2005:** Identify high priority model applications (representing the three JFOCs for collective protection) and compile user and operational requirements to establish design constraints for specific applications. Initiate population of databases based upon data in literature, existing system performance, and module models. **FY2006:** Configure lab-scale systems, define test and evacuation methodology, and measure the required design and system integration data (characterize unit processes). Develop initial version of Advanced Air Purification System Model. Measure laboratory scale design and application integration data to evaluate these configurations. **FY2007:** Develop several potential system configuration designs Fabricate system demonstrators. Initiate test and validation of the Advanced Air Purification System Model; then optimize for design concept. **FY2008:** Complete test and validation of Advanced Air Purification system Model. Modify Advanced air Purification System Model as dictated by test and validation results. Complete final version Advanced Hybrid air purification system Model and transition.

Annex D

Decontamination Programs

Table D-1. Decontamination RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Personnel	- M291 Skin Decontaminating Kit	Production		Rqmt	Rqmt	Rqmt
	- M295 Individual Equipment Decontaminating Kit	Production	Rqmt	Rqmt	Interest	Rqmt
	- M100 Sorbent Decontamination System and Solution Decontaminants	Production	Rqmt	Interest	Rqmt	Interest
	- Joint Service Personnel/Skin Decontamination System	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- CB.44 Oxidative Formulation	DTO				
Combat Equipment, Vehicles, and Aircraft	- M17A2/A3 Lightweight Decontamination System	Production	Rqmt	Rqmt	Rqmt	Rqmt
	- M17 MCHF Lightweight Decontamination System	Production		Int-NIR	Rqmt	Rqmt
	- Joint Service Sensitive Equipment Decon Joint Sensitive Equipment Decon System Joint Platform Interior Decontamination System	 RDTE RDTE	 Rqmt Rqmt	 Rqmt Rqmt	 Rqmt Rqmt	 Rqmt Rqmt
	- Joint Service Family of Decontamination Systems Joint Service Man-Portable Decon. System Joint Service Transportable Decon. System Joint Service Stationary Decon. System	 RDTE RDTE RDTE	 Rqmt Rqmt	 Rqmt Rqmt Rqmt	 Rqmt Rqmt Rqmt	 Rqmt Rqmt
	- I.06 Restoration of Operations ACTD**	DTO				

Rqmt = Product Requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement
* = sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product Requirement or Interest
Defense Technology Objective (Science & Technology Base Program)
** This ACTD support more than the decontamination functional area, but is placed in only one annex to prevent redundancy.

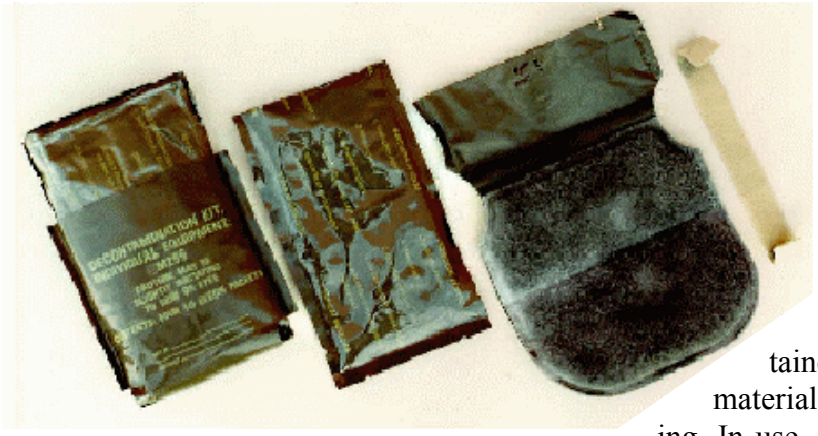
PERSONNEL

FIELDED AND PRODUCTION ITEMS

M291 Skin Decontamination Kit

The M291 consists of a wallet-like flexible carrying pouch containing six individually sealed foil packets. Each packet contains a folded non-woven fiber applicator pad with an attached strap handle on one side. The pad contains a reactive and sorptive resin polymer mixture. The kit enables warfighters to remove, neutralize, and destroy chemical and biological warfare agents on contaminated skin. The kit is carried in a pocket of the battlefield protective suits.

M295 Equipment Decontamination Kit

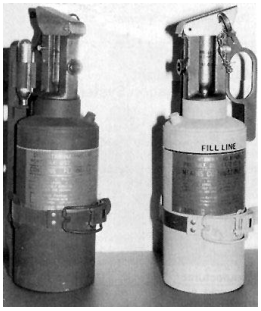


The M295 kit consists of four individual wipedown mitts, each enclosed in a soft, protective packet. The packet assembly is designed to fit comfortably within the pocket of a BDO. Each wipedown mitt in the kit is comprised of a decontaminating sorbent powder contained within a non-woven polyester material and a polyethylene film backing. In use, sorbent powder from the mitt is allowed to flow freely through the non-woven polyester pad material. Decontamination is accomplished through sorption of contamination by both the non-woven polyester pad and by the decontaminating sorbent powder. The M295 enables the warfighter to perform basic decontamination to remove, neutralize, or destroy CB warfare agents and toxins on contaminated personal and load bearing equipment.

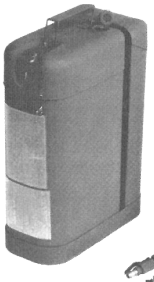
M100 Sorbent Decontamination System

The reactive sorbent decontamination system provides a simple, rapid, and efficient system to decontaminate small and individual issue items of equipment. It is effective in all environments, is less corrosive, and presents a lowered logistics burden through improved shelf life and reduced special handling and storage needs. The M100 system uses a catalytic component that reacts with the chemical agents being adsorbed; this eliminates the potential hazard created by the off-gassing of agents from used adsorbents.

ABC-M11 Portable Decontaminating Apparatus

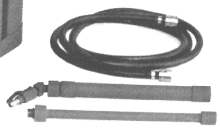


The 1-1/3 quart capacity M11 is used to spray DS2 decontaminating solution onto critical areas (*i.e.*, frequently used parts) of vehicles and crew served weapons. The M11 consists of a steel cylinder, a spray head assembly, and a small nitrogen cylinder (about 3" long). The refillable M11 can produce a spray 6 to 8 feet long, and cover an area of about 135 square feet. The M11 is currently used on tanks and other systems where the larger M13 Decontaminating Apparatus, Portable (DAP) cannot be effectively stowed.



M13 Decontaminating Apparatus, Portable (DAP)

The man portable M13 consists of a vehicle mounting bracket, a pre-filled fluid container containing 14 liters of DS2 decontaminating solution, and a brush-tipped pumping handle connected to the fluid container by a hose. The fluid container and brush head are both disposable. The M13



can decontaminate 1,200 square feet per fluid container. The combination of spray pump and brush allows personnel to decontaminate hard to reach surfaces, and remove thickened agent, mud, grease and other material.

PERSONNEL

RDT&E ITEMS

Joint Service Personnel/Skin Decontamination System (JSPDS)

Rationale:

- Joint Service requirement

Key Requirements:

- Provide Food and Drug Administration (FDA) approved decontaminant for use on skin
- Decontaminate better than the M291 Skin Decontaminating Kit

Description:

The JSFDS program is a joint effort. The JSPDS will provide the warfighter with the ability to decontaminate skin and limited individual equipment. JSPDS will use the latest in technology to reduce or eliminate hazards in a safe and effective manner. The system will be approved by the Food and Drug Administration.

DTO CB.44 Oxidative Formulation

Objectives. This DTO will develop a noncorrosive, material-compatible, nontoxic, environmentally friendly oxidative chemical/biological decontaminant to replace current inventory decontaminants DS2 and STB/HTH. Candidate oxidative formulations will meet threshold and objective levels as specified in the Joint Service Family of Decontaminants Operational Requirements Document for potential insertion as planned product improvement.

Payoffs. Products developed in this effort support the Joint Future Operational Capability of Restoration, Equipment/Facilities/Area Decontamination. This capability provides a means of decontaminating CWAs and BWAs that yield desirable reaction products. This approach will allow for formulation of the solution into a liquid or dry concentrate and allows decon to occur in an acceptable pH range. Dual-use concentrates will eliminate the need for multiple decontaminants and will minimize storage and transportation requirements, reducing the overall cost associated with supporting decon operations. The material friendly nature of the oxidative formulations will greatly reduce the damage to materials that is the case with currently fielded decontaminants, thus reducing the requirement for the costly replacement of decontaminated pieces of equipment. During FY02, optimization of a peroxycarbonate-based decontaminant that shows outstanding efficacy on chemical and biological agents, including at high and low temperature has been completed. Demonstration of efficacy of several non-optimized candidate peracid-based formulations on chemical and biological agents has also been completed.

Challenges. Reactivity, pot life, and long-term storage requirements are significant challenges. In addition, compatibility of formulation components may be an issue. In order to reduce the logistical burden, appropriate packaging must be well thought out. Leveraging off of industry expertise will greatly reduce potential risk in these areas and potentially reduce developmental and production costs.

DTO CB.44 Oxidative Formulation
Milestones/Metrics. **FY2004:** Formulate candidates into dry powder and/or concentrated liquid and demonstrate efficacy still meets requirements. Determine physical properties of candidate solutions. Complete material compatibility testing on high-priority materials and determine which candidate formulations meet requirements. Demonstrate products with applicators and determine suitability for peroxide systems. Modify and/or develop alternative applicators. **FY2005:** Complete safety, health, and environmental testing. Complete robust live agent chamber testing and determine which candidates meet efficacy requirements. Demonstrate limited operational utility of down selected decontaminants and associated applicators using simulant field trials in relevant environments and determine which candidates meet efficacy and operational requirements. Prepare IPR packages.

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

FIELDED AND PRODUCTION ITEMS

M12A1 Power Driven Decontamination Apparatus (PDDA); Skid-Mounted

The M12A1 consists of three main components: a pump unit, a 500 gallon tank unit, and a 600 gallon per hour liquid fuel water heater. The M12A1 is a flexible system that can be used for purposes such as de-icing, fire fighting with water or foam, water pumping and transport, and personnel showering in addition to equipment and area decontamination. The M12A1 can pump 50 gallons of decontaminating solution per minute through both of its hoses. The integral shower assembly provides 25 shower heads. The M12A1 is typically mounted on a 5 ton truck for tactical mobility, but can be dismounted to facilitate air transport. The USMC has replaced the M12A1 PDDA with the M17 MCHF Lightweight Decontamination Apparatus.

M17 Series Lightweight Decontamination System (LDS)

The M17 series Lightweight Decontamination System (LDS) is a portable, lightweight, compact engine driven pump and water heating system. The system is used during decontamination operations. The LDS is capable of drawing water from any source and delivering it at moderate pressure and controlled temperatures. The system has an accessory kit with hoses, spray wands, and personnel shower hardware. It also includes a collapsible water bladder.

M17 MCHF Lightweight Decontamination System

The M17 Marine Corps Heavy Fuel (MCHF) LDS is a portable, lightweight, compact, engine-driven pump and multifuel-fired water heating system. The system is capable of performing the same hasty and deliberate decontamination procedures as required of the M17 series LDS. All components can be moved by a four-man crew, and can be operated using Military Standard Fuels (diesel fuel, JP-8, *etc*.) It can decontaminate both sides of a vehicle or aircraft simultaneously, and can decontaminate personnel, equipment, and other materiel without an external power source and in coordination with a water tank or natural water resource.

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

RDTE ITEMS

Joint Service Sensitive Equipment Decontamination (JSSED)
Joint Sensitive Equipment Decontamination; Joint Platform Interior Decontamination System

Rationale:

- Joint Service requirement

Key Requirements:

- Non-aqueous based decontamination systems for sensitive equipment and vehicle interiors
- Provide decontamination systems for platform (vehicle/aircraft/ship) interiors
- Capable of being used in both mobile and fixed-sites

Description:

Provide a first ever capability to decontaminate chemical and biological warfare agents and toxins from sensitive electronic, avionics, electro-optic equipment, and vehicle interiors. Its use must be compatible with and not degrade sensitive materials or equipment. It must be operator safe and offer protection from off-gassing and direct liquid exposure during decontamination.

Joint Service Man-Portable Decontamination System (JSM-PDS),
Joint Service Transportable Decontamination System (JSTDS) and
Joint Service Stationary Decontamination System (JSSDS)

Rationale:

- Joint Service requirement

Key Requirements:

- Provide restoration capability at fixed site locations
- Provide improved/state-of-the-art CBRN decontamination equipment
- Provide non-hazardous and environmentally safe CBRN decontaminants

Description:

These three programs are part of the Joint Service Family of Decontamination Systems (JSFDS). The program will provide the warfighter with a family of decontaminants and applicator systems to decontaminate equipment, facility equipment and terrain. The JSFDS will include JSM-PDS, JSTDS and JSSDS systems to provide the range of required combat equipment, vehicle and aircraft decontamination capabilities, excluding sensitive equipment. Decontaminants will be less corrosive and hazardous than existing decontaminants. Application systems will reduce the manpower intensive decontamination processes.

DTO JD.22 Restoration of Operations ACTD
Objectives. This DTO will demonstrate mitigating actions taken before, during, and after an attack to protect against and immediately react to the consequences of a chemical/biological (CB) attack. The objective is to restore operating tempo in mission execution and to support logistics and combat operations at a fixed site. **Payoffs.** Potential payoffs include implementation of new CB Defense technologies into core acquisition programs, coupled with the implementation of new concepts of operations (CONOPS) and tactics, techniques, and procedures (TTPs) for critical CB defense activities. The ultimate payoff will be an enhanced capability of fixed sites worldwide to better prepare for and recover from CB attacks. **Challenges.** Challenges include training users to use new technologies and associated CONOPS and TTPs. In addition, training leaders to understand enhancements to existing CBD capability and how creation of new capabilities must be incorporated into existing fixed-site defense procedures. Technical challenges include the effective integration of situational awareness tools with CB sensors and with the USAF Wing's command and control system. **Milestones/Metrics.** **FY2004:** Conclude interim capability support period.

Annex E

Joint Medical Chemical, Biological, Radiological and Nuclear Defense Research Programs

The Joint Medical Chemical, Biological, Radiological and Nuclear Defense Research Programs are addressed in three sections of this annex. Section E.1 addresses medical chemical defense research, and section E.2 addresses medical biological defense research and section E.3 addresses medical radiological defense.

Table E-1. Medical Chemical, Biological, Radiological Defense RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Medical Chemical Defense	- Antidote Treatment – Nerve Agent Autoinjector	Fielded	Joint	Joint	Joint	Joint
	- Convulsant Antidote for Nerve Agents	Fielded	Joint	Joint	Joint	Joint
	- Advanced Anticonvulsant System	RDTE	Joint	Joint	Joint	Joint
	- Cyanide Pretreatment	RDTE	Joint	Joint	Joint	Joint
	- Medical Aerosolized Nerve Agent Antidote	Fielded	Joint	Joint	Joint	Joint
	- Soman Nerve Agent Pretreatment Pyridostigmine	Fielded	Joint	Joint	Joint	Joint
	- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA)	Production	Rqmt			
	- Chemical Agent Prophylaxes	RDTE	Joint*	Joint*	Joint*	Joint*
	- CB.30 Medical Countermeasures for Vesicant Agents II	DTO				
	- CB.48 Improved Oxime	DTO				
	- CB.51 Low-Level CW Agent Exposure: Effects and Countermeasures	DTO				
	- CB.57 Non-Traditional Nerve Agent Medical Countermeasures	DTO				
Medical Biological Defense	- Anthrax Vaccine Adsorbed	Fielded	Joint	Joint	Joint	Joint
	- Smallpox vaccine (Dryvax vaccine (1:1)	Fielded				
	- Clostridium Botulinum Toxins Medical Defense System	RDTE	Joint*	Joint*	Joint*	Joint*
	- Next Generation Anthrax Vaccine	RDTE	Joint*	Joint*	Joint*	Joint*
	- Improved Plague Vaccine	RDTE	Joint*	Joint*	Joint*	Joint*
	- Ricin Vaccine	RDTE	Joint	Joint	Joint	Joint
	- Smallpox Vaccine system (cell cultured derived, IND VIG)	RDTE	Joint*	Joint*	Joint*	Joint*
	- Staphylococcus Enterotoxin Vaccine	RDTE	Joint	Joint	Joint	Joint
	- Tularemia Live Vaccine	RDTE	Joint	Joint	Joint	Joint
	- Venezuelan Equine Encephalitis Vaccine	RDTE	Joint*	Joint*	Joint*	Joint*
	- Joint Biological Agent Identification and Diagnostic System	RDTE	Joint	Joint	Joint	Joint
	- CB.24 Medical Countermeasures for Encephalitis Viruses	DTO				
	- CB.31 Medical Countermeasures for Brucellae	DTO				
	- CB.32 Alternative Delivery Methods for Recombinant Protein Vaccines	DTO				
	- CB.34 Recombinant Plague Vaccine Candidate	DTO				
	- CB.46 Recombinant Ricin Vaccine	DTO				
	- CB.47 Improved Immunodiagnostic Platform	DTO				
	- CB.54 Therapy for Smallpox and other Pathogenic Orthopoxviruses	DTO				
	- CB.27 Therapeutics Based on Common Mechanisms of Pathogenesis (DARPA Program)	DTO				
	- CB.56 Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems	DTO				
	- CB.58 Western and Eastern Equine Encephalitis (WEE/ EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine	DTO				
	- CB.59 Therapeutic Strategies for Botulinum Neurotoxin	DTO				
	- CB.60 Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola viruses) Exposure	DTO				
	- CB.63 Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection	DTO				

Category	Nomenclature	Status	USA	USAF	USMC	USN
Medical Radio-logical Defense	- Radioprotective Drug Development	RDTE				
	- Therapeutic Strategies for Radiation Injury	RDTE				
	- Automation of the Definitive Cytogenetic Assay for Radiation Dose Assessment	RDTE				
	- Molecular Biomarkers for Radiation Dose Assessment	RDTE				
	MD.18 Pharmacologic Prevention of Ionizing Radiation Injury	DTO	Joint*	Joint*	Joint*	Joint*
	MD.20 Cytogenetic-Based Diagnostic Biodosimetry System	DTO				
	- MD.21 Toxicity of Embedded Depleted Uranium	DTO				
	- MD.29 Medical Countermeasures Against Bacterial Sepsis After Irradiation	DTO				

Joint= Joint Service requirement
Joint*=Draft Joint Service requirement
Rqmt= Requirement
DTO = Defense Technology Objective (a Science and Technology Base Program)

E.1 MEDICAL CHEMICAL DEFENSE RESEARCH PROGRAM

E.1.1 Fielded Products

Advances in medical research and development (R&D) significantly improve the war-fighting mission by sustaining unit effectiveness through conserving the fighting strength of our forces and supporting the nation's global military strategy, which requires the ability to effectively deploy and operate. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures 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 have provided a significant increase in military effectiveness in the past and present the potential for future enhancement of military operational effectiveness. Following are fielded medical chemical defense items, including pharmaceuticals, materiel, and technical information and guidance (with initial fielding date shown.)

Pharmaceuticals:

- Nerve Agent Antidote Kit (Mark I), 1983
- Skin Decontamination Kit (M291), 1990
- Convulsant Antidote for Nerve Agent (CANA), 1991
- Medical Aerosolized Nerve Agent Antidote (MANAA), 1994
- Soman Nerve Agent Pretreatment Pyridostigmine, 2003 (Replaces the Nerve Agent Pretreatment (Pyridostigmine), which was fielded as an IND in 1987.)
- Antidote Treatment Nerve Agent Autoinjector (ATNAA), 2003
- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA), 2003

Materiel:

- Test Mate® ChE (Cholinesterase) Kit, 1997.
- Resuscitation Device, Individual, Chemical, 1990.
- Decontaminable Patient Litter (NSN 6530-01-380-7309), 1991.
- Chemical Warfare (CW) Protective Patient Wrap (NSN 8415-01-311-7711), 1991.
- Computer-Based Performance Assessment Battery, 1993.

Technical Information and Guidance:

- Medical Planning Guide of NBC Battle Casualties Chemical, AMedP-8(A), Vol. III, Ratification Draft.
- Field Manual (FM) 8-285, *Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries*, 1995.
- *Field Management of Chemical Casualties Handbook*, Second Edition, July 2000
- Technical Bulletin (TB) Medical (MED) 296, 1996: *Assay Techniques for Detection of Exposure to Sulfur Mustard, Cholinesterase Inhibitors, Sarin, Soman, GF, and Cyanide*.
- Compact Disk - Read-Only Memory (CD-ROM) on "Management of Chemical Warfare Injuries," 1996.
- *Medical Management of Chemical Casualties Handbook*, Third Edition, July 2000.

E.1.2 Medical Chemical Defense R&D Accomplishments

The medical chemical defense R&D technical barriers and accomplishments during FY03 are grouped by the major medical chemical defense strategy areas, which are:

- *Nerve Agent Defense.*
- *Vesicant Agent Defense.*
- *Chemical Warfare Agent Defense.*

Today's chemical threat is not restricted to commonly accepted classical agents, such as vesicants [sulfur mustard (HD)], nerve agents (soman, sarin, tabun, and VX), respiratory agents (phosgene), or blood agents (cyanide). Potential adversaries may develop novel threat agents. Additionally, the potential for transient or sustained systemic toxicity from low dose exposure(s) to chemical warfare agents must be thoroughly investigated to determine the potential effect on Service members. The ability to provide timely and effective medical countermeasures to new threats depends upon maintaining a high level of technological capability. Sustaining and enhancing this technological capability is dependent upon the continued support of a robust program investigating basic pathophysiological mechanisms which, in turn, contributes to the knowledge and database upon which new, innovative, and improved diagnostics, pretreatments, and therapies are based.

Countermeasure strategies to the classical and novel threats include pharmaceuticals, medical equipment, specialized materiel or medical procedures, and concepts for training, doctrine, and organization. Medical countermeasures are designed not only to prevent lethality but also to preserve and sustain combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield by:

- Rapid diagnosis of chemical agent exposure.
- Prevention of the effects of chemical agents (*e.g.*, prophylaxes or pretreatment).
- Far-forward treatment upon exposure to chemical warfare threats (*e.g.*, antidotes).
- Chemical casualty care (*e.g.*, therapy and management).

Medical chemical defense research directly conducted or sponsored by the United States Army Medical Research and Materiel Command (USAMRMC) laboratories yielded the following accomplishments in FY03:

Research Category: Nerve Agent Defense

Overarching Research Objective: Explore the development of medical countermeasures (i.e., prophylaxes/pretreatments and treatments) against chemical warfare nerve agents. Research studies range from basic and applied research in nerve agent countermeasures and associated scientific disciplines to research nearing the point of maturity for elevation to Defense Technology Objective (DTO)status. DTO research efforts are designed so that data generated from these efforts meet requirements for transition out of the technology base and are consistent with technical information required by the advanced developer for development of an Investigational New Drug (IND) application.

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of nerve agent defense are outlined below.

Countermeasures:

- Pretreatment and treatment regimens that protect against rapid action and incapacitating effect of nerve agents and non-traditional agents.
- Pharmaceutical and biological pretreatments, treatments, and antidotes.

Technical Barriers:

- Lack of pretreatments and/or antidotes that are quick acting, long lasting, easy to carry and use on the battlefield.
- Lack of appropriate experimental model systems to predict pretreatment or treatment efficacy and safety in humans.
- Lack of detailed molecular models of all threat agents to understand the mechanism of their unique chemical properties and their effects.
- Potential performance decrement with pretreatments and treatments.

Accomplishments:

The detailed accomplishments that follow are drawn from the basic research, applied research, and advanced technology development investments in research on in nerve agent defense. They are organized under major research thrust areas that comprised the medical chemical defense research portfolio in fiscal year 2003.

Research thrust: *nerve agent bioscavenger (chemical warfare agent prophylactic):*

- Expressed and purified a recombinant human carboxylesterase (CaE) for crystallization.
- Evaluated safety and circulatory stability of recombinant bioscavengers.
- Developed physiological pharmacokinetic models of chemical warfare agents (CWAs).
- Determined the specific carbohydrate structures of human serum butyrylcholinesterase for reference material for Good Laboratory Practices (GLP) and current Good Manufacturing Practices (cGMP) production.
- Generated serum CaE-deficient mice for use in testing efficacy of nerve agent bioscavengers.
- Completed physiological pharmacokinetic model studies of expected human efficacy with various bioscavengers.
- Verified adequacy of transgenic animal model to produce recombinant enzyme scavenger.

Research thrust: ***development of an advanced anticonvulsant***

- Evaluated antidotes representing new strategies to address medical countermeasure requirements against conventional and emerging threats.
- Developed experimental protocol to evaluate drugs, drug combinations and drug treatment protocols with potential to control nerve agent-induced seizures.
- Evaluated ability of midazolam and anticholinergics to terminate nerve agent-induced seizures in a higher animal species model.
- Selected midazolam anticonvulsant and established optimal treatment protocol in higher animal species.

Research thrust: ***development of a neuroprotectant to protect from exposure to nerve agents***

- Evaluated combination therapies for neuroprotection efficacy.
- Developed neurobehavioral assessment.
- Developed and tested neuroprotectant drugs to protect against status-epilepticus following nerve agent exposure.
- Assessed alternate higher animal species as models for nerve agent toxicity and medical countermeasures.

Research thrust: ***medical countermeasures for non-traditional nerve agents:***

- Initiated chemical assay development to detect candidate oxime(s) for use against traditional and non-traditional nerve agents (NTAs) in biological fluids, stability studies, and studies to identify and characterize a surrogate marker for efficacy, drawing from an array of promising compounds already identified.
- Evaluated cardiac toxicity following NTA exposure in cardiac muscle cells and animal models.
- Evaluated bioscavenger pretreatment as medical countermeasure against NTAs in guinea pigs.
- Conducted efficacy studies of candidate oxime(s) against traditional nerve agents and NTAs in guinea pigs; synthesized appropriate quantities of each oxime for required studies.
- Compared all nerve agents for induction of neurochemical changes.
- Evaluated efficacy of anticonvulsants against NTAs.
- Evaluated current nerve agent medical decontamination procedures against percutaneous NTAs.

The following DTOs are key efforts in addressing the issues of medical counter-measures for exposure to non-traditional nerve agents.

DTO CB. 48 Improved Oxime
Objectives. The objective is to identify and characterize a candidate broad-spectrum oxime(s) to replace the current oxime in nerve agent therapy.
Payoffs. Pralidoxime chloride (2-PAM) is an oxime that is currently issued to military personnel in an autoinjector form for emergency treatment of nerve agent intoxication. 2-PAM provides adequate protection against the conventional nerve agents GB and VX but is less effective against other conventional agents (i.e., GA, GD, GF), and emerging threats. The result of this research program will

DTO CB. 48 Improved Oxime
be an improved, broad-spectrum oxime(s) that is significantly more effective than 2-PAM against conventional agents and emerging threats. This medical countermeasure will enhance warfighter survival and sustainability in nerve agent contaminated environments. **Challenges.** Challenges include identifying and characterizing a surrogate marker of the improved oxime efficacy; establishing and clearly articulating the risks and benefits to justify replacing 2-PAM; and developing and qualifying a non-human primate (NHP) model to replace the rhesus monkey. **Milestones/Metrics.** **FY2004:** Initiate efficacy studies in non-human primates (NHPs). Initiate safety/toxicity studies in two species and pharmacokinetic (PK) studies in NHPs. Continue studies to characterize a surrogate marker for efficacy. Continue assay development and stability studies. Initiate discussions with FDA. Continue the downselection process. **FY2005:** Continue efficacy studies in NHPs. Complete assay development, safety/toxicity, PK, and stability studies. Complete characterization of a surrogate marker for efficacy and the down selection process. Prepare Investigational New Drug application and for selection of the best candidate , broad-spectrum candidate oxime(s) out of the technology base.

DTO CB. 57 Non-Traditional Nerve Agent Medical Countermeasures
Objectives. This DTO will enable the development of medical countermeasures against non-traditional nerve agent (NTA) intoxication by identifying and characterizing compounds or medical strategies using laboratory and animal models that demonstrate the ability to prevent, interrupt, or terminate the action of NTAs. **Payoffs.** The number and type of chemical warfare agents (CWAs), beyond the conventional CWAs, has significantly increased. NTAs have the potential of being used as chemical weapons against U.S. military forces and it is critically important to determine the toxicity of these agents and the effectiveness of current medical countermeasures against their acute toxicity. The research efforts will be conducted to identify the mechanism of action of the NTAs and any differences in the absorption, distribution, and metabolism of these agents, to evaluate current medical countermeasures for their efficacy against NTAs, to identify new candidate medical countermeasures that are effective against NTAs, to develop animal models that facilitate research for countermeasures to NTAs, and to characterize candidate countermeasures. The major outcome of this research will be to increase the knowledge base on NTAs and provide the scientific basis for identifying medical products that have the potential for effectively countering NTA exposure, thereby enabling their future development and eventual licensure by the Food and Drug Administration (FDA). Effective countermeasures for NTA exposure would substantially reduce the number of casualties or degree of injury among exposed joint service members, deter their use as chemical warfare agents and enable joint forces to sustain operational tempo. **Challenges.** Major technical challenges include: determine the mechanism of action, determine the in vivo time-course of NTAs to ensure the duration of action of medical countermeasures exceeds the in vivo persistence of NTAs, develop a therapy that works effectively for all non-traditional nerve agents and conventional nerve agents, and develop non-human primate models to extrapolate efficacy test results from animals to man. **Milestones/Metrics.** **FY2004:** Determine the effects of NTAs on energy metabolism of cardiac cells and the effectiveness of

DTO CB. 57 Non-Traditional Nerve Agent Medical Countermeasures
decontamination on percutaneous NTAs. Conduct electrophysiological evaluation of cardiovascular, respiratory, muscular and cortical dysfunction. Begin evaluation of the efficacy of candidate bioscavengers for protection against NTAs in multiple animal models. **FY2005:** Evaluate the effectiveness of anticonvulsants against seizures produced by NTAs, in vivo persistence of NTAs, and current medical countermeasures against NTAs. Conduct evaluation of respiratory dynamics and lung biochemistry. **FY2006:** Complete evaluation of efficacy of human serum butyrylcholinesterase as a bioscavenger for protection against known NTAs in non-human primates. Compare NTAs and conventional nerve agents for induction of neurochemical changes and conduct studies of NTAs on vascular performance and contractility. Evaluate the pharmacokinetics of improved candidate medical countermeasures for comparison to the in vivo persistence of NTAs. Information generated by this research will be used to develop a strategy, in concert with the advanced developer, for development of NTA medical countermeasures.

Research Category: Vesicant Agent Defense

Overarching Research Objective: Explore the development of medical countermeasures (i.e., pretreatments and treatments) against chemical warfare vesicant (blister) agents. Research studies range from basic and applied research in vesicant agent countermeasures and associated scientific disciplines to research nearing the point of maturity for elevation to Defense Technology Objective (DTO)status. DTO research efforts are designed so that data generated from these efforts meet requirements for transition out of the technology base and are consistent with technical information required by the advanced developer for development of an Investigational New Drug (IND) application.

The countermeasures, technical barriers, and accomplishments in the research category of vesicant agent defense are outlined below.

Countermeasures:

- Products that moderate or improve healing of vesicant injury.
- Medical countermeasures to minimize lethality, morbidity, and incapacitation caused by chemical warfare agents (CWAs).
- Specific casualty management techniques to improve survival and minimize lost duty time.
- Pharmaceutical/biological pretreatments, treatments and antidotes.

Technical Barriers:

- Need for quick-acting and long-lasting pretreatments, treatments and antidotes that are deployable.
- Lack of appropriate experimental model systems for pretreatment and treatment efficacy and safety in humans.
- Need for detailed molecular models of vesicant agents to understand the origin of their unique chemical properties.

Accomplishments:

The detailed accomplishments that follow are drawn from the basic research, applied research, and advanced technology development investments in research on vesicant agent defense. They are organized under major research thrust areas that comprised the medical chemical defense research portfolio in fiscal year 2003.

Research thrust: *medical countermeasures for vesicant exposure*

- Targeted mechanism of vesicant injury and explored intervention of pro-inflammatory mediators and calcium modulators.
- Conducted proteomic analysis of sulfur mustard (HD) toxicity.
- Evaluated antagonists of apoptosis and the blockade of HD-induced toxicity.
- Explored the use of antioxidant liposomes as a medical countermeasure to HD exposure.
- Identified therapeutic window for administering compounds to mitigate the effects of HD exposure.
- Evaluated combination therapies for HD exposure in animal models.
- Explored the use of free and liposome-encapsulated antioxidants as a medical countermeasure to HD exposure.
- Completed preclinical studies of selected vesicant therapy candidate compounds.
- Completed preclinical safety and efficacy studies of selected vesicant therapy candidate compounds.
- Completed pharmacokinetic studies of vesicant countermeasure candidates.
- Performed additional studies necessary to completely characterize therapy.
- Initiated preparation of a technical data package to support FDA requirements for an IND application.

Research thrust: *cutaneous therapeutics*

- Evaluated new FDA-approved drugs for treatment of HD-induced ocular injury.
- Optimized formulation for an ocular rinse that treats HD-induced ocular injury.
- Evaluated commercially licensed wound healing medical therapeutics for HD-induced injuries.

DTO CB.30 Medical Countermeasures for Vesicant Agents II
Objectives. The objective of this DTO is to demonstrate a safe and effective pharmacological countermeasure to blister injuries caused by vesicant chemical agents, focusing principally on sulfur mustard. Compounds or combinations of compounds will be evaluated to determine the best therapy for transition out of the technology base. **Payoffs.** Medical management of the injuries produced by blister agents is currently limited to immediate decontamination followed by conventional treatment of the resulting blisters or burns. This work will yield a vesicant agent countermeasure that will substantially reduce the degree of injury among exposed soldiers, with concomitant reductions in the medical logistic burden. In FY02, this DTO demonstrated the efficacy of colony stimulating factor in protecting against mustard-induced neutropenia and the efficacy of iodine preparations in treating mustard-induced skin lesions. Pharmacokinetic and formulation studies were initiated on selected candidates to determine the window of opportunity for administration of therapy(s) for HD exposure.

DTO CB.30 Medical Countermeasures for Vesicant Agents II
Challenges. Challenges include developing therapeutic measures with minimal adverse effects, demonstrating safety and efficacy, developing formulations, and extrapolating test results from animals to humans.

Research Category: Chemical Warfare Agent (CWA) Defense

Overarching Research Objective: Explore the development of medical countermeasures (i.e., pretreatments and treatments) against chemical warfare agents, to include investigating the potential for transient or sustained toxicity of single, repeated, or sustained low dose exposure(s) to CWAs. Develop effective, field-deployable diagnostic equipment; decontamination products; pharmaceutical treatments; and practical clinical strategies to aid in the clinical management of chemical warfare agent casualties. Research studies range from basic and applied research in CWA countermeasures and associated scientific disciplines to research nearing the point of maturity for elevation to Defense Technology Objective (DTO) status. DTO research efforts are designed so that data generated from these efforts meet requirements for transition out of the technology base and are consistent with technical information required by the advanced developer for development of an Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) application.

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of CWA defense are outlined below.

Countermeasures:

- Pretreatment regimen that protects against cyanide exposure.
- Medical countermeasures to minimize lethality, morbidity, and incapacitation caused by chemical warfare agents (CWAs).
- Specific casualty management techniques to improve survival and minimize lost duty time.
- Pharmaceutical/biological antidotes, or decontaminants/protectants.
- Diagnostics for the effects of exposure to rapidly acting nerve agents, vesicants, cyanide, and non-traditional agents.

Technical Barriers:

- Need for quick-acting and long-lasting pretreatments, treatments and antidotes that are deployable.
- Lack of appropriate experimental model systems for treatment efficacy and safety in humans.
- Need for detailed molecular models of agents to understand the origin of their unique chemical properties.
- Lack of simple and sensitive field-portable diagnostic assays for CWA exposure.

Accomplishments:

The detailed accomplishments that follow are drawn from the basic research, applied research, and advanced technology development investments in research on CWA defense. They are organized under major research thrust areas that comprised the medical chemical defense research portfolio in fiscal year 2003.

Research thrust: *develop chemical diagnostic technologies:*

- Incorporated biomarker panels into screening modules.
- Conducted electrophysiological analysis of CWAs in cultured cells.
- Analyzed central nervous system (CNS) and peripheral protein production following soman exposure.
- Developed new assays for HD adducts in plasma and for diagnosing cyanide exposure.
- Continued development of analytical methods to measure biological matrices (e.g., blood, urine, tissue) following CWA exposure.
- Developed confirmatory diagnostic capabilities and rapid screening technology for field applications.
- Pursued development of an ocular device for self-examination of pupillary response to nerve agent exposure.
- Evaluated hand-held cholinesterase monitor for clinical use.

Research thrust: *effective methods for removing chemical warfare agents from exposed skin*

- Evaluated the toxicity of percutaneously applied organophosphorus compounds and the effectiveness of skin decontamination methods.
- Pursued development of polyurethane immobilized cholinesterase and chemical agent hydrolyzing enzymes as skin and wound decontaminants for organophosphate CWAs.
- Developed protocols supporting the sponge decontamination concept and the detoxification of medically sensitive skin project; evaluated formulations for efficacy.

Research thrust: *cyanide medical countermeasures*

- Investigated efficacy of sulfur donors as anti-cyanide pretreatments.
- Developed animal model to test cyanide pretreatment compounds.
- Evaluated several classes of compounds that behave by different mechanisms of action, to include methemoglobin formers and sulfur donors, to pursue development of cyanide pretreatment.

Research thrust: *inhalation therapeutics*

- Assessed respiratory dynamics and lung biochemical function in male and female guinea pigs following exposure to CWAs.
- Evaluated treatments for HD-induced pulmonary injury.
- Evaluated therapeutic agents for pulmonary edema produced by whole-body exposure to CWAs in animal models.

Research thrust: *Low-Level CW Agent Exposure*

- Investigated alterations in muscle physiology due to repetitive low dose CWA exposure.
- Characterized ultrastructural morphology, immunochemistry, and gene expression following low level chemical exposure.
- Studied effects of low level chemical exposure on extracellular neurotransmitter levels.
- Evaluated organophosphate anhydrolase enzyme for potential use as a biomarker to confirm low level chemical exposure.
- Assessed short-term behavioral, physiological, and neuropathological effects of sarin (GB) nerve agent in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness.

The following DTO is a key effort in addressing the issues of Low-Level CW Agent Exposures. This research is being conducted with coordination between the medical and non-medical research communities.

DTO CB. 51 Low-Level CW Agent Exposure: Effects and Countermeasures

Objectives. This DTO will deliver data sets on operationally relevant health effects of exposures to sub-lethal concentrations of Chemical Warfare Agents (CWAs). These data sets will, in turn, support development and refinement of risk assessment tools. Specific objectives are to extrapolate relevant experimental effects to determine post-exposure health problems that may impact subsequent operational readiness; and design and execute studies to generate scientifically valid data to serve as a basis for reducing the error in health risk assessment predictions useful for military Operational Risk Management (ORM) decisions.

Payoffs. This DTO addresses deficiencies in the current understanding of the consequences of CWA exposure that may be encountered by military personnel across a range of deployment settings. For even as clear a toxicological endpoint as lethality, historical assumptions used to extend the prediction of exposures out in time have been shown to be overly conservative for the best studied agent, GB. The major goal of this effort is to understand the dose-response relationship for traditional CWAs (G-series, V-series and HD) with an object to identify the most appropriate endpoint to use for determining response actions. For example, a quantitative description of nerve agent-induced pupil effects (miosis) could serve as such a 'first noticeable effect', but less obvious changes in mental function could more significantly degrade operational performance at low-levels of exposures. Consistent and defendable data generated by this program will significantly reduce the error currently embedded in various estimates of toxicity and will provide a consistent and uniform basis for extrapolating information on health effects and potential short- or long-term performance decrements from exposure times and concentrations relevant to military operations. In addition, these data will be essential in creating requirements criteria for detector design, personal protective gear, and decontamination activities. Finally, the characteristics and magnitude of adverse health effects in these less-than-lethal exposure settings may suggest a need for novel medical protection or prophylaxis strategies.

Challenges. Significant technical hurdles must be addressed to create and maintain stable exposure conditions for some agents. Cross-validation of inhalation, parenteral and dermal routs of exposure conditions must be addressed in a series of integration studies. Selection of appropriate animal model systems must be carefully designed to reduce the difficulty of extending such data to human exposures and to permit optimal detection of performance-degrading health effects. Collation of all results into a unified Operational Risk Management (ORM) framework will require novel approaches to traditional treatments of scientific data.

Milestones/Metrics.

FY2004: Complete inhalation data set to define longer-time, lower-level operational effects for GF in swine and VX in rodents that refine operational human health risk assessments. Deliver assessments of the short-term behavioral and physiological effects of VX in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness.

FY2005: Complete cross-validation of inhalation, percutaneous, and parenteral data sets for exposure route comparison with GB that refine operational human health risk assessments. Deliver assessments of VX and HD induced changes in respiratory function produced by low-dose exposures of varying duration. Complete and deliver assessments of the short term-effects of VX on higher order behavioral tasks in non-human primates following a range of low-dose exposures for varying durations to improve estimates of impact on human operational readiness.

E.1.3 Advanced Development Products

In advanced development, the goals are proof-of-principle and the conduct of studies necessary to obtain FDA approval/licensure of drugs, vaccines, and devices. The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD), through the Joint Project Office for Chemical and Biological Medical Systems (JPM-CBMS) are the materiel developers and the advanced with the Joint Requirements Office for CBRN Defense This arrangement reflects the joint nature of the entire RDA process. Medical chemical defense products now in the advanced development phase are the following:

Product: Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA)

Concept:

- Use perfluorinated formulations.
- Form non-toxic, nonirritating barrier film layer on skin.
- Augments Mission Oriented Protective Posture (MOPP).
- Protection against vesicant and nerve agents.

Accomplishments:

- FDA-required Phase IV studies are ongoing
- Packaging improvement and scale up approved by FDA.
- Accelerated scale up resulted in product availability in support of Operation Iraqi Freedom.
- Government directed manufacturing changes increased manufacturing yield from 56% to over 85%.

Product: Antidote Treatment, Nerve Agent, Autoinjector

Concept:

- Speed administration of life-saving antidotes against nerve agents.
- Replace two-Injector Mark I Nerve Agent Antidote Kit with single autoinjector.

Accomplishments:

- Production line upgrade with a custom-built high-speed autoinjector filling machine to increase capacity was approved by the FDA.
- Accelerated production resulted in product availability in support of Operation Iraqi Freedom.

Product: Advanced Anticonvulsant System

Concept:

- A buddy-aid administered anticonvulsant to protect against convulsions after CWA exposure.
- Replace the currently fielded Convulsant Antidote Nerve Agent (CANA) with a faster acting and more effective anticonvulsant.

Accomplishments:

- Laboratory efforts to develop information required to down select one candidate for human trials continued.

E.2 MEDICAL BIOLOGICAL DEFENSE RESEARCH PROGRAM

E.2.1 Biological Defense Products

Advances in DoD medical R&D significantly impact 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 the ability to effectively deploy and operate in all environments. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures 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 have provided a significant increase in military effectiveness in the past and present the potential for future enhancement of military operational effectiveness. Only two biological defense vaccines are fully licensed by the Food and Drug Administration (FDA) and available for use—Anthrax Vaccine Adsorbed, sold under the trade name BioThrax™ and the smallpox vaccine (Dryvax ™). The BLA supplement was approved January 31, 2002 and the lots released for use. Since January 2002, additional lots have been manufactured and released. Others are in investigational new drug (IND) status, which may only be used consistent with Executive Order 13139. A Prime Systems Contract, which supports the Joint Vaccine Acquisition Program (JVAP) component of the Chemical and Biological Medical Systems office, is responsible for moving vaccine candidates from the technology base through advanced development to FDA licensure and procurement of baseline stockpiles. Section E.2.2 provides a description of biological defense science and technology base activities, and Section E.2.3. provides a description of medical biological defense advanced development activities. Currently licensed and IND vaccines/biologicals for use in medical biological defense R&D include the following:

Vaccines and Antisera:

- Anthrax Vaccine Adsorbed (licensed) (Sold under the commercial name BioThrax™)
- Smallpox Vaccine (limited stockpile of licensed vaccine, Dryvax ™)
- Botulinum Pentavalent Toxoid Vaccine Adsorbed (IND #3723)
- Botulinum Type F Toxoid Vaccine (IND #5077)
- 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)
- Q Fever Vaccine, Formalin inactivated, CM Extract, Gamma Irradiated (Henzerling Strain) (IND #3516)
- NDC (National Drug Company) (Salk) LVS Tularemia Vaccine (IND #157)
- The Salk Institute (TSI) Smallpox Vaccine (Vaccinia Virus, Cell Culture-derived) (IND #4984)
- Cell-cultured Smallpox vaccine (CCSV, Dynport Vaccine Company) (IND#10356)
- Venezuelan Equine Encephalitis Virus Vaccine (attenuated), TC-83 (IND #142)
- Venezuelan Equine Encephalitis Virus Vaccine (inactivated), C-84 (IND #914)
- Eastern Equine Encephalitis Virus Vaccine (IND #266)

- Western Equine Encephalitis Virus Vaccine (IND #2013)
- Vaccinia Immune Globulin, Intramuscular (IND #8429)
- Vaccinia Immune Globulin, Intravenous (IND #9141)
- Vaccinia Immune Globulin, Intravenous (IND#10351,emergency use protocol)

Technical Information and Guidance:

- *Medical Management of Biological Casualties Handbook*, fourth edition, February 2001.
- CD-ROM on "Management of Biological Warfare Casualties," 1999.
- NATO Handbook "Medical Aspects of NBC Defensive Operations, AMedP-6(B), Part II (Biological)," 1998.

E.2.2 Biological Defense Research and Development Accomplishments

The biological defense research and development technical barriers and accomplishments during FY03 are grouped by the following overarching medical defense thrust areas against biological warfare agents:

- Bacterial agent countermeasures
  - Bacterial vaccines
  - Bacterial therapeutics
- Viral agent countermeasures
  - Viral vaccines
  - Viral therapeutics
- Toxin Agent countermeasures
  - Toxin vaccines
  - Toxin therapeutics
- Diagnostic technologies

Several projects and technologies are shared with other agencies, including the Department of Energy (DOE) and the Defense Advanced Research Projects Agency (DARPA). DARPA technology transition and cooperative efforts with the Medical Chemical and Biological Defense Research Program are described in Chapter 2 of this report (section 2.7.5.2). The DOE projects tie into the strengths of the DOE laboratories in developing advanced technologies in order to enable rapid detection of and response to a chemical or biological agent incident. DOE is not involved directly in protection and treatment of personnel, but actively assists DoD with drug/chemical database searches, DNA sequencing, advanced protein chemistry, and modeling/simulation projects. Successful sequencing of plasmids found in the causative agents of plague and anthrax helped create the "lab on a chip". The extensive knowledge and databases available to DOE allow application of computational tools to predict sites of intervention by novel therapies against threat agents.

Medical biological defense research conducted or sponsored by the United States Army Medical Research and Materiel Command (USAMRMC) laboratories yielded the following accomplishments in FY03. Current Defense Technology Objectives (DTOs) associated with the strategic areas are described following the FY03 accomplishments in the following sections. Also, DTOs that were started in FY04 are also listed.

Bacterial Agent Countermeasures

The countermeasures, technical barriers, and accomplishments in the Bacterial Agent Countermeasures area are outlined below.

Countermeasures:

- Vaccines that confer immunity against bacterial threat agents.
- Therapeutics for treatment of diseases and pathologies caused by exposure to and infection from bacterial threat agents.

Technical Barriers:

- Developing accurate and complete genetic information for all known bacterial threat agents.
- Developing appropriate animal model systems for investigation of some bacterial threats and countermeasures.
- Lack of suitable epidemiological situations in which to perform human clinical trials to evaluate efficacy of medical products.
- Difficulty in field testing rapid identification/diagnostic kits under natural conditions.
- Difficulty in defining appropriate surrogate markers of protection.
- Necessity to enhance the otherwise limited data on which to base rational drug design and antibody therapies for bacterial agents of interest.
- Necessity to establish and maintain capabilities to assess the known bacterial threats and provide a sufficiently robust technology base to perform research needed to develop countermeasures for new, emerging, and genetically engineered bacterial threats.

Bacterial Vaccines

Overarching Research Objective: Explore the development of candidate vaccines against bacterial biological warfare threat agents. The principal bacterial threat agents addressed in this research area during FY03 are Burkholderia mallei (glanders), B. pseudomallei (melioidosis), Yersinia pestis (plague), Brucella spp., and Bacillus anthracis (anthrax). Research studies range from basic and applied research in bacterial vaccines and associated scientific disciplines to research nearing the point of maturity for elevation to Defense Technology Objective (DTO)status. DTO research efforts are designed so that data generated from these efforts meet requirements for transition out of the technology base and are consistent with technical information required by the advanced developer for development of an Investigational New Drug (IND) application.

Basic and Applied Research Accomplishments:

- Developed mutations in various biological agents for in vivo expressed genes to examine role in virulence.
- Characterized the mechanism(s) of vaccine resistance in selected strains of various biological agents.
- Initiated a comparison of the safe and most efficacious vaccine candidates against select agent exposures.
- Determined mechanisms and correlates of protection with efficacious Burkholderia mallei vaccines candidates and analyzed data compiled from research studies to date to determine optimum glanders vaccine candidate(s).

- Evaluated differences in the course of Brucella infection in different mouse strains and tested multiagent vaccine constructs based on Brucella for immunogenicity in animal models.
- Demonstrated that a highly attenuated Brucella melitensis mutant that was complemented with a plasmid that expressed both heterologous green fluorescent protein (GFP) and the complementing marker was appropriately attenuated in mice. Developed additional plasmid vectors with improved restriction sites and promoters to facilitate various levels of expression of heterologous antigens in vivo. Collaborators at Virginia Polytechnic Institute expressed anthrax protective antigen (PA) in the host/plasmid system and demonstrated that the complemented strain is attenuated and immunogenic in mice. These studies provide proof of principle for a multiagent vaccine based on expression of heterologous antigens, including anthrax PA.
- In support of rPA vaccine candidate transition to NIAID for development studies and for possible transition into the DoD Technology Development acquisition phase, completed an evaluation of immunogenicity and efficacy of rPA isoform species in the rabbit model; continued to develop reagent standards for use in an in vitro potency assay; and completed the collection of immune serum for evaluation in a higher animal species passive transfer study.
- In related rPA vaccine candidate developmental research, continued to evaluate the efficacy of rPA immunity against B. anthracis strains of diverse geographic origins and continued long-term rPA vaccine efficacy studies in rabbits and higher animal species.
- Demonstrated that the CpG oligonucleotides augment specific and/or non-specific immunity against anthrax spore challenge in mice and guinea pigs. Also found that adding CpG oligonucleotides to the rPA vaccine construct increased both the titer as well as the affinity of the rPA-specific antibodies in nonhuman primates.
- In research to determine the impact of isoforms in rPA vaccine preparations, found derivative vaccines comprising each of the two major rPA isoforms to be equally protective in rabbits against a lethal aerosol challenge of anthrax spores. Also determined that asparagine deamidation is present in rPA and differs in amount correspondingly between lots that show greater and fewer isoforms.
- In support of recombinant plague F1-V vaccine candidate entry into Technology Development, completed development of an anti-V antigen competitive enzyme-linked immunosorbent assay (ELISA) and cytotoxicity inhibition assays; completed a determination of the range of protection of the vaccine candidate against other virulent strains of Y. pestis in animals; and completed studies in mice on alternate vaccine administration routes, dose, formulation and mucosal adjuvants.
- Continued assay support and studies on adjuvants and formulations in support of rPA and recombinant plague F1-V vaccine candidates progress through development at NIAID and the Joint Vaccine Acquisition Program, respectively.
- Completed studies to optimize the performance and sensitivity of the macrophage cytotoxicity assay for the plague V antigen and anti-V antibodies. Also investigated several alternate macrophage-based apoptosis and cytotoxicity assays to identify the one(s) that show the best correlation with protection and exhibit maximal sensitivity and reproducibility. These include assays of cell death such as LDH release.

- Performed research on the mechanisms of pathogenesis and host immunity to anthrax. Showed that anti-protective antigen (PA) specific antibodies (Abs) have anti-spore activities (antibodies against PA and against whole spores inhibited germination). Characterized the kinetics and localization of PA in the dormant and germinating spore by electron microscopy with gold-labeled antibodies, fluorescence microscopy with fluorochrome-tagged antibody, a whole-spore Elisa assay, an electrochemiluminescence assay, and mass spectrometry.
- Investigated the site of germination of anthrax spores in vivo, and postulated the role of host cells in B. anthracis spore germination in the host. Characterized spore germination in peritoneal chambers designed to allow exposure of spores to germinant but prevent direct contact with, and ingestion by, host cells. Obtained results in mouse and guinea pig models that supported the hypothesis that, although extracellular germination can occur, optimal in vivo germination of B. anthracis spores requires that the spores come in contact with or be phagocytosed by the host cells.
- In an effort to develop potential glanders vaccine candidates, isolated capsular polysaccharides and lipopolysaccharides (LPS) in milligram quantities from B. pseudomallei 576 strain. Coupled the isolated polysaccharide to CRM197 (diphtheria toxin mutant) by reductive amination with sodium cyanoborohydride. Western blot of the polysaccharide - CRM197 conjugate against the polyclonal antibody produced against the whole-cell B. pseudomallei 576 indicated that the antigen contained both the capsular polysaccharide and the O – antigen polysaccharide from LPS. Mice were vaccinated with the polysaccharide – CRM197 conjugate and will be subject to aerosol challenge with B. pseudomallei to determine protective efficacy of the vaccine construct.
- Completed a study on the murine aerosol model of melioidosis. Determined that mice exposed by aerosol to B. pseudomallei had systemic infections with bacteremia in a variety of organs. Compared these infections with disease caused by B. mallei and observed that the pathologic changes in mice infected with B. pseudomallei were more severe, suggesting greater pathogenicity of B. pseudomallei. Also observed that B. pseudomallei was able to cross the cribiform plate from the nasal sinus into the brain, where it caused more extensive/severe infection than did B. mallei.
- In research with immunomodulators, CpG preparations were tested for their ability to protect mice from lethal aerosol challenge with B. mallei. It was found that a CpG preparation completely protect mice from lethal effects of a low dose (2 LD_{50}) aerosol challenge and was able to extend the time to death against high dose (25 LD_{50}) aerosol challenge. It was determined from this study that, although CpG was unable to confer sterile immunity, it did reduce the bacterial burden in the lungs compared to controls.

Vaccine Defense Technology Objective (DTO) Research Accomplishments:

Research to develop a vaccine against Brucella melitensis (DTO CB.31)

- Determined whether over-expression of vaccine antigens in candidate live vaccines increases protective efficacy.
- Continued to develop and validate in vitro systems in mice and higher animal species to reliably quantify the intensity of potentially protective immune responses in animals vaccinated with live and subunit vaccines.

- Demonstrated the effectiveness of the candidate live, attenuated vaccine candidate in the nonhuman primate challenge model for protective efficacy against a single pathogenic Brucella species (B. melitensis).
- Demonstrated that antigen-stimulated spleen cells from mice immunized with protective live, attenuated Brucella vaccine accumulate messenger RNA (mRNA) for 12 different cytokines and chemokines and correlated mRNA expression with protein secretion. These studies emphasized the role of IFN-g and IL-2 and suggested that IL-23 may also play a role in response to brucellosis. Found that antigen-stimulated spleen cells from mice immunized with live, attenuated Brucella vaccine up- or down-regulated at least 40 genes by gene array analysis (material from 3 different experiments). These studies indicated that IFN-g-driven processes were strongly up-regulated and documented the consistency of analysis across multiple experiments. Extending the studies from Rag-1 knockout (KO) mice, which lack B and T cells, examined survival of B. melitensis 16M in B cell knockout mice. These studies showed that B cell KO mice have slightly reduced infection in reticuloendothelial organs early after intraperitoneal challenge, but have no long-term impairment or advantage in their ability to control Brucella infection. No difference between B cell KO and normal mice after intranasal challenge was observed. These studies suggest that development of antibody plays little or no role in recovery from infection and suggest that B cell KO mice will be a valuable model to assess the utility of antibody as a correlate of protection against challenge.
- Confirmed usefulness of the conjunctival challenge route in nonhuman primates as a reproducible model of brucellosis. Improved techniques for sampling of temperature data using implantable data recorders and established improved fermentation conditions for newly characterized live, attenuated Brucella vaccine candidates. Determined the stability of the lead vaccine candidate over 8 months when stored frozen using FDA-approved excipients. Developed a novel flow cytometric method to determine relative proportion of smooth and rough variants of fermented live, attenuated Brucella vaccines source organisms.
- Collected information from research studies performed under the DTO and incorporated it into a read-ahead technical data package for a pre-IND meeting planned with FDA in early 2004. However, FDA concluded, based on the submitted read-ahead package, that the proposed vaccine candidate was insufficiently attenuated at immunologically effective doses. They therefore determined that this attenuated vaccine candidate should not be further developed.

Research to develop a vaccine against Yersinia pestis, causative agent of pneumonic plague (DTO CB.34)

- Continued expanded immunogenicity and efficacy studies in higher animal species and downselected the best higher animal species model.
- Continued studies to optimize vaccine production and formulation to support entry of the vaccine candidate into the Technology Development phase.
- Updated and revised the technical data package based on studies completed in FY03, to facilitate development of the F1-V fusion antigen vaccine candidate.
- Prepared and tested new batches of F1-V fusion antigen protein, V protein, and F1 protein.

- Created a new expression system and purification method for V protein and recombinant V protein.
- Transferred pertinent documentation and reagents in support of a National Institute of Allergies and Infectious Diseases (NIAID)-sponsored effort to develop the F1-V plague vaccine.

DTO CB. 34 Recombinant Plague Vaccine Candidate

The objective of this DTO, which completed in FY03, was to complete preclinical development of the recombinant F1-V fusion protein plague vaccine candidate. An effective FDA licensed vaccine against aerosolized plague will enhance force protection and strategic mobility, since the previously licensed plague vaccine's performance was less than adequate and it is no longer manufactured. The program exploited a gene fusion of coding sequences from the F1 capsule subunit and V antigen of Yersinia pestis to produce a unique immunogenic protein, designated as F1-V, from an E. coli expression vector. Biochemical studies of the F1-V fusion antigen conducted under this DTO include characterization of the higher-order structure of the protein by use of a unique technique known as size exclusion chromatography-multiangle light scattering (SEC-MALS). Expanded animal studies for immuno-genicity and efficacy were performed in two different animal models (mice and non-human primates) and comparative pathology was conducted to evaluate an alternative non-human primate (NHP) species as a model for pneumonic plague. The F1-V vaccine candidate induced high levels of efficacy (80% survival) against aerosolized plague in immunized groups of cynomologus macaques. Antibodies to the fusion protein (mouse and NHP) were demonstrated to represent surrogate markers for efficacy by passive transfer into mice. Data collected conducted under the DTO led to acceptance by the advanced developer of the F1-V vaccine candidate into the Technology Development pre-acquisition phase in July 2002. A competitive enzyme linked immunosorbent assay (ELISA) using monoclonal antibodies to both the F1 and V components of the vaccine was established as the basis of an in vitro assay for an immune correlate to protection. A study to examine the range of protection provided by the vaccine against other virulent strains of Y. pestis was initiated under the DTO and a study to elucidate the upper limit of protection in two different NHP species was begun in FY03 and will provide data to support preparation of an investigational new drug (IND) application for phase 1 clinical trials. The limit of protection study will extend into FY04 and will be executed in the non-DTO supporting research program.

DTO CB. 31 Medical Countermeasures for Brucellae

The objective of this DTO, which completed in FY03, was to develop a genetically characterized, live attenuated vaccine that elicits cellular and humoral immunity against the biological warfare (BW) threat of Brucella capable of protecting 90% of vaccinated warfighters against disease after aerosol exposure. Brucellae are highly infectious bacteria that cause incapacitating illness after aerosol exposure. A BW attack using multi-drug resistant organisms, which have been produced as vaccine strains, would complicate an already difficult antimicrobial treatment regimen. The DTO provided proof-of-concept in animals for live, attenuated vaccines designed to protect from disease caused by aerosolized B. melitensis. Vaccine candidates created by genetically engineered deletion of genes required for intracellular survival of Brucella were demonstrated to be effective against pulmonary and/or conjunctival challenge of mice and non-human primates (NHP) by oral vaccine administration. A candidate was downselected and shown to protect NHPs from fever (100%) and bacteremia (75%) following a conjunctival dose of 107 B. melitensis 16M bacteria, which is 10,000-100,000 times the 50 % infectious dose and 100 times the dose used in published estimates of the public health impact of a BW attack. The program developed experimental models of brucellosis in mice and NHPs and several

DTO CB. 31 Medical Countermeasures for Brucellae
vaccine candidates were evaluated. The initial vaccine construct, patented on 17 August 1999, provided the first description of a live, genetically attenuated vaccine in the scientific literature. Four additional genetically engineered bacterial strains were discarded as vaccine candidates and 6 additional strains that show promise for future developmental research were partially characterized. A patent was issued on 3 September 2002 covered some of these strains. A provisional patent application describing additional strains that show promise for development of a polyvalent vaccine against multiple BW threats was filed in December 2002. Data have been collected and summarized in a format appropriate for a pre-IND meeting with FDA. FDA concluded, based on the submitted read-ahead package, that the proposed vaccine candidate was insufficiently attenuated at immunologically effective doses. They therefore determined that this attenuated vaccine candidate should not be further developed.

Bacterial Therapeutics:

Overarching Research Objective: Identify and characterize candidate antibiotics and biologics, using laboratory and appropriate animal models. Demonstrate their capability for reducing mortality or incapacitation in animal models exposed to predicted or presumed battlefield doses of aerosolized bacterial biological warfare agents, to include Bacillus anthracis (anthrax), Yersinia pestis (plague), Burkholderia mallei (glanders), and Burkholderia pseudomallei (melioidosis). Research studies range from basic and applied research in bacterial therapeutics to research nearing the point of maturity for elevation to Defense Technology Objective (DTO) status.

Basic and Applied Research Accomplishments:

- Correlated metabolic measurements as a rapid and sensitive means to detect antibiotic activity with conventional susceptibility determinations and appropriate animal models of infection.
- Established collaborative research and development agreements with pharmaceutical companies to test new and investigational antibiotics.
- Initiated evaluation of selected therapeutic compounds against Brucella.
- Evaluated novel antibiotics and other therapeutics in established in vitro assays and animal models.
- Established a database of therapeutic profiles for various species of bacterial threat agents.
- Conducted comparative assessments in animal models for safety and efficacy of immunomodulators and other types of broad-spectrum compounds against multiple bacterial threat agents.
- Completed development of a model for untreated pneumonic plague in African green monkeys and conducted antibiotic efficacy studies using gentamicin, levofloxacin, and ciprofloxacin in African green monkeys exposed to aerosolized plague bacteria.
- Identified several inhibitors of anthrax lethal factor (LF) by using a multi-stage screening assay system. Identified two new lead therapeutic compounds using x-ray crystallographic data, molecular docking studies, and 3-dimensional database mining from the National Cancer Institute and commercially available chemical repositories. Determined that many of the identified lead compounds exhibited competitive inhibition and that the identified LF inhibitors, when tested in cell-based cytotoxicity assays, had promising protective capability.

- Determined the minimum inhibitory concentration (MIC) for 62 antibiotics against twenty two strains of B. anthracis and determined MICs at two temperatures (37º and 28º C) for 62 antibiotics on eight strains of Yersinia pestis.
- Developed an aerosol model for anthrax challenge in mice and established lethal dose 50% (LD_{50}) doses for B. anthracis Ames spores in four strains of mice. Correlated the antibiotic efficacy for ciprofloxacin and doxycycline in this mouse model to data obtained in the non-human primate model. Tested monoclonal-antibody-antibiotic combinations and some immunomodulator therapies in the mouse aerosol anthrax model to determine their effect on the anthrax toxin.

Toxin Agent Countermeasures

The countermeasures, technical barriers, and accomplishments in the Toxin Agent Countermeasures area are outlined below.

Countermeasures:

- Vaccines that produce long-term protective immunity against toxin agents.
- Drugs that can be administered prior to toxin exposure to protect against toxic effects of the agent.
- Therapeutics for treatment of diseases/symptoms caused by toxin agents.

*Technical Barrier*s:

- Development of appropriate model systems that emulate human aerosol exposure and intoxication.
- Methods for induction of respiratory and mucosal immune responses that produce long term protective immunity at the agent's port of entry.
- Development of markers of pulmonary inflammation in animal models.
- Identification and development of appropriate animal models for investigation of surrogate endpoints of human clinical efficacy.
- Retention of toxin antigenicity without toxic properties for vaccine candidate.
- Insertion of stable genetic alteration of toxin biological targets to produce toxin-resistant biological targets.
- Generic protection from families of toxins with subtle alterations in toxic modes of action.
- Necessity to enhance the otherwise limited data on which to base rational drug design and antibody therapies for toxin agents of interest.
- Necessity to establish and maintain capabilities to assess toxin threats and provide countermeasures for new and emerging toxin threats.

Toxin Vaccines

Overarching Research Objective: Develop candidate prophylactic medical countermeasures (vaccines and pre-treatments), using appropriate laboratory and animal models, and demonstrate their capability for preventing or reducing mortality and morbidity in animals exposed to predicted or presumed battlefield doses of aerosolized toxin biological threat agents. Research studies range from basic and applied research in toxin vaccines to research nearing the point of

maturity for elevation to Defense Technology Objective (DTO) status. DTO research efforts are designed so that data generated from these efforts meet requirements for transition out of the technology base and are consistent with technical information required by the advanced developer for development of an Investigational New Drug (IND) application.

Basic and Applied Research Accomplishments:

- Compared the efficacy of constructs with neutralizing epitopes in other domains of botulinum neurotoxin serotypes with the current heavy chain (Hc) subunit toxin vaccine candidates.
- Completed the scale up production of recombinant BoNT serotype C (Hc) in the Pichia pastoris expression system. Yields obtained were up to 200 mg purified vaccine per kilogram of yeast cells. The candidate vaccine elicited significant protective immunity against toxin in mice.
- Identified additional resources to conduct process development work for botulinum toxin serotypes D and G vaccine candidates in the Pichia yeast expression system.
- Demonstrated that recombinant BoNT serotype B heavy chain subunit vaccine elicited protection in mice against toxins from C. botulinum strains OKRA, 17B, 53B, 169B, and 213B.

Vaccine Defense Technology Objective (DTO) Research Accomplishments:

Research Toward Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB.32):

- Downselected formulations for intranasal, inhalational, and/or transdermal delivery of recombinant protein vaccines.
- Proposed monovalent vaccine formulations for intranasal, inhalational, and/or transdermal delivery systems.
- Evaluated various commercial or proprietary devices and proposed several for further research for delivery of recombinant subunit vaccines.
- Performed initial efficacy studies for single recombinant protein delivered by alternate route(s).
- Proposed an in vitro correlate of immunity for surrogate endpoint of clinical efficacy.

Research Toward the Development of a Recombinant Ricin Vaccine (CB.46):

- Completed efficacy studies in rodents on recombinant ricin toxin A-chain (rRTA) vaccine candidates and downselected to a lead candidate and an alternate for follow-on research studies. These studies demonstrated that the vaccine candidates, in combination with Alhydrogel as an adjuvant, protected mice against super-lethal aerosol exposures of ricin toxin.
- Demonstrated conclusively that the lead recombinant ricin vaccine candidate has a reduced tendency to self-aggregate compared with the parent ricin toxin A-chain molecule.
- Performed scale up process development for lead rRTA vaccine candidate.
- Conducted analytical test qualification for identity and stability studies of lead rRTA candidate.

- Developed a potency assay for rRTA vaccine candidates.
- Accelerated higher animal species model development for testing the lead rRTA vaccine candidate. Outcome of these studies demonstrate that the African green monkey appears to be an excellent model to study the pathophysiology of inhaled ricin toxicity and the efficacy of candidate ricin vaccines.
- Potent immune responses to ricin were induced by skin patch immunization in mice with 10 μg of antigen. Geometric mean ELISA endpoint titers to native ricin were 150,000 and neutralization antibody assays continue. Seventy percent of the mice immunized by transcutaneous immunization (TCI) were protected from intranasal ricin challenge. Experiment directed toward further optimized formulations for TCI continue.

DTO CB. 32 Alternative Delivery Methods for Recombinant Protein Vaccines

Objectives. The objective of this DTO is to explore and evaluate alternatives to the injection of recombinant protein-based vaccines that result in mucosal and systemic immunity to. select validated biological warfare (BW) agent. Technologies that enable respiratory, transdermal, and oral delivery of vaccines will be investigated.

Payoffs. Significant mortality and morbidity are associated with inhalation exposure to threat agents such as staphylococcal enterotoxins (SE), Bacillus anthracis, and Yersinia pestis. Recombinant proteins developed by the tech base for use as vaccine antigens are available for each of these agents, and studies in rhesus monkeys demonstrate that parenterally administered vaccines are effective against inhalational challenge. The SEs are also incapacitants in human subjects. Although parenterally administered SE vaccine candidates protected rhesus monkeys from lethal SE type B challenge, full protection against incapacitation was not obtained. Data suggest mucosal and systemic immunity are required to prevent lethality as well as incapacitation caused by SE exposure. Mice immunized intranasally with SE vaccines were protected from inhalation and intraperitoneal toxin challenges and demonstrated significantly higher levels of mucosal antibodies than in mice immunized intramuscularly. A mucosal respiratory immune response may improve vaccine efficacy by providing immunity at the portal of agent entry. Potential CRADA partners have been identified that can share expertise in technologies for delivery of biological factors. This will facilitate rapid transition of candidates. Needle-less administration of vaccines reduces health and logistical risks involved with the use of needles. Intranasal, transdermal, inhalation, or oral immunization strategies may be safer and more efficacious methods for stimulating mucosal and systemic immunity.

Challenges. Major technical challenges include developing animal models and defining endpoints that predict performance of vaccine candidates in humans, selecting the best route of administration to optimize concomitant respiratory and systemic immunity, selecting adjuvant/device combinations that are safe and stimulate protective immune responses, and developing vaccine formulations with sufficient stability for respiratory (aerosol or intranasal), transdermal, or oral delivery.

Milestones/Metrics.

FY2004: Demonstrate efficacy of needle-less combination vaccines. Propose formulations of combination vaccines for intranasal/inhalation and transdermal delivery. Conduct baseline studies of combination vaccines in animal models.

FY2005: Demonstrate proof of concept of the lead needle-less vaccine delivery strategy(ies). Complete program studies and prepare a technology development plan(s) for follow-on nonclinical studies of the lead/optimum delivery strategy(ies).

DTO CB. 46 Recombinant Ricin Vaccine
Objectives. The objective of this DTO is to develop a safe and effective vaccine for protection against aerosol exposure to ricin toxin. A goal is demonstration of 80% (threshold, objective is 90%) survival of vaccinated animals exposed to aerosolized ricin toxin at levels comparable to hypothetical battlefield exposures. Novel ricin A-chain polypeptides produced by recombinant expression vectors will be evaluated as immunogens capable of protecting against ricin toxicity.
Payoffs. No licensed vaccine, antidote, or other medical therapy is available to protect Service members against ricin toxin. A licensed ricin vaccine will enhance force protection and virtually eliminate the threat of aerosolized ricin as a biological weapon to U.S. forces.
Challenges. Developing vaccine candidates that do not retain the undesirable characteristics of vaccines produced from the natural toxin, e.g., enzymatic activity, aggregation in the vial, and manufacturing process that did not meet current Good Manufacturing Practices (cGMP) standards.
Milestones/Metrics.
FY2004: Develop toxicity assays and assess respiratory pathology in small animal models. Recommend optimal dosing and immunization schedule for the lead immunogen. Conduct breakthrough efficacy studies at recommended dose and schedule. Define a manufacturing process that will yield formulated vaccine candidate in sufficient quantities to conduct non-human primate (NHP) studies. Develop a NHP model for evaluating efficacy of the vaccine candidate.
FY2005: Conduct a formal review of small animal studies prior to initiating NHP work. Conduct efficacy studies (surrogate marker of clinical efficacy) and adjuvant studies in NHP model.
FY2006: Recommend a vaccine formulation for the recombinant Ricin vaccine candidate that meets the advanced developer's requirements for phase 1 clinical trials and demonstrate stability of the protein immunogen in the formulation. Complete pathology studies in the NHP model. Provide technical data from completed vaccine research studies to the advanced developer for incorporation into an Investigational New Drug (IND) application.

Toxin Therapeutics:

Overarching Research Objective: Develop candidate therapeutic countermeasures (therapeutic drugs and immunotherapies), using appropriate laboratory and animal models, and demonstrate their capability for preventing or reducing mortality and morbidity in animals exposed to predicted or presumed battlefield doses of aerosolized biological toxin threat agents, to include botulinum neurotoxins, staphylococcal enterotoxins (SE), and ricin toxin. Efforts target the respiratory tract and other portals of entry and parameters defining the efficacious performance of the therapeutic agent obtained in appropriate animal models of aerosol intoxication. Research studies range from basic and applied research in toxin therapeutics to research nearing the point of maturity for elevation to DTO status.

Basic and Applied Research Accomplishments:

- Identified novel human and chimeric monoclonal antibodies by phage display methodology to aid in determining potential as botulinum neurotoxin therapeutics.
- Research studies provided evidence that the chick DRG neurons cease axonal growth in the presence of Botulinum neurotoxin A (BoNT A), thereby showing that these neurons are sensitive to the toxin and are therefore a good model for use in BoNT therapeutic research studies. This method is being adapted to a high/or medium-throughput

procedure using various innovative scanning methods. Staining chick DRG neurons with the lipid raft marker Cholera toxin subunit B (CTB) showed a concentration of lipid rafts at the growth cone, extending work done earlier for this project that showed lipid rafts concentrated at the growth cones of NGF-treated PC12 cells. Lipid rafts may aid in the entry of toxin.

- In collaboration with the National Cancer Institute and the University of Nebraska, computer modeling studies of BoNT inhibitors, identified in initial high-throughput screening, yielded several bisquinoline compounds that exhibited improved inhibition and specificity, compared to the original compounds.
- Cloned, expressed, and purified BoNT serotype G light chain (LC) for use in screening for inhibitors of protease activity. To date, bulk quantities of recombinant LC for types A, B, C, and G toxins have been produced. These are being used to screen for BoNT inhibitors.
- Completed the synthesis of a series of 15 "second generation" peptide inhibitors of botulinum neurotoxin A. These new analogs will enable better definition of the structural requirements for efficient inhibitor binding.
- Performed custom synthesis of lead compounds identified by high-throughput screening assays for botulinum neurotoxin and SE toxins.
- Co-crystallized toxin and lead therapeutics and collected x-ray diffraction datasets.
- Supported development of combinatorial libraries and diversity sets for potential toxin therapeutics.
- Continued high-throughput assessment of candidate therapeutic inhibitors for botulinum neurotoxin.
- Completed testing and development of cell-free assay for assessment of candidate therapeutic inhibitors of SE.
- Selected lead candidate inhibitors based upon results in cell-free and cell-based assays and prepared toxin-inhibitor crystals for x-ray diffraction analysis.
- Evaluated the outcome of structural stabilization and optimization studies on lead inhibitors of botulinum and SE.
- Prepared sufficient amounts of lead inhibitors of botulinum toxin and SE type B intoxication for testing ex vivo or in vivo.
- Evaluated feasibility of drugs approved by FDA for septic shock as adjunct SE therapeutics using in vitro assays.
- Using a cell-based assay, several inhibitors for SEA and SEB interaction with MHC class II receptors were identified. Many of the compounds showed inhibition in flow cytometry and several contain a common polycyclic aromatic motif. A Pharmacophore hypothesis is being developed to guide the research through subsequent steps.
- Using the cell-based assay, several natural extracts that inhibit SE:MHC class II receptor interactions were identified. The extracts will be further purified and fractionated by HPLC and other biochemical methods. Purified fractions will be retested in the cell-based assay.
- Determined LCT_{50} for aerosolized SEB in HLA-transgenic mice to be about 70 ug/kg. Pathology examination determined that, similar to rhesus monkeys, substantial amounts of perivascular edema and inflammatory infiltrates were noted in the lungs of the transgenic mice exposed to aerosolized SEB. It was also determined that aerosolized

SEB could induce high levels of IFN-gamma in serum even 24 hrs after challenge by aerosol. Currently, IFN data is being correlated with hypothermia to determine feasibility for use biomarkers for incapacitation.

- The antimicrobial drug, doxycycline, is another potent inhibitor of SEB-induced effects in human peripheral blood mononucleocytes (PBMC). Doxycycline was shown to block SEB-induced IL-1b, TNFa, IL-6, IFNg, MCP-1, MIP-1a and MIP-1b, and T cell proliferation in vitro. Bacalin, a flavonoid from a medicinal herb, showed delay in death and prevented lethal effects in 20% of DQ8 transgenic mice exposed to SEB aerosol. Further refinement in dosage and/or timing of administration of bacalin are necessary to maximize the in vivo effects. Two compounds previously shown to be effective in down-regulating SEB-induced effects were found to have different modes of inhibition. Pentoxifylline inhibited SEB-induced cytokines and cell adhesion molecules as well as the effects of proinflammatory cytokines, IL-1 and TNFa. Doxycycline inhibited only SEB-mediated effects but with no additional effect on downstream cytokine action. Oral dosing of pentoxifylline in nonhuman primates was shown to suppress SEB-induced cytokines ex vivo.

Viral Agent Countermeasures

The countermeasures, technical barriers, and accomplishments in the Viral Agent Countermeasures area are outlined below.

Countermeasures:

- Vaccines that confer immunity against viral threat agents.
- Antibodies and antiviral drugs for treatment of viral disease.

Technical Barriers:

- Logistical difficulties from the necessity to work with live viral agents in high- and maximum-containment (BL3 and BL4) laboratories.
- Difficulty in optimizing and comparing different expression vectors for recombinant products (vaccines and antibodies).
- Development of rapid virus identification technology.
- Insufficient or incompletely understood animal model systems for investigation of viral threats and countermeasures.
- Necessity to develop and fully characterize animal models for eventual FDA licensure of vaccines under the Animal Rule.
- Development of multivalent vaccines and compatible vaccine platforms to protect against an array of unrelated viral agents.
- Difficulty in defining surrogate markers of protection.
- Necessity to enhance the otherwise limited data on which to base rational drug design and antibody therapies for viral agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new, emerging, and genetically engineered hazardous viruses.

Viral Vaccines:

Overarching Research Objective: Identify and characterize candidate vaccines, using appropriate laboratory and animal models, and demonstrate their capability to protect or significantly reduce morbidity in animals exposed to predicted or presumed battlefield doses of aerosolized viral biological warfare threat agents, to include filoviruses (Ebola and Marburg viruses), orthopoxviruses and alphaviruses. Focus on molecular virology, applied immunology, and pathogenesis. Research studies range from basic and applied research in viral vaccines and associated scientific disciplines to research nearing the point of maturity for elevation to DTO status. DTO research efforts are designed so that data generated from these efforts meet requirements for transition out of the technology base and are consistent with technical information required by the advanced developer for development of an IND application.

Basic and Applied Research Accomplishments:

- Completed investigating poxvirus immunity to aid in determining the feasibility of replacing vaccinia immune globulin (VIG) with monoclonal antibodies and for constructing a new vaccine to replace the vaccinia virus vaccine for smallpox.
- Investigated the role of cytotoxic T cells in the Ebola virus-mouse model.
- Assessed the mechanism of immunity that protects against disease from filoviruses (Marburg and Ebola viruses) in lower animal species models.
- Developed assays to measure markers to validate the efficacy of vaccine candidates in established model systems for filoviruses.
- Tested promising vaccine strategies in higher animal species for the ability to protect against filoviruses (Marburg and Ebola viruses).
- Developed higher animal species models for western equine encephalitis virus (WEE) vaccine research studies.
- Continued research studies for the development of vaccine candidates for eastern and western equine encephalitis virus (EEE and WEE).
- Completed murine efficacy studies for W2130, resulting in a decision to make it the lead candidate for a live western equine encephalitis (WEE) vaccine. Initiated mixing studies to examine interference between the V3526 vaccine candidate, derived from VEE virus subtype IA/B, and the W2130 candidate. Found that all mice survived Venezuelan equine encephalitis (VEE) challenge, but not WEE challenge when vaccines wee given simultaneously.
- Using a novel approach, isolated a cleavage deletion strain of EEE virus by serial passage in a furin-deficient cell line. Determined that this virus carried a partial deletion of the furin cleavage site, PE2 glycoprotein. Identified an additional virus containing a deletion within the EEE E3 glycoprotein, which significantly attenuated the virus. Vaccinated mice by aerosol with the mutants and found they sustained 100% survival.

Vaccine Defense Technology Objective (DTO) Research Accomplishments:

Research toward the Development of Medical Countermeasures for Encephalitis Viruses (CB.24)

- Completed studies on production of the live attenuated Venezuelan equine encephalitis (VEE) virus vaccine constructs, their genetic stability, and their transmission potential as live attenuated viruses in competent vector mosquitoes.
- Challenged 54 non-human primates that had been vaccinated with the V3526 vaccine candidate (20 at a 'low' challenge dose, 34 at a 'high' challenge dose) and found that V3526 alone was sufficient for protection against VEE-IA/B and VEE-IE.
- Challenged 30 non-human primates with VEE-IIIA after vaccination with V3526 vaccine candidate and found that V3526 alone was sufficient for protection against VEE-IA/B, VEE-IE, and VEE-IIIA.
- Demonstrated that the lead Venezuelan equine encephalitis (VEE) vaccine candidate, V3526, induced protection against the three VEE virus subtypes of concern (IA/B, IE, and IIIA), which would significantly reduce the complexity of a multivalent VEE vaccine.
- Completed analyses of the stability, safety, and efficacy (potency) of V3526 in mouse and higher animal species models.
- Determined the surrogate protection marker to be serum-neutralizing antibody in the higher animal species model.
- Completed the technical data package for the V3526 vaccine candidate and handed it off to the advanced developer.

Viral Therapeutics:

Overarching Research Objective: Identify and characterize candidate therapeutics/ treatments, using appropriate in vitro laboratory and animal models, and demonstrate their capability to reduce mortality and morbidity in animals exposed to predicted or presumed battlefield doses against aerosolized viral biological warfare threat agents, to include filoviruses (Ebola and Marburg viruses) and orthopox viruses. Research studies range from basic and applied research in viral vaccines and associated scientific disciplines to research nearing the point of maturity for elevation to DTO status.

Basic and Applied Research Accomplishments:

- Initiated development of intervention strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy.
- Further characterized the innate immune response in mice, which indicated that a subset of cytokines could protect mice from lethal Ebola virus challenge.
- Continued research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target.
- Developed an assay for high-throughput interaction between Ebola virus proteins (VP40 and TSG101).
- Continued assessing the potential for immunotherapy against Ebola virus in higher animal species models.

- Initiated characterization of sixteen monoclonal antibodies to identify other protective epitopes on Ebola virus glycoprotein (GP).
- Identified pharmacological compounds provided by industry that disrupt filovirus growth in cell culture.
- Assessed therapeutic action of compounds in mouse and higher animal models of filovirus infection.
- Continued research for development of a variola animal model at the Centers for Disease Control and Prevention (CDC).
- Evaluated the combined approach of antiviral drug therapy and immunotherapy in treatment of disease from filoviruses and further characterized three new antiviral targets against Ebola.
- Continued evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox viruses.

DTO CB. 54 Therapy for Smallpox and other Pathogenic Orthopoxviruses

Objectives. The objectives of this DTO are to develop medical countermeasures against smallpox and other orthopoxviruses, focusing on intravenous (IV) cidofovir (Vistide.) as the initial lead candidate but with planned product improvement to an orally active prodrug of cidofovir as the final product. The orally active prodrug will build on the systems developed for and data obtained from the IV cidofovir evaluation. Specifically, research will be performed to develop a therapeutic antiviral drug to treat smallpox and other naturally occurring or genetically modified pathogenic orthopoxviruses.

Payoffs. Smallpox is highly infectious by aerosol and causes severe disease with high mortality. It is highly contagious and release of smallpox would result in a worldwide epidemic unless countered by a combination of vaccinia vaccination, quarantine, and antiviral drug treatment of infected cases. Recent publications on genetically modified ectromelia (mousepox), that contains an inserted mouse cytokine gene expressing IL-4, indicate that the modified virus shows greater pathogenicity than wild type virus. Therapy (pre- and post exposure) based on a drug that inhibits the viral DNA polymerase should still inhibit viral replication and might constitute a first line of defense against either an unmodified smallpox in unvaccinated individuals or genetically engineered smallpox or monkeypox in the entire population. An oral drug could be administered post exposure to large number of troops after a release of genetically modified smallpox as well as protecting the large number of troops for whom vaccinia vaccination is counter-indicated prior to smallpox release.

Challenges. Developing appropriate model systems that emulate human aerosol exposure and infection- if such a demonstration can be made, it can be substituted for a human efficacy clinical trial by using the Food and Drug Administration (FDA) animal efficacy rule. Initial results show that disease can be produced in cynomolgous monkeys with authentic variola virus; however, model development has not been completed. An excellent model using the closely related orthopoxvirus monkeypox in cynomolgous monkeys has been utilized to demonstrate drug and vaccine efficacy. It will be necessary to correlate this model with the variola model. Under the FDA Animal Efficacy Rule, it would be highly desirable to obtain a clinical description of human monkeypox in order to provide correlation to the animal models. The best opportunity is in the Democratic Republic of Congo, currently experiencing ongoing civil strife.

Milestones/Metrics.

FY2004: Complete drug efficacy evaluation in the animal models selected for this project. Compare the

DTO CB. 54 Therapy for Smallpox and other Pathogenic Orthopoxviruses
variola and monkeypox animal models and human monkeypox to facilitate understanding of disease pathogenesis. Complete virology studies and animal efficacy studies to obtain data on the optimum therapeutic approach for treating orthopoxvirus disease. Begin research toward development of an oral prodrug of cidofovir by completing an initial dose seeking study in the monkeypox primate model. **FY2005:** Continue evaluation of oral prodrug of cidofovir to determine if it is a replacement for IV cidofovir. Complete studies to evaluate drug efficacy in primate models that support the FDA Animal Efficacy Rule. Evaluate activity in two monkeypox primate animal models. If the oral prodrug is non-inferior, transition the research effort to the oral prodrug (oral drug delivery is most desirable method of drug administration for military use). **FY2006**: Conduct initial evaluation in pock lesion variola primate model at the Centers for Disease Control and Prevention. Evaluate oral cidofovir prodrug therapeutic window against monkeypox and variola in primate models. Conduct initial studies to determine drug efficacy. **FY2007**: Complete studies to evaluate drug efficacy in primate models that support the FDA Animal Efficacy Rule. Compile technical data to provide to the commercial partner to support consideration of the drug candidate for licensure for use as an oral smallpox therapeutic.

Diagnostic Technologies

Countermeasures:

- Portable common diagnostic systems for a broad range of biological threats.
- Field laboratory capability to identify biological threat agents.
- Reference laboratory for confirmatory identification of biological threat agents.

Technical Barriers:

- Development of identification technologies and reagents of sufficient sensitivity and specificity to support early disease diagnosis.
- Development of rapid processing methods that can be used with a broad array of possible clinical specimens, including whole blood, sputum, swabs, feces, and tissues.
- Reduction of laboratory methods to portable devices.
- Lack of available data on genetic variability pertaining to markers used for diagnostic development.
- Inability to type organisms specifically and determine geographic origin.

Diagnostic Technologies:

Overarching Research Objective: Perform research leading to the development of technology candidates (reagents, protocols and devices) for inclusion into a deployable state-of-the-art identification and diagnostic system that integrates multiple methods for the identification of potential biological warfare agents and the diagnosis of diseases they cause. The aim is to develop and integrate technologies so they will be capable of identifying multiple independent biomarkers from different agents simultaneously. The goal is to transition these technologies out of tech base to the advanced developer for development and fielding of a portable, integrated FDA-approved medical diagnostic system that can be used by medical personnel to identify and confirm health threats and rapidly diagnose disease.

Basic and Applied Research Accomplishments:

- Conducted basic research on new diagnostic approaches to the early recognition of infection.
- Developed reagents and associated assays to aid in identifying new host and agent-specific biological markers that can be used for early recognition of infection.
- Continued research to develop, evaluate, and explore new technological approaches for diagnosis of potential biological warfare threat agents and for concentrating and processing clinical samples to support rapid identification and diagnostics.
- Applied new diagnostic approaches to the early recognition of infection, adapting the technologies to current and future comprehensive integrated diagnostic systems.
- Applied new technological approaches for diagnosis of potential biological warfare threat agents in laboratory and field studies using relevant clinical samples.
- Applied new technological approaches for concentrating and processing clinical samples to support rapid biological agent identification.
- Applied research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.
- Continued comparing alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory.
- Compared overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies.
- Continued to develop, evaluate, and transition diagnostic assays out of the technology base in support of the Joint Biological Agent Identification and Diagnostic System (JBAIDS) acquisition program.

Diagnostic Technologies Defense Technology Objective Accomplishments:

Research Toward an Improved Immunodiagnostic Platform (DTO CB.47)

- Identified immunodiagnostic technology options offering performance and design characteristics capable of addressing operational requirements of the JBAIDS acquisition program.
- Demonstrated technical capability for detection of at least three biological agents (including toxins) in three biological matrices within two hours with the immunodiagnostic technology options.
- Conducted comparative laboratory evaluation trial of the immunodiagnostic technology options and identified top performing immunodiagnostic platform based on results of the laboratory evaluation trial.

DTO CB. 47 Improved Immunodiagnostic Platform
Objectives. One objective is to develop a deployable immunologically-based medical diagnostic system (reagents, protocols and devices) for the identification of biological threat agents and the diagnosis of diseases they cause. The focus is the identification of toxin agents in clinical samples with the levels of sensitivity and specificity required for FDA-approved medical diagnostics. Another objective is development of assays that can serve as confirmatory tests of other medical diagnostic systems. A joint-service/agency product development team will coordinate research and development and develop and update the program strategic plan as required.

DTO CB. 47 Improved Immunodiagnostic Platform
Payoffs. An immunologically based diagnostic capability will allow medical personnel to identify and confirm health threats and rapidly diagnose clinical disease. The outcome of this effort will meet the requirements for Block II improvement to the Joint Biological Agent Identification and Diagnostic System (JBAIDS). Therefore, a major payoff is rapid transition of the technologies (reagents, protocols, and devices) developed under the DTO into an existing acquisition program (JBAIDS). DoD and other laboratories have evaluated improved medical diagnostic technologies for several years. Several promising technologies offer important improvements over more traditional technologies currently being used in forward laboratories for medical diagnostics. In light of recent events and the increased awareness of biological terrorism and bioweapons, the availability of improved immunodiagnostic capabilities and the ability to rapidly transition such technologies presents important opportunities to medical diagnostics in the DoD.
Challenges. The development of rapid processing methods that can be used with a broad array of clinical specimens, including whole blood, sputum, swabs, feces, and tissues and reduction of macro laboratory methods to portable devices.
Milestones/Metrics.
FY2004: Conduct a multi-center evaluation trial of immunodiagnostic platforms identified during the first year. Prepare technical data package detailing the results of the trial. Provide technical data package to JBAIDS overarching IPT and make recommendations on technologies for incorporation into JBAIDS Block II.

Reducing Reliance on the use of Animals as Subjects of Research:

Overarching Objective: The objective in this research thrust area is to develop methods and processes supporting medical CBRNDP objectives while reducing the reliance on animal models. In FY03 the program objectives were to research new computational methods for modeling protein structures at atomic resolution, to apply computational methods to protein structure predictions of genetically engineered toxins, and to explore alternate vaccine designs and therapeutics.

- Developed a fast and accurate solvent model for computer simulations of protein structures.
- Modeled structural genomics of protein conformational loops.
- Successfully predicted molecular interactions between botulinum neurotoxins and their substrates in support of research directed toward botulinum drug discovery.

DARPA Biowarfare Defense Programs

Unconventional Pathogen Countermeasures Program

The focus of this thrust is the development of revolutionary, broad-spectrum medical countermeasures against pathogenic microorganisms and/or their pathogenic products. By identifying those features of biological threat agents that are essential for their ability to cause disease and then undermining these disease-causing mechanisms, the medical countermeasures under development will be versatile enough to eliminate biological threats, whether from natural sources or modified through bioengineering or other manipulation. They will also have

the potential to provide protection both within the body and at the most common portals of entry (*e.g.*, inhalation, ingestion, and transcutaneous). Strategies include:

- Defeat of a pathogen's ability to enter the body, traverse the bloodstream or lymphatics, and enter target tissues;
- Identification of novel pathogen vulnerabilities based on fundamental, critical molecular mechanisms of survival or pathogenesis (*e.g.*, Type III secretion, cellular energetics, virulence modulation);
- Construction of unique, robust vehicles for the delivery of countermeasures into or within the body;
- Development of effective treatments for late stage injections; and
- Modulation of the advantageous and/or deleterious aspects of the immune response to significantly neutralize pathogenic microorganisms and/or their pathogenic products in the body.

The work is divided into three main thrust areas: antiviral/immunizations, anti-bacterials/anti-toxins and multipurpose agents. Specific approaches currently under development include the identification of critical cellular pathways necessary for the proliferation of pathogens in the host, development of broad-spectrum vaccination schemes, development of broad-spectrum antibiotics with reduced chance of resistance development, enhancement of innate immunity, plant-based vaccine production and other protein production, and development of novel decontamination approaches for bio-threat agents. The key part of this research is conducted as part of the following DTO.

DTO CB. 27 Therapeutics Based on Common Mechanisms of Pathogenesis

Objectives. This DTO will to develop a suite of medical countermeasures against broad classes of biological pathogens (bacterial, viral, bioengineered, etc.) that share common mechanisms of pathogenesis.

Payoffs. Effective pathogen countermeasures may not eliminate the threat of biological warfare (BW) by a determined adversary, but they can provide a significant disincentive to its use. Program success will provide vaccine and therapeutic countermeasures that will reduce the threat of biological warfare and its operational impact through the development of new broad-spectrum antivirals and antibacterials. These will be particularly important for emerging and bioengineered threats for which there are no current countermeasures.

Challenges. The exploitation of modern genetic engineering by adversaries to develop "super pathogens" or to disguise virulent agents in harmless and ubiquitous microbes is of concern. A recent unclassified CIA report states "Growing understanding of the complex biochemical pathways that underlie life processes has the potential to enable a class of new, more virulent biological agents engineered to attack distinct biochemical pathways and elicit specific effects. This emerging capability puts an even greater stress on our ability to detect and combat the medical consequences of exposure and infection. In addition, some potential operational environments could cause generalized immuno-suppression, further increasing both the risk from biological threats and the need for robust immune defenses.

Milestones/Metrics.

FY2005: Transition of lead therapeutic candidates to USAMRMC for continued development.

DARPA medical countermeasures research includes: (1) enhance existing vaccines or create new ones that respond to newly discovered signals of microorganisms or protect against many BW pathogens simultaneously, (2) develop new therapeutics to which resistance cannot be developed, (3) prime the human immune system to prevent many, if not all infections, and (4) develop ways of detecting the biosignatures of infection to permit earlier diagnosis, (5) development of an artificial immune system to rapidly develop vaccines against BW threats.

(1a) Among the projects directed toward new or improved vaccines is one that has been accelerated to provide an improved anthrax vaccine in the near term. This project couples an existing DARPA project to develop a synthetic immunostimulant (CPG 7909) with the currently licensed anthrax vaccine. In the last year, the companies involved have developed a consortium to conduct an initial proof-of concept clinical study under FDA supervision that is planned to start in 2QFY04. The goal of this study is to see if a more rapid response can be achieved with the combination that could permit more rapid deployment of troops into a threat environment. If the response of the combination is more robust, it would also allow for a smaller requirement for the vaccine thereby expanding the supply of vaccine, reduce the requirement for number of vaccines or immunization schedules; resulting in greater flexibility and fewer time constraints in fielding a protected force.

(1b) Among the vaccine-oriented projects, efforts are underway to identify new anthrax cell and spore surface targets to enhance vaccine efficacy, develop a single-dose oral/nasal anthrax vaccine, and overcome engineered microorganisms with combinatorial vaccines.

(1c) Another project is trying to determine what coding sequences different organisms have in common in order to come up with a vaccine that will be effective against two or more organisms. The focus of this project is plague and anthrax.

(1d) Molecular engineering is the primary tool of another project that is trying to construct a benign virus that will target lymphoid tissue and carry the portion of the anthrax DNA that codes for PA, the "protective antigen" that serves as the basis of vaccine activity. This project is also using novel chemo-attractant molecules to stimulate vaccine responses.

(1e) A revolutionary project generates a 3-dimensional matrix populated with naive T cells from immature blood-generating cells. This is an approximation of an artificial thymus gland. The value of this system is that it can be used to predict which determinates (epitopes) of a threat agent may be useful for development of improved vaccines.

(1f) Capitalizing on progress in the knowledge of dendritic cells, the initiators and regulators of immunity, or “nature’s adjuvants”, DARPA is manipulating direct and in-vivo enhancement of immunity. These efforts have resulted in protection against pathogens and increase in vaccine efficacy.

(1g) Another effort is underway to produce livestock that exclusively produce human antibodies. If successful, this project will produce large amounts of human polyclonal antibodies directed against the battlefield pathogen of choice.

(2a) The scarcity of national resources for testing the countermeasures developed by DARPA performers necessitated the establishment of a biosafety level 3 (BSL-3) laboratory in which common data sets could be developed. A 3500 square foot laboratory was converted to a BSL-3 facility in which rodent pulmonary models for anthrax, tularemia, plague and cowpox

were developed. In addition, chronic infusion models for delivery of short half-life therapeutics that can enhance current therapy for anthrax were also established. The second hurdle for testing of candidate drugs was the lack of availability of rhesus macaques. This problem was alleviated by sponsoring a bridging study to show equivalency with a cheaper and more available monkey species, the cynomologous monkey. A second bridging study to marmoset species is ongoing at Porton Down, UK.

(2b) Specific inhibitors of bacterial enzymes required for bacterial growth have been identified. These compounds are in a new class of small chemical molecules (antibiotics) that do not inhibit analogous human enzymes.

(2c) A class of small molecule antigenomic therapeutics (SMATs) has been discovered that provide a significant deterrent countermeasure against the use of biological weapons. A single therapeutic agent protects against a broad spectrum of bacterial and viral threat agents by targeting selective DNA signatures. Because of the broad spectrum of action of these molecules and their new mechanism of action, they would be useful for the initial treatment of an individual who had been exposed to an unknown agent while a determination was made of the nature of the organism so that a focused treatment could begin.

(2d) New phage derived enzymes have been discovered that provide precision kill of bacteria in the blood stream with no collateral damage to the host. These are enzymes that selectively destroy biowarfare (BW) bacteria, such as B. anthracis, C. botulinum, Y. pestis. Experiments so far have shown 90% survival rate for mice when challenged with B. anthracis (ames strain) and then treated with PlyG enzyme.

(2e) Thioaptamers are semi-synthetic molecules that specifically bind proteins necessary for controlling the development of pathogenic viruses. Thus far, these molecules have demonstrated improved survival of mice and guinea pigs following a virus infection.

(2f) Another project is developing novel drug targets common to more than one biowarfare agent that are essential for growth in the host. The genes produced in this work will form the basis of high-throughput screens for new drugs. Essential pathways have been identified so far for cholera, tularemia, and tuberculosis.

(2g) Among the efforts to generate therapeutics is a project that utilizes high performance computers to exhaustively generate and optimize alternative conformations of small molecules. This approach greatly reduces the amount of time necessary to develop drug candidates.

(2h) Genome sequence data serves as the basis for identifying new targets for intervention in the processes of anthrax spore resistance and germination. In addition to generating new candidate drugs with new mechanisms of action, this approach will be useful for generating new sporicidal agents that are non-toxic.

(2i) Genetic manipulation for host cell resistance to viral pathogens is a strategy that employs the rationale that virus requires the cooperation of host cell genes to accomplish many of the steps toward propagation/infection. The required host genes have been identified by a novel procedure that enables the selection of cells that consequently become resistant to virus-induced lethality. A series of gene products necessary for infection by ASFV and foot and mouth disease have been identified and will be tested in a transgenic pig production. For

bacterial toxins, screening cDNA libraries are being screened to produce knock-out mice defective in genes required for toxin effects. Both techniques are being utilized to produce transgenic animals for toxin resistance to validate the identified genes as targets for prophylactic and/or therapeutic countermeasures to virus or toxin effects.

(2j) The ability to discriminate between superantigens and conventional antigens using monoclonal antibodies is the focus of another project. The antibodies thus generated will hopefully be useful for diagnostic as well as therapeutic purposes. This project is also screening for immunomodulators that prevent death from toxemia.

(3) In addition to the testing for vaccine enhancement noted above, the immunostimulant CPG 7909 is also being tested as monotherapy in animal models to see if it can provide short-term protection for a variety of threat diseases. This project will soon be transitioned to the NIAID for further development.

(4) Early diagnosis is key to providing effective therapy against BW agents, since many agents cause early nonspecific flu-like symptoms. The goal of the DARPA Advanced Medical Diagnostics thrust is to develop the capability to detect the presence of infection by biological threat agents, differentiate from other significant pathogens, and identify the pathogen, even in the absence of recognizable external signs and symptoms (when the pathogen numbers are low). Several projects in this program are focused on improving our ability to detect disease, particularly in its earliest stages.

(4a) One of these is focused on the innate mechanism of the immune system used to sense a pathogen. Several sensing proteins generated by the immune system have been detected. The mammalian toll-like receptors (TLRs) are at the core of innate immune sensing and detection of essentially all infections. Genetic methods are being utilized to identify new proteins involved in the initiation of innate immune signals with the ultimate goal of creating an artificial sensor for infection.

(4b) A DNA probe has been designed for pathogen identification. It can test for hundreds of virus strains within times as short as 1 hour. The system enables robust in-the-field diagnostics for entire pathogen complex on a single microfluidics card with sensitivity and specificity rivaling a laboratory-based system. Moreover it is resistant to pathogen mutation and does not require pathogen cultures. Microfluidics cards have pre-printed assays with simple two-step sample handling that enable parallel screening for hundreds of pathogen strains for as low as $10 per assay.

(4c) Another project is focused on the biosignatures produced by a host and the way they change during the earliest time of infection. Data are being collected by a variety of micro methods to determine changes in DNA, RNA and protein expressions. Since common data sets are generated for different diseases in the participating labs, it is possible to compare and contrast the results across diseases.

(5) Construction of an artificial immune system for high-throughput vaccine development and testing has many advantages including shortening the time for development of a functional human vaccine to a BW threat. Vaccine development and testing is an expensive and time-consuming process. It can be enhanced by pushing MEM-sorted progenitor cells to become B and T cell lineages, and by using conformal printing of a scaffold that is capable of

sequential growth factor release in new bioreactor technologies, antibody production to fight the BW agents will result. Additionally, the T and B cells developed by this process can be engineered for dry-tolerance (using DARPA developed technology) making them adaptable for transportation without refrigeration.

E.2.3 Advanced Development Accomplishments

The Program Executive Office for Chemical and Biological Defense (PEO-CBD) is a DoD agency chartered to provide intensive centralized management of medical and non-medical programs to expedite materiel solutions for validated biological defense deficiencies. Vaccine products will be further developed by the Joint Vaccine Acquisition Program (JVAP), an ACAT II program under PEO-CBD. Vaccines directed against high threat agents will be produced and stockpiled to fulfill a 1.2 million Troop Equivalent Doses (TEDs) requirement (Note: TED = total amount of vaccine required to immunize a service member to protect against a biological warfare agent.) Vaccines against low threat agents will be produced to fulfill a 300,000 TEDs requirement.

E.2.3.1 Botulism Immune Globulin (Human), Pentavalent (IND #1332)

- The IND remains open to accommodate emergency treatment requirements for exposure or possible exposure to botulinum toxin types A, B, C, D, or E.

E.2.3.2 Anthrax Vaccine Adsorbed (AVA) (BioThrax™)

- Bioport has distributed over 3.8 million doses of BioThrax™ to the DoD as of October 2003.

E.2.3.3 Botulinum (Pentavalent) Toxoid Adsorbed (ABCDE) Vaccine (IND#3723)

- Clinical trial data showed that the vaccination schedule plus 6 months booster does not stimulate sufficient protective immunity against all serotypes (A, B, C, D, and E) to meet battlefield protection level requirements. However, a 15-month booster vaccination stimulates the desired level of immunity for a defined period.
- Based upon the marginal performance of the vaccine, difficulties in producing new lots of vaccine, and progress being made with a new recombinant product, the JVAP PMO is not currently proceeding with efforts to produce and license this product.

E.2.3.4 Botulism Immune Globulin $F(ab')_2$, Heptavalent, Equine, Types A, B, C, D, E, F, & G IND (#7451)

- This product does not meet the Combat Developer's requirements as an effective battlefield countermeasure. Further efforts to develop and license this product have been stopped.

E.2.3.5 Title IX Supplement Funding for Special Studies

- (Smallpox) Support the expansion of Phase 1 clinical smallpox vaccine trials in accordance with the FDA requirement to obtain data sufficient for submission of a licensure application for the DoD cell culture-derived new smallpox vaccine.
- (VIG) Processing, bottling and regulatory approval of all available vaccinia immune globulin (VIG), a product used to treat some adverse reactions to Smallpox vaccine.
- (Plague Vaccine) Increased funding for oral vaccine candidates.

- (NGAV) Increased funding for oral vaccine candidates.
- (NGAV) Stability and toxicity testing of candidate next generation anthrax vaccine candidate products.
- (VEE) Formulation and lyophilization process development studies.
- (BOT) Development of polyclonal humanized BOT A, B, C, E, F antitoxin product.
- (Protocols) Contingency use protocols.

E.2.4 Joint Vaccine Acquisition Program (JVAP) Accomplishments

E.2.4.1 Prime Systems Contract

- DynPort Vaccine Company continued to expand their operations, finding appropriate commercial subcontractors to engage in the advanced development of BD vaccines (Smallpox vaccine, Tularemia vaccine, Recombinant Botulinum vaccine, Botulinum Polyclonal anti sera, Next Generation Anthrax vaccine, recombinant plague vaccine, Venezuelan equine encephalitis vaccine, and Vaccinia Immune Globulin.

E.2.4.2 Contingency Stockpile of Biological Defense (BD) Vaccines

- Testing of potency and other characteristics, continues for legacy EEE, VEE, WEE, Tularemia and Q-Fever vaccines.

E.2.4.3 Advanced Development of the Tularemia Vaccine

- Completed characterization studies and continued development of surrogate marker of efficacy.
- Conducted immunogenicity and toxicity studies.
- Completed cGMP pilot lot production and initiated final container stability testing of pilot lot.

E.2.4.4 Advanced Development of the Smallpox Vaccine

- Under the JVAP Prime Systems Contract, BioReliance Corporation of Rockville, Maryland was selected as the manufacturer of the new Smallpox vaccine. BioReliance continued manufacturing efforts by completing process definition studies, manufacturing a GMP pilot lot suitable for a phase 1 clinical trial, and validating a plaque reduction assay to demonstrate product potency. Validated plaque reduction assay is required by the FDA.
- The final report from a clinical trial to evaluate the candidate vaccine administered by scarification, indicates that the candidate is safe and immunogenic similar to the old licensed product, Dryvax™. A phase 1 trial for the newly manufactured product was completed in February 2003.
- Filed an annual report with the FDA under IND #8429 to insure continued availability of previously manufactured Vaccine Immune Globulin (VIG), which allows clinical trial to proceed.
- DynPort Vaccine Company filed the first annual report for IND (#9141) for a new VIG product for intravenous administration. Three lots have been manufactured by Massachusetts Biologics Laboratory, Boston, Massachusetts. A clinical trial using this material is currently in data analysis, and two more lots are being manufactured.

- A plaque reduction assay necessary for lot release testing of the VIG product and to evaluate clinical specimens from both VIG and Smallpox vaccine trials has been developed and is being validated by BioReliance Corporation, Rockville, Maryland. Clinical specimens from the aforementioned VIG trial will be assayed once this method is validated.

E.2.4.5 Advanced Development of the Plague Vaccine

- Initiated a multi-national (U.S. and United Kingdom) test in non-human primates with the United Kingdom's plague vaccine candidate.
- Initiated process development of the U.S. plague vaccine candidate.

E.2.4.5 Advanced Development of the Next Generation Anthrax Vaccine (NGAV)

- Initiated first-time-in-humans Phase 1 clinical trial of rPA in cooperation with the Walter Reed Army Institute of Research (WRAIR).

E.2.4.6 Advanced Development Venezuelan Equine Encephalitis Vaccine

- Continued assay development and qualification for VEE IA/B component.
- Continued stability and lot release testing on lot of V3526.
- Conducted non-human primate neurovirulence testing and equine safety study with V3526.

E.2.4.7 Advanced Development Recombinant Botulinum Toxin Vaccine

- Completed initial adjuvant formulation studies.
- Completed cGMP manufacture of bulk serotype A.
- Initiated non-clinical safety studies.
- Initiated planning and preparation for Phase I Clinical Trial

E.2.4.8 International Cooperative Research and Development

- The new Chemical Biological and Radiological Memorandum of Understanding (CBR MOU) between the U.S., the UK, and Canada (CANUKUS) was signed and implemented on 1 June 2000. The United States and Canada signed a bi-lateral Project Arrangement (PA) under the CBR MOU on 27 March 2003 to co-operatively develop a Smallpox vaccine system with the U.S. as the lead nation. The PA objectives include development and licensure in both the U.S. and Canada of a Smallpox vaccine and a Vaccinia Immune Globulin (VIG) to treat rare cases of adverse reactions. The VIG portion of the PA is expected to be successfully completed in FY04. The Smallpox vaccine portion of the PA is currently under review by both nations in light of the Department of Health and Human Services (DHHS) efforts to develop a Smallpox vaccine. Pending the results of the Defense Science Board (DSB) review and recommendation of the DoD Smallpox vaccine candidate and DHHS Smallpox candidate to obtain FDA licensure and the availability of funding, the DoD acquisition strategy and the PA will be revised accordingly.
- In addition to the Smallpox vaccine system PA, the DoD is currently negotiating a Plague vaccine PA with the United Kingdom's Ministry of Defence and the Canadian Department of National Defence. Negotiations for the Plague vaccine PA are expected to be completed by December 2003.

E.2.4.8 Joint Biological Agent Identification and Diagnostic System (JBAIDS)

The JBAIDS program is designed to fill a medical mission critical need to rapidly identify and confirm Biological Warfare (BW) and Infectious Disease (ID) agents in both environmental and clinical specimens. JBAIDS will provide medical personnel with the capability to identify the biological agents within one hour of specimen analysis. This system will provide this capability at a lower system cost, reduced logistical burden and with greater reliability than currently available commercial laboratory methods.

JBAIDS will be comprised of commercial and developmental identification technologies, components and military hardware integrated into a single platform. The design will stress modularity and capability for future technology insertion.

The Joint Program Executive Officer for Chemical and Biological Defense has structured the JBAIDS program in a block development format in order to expedite procurement and fielding while reducing technical risk. Block I is focused on quickly transitioning mature technology from the commercial sector to a fielded system; and coordinating the Food and Drug Administration (FDA) clearance process for JBAIDS. The JBAIDS Block I development contract was awarded to Idaho Technology, Inc. in September 2003. System hardware and assay testing is planned to start in March 2004, with system fielding to military users in the second quarter of FY05. Block II will focus on automation of the sample preparation process, inclusion of new technologies for toxin identification, reductions in size and weight, with improved reliability, and obtaining FDA clearance for all remaining gene probes and primer sets.

E.2.4.9 Integrated Digital Environment (IDE)

In order to meet the Under Secretary of Defense for Acquisition, Technology & Logistics mandate to transition acquisition activities to an IDE by 2002, and to achieve the streamlining and savings associated with the mandate the JVAP PMO continued efforts to establish a BD vaccine enterprise-wide IDE in collaboration with DynPort. An automated program assessment tool tailored to vaccine development has been developed and implemented at the PMO. DynPort, LLC has established a web-based, shared data base system. A detailed IDE system requirements analysis was completed in early 2000 and included implementation of an IDE test bed. In 2001, an IPT of government and contractor personnel completed an analysis of Electronic Data Management Systems and recommended Livelink for the JVAP IDE. Livelink licenses have been purchased and full-scale implementation was initiated late CY 2001. Implementation of Livelink has also expanded to include the Biological Defense Research Laboratory - United States Army Medical Institute of Infectious Diseases (USAMRIID). Implementation of common IDEs in both Tech Base and Advanced Development activities will provide significant streamlining opportunities.

E.3 MEDICAL RADIOLOGICAL DEFENSE

E.3.1 Medical Radiological Defense Products

Appropriately applied, advances in medical science and biotechnology can significantly affect the warfighting mission by sustaining unit effectiveness and conserving the fighting strength of our service members. The individual service member whose performance is decremented by injury or illness is significantly more likely to become a traumatic casualty. In this era of small, but highly lethal forces, loss of only a few team members can dramatically diminish a unit's capability. Medical R&D products (materiel and non-materiel solutions) provide the foundation that ensures 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 have provided significant improvements in military effectiveness in the past, and new developments promise even greater improvements in the future.

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

In addressing the issue of currently limited medical countermeasure alternatives, a novel radioprotective compound, 5-androstenediol (5-AED), has been under study the past three years at the Armed Forces Radiobiology Research Institute (AFRRI) in collaboration with a corporate partner, and it is anticipated to be ready for an investigational new drug (IND) application by the end of 2004 under the FDA's new efficacy rule. The compound, one of a number of pharmacologic solutions under investigation at AFRRI, is well tolerated with minimal toxic side effects, and it affords good radioprotection in a rodent model at radiation doses approaching 100% lethality. In recent non-human primate pilot studies, 5-AED also proved efficacious when administered therapeutically after irradiation. If successful, 5-AED would be an important advancement in the area of medical radiological countermeasures, and it would represent a prelude to the probable transitioning of additional medical countermeasures against radiological injury in the near- and intermediate-term future.

The following is a summary of the materiel and non-materiel solutions currently available for medical radiological defense:

- Antimicrobials directed at Gram-negative aerobes and facultative Gram-positive bacteria.

- Cytokine-based therapeutic applications to prevent two major fatal syndromes—sepsis and uncontrolled bleeding—of acute radiation injury.
- Definitive cytogenetic analytical system that accurately measures radiation exposure doses from blood samples.
- NATO Handbook on the Medical Aspects of NBC Defensive Operations, Volume 1-Nuclear (AMedP-6).
- Medical Management of Radiological Casualties Handbook.
- Medical Effects of Ionizing Radiation (MEIR) Course—Training for approximately 864 Medical Department personnel in FY03.
- Videotapes and CD-ROM of MEIR course lectures produced for distribution to military medical units.

E.3.2 Medical Radiological Defense R & D Accomplishments

The medical radiological defense research and development technical barriers and accomplishments during FY 03 are grouped into the following two thrust areas and sub-efforts:

- Medical Radiological Countermeasures
  - Radioprotectants
  - Therapeutics
  - Depleted Uranium
- Diagnostic Biodosimtery
  - Cytogenetic Markers
  - Molecular Markers

Medical Radiological Countermeasures Thrust Area

Countermeasure approaches, technical barriers, and accomplishments in the Medical Countermeasures area are outlined below.

Countermeasure Approaches:

- Pharmacologic agents that neutralize highly reactive oxygen species that are generated in tissues upon the deposition of ionizing radiation and that are a major cause of tissue damage.
- Small molecular weight synthetic agents that modulate cell cycle regulatory checkpoints by reversibly arresting cell division to allow a cell's natural surveillance and repair mechanisms time to correct DNA damage before lethal mutations become incorporated into daughter cells.
- Small molecular weight synthetic molecules that inhibit apoptotic pathways that are activated by ionizing radiation and that lead to programmed cell death.
- Antimicrobial agents to effectively treat systemic infections caused by enteric microorganisms that translocate across damaged intestinal epithelium.
- Recombinant hematopoietic growth factors that stimulate the replication and maturation of bone marrow progenitor cells to help reverse myelosuppression, and restore circulating polymorphonuclear leukocytes and platelets.
- Recombinant keratinocyte growth factor that stimulates the regeneration of epithelial cells from basal progenitor cells.

- Medical treatment strategies to mitigate injuries induced by protracted exposure to radiation from both external and internal sources.
- Improved techniques to detect and remove internally deposited sources of radioactivity.
- Improved drug delivery systems that provide non-encumbering protection during the entire period of radiation exposure.

Technical Barriers:

- Minimizing the performance-degrading effects of prophylactic drugs that otherwise have good efficacy for the prevention of radiological injury.
- Advancing knowledge of cellular, sub-cellular, and molecular mechanisms of radiological injury to improve rational development of prophylactic and therapeutic drugs.
- Increasing drug stability in order to improve bioavailability and enhance therapeutic and prophylactic efficacy.
- Formulating slow-release drug delivery preparations that extend bioavailability and enhance efficacy.
- Engineering pharmacologic means of up-regulating cellular damage surveillance and repair mechanisms.
- Toxicity of chelating agents used to remove internally deposited radionuclides.
- Evolving microbial resistance to antibiotics.
- Developing appropriate animal models and bridging endpoints for extrapolating data from animal studies to human efficacy predictions acceptable to the FDA for licensure of drugs under the new efficacy rule.

Accomplishments:

- Demonstrated radioprotective efficacy of the soybean-derived isoflavone genistein in a rodent model when administered subcutaneously 24-hours prior to irradiation.
- Demonstrated in preliminary experiments that daidzein, a compound related to genistein, also provides radiation protection.
- Demonstrated that the radioprotective Vitamin E analogue, alpha-tocopherol, stimulates an increase in circulating erythrocytes in irradiated mice.
- Improved the original formulation of a sustained-release, lipid-encapsulated (liposomal) drug delivery system for the combined administration of aminothiol and Vitamin E to achieve approximately 35% drug loading.
- Completed a pilot study demonstrating that the epidermal cytokine, keratinocyte growth factor (KGF), likely provides therapeutic benefit in an irradiated mouse model challenged with the exogenous infectious pathogen *Klebsiella pneumoniae*.
- Completed preliminary *in vitro* studies to assess the effects of the pharmacologic agents 5-AED, epigallocatechin (EGCG), and phenylacetate on expression of radiation-induced biomarkers that correlate with carcinogenicity under a project area to identify countermeasures against the latent effects of ionizing radiation injury.
- Developed a leukemogenesis mouse model that can be used to study the pre-leukemic phase, to identify oncogenic changes and to define factors that contribute to the development of leukemia, and that can be used to test the efficacy of prophylactic or therapeutic drugs.

- Identified patterns of host-defense modulation at the molecular level in macrophage cell lines following sublethal irradiation and viral (influenza) infection, and determined that NFkB is a primary regulatory element of macrophage response to virus.
- Initiated collaborative studies with a corporate partner to evaluate the cellular and molecular mechanisms of action of the radioprotective compound Ex-Rad ON01210.
- Completed a pilot study in a canine model demonstrating synergistic efficacy with a combined therapeutic regimen consisting of the cytokines IL-11 and G-CSF.
- Initiated efforts to improve the sensitivity of the earlier developed rapid urine uranium detection assay by testing synthetic imprinted polymer resins to concentrate uranium from urine prior to analysis.

***Medical Radiological Defense Technology Objective (DTO) Research Accomplishments*:**

Research to develop pharmacologic prevention of ionizing radiation injury (DTO MD.18)

- Determined 5-AED's radioprotective action is related to induced radioresistance of vital hematopoietic stem cells.
- Demonstrated in a rodent model that 5-AED stimulates phagocytotic activity in circulating granulocytes and oxidative burst in circulating monocytes.
- Radioprotective efficacy of 5-AED prophylaxis demonstrated in a large experimental animal model.
- Comparable radioprotective blood cell mobilizations demonstrated in small and large experimental animal models following 5-AED prophylaxis.
- Initiated pre-clinical cGLP pharmacokinetic and toxicology studies of 5-AED with a contract laboratory in preparation for an investigational new drug application.

DTO MD.18 Pharmacologic Prevention of Ionizing Radiation Injury
Objectives. This DTO will develop advanced medical strategies for the prevention of radiation injuries. Pharmacologic interventions based on 5-androstene steroids (5-androstenediol and analogs), a novel class of radioprotectants, will be designed and tested in preclinical model systems. Results will define the decision point for possible transition to clinical testing of preventive treatments designed to maximize protection of personnel against early arising radiation syndromes (e.g., performance decrement and lethality).
Payoffs. Effective mitigation of health consequences and performance-degrading effects will (1) reduce the casualty load at medical treatment facilities; (2) sustain a more effective operational force after a radiation exposure event; (3) allow commanders to conduct operations in radiation field environments with reduced risk of decremented performance due to acute tissue injury; and (4) reduce the negative psychological impact on personnel tasked to operate in contaminated environments. Very significant reductions in acute casualty rates are expected based on recent animal studies.
Challenges. The major technical challenges include: (1) determining the efficacy of protective treatments under multiple exposure conditions; (2) determining the optimal routes of drug administration; (3) determining effects of slow-releasing radioprotective drug during protracted external radiation exposures; and (4) sustaining optimum therapeutic drug levels in the blood and tissues without undue toxicity.
Milestones/Metrics.

DTO MD.18 Pharmacologic Prevention of Ionizing Radiation Injury
FY2004: Generate data sets under preclinical current Good Laboratory Practices-controlled conditions for drug safety, toxicity, and efficacy in small- and large-animal models that will meet FDA guidelines for IND application under the new efficacy rule governing drugs that cannot be ethically tested in human trials.

Research to develop countermeasures against bacterial sepsis after irradiation (DTO MD.29)

- Determined the efficacy of several antibiotics including ceftriazone and gentamicin and three quinolones (trovafloxacin, gatifloxacin, and moxifloxacin) to protect against opportunistic infection with *K. pneumoniae* in sublethally irradiated mice.
- Identified some of the microorganisms that cause sepsis following radiation in an animal model.
- Developed an experimental mouse model to assess the effectiveness of *Lactobacillus reuteri* to protect against radiation-induced enteric infections.

DTO MD.29 Medical Countermeasures against Bacterial Sepsis after Irradiation
Objectives. This DTO will develop combined treatment modalities against lethal or incapacitating radiation-induced bacterial sepsis. Polymicrobial sepsis is the leading cause of death following acute, whole-body irradiation. Ionizing radiation depresses immunity and damages intestinal epithelium, both of which promote microbial translocation from the intestines and sepsis. Effective medical counter-measures for battlefield-sustained radiation mass casualties will require a radically different approach than what is used to manage patients receiving chemotherapy or fractionated radiation therapy under highly controlled conditions. Appropriate antimicrobial therapy is critical because bacteria develop resistance; use of the inappropriate antimicrobial therapy exacerbates the injury. Therapy must target only the endogenous and exogenous bacteria – both Gram-positive and Gram-negative – causing sepsis and not the beneficial gut microflora including anaerobic bacteria. Use of antimicrobial agents alone does not assure recovery from sepsis in an irradiated, neutropenic animal; nonspecific biological response modifiers (BRMs) can improve outcomes by promoting innate resistance to infection. This effort will examine BRMs and antibiotics separately and in combinations in a rodent model to enhance treatment strategies for radiation-induced infections. Findings can be transitioned to preclinical studies to secure an FDA indication for combination therapy for managing bacterial infections in irradiated personnel. Results will allow recommendations for optimal choices for treatment that will enhance survival in military operational environments. **Payoffs**. Successfully achieving the objective will provide a treatment strategy for radiation-induced bacterial sepsis that: (1) Effectively reduces morbidity and mortality; (2) reduces casualty loads at medical treatment facilities; (3) shortens therapeutic intervention and accelerates return to duty; (4) reduces the requirement for prolonged antibiotic therapy, thereby lessening the likelihood of inducing antimicrobial resistance; and (5) helps to sustain a robust fighting force in nuclear or radiological environments. **Challenges.** Technical challenges include: (1) selecting most appropriate antimicrobial agents in the face of continuously changing bacterial causes of sepsis and patterns of antimicrobial resistance; (2) use of selected BRMs to support antimicrobial therapy; (3) evaluating efficacies of therapeutic combinations; and (4) extrapolating animal data to humans.

DTO MD.29 Medical Countermeasures against Bacterial Sepsis after Irradiation
Milestones/Metrics. **FY2004**: Report predominant Gram-positive and Gram-negative bacterial pathogens isolated from heart blood following lethal irradiation in a rodent model, and report their susceptibilities to selected antimicrobial agents. Evaluate agents such as gatifloxacin, ciprofloxacin, levofloxacin, ceftriaxone, cefepime, and gentamicin to identify the most efficacious drugs for radiation-induced infections to cover Gram-positive and Gram-negative bacteria in an irradiated rodent model. Achieve 80% or better survival following lethal irradiation. **FY2005**: Determine benefit of BRMs for preventing and alleviating radiation-induced infections in a rodent model. Demonstrate efficacy of BRMs beta-1,3-glucan and 5-androstenediol. Achieve 50% or better survival following a lethal radiation dose combined with a lethal bacterial challenge. **FY2006**: Complete studies in rodent model to identify the best combination BRM/antimicrobial strategy for radiation-induced infections. Achieve 95% or better survival using a combined BRM/antimicrobial strategy following lethal irradiation.

Research to understand the toxicity of embedded depleted uranium (DTO MD.21)

- Uranium redistributes with time to various organs and tissues, especially bone and kidney
- Embedded DU causes no apparent changes in kidney or bone histology
- Determined that DU induces mutations in a marker gene (HPRT) *in vitro*. DU causes genomic instability and transforms cells to a cancer phenotype. This research using cultured cells indicates that DU is a potential carcinogen.
- Genotoxicity and mutagenicity of DU *in vivo* is under investigation.

DTO MD.21 Toxicity of Embedded Depleted Uranium
Objectives. The objective is to determine the long-term health effects of exposure to depleted uranium (DU) fragments by characterizing multiple biological indices indicative of carcinogenicity using experimental model systems. **Payoffs.** Friendly fire incidents in the Gulf War produced DU shrapnel injuries among U.S. soldiers. The success of this new class of munitions guarantees its large-scale deployment by future adversaries, greatly increasing the number of casualties with DU fragment injuries. Little is known of the health risks from chronic exposure to embedded DU fragments due in part to DU's unique combination of radiological and toxicological properties. Current treatment strategies are in the most basic stage of development, and conventional diagnostic capabilities do not differentiate DU from other shrapnel injuries. This technology effort will define the pathologic consequences of chronic exposure to tissue-embedded DU fragments using generally accepted in vitro and in vivo experimental systems, and develop rapid assessment tools to identify personnel wounded with DU. Data will provide risk analyzers and managers the information needed to develop policies addressing the health hazards of DU, and to establish safe and effective treatment strategies to minimize the long-term health risks from DU shrapnel. **Challenges.** Groups such as the U.S. National Toxicology Program have established guidelines for carcinogenicity studies that propose testing not only whether a suspected carcinogenic agent can induce

DTO MD.21 Toxicity of Embedded Depleted Uranium
tumors in animals, but also whether the agent can induce physiological and genetic changes in cells that indicate a carcinogenic potential. Such experiments are complex and labor intensive, involving both cultured cells and lifespan studies with laboratory animals. The greatest challenge of this effort is the design of specific experimental models (i.e., choice of cells or animals used, routes and levels of exposure, and methods of endpoint analysis) that most accurately reflect the specific health hazard. **Milestones/Metrics.** **FY2004**: Complete in vivo 24-month rat study and submit final pathology report on findings.

Diagnostic Biodosimetry Thrust Area

Countermeasure approaches, technical barriers, and accomplishments in the Diagnostic Biodosimetry area are outlined below.

Countermeasure Approaches:

- Cytologic methods to estimate the absorbed dose of radiation based on microscopic imaging of aberrant chromosome morphologies arising from damage to nuclear DNA.
- Quantitative analytical methods that measure alterations in blood protein levels, cellular messenger RNA levels, or DNA sequences (mutations), the degrees to which correlate with absorbed radiation dose.
- Computer and personal digital assistant (PDA) based software tools for collecting, managing, interpreting and archiving clinical and physical data for individual radiation casualties.

Technical Barriers:

- Difficulty in identifying and calibrating biological markers that correlate quantitatively with absorbed radiation dose and that differentiate between whole-body and partial-body exposures.
- Difficulty in automating sample preparation and reducing sample preparation times for cytogenetic-based biodosimetry tests.
- The challenge of developing automated image analysis software for scoring of chromosome aberrations in definitive cytogenetic-based biodosimetry tests.
- Establishing calibration curves for molecular biomarkers that encompass the entire spectrum of radiation qualities.
- Establishing calibration standards for non-persistent biomarkers that change quantitatively with time following irradiation.
- Validating the performance of novel molecular biomarkers for use in assessing human exposures.

Accomplishments:

- Developed a real-time PCR system for quantifying deletion mutations in mitochondrial DNA from circulating lymphocytes as a novel molecular biomarker for assessing absorbed radiation dose.
- Initiated studies to optimize the real-time and cytological DNA mutation bioassay to detect low-frequency DNA mutations.

- Developed biotinylated antibody cocktails for detecting radiation responsive proteins in serum to optimize the molecular biodosimetry microassay, and demonstrated the assay's ability to measure the radioresponsive protein GADD45 in an *ex vivo* irradiated human blood model.
- Demonstrated that radiation dose-dependent changes in gene expression molecular biomarkers can be measured in less than 3 hours after sample processing using nucleic acid amplification procedures on field-deployable analytical platforms.
- Incorporated an updated database for post-irradiation kinetic changes in lymphocyte and monocyte counts from the REAC/TS accident registry to enhance the clinical utility of the computer-based Biodosimetry Assessment Tool (BAT).
- Initiated a software engineering project to develop a BAT operating system compatible for use on personal digital assistants (PDA).

Diagnostic Biodosimetry Defense Technology Objective (DTO) Research Accomplishments:

- Filed patent application for the novel premature chromosome condensation (PCC) aberration assay under development for rapid cytogenetic analysis of radiation exposure across a broad dose range from interphase lymphocytes of peripheral blood.
- Developed an alternative rapid protocol suitable for automated scoring of chromosome aberrations in interphase cells.
- Validation of the premature chromosome condensation (PCC) assay using clinical samples acquired from victims of a radiation exposure accident in Thailand and from radiotherapy patients.

DTO MD.20 Cytogenetic-Based Diagnostic Biodosimetry System

Objectives. This DTO will develop a biodosimetry assay system based on chromosomal aberrations that permits a rapid, high-throughput capability to assess ionizing radiation exposure for large numbers of casualties.

Payoffs. Symptomatology and physical dosimeters, even when available, do not provide adequate diagnostic information to treat life-threatening radiation injuries. The objective assay system will provide physicians with the ability to definitively triage radiation victims, make appropriate treatment decisions, reduce the uncertainties associated with the variability of individual response to radiation exposure, and discriminate between cases of whole- versus partial-body exposures.

Challenges. Difficulties include reducing labor-intensive requirements for sample preparation, automating scoring of the chromosomal aberration assay, validating the assay for human use, and incorporating the assay into a rapid field-based system operable by a medical technician.

Milestones/Metrics.

FY2004: Complete in vivo studies validating chromosome aberration assay over a broad dose range and in partial-body exposure situations, and complete developments to automate scoring of the chromosome aberration assay.

FY2005: Deliver a biodosimetry system ready for Advanced Technology Demonstration.

Annex F

Homeland Security and Force Protection Programs

Table F-1. Homeland Security and Force Protection Programs RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
CBRN Defense Homeland Security Programs	- National Guard Weapons of Mass Destruction Civil Support Teams (WMD-CSTs)	RDTE/Prod Fielded*	*Rqmt,*	*Rqmt*	*Rqmt, Interest*	*Rqmt, Interest*
Force Protection/ Installation Protection	- JSIPP - Installation Protection Program	Prod/Fielded* Prod/Fielded*	Joint Joint	Joint Joint	Joint Joint	Joint Joint

Rqmt = Product Requirement
Interest = Product Interest
Int-NIR = Product Interest, No Imminent Requirement
* = sub-Product(s) of a Consolidated Joint Service Project
Rqmt, Interest = Sub-Product Requirement or Interest
Defense Technology Objective (Science & Technology Base Program)

CBRN Defense Homeland Security Programs

National Guard Weapons of Mass Destruction Civil Support Teams (WMD-CSTs)

Rationale:

Army requirement. Congress has authorized 32 WMD-CSTs. The first 10 teams authorized in the National Defense Appropriations Act for fiscal 1999 have achieved the certification required by law and in accordance with Department of Defense criterion. Seventeen additional teams were authorized in fiscal 2000, and five more teams were authorized in fiscal 2001. All of these teams are certified as well.

Key Requirements:

- The Analytical Laboratory System (ALS) capable of conducting presumptive analysis of unknown or potential agents (Chemical Warfare (CW) agents, Toxic Industrial Materials (TIM), Toxic Industrial Chemicals (TIC) and Biological Warfare (BW) agents) at an incident site and transmit that information electronically through the means of the Unified Command Suite (UCS).
- The UCS provides a full range of communications (both secure and non-secure data) necessary to support the CST mission. It is the primary means of reach back communications for the ALS for the WMD-CSTs, and acts as a command and control hub to provide a common operational picture for planning and executing an incident response.

Description:

The WMD-CST mission is to support civil authorities at a domestic CBRNE incident site by identifying CBRNE agents/substances, assessing current and projected consequences, advising on response measures, and assisting with appropriate requests for state support to facilitate additional resources. The WMD-CST is a high-priority response unit supporting civil authorities in responding to a weapon of mass destruction

situation. The unit is made up of 22 full-time National Guard members. It consists of six sections: command, operations, communications, administration/logistics, medical, and survey, who have been specially trained and equipped to provide a technical reach-back capability to other experts. The team is formed specifically to provide advice to the Incident Commander to help make assessments of the requirements for follow-on forces.

Force Protection/ Installation Protection

Joint Service Installation Pilot Program (JSIPP)

Rationale:

Army, Navy, Air Force, and Marine Corps requirement for the outfitting of nine installations, three from each Service Department. The Installations selected by Services are:

- Air Force: Warner-Robbins AFB, Pope AFB, Barksdale AFB,
- Army: Ft Campbell, Ft Lewis, Ft Gordon,
- Navy: NSWC Dahlgren, Naval Base San Diego,
- Marine Corps: Camp Lejeune.

Key Requirements:

- Equip nine diverse DoD installations with CBRN detection equipment.
- Enhance DoD installation emergency response capabilities with emergency responder equipment and training for installation consequence management of CBRN incidents
- Collect data and refine concepts of operations (CONOPS) for CBRN defense of similar DoD installations
- Based on CONOPS refinement, provide recommendations on resource requirements (personnel, equipment, and logistics support) to support development of future joint CB defense requirements to support installation CBRN defense preparedness and CBRN emergency responder needs.

Description:

The purpose of the JSIPP is to provide equipment and training to enhance detection, protection and emergency response capabilities for CBRN incidents on DoD Installations. The JSIPP will identify installation CBRN improvements for the military Services' requirements generation process. It includes two procurement efforts. The first effort is the procurement and installation of CBRN detection equipment designed to provide the installation commander increased preparedness and situational awareness supporting decision-making during a CBRN incident. The second effort will equip and train emergency response elements in consequence management procedures for CBRN incidents. JSIPP will provide guidance for training and exercises for installation CBRN defense efforts, collecting data and coordinating the assessments to support CBRN requirement recommendations for institutionalization throughout the Services. The JSIPP will provide CBRN defense force protection packages at nine installations (three per Service) in FY03. It will also fund related installation support equipment, integrated

logistics support (ILS), and operations and maintenance (O&M) and training. In addition to the CBRN defense force protection package, JSIPP will also provide each installation with equipment and training to enhance emergency response capabilities for CBRN incidents on military installations. It will involve organizing, equipping, training, and conducting exercises for installation emergency response personnel.

Installation Protection Program (IPP)

Rationale:

- Army, Navy, Air Force, and Marine Corps requirement: Urgent Requirements Capability Document (URC) signed 14 October 2003

Key Requirements:

- Capable of defending installations from CBRN threats
- Capable of preventing disruption of critical missions, rapidly resuming essential operations, and minimizing personnel impact.

Description:

The JPEO-CBD Joint Program Manager (JPM) Guardian Installation Protection Program (IPP) constitutes the DoD's first effort to field a full spectrum of CBRN installation protection capabilities designed as a family-of-systems (FoS) to military installations and DoD-owned or leased facilities. The JPM Guardian plans to procure Government and Commercial-Off-The-Shelf (GOTS/COTS) systems designed to meet the operational requirements as identified in the Urgent Requirements Capabilities Document (URC), 14 October 2003.

The IPP is designed to fill a critical gap in an installation's ability to react to a CBRN incident. This program will provide DoD prioritized installations with an integrated CBRN protection and response capability to reduce casualties, maintain critical missions, and effectively restore essential operations. JPM Guardian has an assigned mission to:

- Provide an effective CBRN detection, identification, warning, and protection system for each installation.
- Ensure integration of CBRN networks with existing Command, Control, and Communications, and augment capabilities to provide effective information management.
- Provide a CBRN capability that will allow for rapid restoration of critical installation operations.
- Protect DoD civilians, contractors, and other persons working or living on U.S. military installations and facilities from a WMD event.

The program is structured using a spiral acquisition strategy to expedite procurement and fielding. Technical risk will be reduced by focusing on mature GOTS/COTS technologies and products. This FoS package will be fielded as a single, integrated system designed to meet the specific needs of the installation. The design will stress flexibility and the capability for future technology insertion.

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Annex G

CBRN Defense Logistics Readiness Data

G.1 BREAKOUT OF SERVICE WAR REQUIREMENTS, STOCKS ON-HAND, AND PLANNED ACQUISITIONS

The following tables (**Tables G-1 through G-5**) display CBRN defense equipment FY03 stocks on-hand quantities (as of 30 September 2003), and FY04–05 planned procurements for each of the four Services and Defense Logistics Agency. As described in Chapter 3, the 1 Win Decisively (1 WD) and 2 Swiftly Defeat (2 SD) war requirements for consumables and for end items (non-consumables) are not yet available. The Services will develop new requirements from the results of the *Joint Chemical and Biological Defense Expendable Equipment Combat Consumption* (E^2C^2) study to meet the operational needs of the 1-4-2-1 force planning construct. Until the E^2C^2 study is complete, the Services do not have a current analytical basis for requirements modeling. Previous requirements have become outdated and are not consistent with the 1-4-2-1 construct. During this interim period while new requirements are being modeled and validated, numerical requirements are not yet available to be listed in this Annex.

The Services update these data call sheets on a frequent basis and consider these working papers rather than a static set of figures. The Services and DLA are working through the FY04 Joint Service CBRN Defense Logistics Support Plan to update all figures and to provide the essential information required for logistics readiness and sustainment assessments.

The 135 CBRN defense items listed under "**NOMENCLATURE**" in the tables are items that are currently fielded in the Services. The "**STOCKS ON-HAND**" represents the total of all serviceable CBRN defense materiel available in each of the Services (stocks positioned with troops, stocks in the supply system and stocks stored in depots/facilities, both peacetime stores and war reserve) minus any medical consumable that has been issued to individual service members (this materiel is considered dispensed and is no longer visible in the supply system). This number represents only those items physically "on-hand". Quantities for which a Service or agency has submitted a funded requisition or purchase order in FY03, but has not received the requisitioned items are included in FY04. Finally, the quantities depicted as "**PROJECTED DUE-IN**" are quantities the Services plan to buy to replace consumption of CBRN defense assets (to include training use and shelf-life expiration), and to buy wartime sustainment stocks. It must be emphasized that these numbers are based on major command estimates of requirements. Actual procurements are contained within the On-Hand Column.

"**TOTAL SERVICE REQUIREMENTS**" will be based on the results of the E^2C^2 study, and will include the quantity required for the entire Service (to include active and reserve forces), and will include peacetime replacements (wear and tear) and training requirements. "**TOTAL MODERNIZATION REQUIREMENTS**" will reflect the quantities of end items projected to be needed for active and reserve forces in the year 2009, based on the basis of issues for each item and the projected force strength.

Table G-1a. Army Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS				FY03	PROJECTED DUE IN							
		TOTAL SERVICE RQMT	TOTAL MODERN. RQMT	1 WD REQUIREMENT	2 SD REQUIREMENT	STOCKS ON HAND (as of 30 Sept 03)	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
INDIVIDUAL PROTECTION COMMODITY AREA														
CB MASK														
MASK, CB, M17A2	4240-01-143-2017-20					26,352	15,853							
MASK, CB, M40/M40A1	4240-01-258-0061-63					711,824	256,388							
MASK, M24, AVIATOR	4240-00-776-4384					888	5,980							
	4240-01-370-3821/3/4					2,120	23							
MASK, M25A1, TANK	4240-00-994-8750-52					303	3,140							
MASK, M42, TANK	4240-01-258-0064-66					84,469	44,770							
	4240-01-413-4100-02					3,680	73							
	4240-01-370-2622					1	0							
MASK, M43, APACHE	4240-01-208-6966-69					415	1							
	4240-01-265-2679					3	0							
MASK, M45, AVIATOR	4240-01-414-4034-35/-4051-52					13,849	5,554							
MASK, M45, LAND WARRIOR	4240-01-447-6987-9, 8967					0	0							
MASK, M48, APACHE	4240-01-386-0198/-4686/-0201/-0207					1,151	0							
MISC PROTECTION														
PATS, M41	4240-01-365-8241					3,118	1,643							
CONTAMINATION AVOIDANCE COMMODITY AREA														
NUCLEAR DETECTION EQUIPMENT														
AN/PDR-75	6665-01-211-4217					5,147	544							
AN/PDR-77	6665-01-347-6100					868	361							
AN/UDR-13	6665-01-407-1237					28,674	1,171							
AN/VDR-2	6665-01-222-1425					37,035	12,836							
BIOLOGICAL DETECTION EQUIPMENT														
BIDS, M31	6665-01-392-6191					59	14							
CHEMICAL DETECTION EQUIPMENT														
ACADA, M22	6665-01-438-6963					13,911	233							
ALARM, CAA, M8A1	6665-01-105-5623					17,877	7,819							
CAM/ICAM	6665-01-357-8502					17,998	1,432							
	6665-01-199-4153					5	0							
M21 RSCAAL	6665-01-324-6637					63	0							
NBC RECON SYS, M93A1	6665-01-372-1303					182	0							
DECONTAMINATION COMMODITY AREA														
DECON APPAR, M11	4230-00-720-1618					1,337	842							
DECON APPAR, M13	4230-01-133-4124					6,883	1,905							
DECON APPAR, PDDA, M12A1	4230-00-926-9488					522	276							

Table G-1a. Army Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS				FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN							
		TOTAL SERVICE RQMT	TOTAL MODERN. RQMT	1 WD REQUIREMENT	2 SD REQUIREMENT		FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
L/WT DEC SYS, M17A1	4230-01-303-5225					1,519	93							
	4230-01-346-1778					1	0							
	4230-01-150-8660					65	0							
	4230-01-346-3122					56	0							
	4230-01-251-8702					7	0							
COLLECTIVE PROTECTION COMMODITY AREA														
CP DEPMEDS (HUB, CP, M28)	4240-01-395-5179					0	0							
SHELTER, CB PROTECT	5410-01-441-8054					0	0							
SHELTER, CP, M20/M20A1	4240-01-166-2254/4240-01-330-7806					1,105	17							
MEDICAL COMMODITY AREA														
LITTER, DECONTAMINABLE	6530-01-380-7309					2,266								

Table G-1b. Army Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
INDIVIDUAL PROTECTION COMMODITY AREA							
OVERGARMENTS							
CHEM PROT UNDERGARMENT TOP	8415-01-363-8692-00				15,123		
CPU DRAWERS	8415-01-363-8683-91				15,167		
JSLIST SUITS							
Woodland Coat	SEE TABLE G-5				291,179	38,011	
Woodland Trousers	SEE TABLE G-5				295,792	32,158	
Desert Coat	SEE TABLE G-5				127,683	26,304	
Desert Trousers	SEE TABLE G-5				157,742	18,089	
SCALP (TAN AND GREEN)	8415-01-333-0987-89				10,227		
	8415-01-364-3320-22				303		
SUIT, CP CAMO (BDOs)	8415-01-137-1700-07				381,521		
OVERBOOTS/GLOVES							
JLIST MULO	8430-01-464-9453-84						
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85				894,972	25,653	
	8430-01-049-0878-87				6,417	3,459	
CP FOOT COVERS	8430-01-021-5978				10,937		
CP GLOVES 7 MIL	8415-01-138-2501-04				63,719		
CP GLOVES 14 MIL	8415-01-138-2497-00				142,212	19,860	
CP GLOVES 25 MIL	8415-01-033-3517-20				621,998	38,662	
MISC PROTECTION							
2D SKIN, M40 SERIES	4240-01-413-1540-43				153,219	8,871	
BATTERY, BA-5800 (PRO MASK)	6665-99-760-9742				3,480		
CP HELMET COVER	8415-01-111-9028				696,672	82,459	
FILTER CAN, C2A1	4240-01-361-1319				551,767	2,065	
FILTER CAN, M10A1	4240-00-127-7186				996		
FILTER ELEMENT, M13A2	4240-00-165-5026				48,622		
HOOD, M40/42 (ONE-PIECE)	4240-01-260-8723				19,845		
HOOD, M40A1 (QUICK DOFF)	4240-01-376-3152				591,656		
HOOD, M5 (FOR M25A1)	4240-00-860-8987				4,596		
HOOD, M6A2 (FOR M17)	4240-00-999-0420				2,086		
HOOD, M7 (FOR M24)	4240-00-021-8695				2,070		
CONTAMINATION AVOIDANCE COMMODITY AREA							
CHEMICAL DETECTION EQUIPMENT							
BATTERY, ACADA BA-5590	6135-01-036-3495				6,642	48	
BATTERY, BA-3517	6135-00-450-3528				2,168		
BATTERY, ICAM BA-5800	6665-99-760-9742						
BATTERY, M42 BA3030	6135-00-930-0030						
DET KIT, M256A1 (Boxes of 10 tickets)	6665-01-133-4964				27,056	1,820	
DET PAPER, M8 (Indiv. Books)	6665-00-050-8529				354,351	44,768	
DET PAPER, M9 (Indiv. Rolls)	6665-01-226-5589				148,332	2,484	

Table G-1b. Army Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
MAINT KIT, M312 MAINT KIT, M273	5180-01-462-7469 5180-01-108-1729				1,488 185		
NBC MARK SET, M274	9905-12-124-5955				5,755	30	
WATER TEST KIT, M272	6665-01-134-0885				442	14	
DECONTAMINATION COMMODITY AREA							
DECON KIT, M291 (Box of 20)	6850-01-276-1905				461,441	4,543	
DECON KIT, M295 (Box of 20)	6850-01-357-8456				346,728	1,535	
DS2, 1 1/3 QT	6850-00-753-4827				784		
DS2, 5 GAL	6850-00-753-4870				394		
DS2, M13 CAN	6850-01-136-8888				5,376		
NITROGEN CYLINDERS	4230-00-775-7541						
STB, 50 LB	6850-00-297-6653				11,228		
COLLECTIVE PROTECTION COMMODITY AREA							
FILTER, CP, M12A2 (M14 GPFU)	4240-01-365-0981				0		
FILTER, CP, M13 SERIES (M14 GPFU)	4240-00-368-6291				0		
FILTER, CP, M18A1	4240-01-365-0982				0		
FILTER, CP, M19	4240-00-866-1825				3		
FILTER, GP, M48A1	4240-01-363-1311				250		
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533				21	9	
M28 Liner, End Section	4240-01-330-8882						
M28 Liner, End Section, Type II	4240-01-461-5983						
M28 Liner, Center Section	4240-01-330-8884						
M28 Liner, Center Section, Type II	4240-01-460-9058						
M28 Liner, Vestibule	4240-01-330-8891						
M28 Liner, Vestibule, Type II	4240-01-460-9059						
M28 Liner, ISO Adapter	4240-01-330-8890						
M28 Liner, ISO Adapter, Type II	4240-01-460-9056						
MEDICAL COMMODITY AREA							
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248				1,704,256		
ATROPINE AUTOINJ	6505-00-926-9083				557,967		
CANA AUTOINJ	6505-01-274-0951				703,093	74,062	74,062
NAAK, MKI	6505-01-174-9919				550,044		
PYRIDOSTIGMINE TAB	6505-01-178-7903				205,089	14,813	14,813
SODIUM NITRITE INJ (300 MG) KIT	6505-01-206-6009						
SODIUM THIOSULFATE INJ (12.5 G) KIT	6505-01-206-6010						
SODIUM THIOSULFATE INJ (50 ML AMPULE)	6505-01-334-8781				8,710		
ATROPINE 1MG/ML 1 ML VIAL, 25s	6505-00-957-8089				52		
ATROPINE 2MG/ML 25ML VIAL	6505-00-299-9673				29		

Table G-1b. Army Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
POTASSIUM IODIDE TABS 14's BTL	6505-01-116-8198				0		
POTASSIUM IODIDE TABS 14's IS	6505-01-496-4916				9,609		
PATIENT WRAPS	6530-01-383-6260				194		
ATROPINE SULFATE AEROSOL	6545-01-332-1281				4,363		
OTHER TREATMENTS							
CIPROFLOXACIN (500 mg tabs 50s)	6505-01-272-2385				4,439,200		
(500 mg tabs 100 IS)	6505-01-273-8650				1,044,900	970,600	514,300
(500 mg tabs 100s)	6505-01-333-4154				25,300		
(500 mg tabs 10 ISs)	6505-01-491-6143				321,070		
(500 mg tabs 30 IS)	6505-01-491-2834				3,001,680		
DOXYCYCLINE CAPS (100 mg tabs 500s)	6505-01-153-4335				11,237,500	0	3,600,000
(100 mg tabs 30s)	6505-01-491-5506				7,294,740		
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-143-4641				1,426	2,175	2,175
	6505-01-457-8901				1,334		

Table G-2a. Air Force Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS				FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN							
		TOTAL SERVICE RQMT	TOTAL MODERN. RQMT	1 WD REQUIREMENT	2 SD REQUIREMENT		FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
INDIVIDUAL PROTECTION COMMODITY AREA														
CB MASK														
MASK, A/P 22P-14(V)2	NOT ASSIGNED													
MASK, AERP	8475-01-339-9782(S)					5,366								
MASK, CB, M17A2	4240-01-143-2017-20					530								
MASK, M45, AVIATOR	4240-01-414-4034-35/-4051-52													
MASK, M45, LAND WARRIOR	4240-01-447-6988/6989													
MASK, MCU-2/P,	4240-01-415-4239-41					236,010								
MASK, MCU-2A/P	4240-01-284-3615-17					24,194								
MASK, MCU-2A/P (WR) USAF	4240-01-327-3299-01					23,610								
MISC PROTECTION														
PATS, M41	4240-01-365-8241					23								
MASK COMM AMPLIFIER M7	5996-01-381-9012													
CONTAMINATION AVOIDANCE COMMODITY AREA														
NUCLEAR DETECTION EQUIPMENT														
ADM 300 - A KIT	6665-01-363-6213NW					49								
- B KIT	6665-01-342-7747NW					98								
- C KIT	6665-01-320-4712NW					196								
- E KIT	6665-01-426-5071NW					56								
CHEMICAL DETECTION EQUIPMENT														
ACADA, M22	6665-01-438-6963					1,584								
ALARM, CAA, M8A1	6665-01-105-5623					81								
CAM/ICAM	6665-01-357-8502					92								
	6665-01-199-4153					73								
M90 CHEM WARFARE ALARM	6665-01-408-5108					22								
DECONTAMINATION COMMODITY AREA														
A/E32U-8 DECON SYS	4230-01-153-8660					1								
L/WT DEC SYS, M17	4230-01-251-8702					14								
L/WT DEC SYS, M17A1	4230-01-303-5225					5								
L/WT DEC SYS, M17A2	4230-01-349-1778					10								
L/WT DEC SYS, M17A3	4230-01-346-3122													
COLLECTIVE PROTECTION COMMODITY AREA														
CHATH (HUB, CPE, M28)	NOT ASSIGNED													
CP EMEDS	NOT ASSIGNED					32								
CP SSS	NOT ASSIGNED					100	10							

Table G-2a. Air Force Readiness Data – Non-Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS				FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN							
		TOTAL SERVICE RQMT	TOTAL MODERN. RQMT	1 WD REQUIREMENT	2 SD REQUIREMENT		FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
MEDICAL COMMODITY AREA														
LITTER, DECONTAMINABLE	6530-01-380-7309					6,067								

Table G-2b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
INDIVIDUAL PROTECTION COMMODITY AREA							
OVERGARMENTS							
AIRCREWMAN CAPE	8415-01-040-9018				89,733		
CP UNDERCOVERALL	8415-01-040-3136-44				3,091		
EOD HGU-65P HOOD	4240-01-338-1646				54		
EOD M-3 TAP	8415-00-099-6962/68/70				10		
	8415-01-105-2535				0		
EOD TAP BOOTCOVER	8430-00-820-6295-6306				48		
EOD TAP GLOVES	8415-00-753-6550-54				48		
JSLIST SUITS					339,260		
Woodland Coat	SEE TABLE G-5						
Woodland Trousers	SEE TABLE G-5						
Desert Coat	SEE TABLE G-5						
Desert Trousers	SEE TABLE G-5						
M-2 APRON	8415-00-281-7813-16				44		
M3 COOLING HOOD	8415-00-261-6443				9		
M3 COOLING SUIT	8415-00-264-2929				4,572		
SUIT, AIRCREW, CWU-66/77P	8475-01-328-3434-57				61,834		
SUIT, CP CAMO (BDO)	8415-01-137-1700-07				303,578		
SUIT, CP CAMO-DESERT 3 clr	8415-00-327-5347-53				31,496		
SUIT, CP CAMO-DESERT 6 clr	8415-01-324-3084-91				984		
OVERBOOTS/GLOVES							
JLIST MULO	8430-01-464-9453-84						
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85				1,001,985		
GVO	8430-01-049-0878-87				50,531		
CP FOOTWEAR COVERS	8430-01-118-8172				1,059		
	8430-01-021-5978				600		
CP GLOVES 7 MIL	8415-01-138-2501-04				247,261		
CP GLOVES 14 MIL	8415-01-138-2497-00				1,120,417		
CP GLOVES 25 MIL	8415-01-033-3517-20				25,657		
CP SOCKS	8415-01-040-3169				70,000		
DISP FOOTWEAR COVER	8430-00-580-1205-06				204,232		
GLOVE INSERTS	8415-00-782-2809 (S)				820,341		
MISC PROTECTION							
FILTER CAN, C2/C2A1	4240-01-119-2315				1,056,867		
	4240-01-361-1319				306,273		
FILTER, GP	4240-01-161-3110				667		
FILTER ELEMENT, M13A2	4240-00-165-5026				36,094		
HOOD, M6A2 (FOR M17)	4240-00-999-0420				55,556		
HOOD, MCU-2/P	4240-01-189-9423				946,809		

Table G-2b. Air Force Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
HOOD, M45, LAND WARRIOR	4240-01-441-0553						
HARNESS, HEAD, MCU	4240-01-390-3057						
SECOND SKIN, M45 LAND WARRIOR	4240-01-440-0638, 0555						
HARNESS, HEAD, M45	4240-01-441-0562						
SECOND SKIN, MCU	NOT ASSIGNED						
CONTAMINATION AVOIDANCE COMMODITY AREA							
CHEMICAL DETECTION EQUIPMENT							
BATTERY, ACADA BA-5590	6135-01-036-3495				919		
BATTERY, BA-3517	6135-00-450-3528				263		
BATTERY, ICAM BA-5800	6665-99-760-9742				250		
DET KIT, M18A2	6665-00-903-4767				266		
DET KIT, M256A1	6665-01-133-4964				21,099		
DET PAPER, M8	6665-00-050-8529				704,196		
DET PAPER, M9	6665-01-049-8982				184,888		
	6665-01-226-5589				140,008		
MAINTENANCE KIT, M293	5180-01-379-6409				1,815		
NBC MARK SET, M274	9905-12-124-5955				428		
WATER TEST KIT, M272	6665-01-134-0885				113		
KIT, DOD BIOSAMPLING	6665-01-494-8725						
DECONTAMINATION COMMODITY AREA							
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471						
CALCIUM HYPOCHLORITE (45 lb)	6840-00-242-4770						
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439				5,419		
DECON KIT, M291 (Box of 20)	6850-01-276-1905				19,292		
DECON KIT, M295 (Box of 20)	6850-01-357-8456				20,312		
SODIUM HYPOCHLORITE	6810-00-598-7316						
STB, 50 LB	6850-00-297-6653						
COLLECTIVE PROTECTION COMMODTY AREA							
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291						
FILTER, GP M48A1	4240-01-363-1311						
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533						
CP EMEDS, CB Liner	NOT ASSIGNED						
CP SSS, CB Liner	NOT ASSIGNED						
MEDICAL COMMODITY AREA							
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248				743,001		
ATROPINE AUTOINJ	6505-00-926-9083				730,568		
CANA AUTOINJ	6505-01-274-0951				274,960		
NAAK, MKI	6505-01-174-9919				0		

Table G-2b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
PYRIDOSTIGMINE TAB	6505-01-178-7903				55,505		
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-143-4641				0		
ATROPINE 1MG/ML 1ML VIAL, 25s	6505-00-957-8089				34,078		
ATROPINE 2MG/ML 25ML VIAL	6505-00-299-9673				1,691		
POTASSIUM IODIDE TABS 14's BTL	6505-01-116-8198				1,600		
OTHER TREATMENTS							
DOXYCYCLINE TABS, 100 MG, 500s	6505-01-153-4335				4,051		
100 MG, 50s	6505-01-095-4175				31,417		
CIPROFLOXACIN 500 MG TAB 100s IS	6505-01-273-8650				127,330		
500 MG TAB 100s BTL	6505-01-333-4154				9,422		

Table G-3a. Navy Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS				FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN							
		TOTAL SERVICE RQMT	TOTAL MODERN. RQMT	1 WD REQUIREMENT	2 SD REQUIREMENT		FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
INDIVIDUAL PROTECTION COMMODITY AREA														
CB MASK														
MASK, A/P 22P-14(V)	NOT ASSIGNED					6,526	1,070							
MASK, CB, M40A1	4240-01-370-3821-23					39,769								
MASK, M45, AVIATOR	4240-01-414-4034-35/-4051-52					120								
MASK, MCU-2/P	4240-01-175-3443-45 4240-01-497-7467 (S) 4240-01-497-7783 (M) 4240-01-498-1189 (L)					57,618								
MASK, MCU-2A/P	4240-01-284-3615-17					7,476								
MASK, MCU-2A/P USN	4240-497-7783					37,632								
CONTAMINATION AVOIDANCE COMMODITY AREA														
NUCLEAR DETECTION EQUIPMENT														
AN/PDR-27	6665-00-543-1435					3,566								
AN/PDR-43	6665-00-580-9646					3,587								
AN/PDR-56	6665-00-086-8060					1,327								
AN/PDR-65	6665-01-279-7516					619								
CP-95	6665-00-526-8645					5,478								
PP-4276	6665-00-489-3106					656								
IM-143	6665-00-764-6395					7,899								
IM-143B/PD	6665-01-134-9714					1,699								
DT-60	6665-00-978-9637					144,642								
DT-60/E	6665-01-361-6066					4,477								
AN/PDQ-1 MFR	6665-01-435-0127					9,038	400	476	337	884	884	0	0	0
OA-9449/PDQ	6665-01-435-0131					6,262								
BIOLOGICAL DETECTION EQUIPMENT														
IBAD	NOT ASSIGNED					13								
DRY FILTER UNIT	NOT ASSIGNED					575	125	0	0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT														
ACADA, M22	6665-01-438-6963					415	0	0	0	0	0	0	0	0
ACADA, SHIPBOARD	6665-01-484-7823					501	1,229	0	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623					109								
CAPDS	6665-01-294-2556					15	0	0	0	0	0	0	0	0
CHEM AGENT MONITOR/ICAM	6665-01-199-4153					1,021	120	0	0	0	0	0	0	0
CWDD, AN/KAS-1	5855-01-147-4362					644	0	0	0	0	0	0	0	0
IMP POINT DETECTION SYSTEM	6665-LL-HAL-5532					215	39	0	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA														
DECON APPAR, M11	4230-00-720-1618					29								
L/WT DEC SYS M17A3 DIESEL	4230-01-346-3122					10								

Table G-3a. Navy Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS				FY03	PROJECTED DUE IN							
		TOTAL SERVICE RQMT	TOTAL MODERN. RQMT	1 WD REQUIREMENT	2 SD REQUIREMENT	STOCKS ON HAND (as of 30 Sept 03)	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
COLLECTIVE PROTECTION COMMODITY AREA														
SHELTER, CP, M20/M20A1	4240-01-166-2254					27	0	0	0	0	0	0	0	0
MEDICAL COMMODITY AREA														
LITTER, DECONTAMINABLE	6530-01-380-7309					596								

Table G-3b. Navy Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
INDIVIDUAL PROTECTION COMMODITY AREA							
OVERGARMENTS							
APRON, TAP M-2	8415-00-281-7813-16				151		
JSLIST SUITS [1]							
Woodland Coat	SEE TABLE G-5				103,993		
Woodland Trousers	SEE TABLE G-5				106,397		
Desert Coat	SEE TABLE G-5				103,773		
Desert Trousers	SEE TABLE G-5				92,359		
SUIT, TAP M-3	8415-00-099-6962/68/70				0		
	8415-01-105-2535				0		
SUIT, CP, OG MK3	8415-01-214-8289-92				0		
SUIT, CP, SARATOGA	8415-01-333-7573-76				6,045		
SUIT, CP SARATOGA-DESERT	8415-01-333-7577-80				0		
OVERBOOTS/GLOVES							
JSLIST MULO	8430-01-464-9453-84				0		
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85				60,910		
GVO	8430-01-049-0878-87				0		
CP FOOTWEAR COVERS	8430-01-118-8172				47,226		
	8430-01-021-5978				35,382		
CP GLOVES 7 MIL	8415-01-138-2501-04				49,162		
CP GLOVES 14 MIL	8415-01-138-2497-00				13,560		
CP GLOVES 25 MIL	8415-01-033-3517-20				241,178		
(ACTON) GLOVE	8415-21-921-2167-2172				19,661		
CP SOCKS	8415-01-040-3169				0		
DISP FOOTWEAR COVER	8430-00-580-1205-06				11,309		
	8430-00-591-1359				3,625		
GLOVE INSERTS	8415-00-782-2809				148,039		
CP GLOVE INSERTS	8415-01-138-2494-96				30,149		
MISC PROTECTION							
CP HELMET COVER	8415-01-111-9028				44		
FILTER CAN, C2/C2A1	4240-01-119-2315				348,971		
HOOD, MCU-2/P	4240-01-189-9423				227		
HOOD, M40/42 (ONE-PIECE)	4240-01-260-8723				302		
HOOD, M40A1 (QUICK DOFF)	4240-01-376-3152				682		

[1] Although the Navy estimated a non-wartime need for 519,600 suits in the 2002 Annual Report, there were zero suits allocated for non-warfighters for the 2003 Annual Report since the total service requirement of 1,608,242 suits was predicated on the total population of Navy warfighters. However, a non-wartime need could be assessed at 15% since the total requirement includes 15% for training and sizing allowances. Completion of the E^2C^2 study will permit these and other consumable requirements to be formally aligned with the latest defense planning guidance scenarios.

Table G-3b. Navy Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
CONTAMINATION AVOIDANCE COMMODITY AREA							
CHEMICAL DETECTION EQUIPMENT							
DET KIT, M256A1	6665-01-133-4964				9,008		
DET PAPER, M8	6665-00-050-8529				58,651		
DET PAPER, M9	6665-01-226-5589				21,319		
NBC MARK SET, M274	9905-12-124-5955				78		
TUBE PHOSGENE	6665-01-010-7965				1,305		
WATER TEST KIT, M272	6665-01-134-0885				170		
BIOLOGICAL DETECTION EQUIPMENT							
HAND HELD ASSAYS	6665-01-504-8534				4,000	30,000	
DECONTAMINATION COMMODITY AREA							
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471				8,084		
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439				0		
DECON KIT, M291 (Box of 20)	6850-01-276-1905				163,269		
DECON KIT, M295 (Box of 20)	6850-01-357-8456				55,546		
DS2, 5 GAL	6850-00-753-4870				0		
SODIUM HYPOCHLORITE	6810-00-598-7316				127		
STB, 50 LB	6850-00-297-6653				436		
COLLECTIVE PROTECTION COMMODITY AREA							
FILTER, GP, M48A1	4240-01-363-1311				0		
FILTER SET, SHIPBOARD (M98)	4240-01-369-6533				3		
PRE-FILTER, SHIPBOARD CPE	4240-01-474-8855				0		
PRE-FILTER, SHIPBOARD CPS	4130-01-474-8851						
LP FILTER, 1000 CFM	4240-01-347-6190						
MEDICAL COMMODITY AREA							
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248				307,353		
ATROPINE AUTOINJ	6505-00-926-9083				240,242		
CANA AUTOINJ	6505-01-274-0951				75,494		
NAAK, MKI	6505-01-174-9919				20,245		
PYRIDOSTIGMINE TAB	6505-01-178-7903				154,056		
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-143-4641				1		
SODIUM NITRITE INJ (300 MG) KIT	6505-01-206-6009				610		
SODIUM THIOSULFATE INJ (12.5 G) KIT	6505-01-206-6010				110		
ATROPINE 1MG/ML 1ML VIAL, 25s	6505-00-957-8089				5,129		
ATROPINE 2MG/ML 25ML VIAL	6505-00-299-9673				31,409		
POTASSIUM IODIDE TABS 14's BTL	6505-01-116-8198				20,964		
POTASSIUM IODIDE TABS 14's IS	6505-01-496-4916				63,600		

Table G-3b. Navy Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
OTHER TREATMENTS							
CIPROFLOXACIN 500 MG TAB 100s IS	6505-01-273-8650				379,428		
500 MG TAB 100s BTL	6505-01-333-4154				60,126		
DOXYCYCLINE CAPS, 100s	6505-00-009-5060				94,182		
500s	6505-00-009-5063				94,402		

Table G-4a. Marine Corps Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS				FY03	PROJECTED DUE IN							
		TOTAL SERVICE RQMT	TOTAL MODERN. RQMT	1 WD REQUIREMENT	2 SD REQUIREMENT	STOCKS ON HAND (as of 30 Sept 03)	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11
INDIVIDUAL PROTECTION COMMODITY AREA														
CB MASK														
MASK, CB, M40/M40A1	4240-01-258-0061-63					126,846	24,550	24,550	24,550					
MASK, CB, M17A2	4240-01-143-2017-20					5,161								
MASK, M24, AVIATOR	4240-00-776-4384					0								
MASK, M42, TANK	4240-01-258-0064-66					267								
MASK, MCU-2/P, -2A/P	4240-01-284-3615-17					43								
MISC PROTECTION														
MASK COMM AMPLIFIER M7	5996-01-381-9012					22,080								
PATS, M41	4240-01-365-8241					173								
CONTAMINATION AVOIDANCE COMMODITY AREA														
NUCLEAR DETECTION EQUIPMENT														
AN/PDR-75	6665-01-211-4217					326								
AN/VDR-2	6665-01-222-1425					1,386								
CHEMICAL DETECTION EQUIPMENT														
ACADA, M22	6665-01-438-6963					478	24	23	23					
ALARM, CAA, M8A1	6665-01-105-5623													
CAM 1.5	6665-01-359-9006					36								
CAM 2.0	6665-99-725-9996					1,944	103	102	102					
M21 RSCAAL	6665-01-382-1968					82								
NBC RECON SYS, M93	6665-01-372-1303					8								
NBC RECON SYS, FOX	6665-01-372-2582					2								
DECONTAMINATION COMMODITY AREA														
DECON APPAR, M11	4230-00-720-1618					25,207								
DECON APPAR, M13	4230-01-133-4124					13,661								
HEAVY FUEL DECON	4230-01-492-1540					866								
COLLECTIVE PROTECTION COMMODITY AREA														
JOINT EXPEDITIONARY CP SHELTER	4240-01-346-2564					155								
MEDICAL COMMODITY AREA														
LITTER, DECONTAMINABLE	6530-01-380-7309					0								

Table G-4b. Marine Corps Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
INDIVIDUAL PROTECTION COMMODITY AREA							
OVERGARMENTS							
JSLIST SUITS					110,351	35,145	26,308
Woodland Coat	SEE TABLE G-5						
Woodland Trousers	SEE TABLE G-5						
Desert Coat	SEE TABLE G-5						
Desert Trousers	SEE TABLE G-5						
SUIT, CP, SARATOGA	8415-01-333-7573-76				272,060		
SUIT, CP SARATOGA-DESERT	8415-01-333-7577-80				23,020		
OVERBOOTS/GLOVES							
JLIST MULO	8430-01-464-9453-84				320,939	124,313	124,312
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85				252,851		
GVO	8430-01-049-0878-87				261,125		
CP FOOT COVERS	8430-01-021-5978				56,500		
CP GLOVES 25 MIL	8415-01-033-3517-20				307,610	118,498	118,498
MISC PROTECTION							
2D SKIN, M40 SERIES	4240-01-413-1540-43				80,627	18,607	18,607
FILTER CAN, C2/C2A1	4240-01-119-2315				154,255	24,000	24,000
	4240-01-361-1319				250,468		
FITLER CAN, M10A1	4240-00-127-7186				0		
FILTER ELEMENT, M13A2	4240-00-165-5026				20,440		
HOOD, M40	4240-01-376-3152				51,749		
HOOD, M5 FOR M25A1	4240-00-860-8987				0		
HOOD, M6A2 FOR M17	4240-00-999-0420				0		
HOOD, M7 (FOR M24)	4240-01-021-8695				0		
CONTAMINATION AVOIDANCE COMMODITY AREA							
CHEMICAL DETECTION EQUIPMENT							
BATTERY, BA-3517	6135-00-450-3528				0		
BATTERY, ICAM BA-5800	6665-99-760-9742				3,546		
BATTERY, ACADA BA-5590	6135-01-036-3495				95		
DET KIT, M256A1	6665-01-133-4964				5,751		
DET PAPER, M8	6665-00-050-8529				95,695		
DET PAPER, M9	6665-01-049-8982				837		
	6665-01-226-5589				17,245		
NBC MARK SET, M274	9905-12-346-4716				0		
WATER TEST KIT, M272	6665-01-134-0885				389		
DECONTAMINATION COMMODITY AREA							
DECON KIT, M291	6850-01-276-1905				3,976		
DECON KIT, M295	6850-01-357-8456				37		
DS2, 1 1/3 QT	6850-00-753-4827				7,231		
DS2, 5 GAL	6850-00-753-4870				3,615		

Table G-4b. Marine Corps Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	DATA BELOW ARE PENDING VALIDATION OF REQUIREMENTS			FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN	
		TOTAL SERVICE RQMT	1 WD REQUIRE-MENT	2 SD REQUIRE-MENT		FY04	FY05
DS2, M13 CAN	6850-01-136-8888				137		
NITROGEN CYLINDERS	4230-00-775-7541				16,796		
STB, 50 LB	6850-00-297-6653				3,645		
COLLECTIVE PROTECTION COMMODITY AREA							
FILTER, CP, M12A2 (M14 GPFU)	4240-01-365-0981				123		
FILTER, CP, M13 SERIES (M14 GPFU)	4240-00-368-6291				123		
FILTER, CP, M18A1	4240-01-365-0982				113		
FILTER, CP, M19	4240-00-866-1825				62		
FILTER, GP, M48A1	4240-01-363-1311				204		
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533						
FILTER, HSFS	.4240-01-366-6243						
ICPS (MGPTS), CB Liner	8340-09-000-2480						
MEDICAL COMMODITY AREA							
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248				151,267		
ATROPINE AUTOINJ	6505-00-926-9083				210,339		
CANA AUTOINJ	6505-01-274-0951				51,882		
NAAK, MKI	6505-01-174-9919				3,551		
PYRIDOSTIGMINE TAB	6505-01-178-7903				18,565		
ATROPINE 1 MG/ML, 1ML VIAL, 25s	6505-00-957-8089				4,594		
CIPROFLOXACIN 500 MG TAB 100s IS+	6505-01-273-8650						
500 MG TAB 100s BTL+	6505-01-333-4154				552		
OTHER TREATMENTS							
DOXYCYCLINE CAPS, 500s	6505-00-009-5063				4,112		

* Includes SOF, Training, Chemical Testing, and Surveillance

** Includes Joint Service stocks held for all Services prior to fielding

Table G-5. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	FY03 STOCKS ON HAND (as of 30 Sept 03)	PROJECTED DUE IN FY04	PROJECTED DUE IN FY05
INDIVIDUAL PROTECTION COMMODITY AREA				
OVERGARMENTS				
CAPE, AIRCREWMAN	8415-01-040-9018	129,195	7,009	7,009
CHEM PROT UNDERGARMENT TOP	8415-01-363-8692-00	6,948	6,958	12,965
CPU DRAWERS	8415-01-363-8683-91	12,324	6,256	11,685
EOD M-3 TAP	8415-00-099-6962/68/70	4,397	3,115	0
	8415-01-105-2535	0	0	0
EOD TAP BOOTCOVER	8430-00-820-6295- 6306	N/A		
EOD TAP GLOVES	8415-00-753-6550-54	32,925	13,230	11,000
JSLIST SUITS *				
Woodland Coat	8415-01-444-1163/-1169/-1200/38/49/65/70	0	1,400,000	1,400,000
Woodland Trousers	8415-01-444-1435/39/-1613-/2308/10/25/38	53	1,400,000	1,400,000
Desert Coat	8415-01-444-5902/05/13/26/-6116/31/38	101,088	1,200,000	1,200,000
Desert Trousers	8415-01-444-5417/5504/06/-5892/93/98/-5900	76,870	1,200,000	1,200,000
OVERBOOTS/GLOVES				
JLIST MULO	8430-01-464-9453-84	N/A		
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85	40,400	2,152,529	1,344,876
CP GLOVES 7 MIL	8415-01-138-2501-04	2,176	13,095	13,095
CP GLOVES 14 MIL	8415-01-138-2497-00	0	72,263	72,263
CP GLOVES 25 MIL	8415-01-033-3517-20	0	71,928	71,928
CP SOCKS	8415-01-040-3169	210,199	0	0
DISP FOOTWEAR COVER	8430-00-580-1205-06	20,800	33,119	47,928
MISC PROTECTION				
CP HELMET COVER	8415-01-111-9028	70,430	33,853	33,853
CONTAMINATION AVOIDANCE COMMODITY AREA				
CHEMICAL DETECTION EQUIPMENT				
BATTERY, BA3517	6135-00-450-3528	18,971	523	0
TUBE, DET, PHOSGENE GAS	6665-01-010-7965	26	218	0
DECONTAMINATION COMMODITY AREA				
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	22,779	21,533	0
STB, 50 LB	6850-00-297-6653	9,074	3,806	0
MEDICAL COMMODITY AREA				
2-PAM CHLORIDE, AUTOINJ	6505-01-125-3248	48,000	550,000	550,000
ATROPINE AUTOINJ	6505-00-926-9083	28,800	700,000	700,000
CANA AUTOINJ	6505-01-274-0951	105,000	600,000	600,000
NAAK, MKI	6505-01-174-9919	768,000	800,000	800,000
PYRIDOSTIGMINE TABLETS	6505-01-178-7903	70,000	70,000	70,000
LITTER, DECONTAMINABLE	6530-01-380-7309	1,534	5,000	5,000
ATROPINE SULFATE AEROSOL	6545-01-332-1281	0	0	0
ANTIDOTE TREAT KIT, CYANIDE	6505-01-457-8901	0	0	0

* DLA purchases JSLIST suits for the Services. Projected Service allocations are included in the individual Service totals.

G.2 FIELDED CBRN DEFENSE ITEMS - ISSUES AND CONCERNS

CBRN defense items are generally used in combination to form a system or subsystem for a particular function. Therefore, this report will address items used as a system. These systems are categorized into five functional areas: (1) Contamination Avoidance, (2) Individual Protection, (3) Collective Protection, (4) Decontamination, and (5) Medical.

G.2.1 CONTAMINATION AVOIDANCE

Contamination avoidance programs generally include equipment that is used to conduct NBC agent reconnaissance, detection, and identification. This area represents approximately half of the annual DoD CBRN defense RDT&E budget. Due to recent type-classification of several programs that are intended to modernize contamination avoidance programs, this area has an unusually high number of developmental programs, as compared to other commodity areas. Many programs will complete their fielding beyond FY05. Thus several systems may appear to be initially low in inventory, but their quantities will improve with continued procurement in coming years.

The number of biological detection devices, to include the Biological Integrated Detection System (BIDS), Interim Biological Agent Detector (IBAD), Dry Filter Unit (DFU), and Joint Portal Shield has historically been low as measured against requirements. Automatic biological agent point detectors and stand-off detectors are currently in development, and will not be deployed in significant numbers prior to FY04. The USAF is fielding an off-the-shelf capability called the Ruggedized Advanced Pathogen Identification Device (RAPID). RAPID is a medical tool used for clinical identification of pathogenic agents within 25 minutes. It is capable of processing up to 32 samples simultaneously. Also, the USAF has limited quantities of the Joint Portal Shield biological networked Sensor Systems. Until fielding of the Joint Biological Point Detection System (JBPDS), Marine Corps will not have that capability either. The Navy is fielding the DFU, which is a commercially available system, thus lowering risks sometimes associated with defense industries. The DFU is an environmental air sampling system designed to be used with biological agent assays and confirmatory laboratories to provide a "Detect to Treat" capability for US Naval forces ashore and afloat. It may be employed for periodic environmental sampling to detect covert releases or may be used to collect air samples from a suspected incident scene. The DFU is a high volume air sampler whose purpose is to collect airborne particulate matter as it is drawn through a 1 micron filter. Used filters are removed from the unit and the residue rinsed into a buffer solution. The filters, solution and other items needed to collect particles and perform presumptive testing are packaged in a consumable DFU kit. The sample solution is analyzed via disposable hand held assays (HHAs) for the detection and identification of biological agents. Training and operational HHAs have a shelf life of one year if kept at constant temperature. Shipboard conditions may not be optimal, increasing risk of insufficient quantities being available. The operational and training HHAs received NSNs and the DFU kit has received an NICN. The Navy has begun barcoding to better track items and to reduce risk of spoilage.

The combined total of chemical agent detection systems will improve slowly as the M22 Automatic Chemical Agent/Detector (ACADA) supplements the M8A1 Automatic Chemical Agent Alarm. There is a shipboard variant of the ACADA, the MK 27 Mod 0, which is able to operate in a marine environment. An Army initiative to inspect and repair M8A1 alarms at Anniston Army Depot has resulted in the quick assessment and return of 1,600 units to the

field. Another 1,500 alarms were coded as requiring depot maintenance and are undergoing repairs. As a result of this program, the Army has no shortage of alarms for training purposes and there is no longer an acquisition gap between the combined acquisition of M8A1 and M22 alarms.

The combined number of CAM/ICAMs reported by the Services are sufficient, and reflects the success of refurbishment actions that were completed during FY02, and continued buys in FY03.

The M93A1 NBCRS is currently fielded according to schedule. This system adds improved mass spectrometer sampling system along with stand-off chemical vapor detection. Several units continue to use trained reconnaissance personnel in HMMWVs and APCs, thus adding a supplemental capability.

Traditional consumables in this commodity area (M8 and M9 detection paper, M256A1 kits and M272 water test kits) are usually available in sufficient quantities to meet wartime requirements. Some shortages may exist in individual Services, but overall there is little risk. Shelf life concerns may change this projection; this area remains under review.

The Army and Air Force RADIAC programs are expected to meet requirements. The Army National Guard still has a large number of obsolete RADIACs. These will be replaced in the near future by the AN/VDR-2, which is available through the depot system. The Navy has small quantities of older RADIACs still in the inventory, which are being replaced through a modernization program. The Navy is in the process of replacing the AN/PDR-27 and AN/PDR-43 with the AN/PDQ-1 (Multi-Function RADIAC) and OA-9449/PDQ (Gamma Beta Probe). Inventories of legacy equipment are sufficient to meet fielding needs, and the remaining procurement of the AN/PDQ-1 is currently fully funded and programmed to be completed in FY08. The Marine Corps is estimated to have sufficient AN/VDR-2s and about half of the necessary AN/PDR-75s, putting RADIACs in the moderate risk category. While Army stores or industry could compensate for this shortfall, it represents a potential risk, especially at the onset of any contingency.

G.2.2 INDIVIDUAL PROTECTION

Individual protection equipment is designed to protect against all known CB warfare threat agents, Toxic Industrial Chemicals (TICs), and Toxic Industrial Materials (TIMs). Past Service-unique requirements led to Service-specific procurements and some duplication in capability resulting in the procurement of six different chemical protective suits and six different masks. This has caused difficulties in meeting current needs and exacerbated logistics planning.

The Joint Program Manager for Individual Protection (JPM-IP) has organized his Program Office into 5 teams: Surface Protection Ensembles, Aviation Protection Ensembles, Surface Respiratory Protection, Aviation Respiratory Protection and Universal “Common” Individual Protective Equipment (IPE). Fielding of Joint Individual Protection equipment through these teams has begun to resolve many of these former challenges.

G.2.2.1 Surface Protection Ensembles

Garments. The Services are continuing acquisition of the Joint Service Integrated Suit Technology (JSLIST) suits as a replacement for the Battle Dress Overgarment (BDO) and other chemical protective suits. As such, the protective suits should be viewed as a system with the

older suits providing readiness stocks until the end of their service life. The initial JSLIST contracts did not include surge option clauses. Defense Supply Center Philadelphia (DSCP), whose solicitations include the surge option as a requirement, took management of JSLIST in FY98. DLA/DSCP has surge clauses in current contracts that would bring production up to about 120,000 suits per month. However, through bilateral agreement DLA/DSCP contractors began to produce more than 128,000 suits per month beginning in April 2003. By examining the year-by-year status of protective suits, a number of older suits still within service life were added to the number of JSLIST suits purchased by that year and matched the total against the requirements. In FY04, the total Services' inventory of protective suits is at high risk of not meeting projected requirements. Additionally, available inventory will continue to drop as the service life of older protective suits, such as BDOs, expires in large quantities. Near term buys will moderate that risk, however. Also, DLA is taking steps to identify alternative sources for manufacture of JSLIST suits, which will add to the overall production capacity.

The BDO is reaching its maximum extended shelf life limit (14 years), and the Services have no plans for new production. There are no companies currently manufacturing the BDO. The Army and Air Force typically have sufficient suits on hand in war reserves to sustain its requirements for the near term. The Saratoga suit, purchased by DSCP for the Marine Corps, is also out of production, but current stocks will sustain the Marine Corps and Navy until the JSLIST is available in adequate numbers. The Navy is relying on existing stocks of their Chemical Protective Overgarment (also out of production) as stocks of JSLIST are being procured.

Combat Vehicle Crewmen (CVC) and aircrews require special protective ensembles to integrate with their weapon systems. To protect armor crewmen from gross liquid contamination when they exit their vehicles, the Services have developed the Suit Contamination Avoidance Liquid Protection (SCALP), which is available in sufficient quantities. The Joint Protective Aircrew Ensemble (JPACE) is scheduled to replace present protective ensembles for both CVC and aircrew personnel.

Gloves. The Services are expected to have adequate stocks of 14 and 25-mil chemical protective gloves in FY04 for contingency use. In FY03, 7-mil gloves were in short supply. An additional buy will be made to ensure that DLA will have adequate stock on hand. Recent DoD surveillance tests are validating the protective qualities of the existing butyl rubber glove stocks. The status of the Services on-hand inventories has allowed DLA to pursue an Industrial Base Maintenance Contract (IBMC) with both current manufacturers to sustain the industrial base with "War Stopper" funding. The purpose of the IBMC is to maintain the equipment only. The JSLIST Block 1 Glove Upgrade (JB1GU) may be fielded by the Services as an interim replacement for the current butyl rubber gloves and will reduce reliance on them.

Footwear. Chemical Protective Footwear Covers, also known as the "fishtail", have been out of production for several years. Their shortages are supplemented by the Black/Green Vinyl Overboot (BVO/GVO), which is the interim chemical protective footwear until the JSLIST MULO boots have been completely fielded. Because the GVO's primary purpose is not chemical protection, current contracts do not include surge option clauses. Again, one should view protective footwear as a system with older GVOs providing readiness stocks until the MULO or suitable boot is fielded in sufficient quantities. Currently, the total DoD inventory shows adequate quantities of protective footwear, resulting in low risk assessment. The USMC and the Navy are the only services reporting a shortage of footwear, but DLA can fill the

shortfall for shore units. However, shipboard requirements for a lightweight boot cannot be met by anything in the stock system since the GVO/BVO is not suitable for shipboard use.

Other: The Chemical Protective Helmet Cover is intended to provide Chem/Bio protection for the standard helmet. It is a one-piece configuration made of butyl coated nylon cloth and gathered at the opening by elastic webbing enclosed in the hem.

G.2.2.2 Aviation Protection Ensembles

Services usually have sufficient numbers of aircrew suits to meet minimum requirements, given the smaller total requirements for aircrews (relative to ground troops). An exception is the Chemical Protective Undercoverall, which is now obsolete. For the USAF, it is replaced by the CWU-66/77P Aircrew Chemical Protective Suit. The USN and USMC aircrew are now using the CMU-34/P undershirt and CMU-35/P drawers (formerly known as Navy modified Chemical Protective Undergarment) in conjunction with the flyer's Summer Coverall for adequate protection.

Disposable Footwear Covers are worn over the flyer's boots. They protect the aircrew member from contamination en route between the shelter and the aircraft. They must be removed before entering the aircraft. The footwear covers come in three sizes: medium, large, and extra large. The Aircrew Cape is a large, clear, disposable, 4-mil polyethylene bag worn over the body. The cape protects the aircrew member from liquid contamination en route between the shelter and the aircraft and must be removed before entering the aircraft. It is available in one size. The JPACE is scheduled to replace existing aircrew ensembles for both fixed and rotary wing aircrew personnel.

G.2.2.3 Surface Respiratory Protection

The Services continue modernizing their chemical protective mask inventories. Different versions of the protective mask were developed to meet the requirements of different military occupational specialties (*e.g.*, air crew, tank crew, *etc.*). For the Army and Marine Corps, the M40 (for generic use) and M42 (for armor crew members) series masks replace the M17 and M25-series masks, respectively. Some Navy shore activities are also using the M40 series masks.

The Marine Corps is performing a product improvement program (PIP) to modify the existing M40/M42 series mask. The PIP will be completed in Fiscal Year 2004. PIP actions include installation of a new nose cup, polycarbonate eye lenses, drink tube coupling, and drink tube quick disconnect: banding of the outlet valve housing: and laser etching serial numbers on the mask. The new components and banding procedure will improve the mask's durability and protective capability requirements established by the Marine Corps and eliminate inadvertent damage to the mask by the unit (*i.e.*, painting a number on the head harness, engraving in the eye lens-retaining ring). The cost to perform the PIP is estimated at $12M with the Marine Corps saving approximately $10M by performing the rebuild vice buying new modified masks.

The MCU-2/P and MCU-2A/P masks are designed to meet the needs of the Air Force ground crews, and Navy shipboard and shore-based support missions. In FY03 increased Navy requirements resulted in localized shortfalls, particularly in size large. Also, recent testing of MCU-2P Masks as part of the Navy Readiness Improvement Program (RIP) have generated failure rates of up to 30%, resulting in additional shortages that are not being offset by delivery of new masks.

In order to provide complete protection to our forces on the contaminated battlefield, particularly from liquid chemical agents, protective hoods and helmet covers are required as part of the individual protective ensemble. The protective hood for the M40 is usually rated as low risk. The MCU-2P hood also typically has abundant inventory. Second skins for the MCU-2/P and MCU-2A/P are in development and will be issued beginning in FY04. Protective hoods for the M17-series, M24, and M25A1 masks are also in good supply, and thus are not a readiness issue. These masks are leaving the inventory, however. Historically, the Chemical Protective Helmet Cover has also been available in sufficient quantities. The Joint Service General Purpose Mask (JSGPM) will replace the M40/M42 series and the MCU-2/P series of protective mask.

G.2.2.4 Aviation Respiratory Protection

Some Army aviation units are still equipped with the old M24 mask, which will be replaced by the M45 mask. The M43-Type I mask was designed to be used by Apache equipped units. It is being replaced by the M48 (Apache) series mask. The M45 will replace the M24 and the M43 Type II masks as the general aviation mask for Army aircrew (except Apache). This modernization effort is still ongoing; not all units have replaced their M43-series masks. All of these masks are seen as low risk, as the combined numbers of all aviator masks on hand usually exceeds the requirement. The USN & USMC aircrew are currently using the A/P22P-14(V1-4), also known as the NDI Respirator, which is a common man-mounted system with variants to address Naval aircraft oxygen connections. These masks provide increased protection, improved fit and comfort, and compatibility with most Services' weapons systems' optics and sights. The Joint Service Aircrew Mask (JSAM) is scheduled to replace all existing aircrew protective masks.

The USAF has some shortages in masks. Second skins, which provide complete personal protection, are currently in First Article Testing in preparation for production. The MCU-2/P and MCU-2A/P masks will continue to be the mainstay of these units until the JSGPM is fielded. The Aircrew Eye/Respiratory Protection (AERP) mask is specially designed to enable pilots of high performance aircraft to conduct missions in a contaminated environment.

Key Component Consumables for Respiratory Protection. Filters and canisters provide the active ingredients that absorb the chemical and biological agents and provide the essential protection required. The C2/C2A1 canister is used with the M40, M42, M43, M45, M48, A/P22P-14(V1-4), and MCU-2/P series masks. The M13A2 filter element will be leaving the inventory with the retirement of the M17-series mask. The M10A1 filter canister used on the M24/25 is in short supply, but these masks will also leave the inventory and will not be a readiness problem.

The Mask Communicator Amplifier, M7 provides effective voice communication between masked personnel enhancing command and control on the NBC contaminated battlefield.

The Universal Second Skin was a pre-planned product improvement that provides liquid agent protection for the mask face blank material. It is a butyl rubber blend that is very durable. A Second Skin is also being fielded for the Air Force's MCU-2A/P.

G.2.2.5 Universal "Common" IPE

During the issuing process for Protective Masks it is absolutely essential that the mask be properly fitted to the individual to ensure the highest protective value. The M41 Protection Assessment Test System (PATS) validates proper fit of a mask to the face of the individual. It tests all current military and several commercial masks. The system provides a visual display of the fit achieved by the mask when worn by the individual and requires calibration every 18 to 24 months. It is currently in use by the Army, Air Force and Marines.

The MQ1A mask tester also validates proper fit of a mask to the face of the individual. It tests currently fielded AF MBU-5/P and MBU-12/P aviator masks and the MBU-13/P and MBU-19/P aviator NBC protective masks. The system provides a visual display of the fit achieved by the mask when worn by the individual. It is currently in use by the Air Force at units supporting the MBU-5/P, MBU-12/P, MBU-13/P and MBU-19/P.

G.2.3 COLLECTIVE PROTECTION

There are two general categories of collective protection: stand-alone shelters and integrated systems. Integrated collective protection equipment is component equipment designed to provide protection against CB agents through the use of filtered air under positive pressure to a variety of facilities, vans, vehicles, aircraft and ships. Filters for these integrated collective protection systems (CPS) are usually in short supply due to low peacetime demand and low production quantities.

The Air Force has expressed interest in a greater collective protective shelter capability. The Air Force fielded through FY00 the Pacific Air Force Interim Transportable Collective Protection System (PITCOPS). PITCOPS is an above ground NBC shelter that provides NBC filtration integrated with an environmental control unit and auxiliary power unit. The Air Force is assessing fielding Chemical Protection of the small shelter system currently in production and fielding to the medical troops. The Army and the Air Force plan to field the Joint Transportable Collective Protection System (JTCOPS). Combined with the Navy's increasing shipboard collective protection filter requirements due to a continually increasing number of ships with CPS, and the Army and Marine Corps traditional integrated vehicular systems and tactical shelter requirements, the near-term requirements for large carbon-based filters have outpaced current inventories even aided by industrial surge capability. As a result, much of this sector may be assessed as high risk, though the risk is primarily due to the level of funding rather than technical shortfalls. Most of the filter manufacturers retain the industrial capability to produce them.

In the near term, the M51 shelter is being replaced by the Chemical and Biological Protective Shelter (CBPS). All Army M51 shelters have been coded as unserviceable. The CBPS received Milestone C approval and is presently in full rate production. Limited quantities of CBPS were fielded to U.S. Army and U.S. Marine Corps units in support of an Urgent Materiel Release for Operation Enduring Freedom/Operation Iraqi Freedom. Current funding supports the production of 364 of the 779 CBPS systems identified by previous Defense Planning Guidance. CPBS will experience a break in production in FY04 and FY05 due to recent budget adjustments. Both Army and Air Force field hospitals are being integrated with environmentally controlled collective protection. The Army's Chemically Protected Deployable Medical Systems (CP DEPMEDS) and the Air Force's Chemically Hardened Air Transportable Hospital (CHATH) achieve collective protection through the integration of the M28 Simplified CPE,

chemically protected air conditioner, heaters, water distribution and latrine and alarm systems. The M28 Simplified CPE is in production and production of chemically protected heaters and air conditioners was initiated in FY99. Procurement and production of CP DEPMEDS components are ongoing. All components will be assembled into CP DEPMEDS sets at depot. The budget supported the production of 12 of the 18 CP DEPMEDS sets identified by previous Defense Planning Guidance (DPG). No additional funding was programmed beyond FY03. Limited quantities of CP DEPMEDS were fielded to U S Army hospitals in support of an Urgent Materiel Release for Operation Enduring Freedom/Operation Iraqi Freedom. The Collective Protection for Expeditionary Medical Shelter System (CP EMEDS) program is an effort to fill the shortfall by inserting environmentally controlled collective protection into currently fielded hospital Alaska shelters. In FY00, production was initiated for remaining M28 CPE, CB protected water distribution and latrine systems, CB ISO Shelter Seals and Low Pressure Alarms.

The M20/20A1 Simplified CPEs are used to provide a contamination-free, environmentally controlled workspace for Echelon I and II forward area medical treatment facilities. Current funding levels, however, only will meet Force Package I requirements. There are some Force Package II units designated for deployments into high threat regions that will not be equipped with M20 shelters. M20A1 SCPE procurement was initiated in FY03 and production is ongoing. This leads to a reduced risk assessment since production delivery is scheduled to begin in early 2004. The M20/M20A1 Simplified CPE is no longer a free issue item since the class of supply was changed from class VII to a class II secondary major end item and as such is funded by Army Working Capital Funds. The Marine Corps has Portable Collective Protection Shelters (PCPS) but does not plan to field them. The Marine Corps is instead using them for training purposes. The M20A1 SCPE is by default the only modern collective protection shelter outside of the medical community in the inventory.

The Services have continued to improve integrated collective protection systems in armored vehicles, vans, and ships. All modern armored vehicles and armored vehicles in development have either filtered air systems, hybrid collective protection or full collective protection systems designed into their chassis. Notable progress has been made in providing shipboard collective protection. By the year 2007, most Naval ships that have close-in support roles (including amphibious ships, gunfire support combatants, and new logistics support ships) will contain significant CPS capabilities.

Collective protection filters for integrated systems (such as armored vehicles, ships and planes) continue to suffer from low stocks. While the Services have been proactive in selecting more capable industrial sources, actual procurement and storage of these filters to meet requirements has not been initiated for all filters primarily due to insufficient funding but also since procurement of such filters is demand-driven. As a result, stocks of some filters remain at a low level. However, the filters associated with the 200 CFM Particulate Filter Set for Shipboard Collective Protection Systems (M98) are being procured in sufficient quantities, although filters are backordered due to current manufacturing limitations. Continued difficulties in obtaining a strong industrial base in this field compounds the issue of fielding and sustaining these items.

G.2.4 DECONTAMINATION

Current decontaminants are highly effective against all CB agents, but most present environmental hazards and are manpower intensive. The services are attempting to find environmentally safe decontaminants that are less labor intensive.

Basic soldier skills for decontamination of vehicle and crew-served weapons rely on the M11 Decontamination Apparatus, Portable (DAP) and M13 DAP. The M11 has typically been available in sufficient quantities while the M13 DAP is in short supply. The 1-1/3 quart M11 can be used in place of the 14-liter M13 DAP, but they do not fulfill the same exact capability (in part due to the volume of DS-2). The M100 Sorbent Decon System replaces the M11 and the M13 apparatuses for immediate decon. The M100 began fielding in 2002 and continues through 2004. Army Working Capital funded quantities were available for purchase beginning in 2003.

The M17-series Lightweight Decontamination System (LDS) is used to provide operational equipment decontamination in many battalion-level units and dual-purpose (smoke/decontamination) chemical companies. The Air Force employs the M17 at the squadron level for operational equipment decontamination. The M17 is assessed as having some risk, due in part to a delay in rebuilding several hundred systems caused by a lack of funding since 1990. There is still a large mix of different models in the inventory, forcing the Services to retain a large number of differing spare parts to maintain the different models. Based on projected inventory, should spare parts become difficult to obtain for the different models, the risk may become high. Overall, this risk should drop as more systems are produced and the older models are upgraded or replaced. The Marine Corps is upgrading all of their LDS to the diesel engine. The Air Force is deleting stocks of A/E32-U systems by attrition, modifying existing M17s to M17A2s, and procuring additional M17A3s to satisfy shortages.

In the Army, the M12A1 Power-Driven Decontamination Apparatus (PDDA) and the M17A3 LDS are the primary pieces of equipment used to decontaminate vehicles, crew-served equipment and large areas of terrain. The M12A1 is typically viewed as high risk because the maintenance requirements due to the age of this item limit its full utilization. The use of commercial off-the-shelf technologies will help lessen the risk of shortages. The Marine Corps is replacing their M12A1 PDDAs with the M17-series LDS.

Service plans for stocking containers of DS-2 (5-GAL and M13 Can) are now typically below the requirements expected for decontamination operations. The situation is compounded by the decreasing availability of DS-2. Bulk DS-2 stored at Seneca Army Depot underwent lot testing to ascertain how much has deteriorated and is unusable. As a result, stocks of DS-2 are being released for contingency use only. While less hazardous replacement decontaminants, such as sorbent decon are being fielded, the quantities and packaging of current decontaminants present potential risk. The projected stockage of STB has been considered a high-risk category in the past. Slight shortages in calcium hypochlorite and sodium hypochlorite can be made up by the industrial base, using commercially available alternatives. These increased requirements come as a result of increased attention to the need for decontamination capabilities in the 1-4-2-1 construct scenario, and will be further refined. Continued monitoring is recommended.

The M291 Skin Decontaminating Kit is the only personal decontamination kit approved for use on skin in the U.S. military inventory. Although the kit is currently in backorder, projected buys are expected to meet service requirements. Rohm & Haas Co. was the sole supplier of the resin and made over 150,000 boxes in 1990–91 then sold their automated manufacturing line to the U.S. government. Rohm & Haas no longer supplies one of the XE-555 resin components. Since October 1996, Pine Bluff Arsenal, Arkansas, has been the sole producer of the M291 Decontaminating Kit. Over 60,000 pounds of this proprietary resin was purchased by the item manager and is now being provided to Truetech, Inc. for production of XE-555. When

the 60,000 pounds are gone, XE-555 can no longer be procured. Block I of the Joint Service Family of Decon Systems (JSFDS) program will field a new skin decon kit to replace the M291 in 2007. In the meantime, an interim replacement is nearly ready and a backup program is also in the works just in case. The interim replacement is a Canadian product, Reactive Skin Decon Lotion (RSDL), paid for using Foreign Comparative Test funds. RSDL is expensive while the backup program, using sorbent powder in the M291, is inexpensive compared to the current M291. Testing for the use of sorbent on skin is being paid for using Operating & Support Cost Reduction (OSCR) funds. These replacement programs may become critical if M291 stocks continue to fail shelf life testing.

The projected stockage of the M295 Individual Equipment Decontamination Kit typically puts it in a low risk category. The M295 Decontamination Kit used to contain the same resin mix as the M291 Decontaminating Kit, but since January 2000, it contains an alumina-silica sorbent. The sorbent is much cheaper than XE-555 and readily available. Truetech, Inc. is the main producer of this item, with Pine Bluff Arsenal available for surge capability. Increased funding for its procurement would maintain the low risk.

G.2.5 MEDICAL

Medical CBRN defense items are used to counteract the effects of exposure to chemical, biological, or nuclear agents through pre-treatment, vaccines, or post-treatment. Current projections for medical chemical defense material indicates that sufficient quantities should be on hand through the far-term. Quantities of Nerve Agent Antidote Kits (NAAK), and Atropine and 2-PAM Chloride Autoinjectors may fall short of requirements. Convulsant Antidote Nerve Agent (CANA), and Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP) Tablets (also known as PB Tablets) will probably remain at low risk because of continued purchases. This report includes medical treatments for biological warfare agents and cyanide exposure along with the addition of new chemical treatments.

The FDA has approved SNAPP for the Military, in Jan 2003, for the use as a nerve agent pre-treatment for Soman, with a 10-year shelf life. This new material will require periodic testing after it reaches 5 years, but may not be extended beyond its original 10-year shelf life. The use of SNAPP will still require a complete audit trail, all the way to the user. Defense Supply Center – Philadelphia (DSCP) is working with ICN Pharmaceuticals to establish a requirements contract for the manufacture of SNAPP.

The sole supplier to DoD for NAAK, atropine autoinjectors, pralidoxime autoinjectors and CANA is Meridian Medical Technologies, St Louis, Missouri. The medical chemical defense production line is being maintained with an IBMC. Meridian is a U.S. company but it obtains its atropine for the autoinjectors from a German supplier. Currently there is no domestic source for this drug. Pralidoxime and diazepam (CANA) for the autoinjectors is available from U.S. sources. The replacement for NAAK is the Antidote Treatment, Nerve Agent, Autoinject-tor (ATNAA), which is a multi-chambered injector that began procurement in FY03. ATNAA will replace 2-PAM Chloride Autoinjectors and NAAK over the next 5-7 years. The Atropine Autoinjectors will still be required, but in a smaller quantity.

Patient Chemical Wraps, which are used to transport a patient, who is unable to wear a mask or suit due to their injuries, through an area that may still have a vapor hazard, have not been procured since 1991. The Wraps are made of a special five –layer material that provides protection from a chemical agent, but still allows the required carbon dioxide-oxygen exchange

so no additional breathing apparatus is required. The material is no longer produced. The Office of the Surgeon General and the U.S. Army Medical Materiel Agency (USAMMA) with the Natick Soldier Center are currently assessing new material for the patient wrap before initiating new procurement of this item. The current stock of wraps has been tested for extended use and their use has been modified to a maximum of 3 hours. There is a very large stockpile of canvas litters that may be used once in an NBC environment and then destroyed. As the canvas litters are depleted, they will be replaced with the new nylon decontaminable litter.

The Office of the Surgeon General of the Army has centrally programmed and funded the Army's Medical Chemical Defense Materiel since 1994. USAMMA has procured, stored and maintained this materiel for the Army in strategic locations for early deployers and forward deployed forces Deployable Force Packages (DFP), which will support various sized groups of personnel, based on location and mission. The Marine Corps has consolidated its medical defense materiel into five centralized locations. The materiel is issued from one of the centralized locations whenever a Marine Corps element deploys, and is returned to the centralized program upon redeployment. The Air Force and Navy maintain their medical CB materiel in decentralized unit locations. Visibility of on-hand assets has been improved with the release of the Joint Medical Asset Repository, which is the Class VIII (medical) portion of JTAV.

Currently, the U.S. total force (active and reserve forces) is being vaccinated against anthrax, which is considered the primary high-threat BW agent. The anthrax vaccination program is a three-phase program, starting with the troops serving in—or identified to deploy to—the two high-threat areas where hostile anthrax-use poses the greatest potential danger. The status and schedule of the anthrax vaccination program is provided in Table 2-18 in Chapter 2 of this report.

In the area of medical therapeutics, the Department is maintaining a stockpile of antibiotics (*e.g.*, ciprofloxacin, doxycycline) sufficient to address the treatment needs of potential BW exposures, where such treatment is medically indicated.

The Office of the Assistant Secretary of Defense Health Affairs and the Military Medical Departments in response to Congressional concern over the conservation of military medical resources developed the DoD/FDA Shelf Life Program. The program's focus is to save replacement cost of date sensitive medical materiel especially medical materiel in War Reserve Stocks, Medical Biological Defense Materiel Programs and Medical Chemical Defense Materiel Programs. The Joint Readiness Clinical Advisory Board (JRCAB) manages the shelf-life extension program for the Services and interfaces with the FDA. The FDA requests samples from the JRCAB and the Services. The samples have an initial potency test performed, followed by a 90-day stress test, and then a final potency test. The potency results are compared against a degradation curve, and a new potency period is assigned. The FDA sends the information to the JRCAB and Services who disseminate instructions to extend and re-mark or destroy the materiel to activities and units worldwide. The same lots are subjected to yearly retest and subsequent extensions until the materiel fails or is removed for lack of sufficient on-hand quantities required for testing. The Army maintains its extended materiel at Meridian Medical Technologies for use by Force Package 3 and 4 units. The Air Force maintains its materiel at its local medical logistics activities that re-mark the materiel and maintains it for the deploying units. The Navy re-marks the materiel and maintains it with the unit. The Marines re-mark the materiel at its centralized storage locations. The FDA no longer allows changes to expiration dates to be pen and ink changes. All extended materiel must have a new label, of the same

color, font, and points as the original. The complete label may be replaced, or only the Lot with the new expiration date. The DoD/FDA Shelf Life Program has saved an average of $75.00 of medical chemical defense materiel from having to be destroyed and repurchased for every $1.00 it has cost the Services to get materiel tested and extended by the FDA.

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Annex H

DoD Joint Service CBRN Defense Program Funding Summary

In accordance with 50 USC 1522, *Department of Defense Chemical and Biological Defense Program*, research, development, test and evaluation (RDT&E) and procurement for all DoD chemical and biological defense programs (with the exception of those biological warfare defense RDT&E programs conducted by the Defense Advanced Research Projects Agency, DARPA) are consolidated into defense-wide program element (PE) funding lines. Fiscal year 1996 was the first year in which all Service and Defense Agency CB defense programs were consolidated into defense-wide funding lines. Prior to FY1996, funding was included in several separate Service and Defense Agency funding lines.

The detailed funding information in this annex is provided annually to Congress in the DoD Joint Service Chemical and Biological Defense Program, President's Budget Submission, Research, RDT&E, Defense-Wide and Procurement, Defense-Wide budget exhibits, and in the Department of Defense Extract found in the Budget of the United States. These budget submissions provide a detailed account of prior year accomplishments and planned activities for the budget request period. Table H-1 (and Figure H-1) provides a summary of appropriated and requested funding from FY2002–FY2009. Detailed funding request for FY 2004–2009 are provided separately in the President's FY2004 Budget Submission.

Table H-2 (and Figure H-2) provides a summary of expenditures by the DoD CBRN Defense Program. Expenditures represent the amount of checks issued or other payments made (including advances to others), net of refunds and reimbursements. The term is frequently used interchangeably with the term "outlays," which are the measure of government spending (*i.e.*, payments to liquidate obligations (other than the repayment of debt), net of refunds and offsetting collections.) It is important to note that funds appropriated for a given year may be expended incrementally over a period of years. Thus, expenditures shown in Table H-2 will be updated in following years to show total expenditures of appropriated funds.

Table H-1. CBRN Defense Program Appropriations Summary

Program Element PE ($ in millions)	FY02‡	FY03‡	FY04‡	FY05**	FY06**	FY07**	FY08**	FY09**
0601384BP – Basic Research	43.986	53.162	51.380	36.769	37.839	40.913	43.835	42.399
0602384BP – Applied Research	142.706	170.183	151.372	104.385	101.628	88.519	86.004	85.129
0603384BP – Advanced Tech. Dev.	76.198	105.700	156.496	117.343	84.778	89.432	89.810	86.916
Science & Technology Base Subtotal	**262.89**	**329.045**	**359.248**	**258.497**	**224.245**	**218.864**	**219.649**	**214.444**
0603884BP – Advanced Component Development and Prototypes	119.210	91.567	131.433	104.195	85.825	74.886	61.904	49.999
0604384BP – System Development and Demonstration	168.081	168.723	176.337	152.379	72.702	58.133	93.488	114.511
0605384BP – Management Support	34.091	39.408	38.928	42.652	47.333	45.013	40.145	37.826
0605502BP- Small Business Innovative Research (SBIR)	9.300	9.270	0.000	0.000	0.000	0.000	0.000	0.000
0607384BP – Operational Systems Development	0.000	0.000	0.000	2.178	1.944	0.000	0.000	0.000
RDT&E Subtotal	**593.572**	**638.013**	**705.946**	**559.901**	**432.049**	**396.896**	**415.186**	**416.780**
0208384BP – Procurement Subtotal	**529.637**	**658.139**	**547.401**	**637.741**	**766.668**	**811.519**	**860.263**	**864.633**
CB Defense Program Total	**1123.209**	**1296.152**	**1253.347**	**1197.642**	**1198.717**	**1208.415**	**1275.449**	**1281.413**

‡ Total Obligation Authority (TOA) ** Estimated [from FY2005 President's Budget Request]

Table H-2. CBRN Defense Program Expenditures Summary

Program Element (PE) ($ millions)	FY96†	FY97†	FY98†	FY99†	FY00†	FY01†	FY02†	FY03†
RDT&E, Defense-Wide	251.160	287.824	333.412	332.815	382.171	385.083	443.917	333.321
Procurement, Defense-Wide	135.478	231.714	230.505	299.373	350.708	424.058	373.332	204.637
CB Defense Program Total	386.638	519.538	563.917	632.188	732.879	809.141	817.249	537.958

† Expenditures as of September 30, 2003

Table H-3. DARPA Biological Warfare Defense Program Appropriations Summary

Program Element PE ($ in millions)	FY02‡	FY03‡	FY04‡	FY05**	FY06**	FY07**	FY08**	FY09**
PE 0602383E,– (BW-01) Applied Research	171.878	157.861	149.105	147.533	147.975	146.604	144.888	125.745

‡ Total Obligation Authority (TOA) ** Estimated [from FY2005 President's Budget Request]

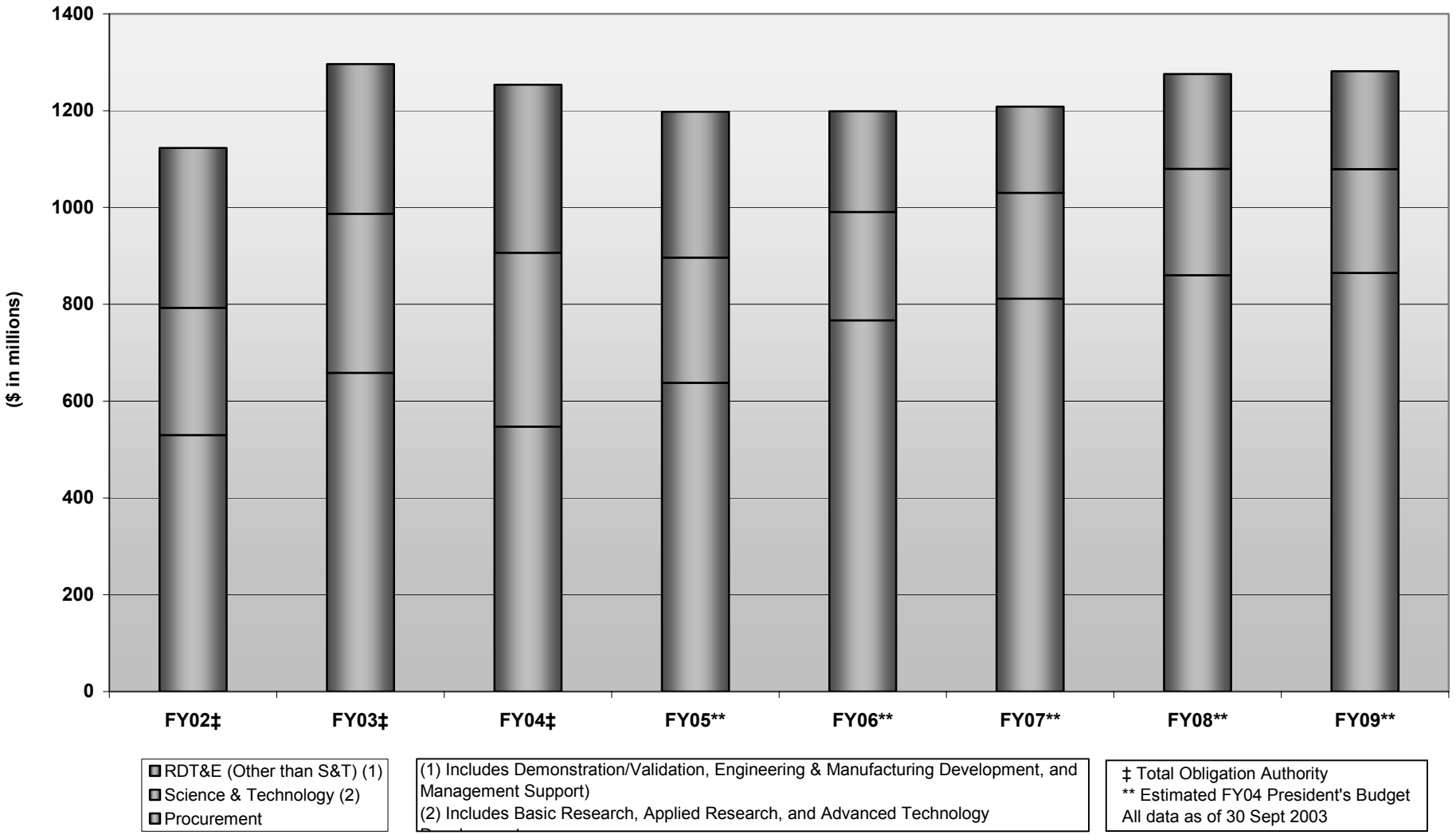
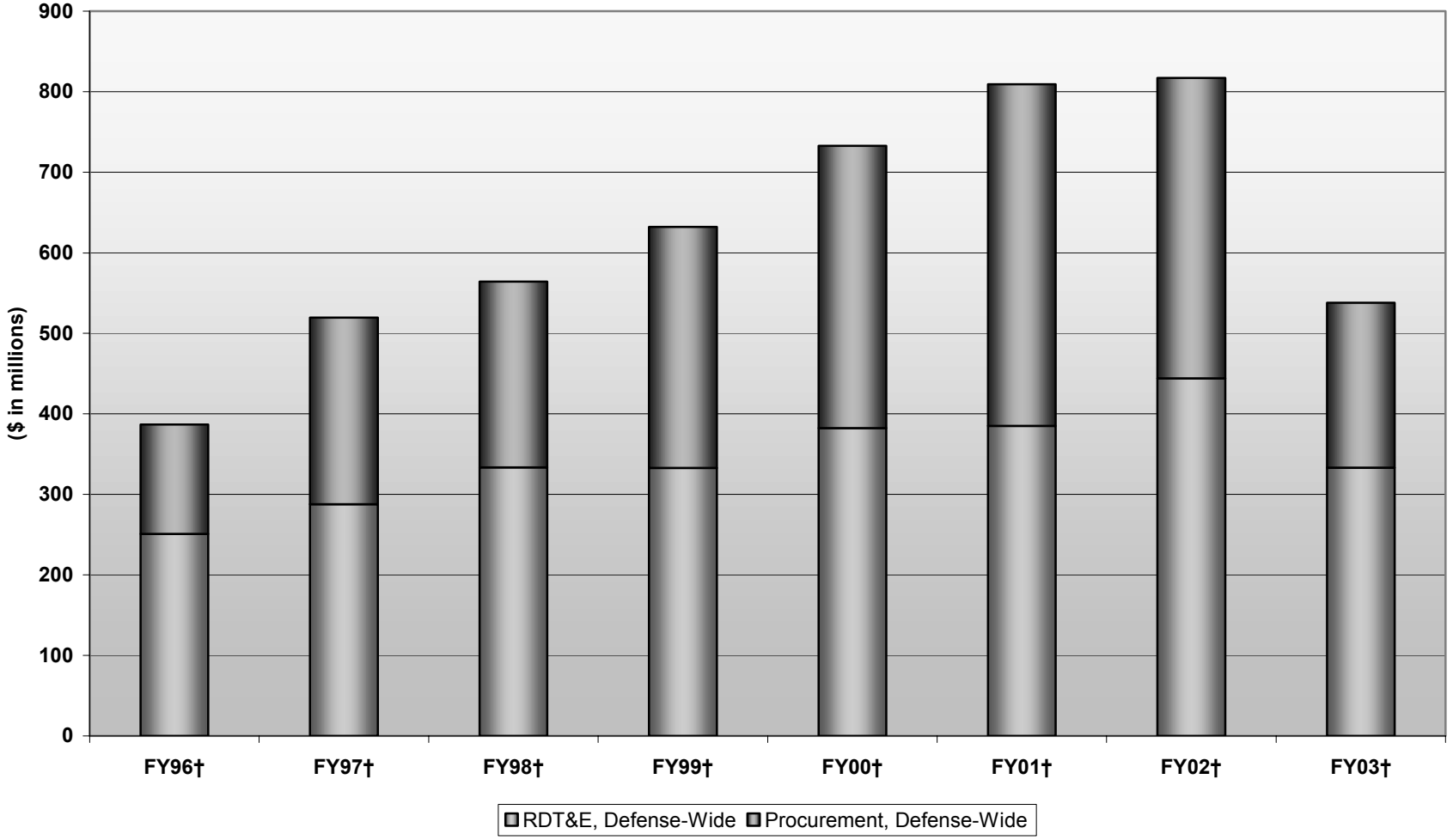


Figure H-1. CBRN Defense Program Appropriations Summary



†as of September 30, 2003

Figure H-2. CBRN Defense Program Expenditures Summary

Annex I

Statement Regarding Chemical and Biological Defense Programs Involving Human Subjects

The reporting requirement (50 USC 1523) for the annual report to Congress on the DoD Chemical and Biological Defense Program was modified by Section 1086 of the FY98 National Defense Authorization Act. 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 Department of Defense 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.

Table I-1 provides a summary of prior and planned tests conducted by the Department of Defense, both 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, since 1975 for chemical agents, and no testing is planned.

Table I-1. Summary of Experiments and Studies with Human Subjects Involving the Use of Chemical or 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 ended

The Department is in full compliance with the requirements of all laws regarding the use of human subjects involving chemical or biological agents. DoD is involved in no experimentation or any other efforts that involve the exposure of unprotected human subjects to chemical or biological agents. All individuals involved in training or RDT&E activities involving live chemical or biological agents are fully protected and carefully monitored.

As part of the DoD CBRN Defense Program, DoD requires the use of small quantities of chemical and biological agents in the research, development, test and evaluation of detection, protection, and decontamination equipment and systems. Chemical and biological agents are also used in small quantities in training U.S. forces to operate in protective equipment and to operate detection and decontamination systems in a chemical or biological environment.

However, no research, development, test or evaluation involves the exposure of unprotected human subjects to chemical or biological agents.

Medical chemical and biological defense programs involve the use of human subjects in controlled clinical trials to test and evaluate the safety, immunogenicity, and other effects of medical products (drugs, vaccines, therapies, *etc.*) to protect against chemical and biological agents. The use of 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, Food and Drug Administration (FDA) regulations, Federal Acquisition Regulations (FAR), DoD Directives and Instructions, and *all* other applicable laws, regulations, issuances, and requirements. The FDA has a proposed rule "New Drug and Biological Drug Products; Evidence needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Human Ethically Cannot be Conducted" October 5, 1999. No medical chemical or biological defense programs involving human subjects involves the exposure of these subjects to chemical or biological agents.

While DoD conducted tests involving the exposure of human subjects to chemical and biological agents in the past, all such tests and programs have been halted and disbanded. 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 biological warfare agents was never done and testing with incapacitating biological warfare agents was ceased in 1969. The last human testing of chemical warfare agents occurred on July 25, 1975. Acting Secretary of Army Norman Augustine suspended testing of chemical compounds on human volunteers on July 28, 1975.

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. See for example, Department of Army, Inspector General Report, DAIG-IN 21-75, *Use of Volunteers in Chemical Agent Research*, March 1976. In addition, there was extensive congressional testimony on this subject during 1975 and 1976. DoD has not conducted any experimentation since that time involving the exposure of human subjects to chemical warfare agents.

As part of some training and RDT&E activities sponsored by the DoD Chemical and Biological Defense Program and by the Military Departments, simulants are sometimes used to enhance the realism of operations in a chemical or biological contaminated environment. Simulants are not chemical or biological agents, but may simulate some of their properties (e.g., particle size, surface absorption). For all personnel involved in testing with simulants, (a) all personnel are informed of any hazards, if any, associated with the simulant, (b) all personnel are provided with appropriate protective equipment, and (c) all names are carefully recorded, and if at some point in the future it is determined that a simulant used in testing presents a potential health hazard, DoD notifies the personnel of potential risks to their health.

Annex J

Chemical and Biological Test and Evaluation Facilities

J.1 BACKGROUND AND REPORTING REQUIREMENT

In the FY04 Senate Armed Services Committee (SASC) Authorization Report (S. Rpt. 108-46 Report Language, p. 239), the SASC directed the Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs (ATSD(NCB)) and the Director, Operational Test and Evaluation (DOT&E) to report on the status of the test and evaluation facilities for chemical and biological defense programs. This annex provides the response to the reporting requirement.

The SASC understands that the development of chemical and biological defense equipment and medical countermeasures (see Annexes A-E) requires adequate test and evaluation (T&E) facilities. The committee is interested in the degree to which these facilities support the Chemical and Biological Defense Program (CBDP). The report should include the following: an analysis of the capacity and versatility of the T&E infrastructure to meet the requirements of current and planned chemical and biological defense research and development programs, including facilities for testing equipment with live agents and simulants and for animal testing; and, an identification of any actions needed to meet testing requirements.

J.2 ANALYSIS OF TEST & EVALUATION INFRASTRUCTURE

J.2.1 Overview.

Currently, T&E facilities are not adequate in terms of either capacity or versatility to meet the needs of CBDP equipment. The program has a limited ability to test and evaluate equipment against evolving threats. Also, in many cases, state-of-the-art technology and analytical methods are lacking or inadequate. The Deputy Undersecretary of the Army (Operations Research) (DUSA(OR)), as the DoD T&E Executive Agent, was designated in mid-2003 to develop programs and integrated approaches to improve the T&E infrastructure to support the CBDP. Recommended programs and approaches will be identified for funding in the Fiscal Year (FY) 06–11 Program Objective Memorandum (POM), which will provide the basis for the FY06 President's Budget Submission, which will be submitted to Congress in February 2006.

J.2.2 Analysis of Capacity.

J.2.2.1 <u>Description of Selected T&E Facilities</u>. The following is an outline of key T&E facilities that are available to provide test data for the CBDP.

a. <u>Medical research facilities</u>. These facilities primarily provide research data, including animal testing with chemical and biological agents to demonstrate the safety and efficacy of medical products.
    i. *U.S. Army Medical Research Institute of Infectious Disease (USAMRIID)*: USAMRIID investigates infectious diseases that require special containment and provides a critical capability to infectious disease research as the only DoD

laboratory equipped to study highly hazardous viruses at Biosafety Level 4. The Institute also operates a reference laboratory for definitive identification of biological threat agents and diagnosis of the diseases they produce.

ii. *U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)*: USAMRICD provides extensive, world-renowned research capabilities to support the identification, development, and fielding of medical countermeasures against chemical and toxin agents.

iii. *Navy Medical Research Center (NMRC)*: The Biological Defense Directorate at NMRC provides rapid and confirmatory diagnosis of infectious diseases through analysis of a wide variety of clinical materials. The directorate explores basic and applied microbiological, immunological and related scientific research methodologies for the development of medical diagnostics. Research personnel have designed, developed, and tested a broad variety of methodologies that have allowed for swift and accurate disease diagnosis essential for substantive medical protection and readiness. In addition, researchers have been instrumental in the advancement and refinement of confirmatory diagnostic methods utilizing polymerase chain reaction (PCR) methodologies in tandem with innovative, state of the art biosensor technologies.

iv. Other Government and extramural facilities exist outside of the Department, but which are leveraged by the CBDP, including the National Institute of Allergies and Infectious Diseases (NIAID). Medical testing is conducted in compliance with the rules, regulations, and requirements established by the Food and Drug Administration (21 CFR).

b. Non-medical Research & Development (R&D) and T&E Facilities.

i. *U.S. Army Edgewood Chemical and Biological Center (ECBC)*: BL-3 and live chemical agent and simulant aerosol particulate bench chambers; CB protective filter and mask testing with live agents and simulants; Small animal live agent testing; Limited field simulant and interferent testing; Two Hazardous Material Explosion Facilities (16,000 cu ft) for testing military unique chemical material and industrial material, which can use one pound of explosives when combined with chemical material, and five pounds of explosives without chemical material; Aerosol stimulant chambers and the Aerodynamic Research Laboratory, comprising approximately 11,000 ft^2 of experimental aerodynamic facilities that include four wind tunnels for component and materials tests; 5 mph Breeze Tunnel, which primarily supports early R&D phases (research on acute and subacute toxicity effects of chemical warfare agent surety materials, terrestrial environmental fate and effects, and effects of chemicals of military interest on varying species of the aquatic ecosystem).

ii. *U.S. Army Dugway Proving Ground (DPG)*: DoD Major Range and Test Facility Base for CB defense: BL-3 and live chemical agent chambers; Life Sciences Test Facility with multiple live biological agent test chambers; Materiel Test Facility with three environmentally controlled, vehicle-size live chemical agent chambers; Environmental permits, test grids, and instrumentation for chemical and biological simulant field and chamber tests. Initial capability for transport-

able instrumentation to support simulant tests and operational tests in off-site environments.

iii. *Air Force Operational Test & Evaluation Center (AFOTEC)*: Utilizes BL-1 lab for simulants at Eglin Air Force Base (AFB); Environmental permits for chemical and biological simulants at Eglin AFB; Capabilities include simulant vapor challenge test chambers and several test ranges, including outdoor decontamination pad for use with chemical simulants. Air Force Research Lab (AFRL): BL-3 lab and chemical simulant testing, component and material level.

iv. *Naval Surface Warfare Center (NSWC), Dahlgren*: BL-3 lab and chemical agent simulants only; Ship wash-down decontamination test facility with simulant; Small scale component and material decontamination tests using simulants; Collective protection development systems for development and simulant testing of airlocks and filter assemblies.

v. *U.S. Navy Operational Test & Evaluation Force* and the *Marine Corps Operational Test & Evaluation Agency*: These facilities provide limited field tests in support of the CBDP; however, they do not possess instrumentation nor facilities to utilize chemical or biological agent, nor simulants. Navy and Marine operational tests leverage DPG or other mobile capabilities if required to use simulants in a field test.

vi. Other Government/International and extramural facilities exist outside of the CBDP that are leveraged to the fullest extent possible on a case by case basis, including: Nevada Test Site (outdoor field tests), Defence Research Establishment (DRES) Canada, and Porton Down United Kingdom (chamber and field tests); Battelle Memorial Institute, Geomet, Southern Research Institute, Arvin/Calspan, Environmental Technologies Group, ITT Research Institute, Midwest Research Institute, and Truetech also have small-scale agent and simulant test capabilities. Other R&D facilities include Los Alamos National Lab (research on biological and radiological defensive systems), MIT Lincoln Labs (laser technology research for defensive biological systems), and Research Triangle Institute (R&D of chemical and biological defense systems).

J.2.2.2 <u>Analysis of T&E Facilities' Capacity</u>. In total, the test facilities possessed by and accessible to the CBDP are not adequate in terms of capacity over the next decade, given the expanding requirements to test whole systems. Myriad R&D, component, and simulant capabilities exist. The test capabilities at R&D facilities do not provide appreciable additions to the total capacity for full system T&E, in that their capabilities are research-oriented and primarily component or material focused. The gravest T&E shortfalls lie in the full systems and platform test chambers and supporting instrumentation and fixtures which can introduce and adequately control live chemical and biological agent challenges and provide a range of environmental and challenge conditions to simulate evolving threats, while performing end-to-end systems operations of CBD equipment. Shortfalls in instrumentation and methodology to support multiple and diverse concurrent natural environmental, full systems operational tests also exist. Specifically, tests for full systems decontamination capabilities, moving platform biological and chemical long range detectors, and full scale battlefield hazard mitigation of protective ensembles do not exist.

Requirements for CBDP-related T&E capabilities for which funding has not been programmed have been frequently identified over the past decade, resulting in a rolling backlog of unimproved or unavailable test facilities, thus resulting in limited capabilities.

J.2.3 Analysis of Versatility.

CBDP T&E capabilities are not sufficiently versatile to provide full decision support to the warfighter commander to address evolving threats, to provide advanced technology test systems and methodologies, to provide the intellectual infrastructure necessary to maintain a core of expertise to plan for test capabilities and program tests, and to provide fully validated characterization data of the CB battlespace.

For the DoD T&E facilities accessible to support the CBDP (see §J.2.2.1), there has been no integrated approach to ensure documentation, validation, and repeatability of test procedures in many cases; no basis or mechanism to standardize procedures among labs, and no advanced planning nor investment for evolving threats and testing of diverse battlespace conditions and missions. This has resulted in specific compartmentalized test capabilities and a lack of versatility. Additionally, correlations of agents and simulants required to support analyses of simulant performance in terms of live agents have not been established.

In the past, the acquisition programs have sponsored expedited applications of existing test capabilities (either in government or commercial facilities) in order to meet immediate urgent needs. This has often resulted in inadequate or incomplete data for milestone decisions, unsuccessful operational evaluations, increased operational risks, or only partial ability to analyze data. Data analysis was limited because the focus did not include characterization of the underlying physical mechanisms of the CBD system performance and operational environment, agent-simulant correlations, nor development of the required analytical tools and models to provide complete CBD system performance information to evaluators or commanders.

The T&E infrastructure in terms of intellectual capital/personnel resources required to support the CBDP is currently not adequate; however, efforts are underway to identify and plan for these resources. As required by Public Law 103-160, Section 1703, all CBDP T&E funds are provided through a defense-wide account, thus the Services may not independently support the T&E infrastructure through Service research, development, test and evaluation (RDT&E) accounts. Other than the individual direct test programs, much of the current Operational Test Agency (OTA) infrastructure that supports the CBDP has limited or no funding from each Service, thus hampering the ability to perform early T&E methodology planning and continuous evaluation. The OTA intellectual infrastructure is critical for the advanced planning for test capabilities, for adequate testing in terms of scope and threat and scenario types, and for the validation and standardization of test methods to provide robust and defensible data and agent-simulant correlations.

J.2.4 Path Forward.

J.2.4.1. <u>Integrated Approach to Plan for T&E Infrastructure</u>. In 2003, the DoD T&E Executive Agent was established to develop an integrated approach to plan for and obtain the T&E infrastructure required to support the CBDP. However, funding does not exist to fully develop and sustain this infrastructure, nor the improvements and new test methods required to address evolving threats. An assessment of funding needs will be conducted as the basis for the

development of the FY06 President's Budget Submission. If full funding is provided, this integrated T&E infrastructure development approach will provide the mechanisms to plan for test capabilities and methodologies development and validation such that these are synchronized with acquisition programs' T&E requirements, to invest synergistically in capabilities that have multiple utilities and leverage among test technologies, to perform the studies to characterize physical phenomena and interaction of variables affecting CBD system performance, and to develop the models and analytical methods necessary to provide commanders' guidance for CBD operations and equipment use. A key element of the developmental T&E work required is the correlations of agents and simulants performance for all CBD materiel.

As an example of the status of the T&E integration, AFOTEC conducted field simulant testing of the biological detection systems as a Multi-Service Operational Test & Evaluation (MOT&E), which involved all OTAs including DPG support, and completed an integrated MOT&E report. The primary focus of Navy CBD testing in 2003 has been on preparations for operational tests in 2004. There was a limited amount of developmental testing conducted, primarily for JSLSCAD and JBPDS; however, the major effort was participation in joint Test & Evaluation Master Plan (TEMP) development. These efforts by AFOTEC and the U.S. Navy Operational T&E Force reflect the spirit of the joint integrated T&E infrastructure approach and indicate a sound direction in establishing a common set of processes and procedures for joint CBDP T&E.

J.2.4.2. Specific T&E Needs. Efforts are ongoing to fully identify T&E infrastructure shortfalls critical to the CBDP, counter-terrorism, and to address evolving threats. Following is a description of activities and capabilities needed to address the full scope of ongoing and planned T&E needs. The activities below have limited or no funding. A programmatic assessment to determine funding needs is being conducted in the development of the FY06–11 POM.

J.2.4.2.1 ***Whole System Live Agent Testing.*** The DOT&E has identified the requirement to conduct Whole System Live Agent Testing (WSLAT) of biological agent point detection systems with live biological agent aerosols. Currently, active agent testing is conducted only at the subcomponent level, due to size constraints associated with existing aerosol containment chambers. Whole system testing is conducted solely with biological agent simulants. While the current approaches have met minimal requirements to test and field detectors, DOT&E requires the WSLAT to provide data sufficient for system evaluation. Initial funding to develop a WSLAT capability is available for FY04, but this is insufficient to fully develop, operate, and maintain the capability.

J.2.4.2.2 ***Field Trials***. Since more than thirty years have passed since the last outdoor test with live chemical agent, much of the infrastructure for field testing of chemical detectors no longer exists or is seriously outdated. A long-range field test development effort was started two years ago at Dugway Proving Ground, including a safari capability for testing at other locations, including internationally. Currently this area depends on bio-field test equipment and location for testing. This impacts both chemical and biological defense detection programs.

J.2.4.2.3 ***Live Agent Test Chamber***. A test chamber and validated methods adequate to perform live CB agent testing of active standoff CB detectors is a critical need of the CBDP program. Work with actual agents is necessary for both development and testing to establish the library of algorithms for the system to detect CB agents, and to test the efficiency of detection.

An active system test chamber for chemical agents is currently being designed and should be ready for testing in FY07, but a building to house the facility is not due to start construction until FY08, which will delay testing with agents an additional 2-3 years. There are technical risks associated with the development of this capability that could delay testing even longer, causing greater programmatic impacts in this top priority capability area.

J.2.4.2.4 ***Emerging Threats.*** For individual protection, test methods are required to address emerging threats, including Non-Traditional Agents (NTAs), Toxic Industrial Materials (TIMs), and dusty agents. A critical requirement exists for a whole system live agent CB ensemble test supported by modeling to allow integration of toxicological data into valid estimates of casualty predictions. Whole ensemble testing is currently conducted with one simulant that has been determined to be safe for human use. Methodology studies are needed to characterize physical properties affecting protection and to understand the interactions among variables that affect protection in order to link all the tests in an analysis and model to predict hazard levels in order to optimize CB ensemble design and deployment. There is no established, quantifiable correlation between the simulant leakage and that of either chemical or biological agents, nor among protection test data and toxicological hazard data. For both individual and collective protection equipment testing, fixtures used to test swatches of material for leakage against chemical agents are outdated and were not designed to represent field wear conditions. Fixtures containing new sample cells that will more accurately sample the air behind the protective material, provide dynamic subsystem tests, and enable tests to characterize the effects of high winds on system protection are technologically feasible and have been designed, but require funding to develop and validate.

J.2.4.2.5 ***Decontamination Testing.*** The testing of decontaminants and decontamination systems is hampered by the lack of any acceptable simulants for field testing and training and lack of agent-simulant correlations. Due to the unique qualities of chemicals and biologics, even within the same family, no two chemicals or biologics act the same when exposed to the same decontaminant or environment. Decontamination is a physical process that will always be dependent upon the exact chemical or biologic present. Testing is currently conducted with small components or panels of hardware in test chambers. While whole systems are tested with simulants, this testing is inadequate, since even the correct level and type of contamination is not realistic. The recommendation is to remove unserviceable equipment from DoD's inventory for testing with chemical and biological agents. The Multipurpose Chamber at DPG was designed for this type of testing, being capable of testing up to helicopter and fighter jet-sized test items. Unfortunately this chamber is completely scheduled with detector testing and unavailable until FY10 or later, when CB detector test facilities are completed.

The decontamination pad used at Dugway Proving Ground was contaminated in the 1980s with C8 Emulsion decontaminant. The area is a Solid Waste Management Unit regulated under RCRA. This limits the type and quantity of testing that can be done there. This pad needs to be replaced with an environmentally sound system that will collect all run-off.

J.2.4.2.6 ***Simulants and Agent Characteristics.*** Agent/simulant correlations are a cross-commodity testing need in the CBDP. Also in this category are test chambers and methods for NTAs, aerosol chemical agents, testing with TIMs (chemical, biological, and radiological), new ground-truth sampling systems, realistic threat chemical and biologic dissemination and

characterization, surface sampling methods, and an acceptable contact hazard model based on actual data.

J.2.4.2.7 ***Animal Research Facilities.*** Animal Test Research that supports the CBDP requires work with chemical surety materials will require an increase in scope to support specific hazard definition and protective ensemble performance. Simulant research cannot accurately predict biomedical outcomes of chemical warfare agents. By Federal Law chemical surety materials, including dilute agents, must be under DoD/Department of the Army control. The animal research test facilities at the U.S. Army ECBC must be augmented to meet these requirements.

J.2.4.2.8 ***Updating T&E Infrastructure.*** Test infrastructure for other CBDP systems in development meet minimal testing requirements, but in most cases are either outdated, incapable of a high degree of reproducibility or precision, underfunded, or otherwise inadequate to meet schedule or quality requirements for operational evaluations or commanders' guidance. Most testing currently performed is neither as operationally relevant, or based on actual threat scenarios as the warfighters require.

The development of all CBDP materiel—from detectors, individual protective gear, and decontaminants—require test validation against actual chemical warfare agents (CWAs) in systems validated with animal models. Inhalation exposures are the most likely exposure route for volatile CWAs and a likely route for weaponized agents. Such exposures, to either vapor or aerosol forms of CWA, require specialized equipment found in few areas of the world and expert personnel to supervise and run the exposure trials. At a minimum, expertise is required in inhalation toxicology, analytical chemistry and respiratory physiology. An inhalation agent testing capability has been firmly established at ECBC in accordance with all DoD safety, surety, security and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) requirements and in compliance with Good Laboratory Practices (GLP) in the new state of the art Life Sciences Research facility.

This current state of the art research facility is underfunded in terms of its maintenance, routine replacement, and capacity to meet current increased needs. Lack of continued maintenance funds could deteriorate these capabilities. As with overall T&E infrastructure, sustainment and instrumentation costs have been passed to CBDP research programs that are not adequately budgeted for these expenses.

For CB defense medical countermeasures, Annex E provides a detailed description of technical barriers for the various prophylaxes, therapeutics, and diagnostics, and outlines T&E needs to be overcome to ensure development of FDA licensed medical products.

J.3 ACTIONS NEEDED TO MEET TESTING REQUIREMENTS

This section supplements section J.2.4.2 above and outlines activities that are either unfunded or only partially funded The following have been identified as critical test capability shortfalls for CBDP programs: Note: These shortfalls primarily comprise needs for tests that do not presently exist, but also include tests that require improvement in order to provide data adequate for evaluator, decision maker, and Combatant Commander information needs. In addition, continued identification and development of CBDP T&E intellectual and capabilities infrastructure is required as a significant investment of the CBDP. T&E needs below are

organized according to the Joint Enabling Concept they support, that is, Sense, Shape, Shield, and Sustain.

J.3.1. SHIELD: Individual/Collective Protective Equipment (IPE/CPE).

- Tests to address NTAs, TIMs, and dusty agents.
- Development of modeling and analysis methods to characterize system protection in terms of toxicological hazard levels to give commanders guidance for effective CB ensemble use.
- Whole system live agent testing of CB protective ensembles.
- Next Generation Man-in-Simulant Test (MIST): Provide near real-time sampling technology for material and system tests to better characterize CB performance and provide operationally useful information regarding effects of changing battlefield conditions and warfighter movement. The current test capacity and challenge types for system testing of CB ensembles needs to be improved to meet the rising test demands of new RDA Plan systems, including liquid challenges and expanded processing capability. Increase the test aerosol CB simulant challenges beyond the present capability of 1-2 subjects per trial. Current IPE systems being tested require a larger chamber and increased test capacity. Also, a larger and more controlled range of particle sizes will be available to better simulate a range of dusty CB agents.
- Obtain CB ensemble subsystem tests with live agents (CB gloves, footwear, and masks) to include testing of CB masks with biological challenges and with a wider range of helmets and respiratory conditions.

J.3.2. SENSE: CB Standoff Detection.

- Implementation of National Research Council (NRC) test requirements that require environmental modeling be used to augment live-agent testing.
- Better characterized threats for realistic threat scenarios for developmental and operational tests. This needs to include the ability to establish the relationship between lab agent performance and field simulant performance.
- Provide additional ground truth instrumentation, including augmenting the ability to exploit future advances in imaging spectrometer and Raman light detection and ranging (LIDAR) technologies.
- Provide for improved data collection, archiving, and automated processing of trial results to enable test schedules to proceed and for test conditions to be adjusted as necessary to account for previous trial data. This significantly improves the ability to characterize system performance over a wider and better-defined set of operational conditions and greatly lessens lost data and repeated trials required.

J.3.3. SENSE: Chemical Point Detection.

- Provide technological improvements that reduce cost, improve test schedules and efficiency, and minimize test performance impacts.
- Relocate detector test fixtures from the current Materiel Test Facility (MTF) chamber, which is required to test new systems.

- Correlate chamber agent performance with field simulant performance with additional detectors, decontaminants, and protective materials that establish ground truth data comparing agent and simulant under comparable conditions.
- Full characterization of the chemical agents of varying grade or quality, interferent, and development and documentation of more effective test methods for non-traditional agents.
- Improved and accelerated development of referee systems, sampling and analysis, validation testing, and Test Operating Procedures. Final studies on uniform dissemination and reproducibility of dusty challenge materials also will be accelerated and completed.
- Building upgrades (test fixture mechanical systems, safety systems, controls, and data systems) need to be funded, which will result in shorter and less expensive tests and more efficient test operations at reduced direct cost to customers.

J.3.2.4. SENSE: Biological Point Detection.

- Purchase equipment for modular BL-3 laboratory space to support WSLAT.
- Projects that validate and expand current Polymerase Chain Reaction (PCR) technologies, characterize interferent challenges, develop improved chamber bioaerosol dissemination methods, develop encapsulated simulants, and develop robust simulants.

J.3.2.5. SUSTAIN: Decontamination.

- Replace and enlarge decon pad to support both developmental and operational testing.
- Support full-system, end-to-end decontamination procedure development and demonstration, including means to determine success of decontamination, characterization of decon chemistry and mechanisms, and agent-simulant correlation for use in field testing and training.
- Accepted methods for measuring chemical agent vapor and contact hazards, and determining decontaminability of RDA systems exposed to agents of biological origin.
- Tests and models to characterize degradation of system function by decontamination processes

J.3.2.6. Sustainment of Existing Infrastructure.

- Prepare sustainment plans and finance sustainment for existing CBDP laboratories, test facilities, chambers and outdoor test grids.
- Includes sustainment plans and funding for new test capabilities developed under the CTEIP or Modernization Programs.
- Fund all Direct Test Support requirements at Dugway Proving Ground.

J.3.2.7. New T&E Technologies. Examples of requirements and test conditions for which test technology must be developed and validated include:

Unique agent challenge profiles, jet aircraft flight conditions, and simulated effective respiratory rates in CB mask protection agent tests; and expanded environmental and agent challenge conditions for individual protection materials and systems. Test technology will also provide agent (lab) and simulant (lab and field) challenge generation and control, agent-simulant correlations, and near real-time measurements of CBD systems responses. Provide mobile, deployable test capabilities to perform field simulant testing in multiple natural

environments to ensure that CBD systems are effective, suitable, and survivable across the range of environments in which they will be deployed.

Capabilities to enable testers to provide evaluators and unit commanders specific information about how to properly use the CBD systems tested to mitigate risks in the CB environment, and also to provide system developers the information required to adequately develop and mature the systems. Test infrastructure will be adequate to ensure that data are available to certify that critical CBD systems are ready for operational tests and to identify any potential vulnerabilities.

Establish the test methods, instrumentation, and Test Operating Procedures (TOPs) required to meet evaluator data requirements for lab CB agent testing and outdoor simulant testing in multiple environments. Validation trials will be conducted on initial general capabilities to support finalization of the TOPs.

Annex K

Congressional Reporting Requirement: 50 USC 1523

Text of Public Law Mandating Report on
The Department of Defense Chemical and Biological Defense Program

Title 50 of the U.S. Code, Sec. 1523. Annual report on chemical and biological warfare defense
Implemented by Public Law 103-160, The FY94 National Defense Authorization Act

(a) Report required

The Secretary of Defense shall include in the annual report of the Secretary under section 113(c) of title 10, a report on chemical and biological warfare defense. The report shall assess--

(1) the overall readiness of the Armed Forces to fight in a chemical-biological warfare environment and shall describe steps taken and planned to be taken to improve such readiness; and

(2) requirements for the chemical and biological warfare defense program, including requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical or biological weapons.

(b) Matters to be included

The report shall include information on the following:

(1) The quantities, characteristics, and capabilities of fielded chemical and biological defense equipment to meet wartime and peacetime requirements for support of the Armed Forces, including individual protective items.

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

(3) Measures taken to ensure the integration of requirements for chemical and biological defense equipment and material among the Armed Forces.

(4) The status of nuclear, biological, and chemical (NBC) warfare defense training and readiness among the Armed Forces and measures being taken to include realistic nuclear, biological, and chemical warfare simulations in war games, battle simulations, and training exercises.

(5) Measures taken to improve overall management and coordination of the chemical and biological defense program.

(6) Problems encountered in the chemical and biological warfare defense program during the past year and recommended solutions to those problems for which additional resources or actions by the Congress are required.

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

(8) A summary of other preparations undertaken by the Department of Defense and the On-Site Inspection Agency to prepare for and to assist in the implementation of the convention, including activities such as training for inspectors, preparation of defense installations for inspections under the convention using the Defense Treaty Inspection

Readiness Program, provision of chemical weapons detection equipment, and assistance in the safe transportation, storage, and destruction of chemical weapons in other signatory nations to the convention.

(9) A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, 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.

Annex L

Acronyms and Abbreviations

Note: The acronyms and abbreviations in this annex reflect an extensive, though not exhaustive, list of terms related to the various and diverse CB defense activities. The acronyms might have different meanings in other contexts.

–A–

AAAV – Advanced Amphibious Assault Vehicle
AAR – after action report
AARS – Advanced Airborne Radiac System
AB – Air Base
ABDU – Aviation Battle Dress Utilities
ABO – Agent of Biological Origin
AC – Active Component
ACAA – Automatic Chemical Agent Alarm
ACADA – Automatic Chemical Agent Detector
ACAT – Acquisition Category
ACC – Air Combat Command
ACD&P – Advanced Component Development & Prototypes
ACES – Air Force Command Exercise System
Ach – acetylcholine
ACPLA – agent containing particle per liter of air
ACPM – Aircrew Protective Mask
ACTD – Advanced Concept Technology Demonstration
ADS – Area Detection System
AEL – Allowance Equipage List
AERP – Aircrew Eye/Respiratory Protection
AFB – Air Force Base
AFI – Air Force Instruction
AFIP – Armed Forces Institute of Pathology
AFMAN – Air Force Manual
AFMS – Air Force Medical Service
AFRRI – Armed Forces Radiobiology Research Institute
AICPS – Advanced Integrated Collective Protective System
AIDET – Aircraft Interior Detector
AIT – Aeromedical Isolation Team
ALAD – Automatic Liquid Agent Detector
ALS - Analytical Laboratory System
ALSA – Air Land Sea Application
AMAD – Automatic Mustard Agent Detector
AMC – U.S. Army Materiel Command
AMEDD – Army Medical Department
AMEDDC&S – Army Medical Department Center & School
AMFN – AMEDD Medical Fusion Network
AMSNY – Associated Medical Schools of NY
ANCOC – Advanced NCO Course
ANG – Air National Guard
AN/VDR-2 – Portable dose-rate gamma/beta radiation meter
AN/VDR-13 – Compact, digital whole body radiation meter
APC – Armored Personnel Carrier
APODS – Aerial Port of Debarkation
ARNG – Army National Guard
ARTEP – Army Training and Exercise Plan
ASA(ALT) – Assistant Secretary of the Army for Acquisition, Logistics, & Technology
ASBREM – Armed Services Biomedical Research Evaluation and Management
ASCC – Air Standardization Coordinating Committee
ASD(HA) – Assistant Secretary of Defense for Health Affairs
ASD(S&TR) – Assistant Secretary of Defense for Strategy & Threat Reduction
ASD(SO/LIC) – Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict
ATD – Advanced Technology Demonstration
AT/FP – Antiterrorism Force Protection
ATG – Afloat Training Group
ATH – Air Transportable Hospital
ATNAA – Antidote Treatment Nerve Agent Autoinjector
ATP – Adenosine Triphosphate *or* Allied Tactical Publication
ATS – Automatic Transfer Switch
ATSD(NCB) – Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs
ATSO – Ability to Survive and Operate
aTSP – active Topical Skin Protectant
AVA – Anthrax Vaccine Adsorbed
AVIB – Aircrew Uniform Integrated Battlefield
AVIP – Anthrax Vaccine Immunization Program

–B–

B. anthracis – Bacillus anthracis (anthrax)
B. mallei– Burkholderia mallei (glanders)
BAT – Biodosimetry Assessment Tool
BBS – Brigade Battle Simulation

BCTP – Battle Command Training Center
BD – biological detector (*also,* biological defense)
BDO – Battledress Overgarment
BDU – Battledress Uniform
BES – Budget Estimate Submission
BG – *Bacillus Globigii*
BIDS – Biological Integrated Detection System
BIODET – biological detection
BL – Biosafety Level
BLA – Biologics Licensing Application
BNCOC – Basic Non-Commissioned Officer Course
BOG – Board of Governors
BoNT – Botulinum Neurotoxin
BoNT/A – Botulinum Neurotoxin A
BoNT/B – Botulinum Neurotoxin B
BRP – Basic Research Plan
BSPS – Biological Sample Preparation System
BTN – below the neck
BTRC – Biological Threat Response Cell
BuChE – butyrylcholinesterase
BVO/GVO – black vinyl overboot/green vinyl overboot
BW – biological warfare
BWC – Biological Weapons Convention
BWD – Biological Warfare Defense

–C–

C3 – Command, Control, & Communications

C4I – command, control, communication, computer, and intelligence
C4ISR – command, control, communication, computer, intelligence, surveillance, and reconnaissance
C. burnetii – *Coxiella burnetii* (Q fever)
CA – Commodity Area
CAA – Center for Army Analysis
CA/D – Chemical Activity/Depot
CaE – carboxylesterase
CAM – Chemical Agent Monitor (*also,* Commodity Area Manager)
CAMEX – Computer Assisted Map Exercise
CANA – Convulsant Antidote Nerve Agent autoinjector
CANE – Combined Arms in a Nuclear/Chemical Environment
CAPDS – Chemical Agent Point Detection System
CARDS – Chemical Agent Remote Detection System
CASPOD – Contamination Avoidance at Sea Ports of Debarkation
CASTFOREM – Combined Arms and Support Task Force Evaluation Model
CatOx – catalytic oxidation
CATS – Consequence Assessment Tool Set
CAWM – Chemical Agent Water Monitor
CAX – Combined Arms Exercise
CB – chemical and biological (*also,* C/B)
CBAAG – Chemical and Biological Agent Advisory Group
CBAT – Chemical Biological Augmentation Team
CBAWM – Chemical Biological Agent Water Monitor
CBD – chemical and biological defense
CBDP – Chemical/Biological Defense Program
CBIAC – Chemical and Biological Information Analysis Center
CBIRF – Chemical Biological Incident Response Force
CBIS – CB Individual Sampler
CBM&S – Chemical/Biological Modeling & Simulation
CBMS – chemical biological mass spectrometer
CBMS – Chemical Biological Medical Systems
CBNP – Chemical Biological National Security Program
CBPS – Chemical Biological Protective Shelter
CBR – Chemical, Biological, and Radiological
CBR-D – Chemical, Biological, and Radiological Defense
CBRD TAVMS – CBRD Total Asset Visibility Management System
CBRNE – Chemical , Biological, Radiological, Nuclear, and High-Yield Explosives
CBRNC – Chemical, Biological, Radiological, and Nuclear Countermeasures
C/B-RRT – Chemical/Biological Rapid Response Team
CBS – Corps Battle Simulation
CBSD – Chemical Biological Stand-off Detector
CBTAP – Chemical and Biological Threat Agent Program
CBW – chemical and biological warfare
CCD – Camouflage, Concealment, and Deception
CCTI – Chairman's Commended Training Issues
CDC – Centers for Disease Control and Prevention
CD-ROM – Compact Disk - Read Only Memory
CDTF – Chemical Defense Training Facility (at the U.S. Army Chemical School)
CE – Civil Engineering
CEES – half mustard (2-chloroethyl ethylsulfide)
CEM – Concept Evaluation Model
CENTCOM – Central Command
CESM – Chemical Environment Survivability Mask
CESS – Chemical Environment Survivability Suit
CFD – Computational Fluid Dynamic(s)
CFM – cubic feet per minute
CFR – Code of Federal Regulations
CFX – computational fluid effects

cGMP – current Good Manufacturing Practices
CHAMP – Chemically/biologically Hardened Air Management Plant
CHATH – Chemically/Biologically Hardened Air Transportable Hospital
ChE – Cholinesterase
CIA – Central Intelligence Agency
CJCS – Chairman of the Joint Chief of Staff
CM – Chloroform-Methanol (*also,* consequence management, crisis management, or countermeasures)
CMO – Central MASINT Office
CMR – Chloroform-Methanol Residue
CMTC – Combat Maneuver Training Center
CMX – Crisis Management Exercise
CNS – Central Nervous System
COBC – Chemical Officer Basic Course
CoM – Consequence Management
COMMZ – Communications Zone
COMPTUEX – Composite Training Unit Exercise
CONOPS – Concept of Operations
CONUS – continental United States
COTS – Commercial Off-the-Shelf
CP – chemical protective (*also,* collective protection, command post, *or* counterproliferation)
CPDEPMEDS – Chemically Protected Deployable Medical System
CPE – Collective Protection Equipment
CPEMEDS – Collective Protection for Expeditionary Medical Support
CPO – Chemical Protective Overgarment
CPRC – Counterproliferation Review Council
CPS – Collective Protection System
CPU – Chemical Protective Undergarment
CRDA – Cooperative Research and Development Agreement
CREST – Casualty and Requirements Estimation Tool
CRG – Compliance Review Group
CRP – Critical Reagents Program
CS – tear gas
CSAT – Command and Staff Awareness Training
CSST – Chemical Casualty Site Team
CT – Concentration over time
CTB – *cholera toxin subunit B*
CTC – Combat Training Center
CTR – Cooperative Threat Reduction
CTS – Casualty Training System
CVC – Combat Vehicle Crewmen
CVIP – Chemical Vision Implementation Plan
CW – Chemical Warfare
CWA – Chemical Warfare Agent
CWC – Chemical Weapons Convention
CWCIWG – Chemical Weapons Convention Implementation Working Group
CWDD – Chemical Warfare Directional Detector (AN/KAS-1A)
CWICS – Chemical Weapons Interior Compartment System
CWNAVSIM – Chemical Warfare Naval Simulation

–D–

DAB – Defense Acquisition Board
DAIG – Department of the Army Inspector General
DAP – Decontaminating Apparatus Portable
DARPA – Defense Advanced Research Projects Agency
DASG-HCO – Department of the Army Surgeon General-Health Care Office
DATSD (CBD) – Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense
DCSOPS – U.S. Army Deputy Chief of Staff for Operations
DDR&E – Director, Defense Research & Engineering
DEA – Data Exchange Agreement
DEMP – Defense Equipment Management Program
DEPMEDS – Deployable Medical Systems
DEST – Domestic Emergency Response Team
DFU – Dry Filtration Unit
DHS – Department of Homeland Security
DHHS – Department of Health and Human Services
DLA – Defense Logistics Agency
DMMP – Dimethyl Methyl Phosphonate
DMRTI – Defense Medical Readiness Training Institute
DNA – Deoxyribonucleic Acid
DNBI – Disease and Non-Battle Injury
DNWS – Defense Nuclear Weapons School
DoD – Department of Defense
DoE – Department of Energy
DPE – Demilitarization Protective Ensemble
DPG – Defense Planning Guidance (*also,* Dugway Proving Grounds)
DRB – Defense Review Board (*also,* Defense Resources Board, or Division Ready Brigade)
DRI – Defense Reform Initiative
DRMO – Defense Reutilization and Marketing Service
DS2 – Decontamination Solution 2
DSCP – Defense Supply Center, Philadelphia
DSO – Defense Sciences Office
DSTAG – Defense Science and Technology Advisory Group
DTO – Defense Technology Objective
DTAP – Defense Technology Area Plan

DTIRP – Defense Technical Inspection Readiness Program
DTLOMS – Doctrine, Training, Leader Development, Organization, Material, and Soldier/Personnel
DTN – Decision Tree Network
DTO – Defense Technology Objective
DT/OT – developmental/operational testing
DTRA – Defense Threat Reduction Agency
DTRA(CB) – Defense Threat Reduction Agency's Chemical and Biological Defense Directorate

–E–

E. coli – *Escherichia coli*
EBO – Ebola virus
ECBC – Edgewood Chemical & Biological Center
ECLA – electrochemilluminescense assay
ECTA – Embedded Common Technical Architecture
ECU – Environmental Control Unit
ECV – Expanded Capacity Vehicle
ED – ethyl dichlorarsine
EEE – Eastern Equine Encephalomyelitis
EEG – electroencephalographic
ELISA – Enzyme-Linked Immunosorbent Assay
EMW – Expeditionary Maneuver Warfare
ENCOMPASS – Enhanced Consequence Management Planning and Support System
EOD – Explosive Ordnance Disposal
ESS – Environmental Support System
EUCOM – European Command

–F–

F1 – Fraction 1
F1-V – Fraction 1 - "V" Antigen
Fab – Fragment Antigen Binding
FABS – Force Amplified Biosensor
FAR – Federal Acquisition Regulations
FBI – Federal Bureau of Investigations
Fc – Fragment Crystallizable
FCBC – Field Management of Chemical and Biological Casualties Course
FDA – Food and Drug Administration
FDTE – Force Development Testing and Experimentation
FEST – Foreign Emergency Response Team
FLEETEX – Fleet Exercise(s)
FM – Field Manual
FORCEM – Force Evaluation Model
FORSCOM – Forces Command
FR – flame resistance
FUE – First Unit Equipped
FY – fiscal year
FY99 – Fiscal Year 1999
FYDP – Future Years' Defense Plan

–G–

G-CSF – Gramucolyte Colony Stimulating Factor
GA – tabun, a nerve agent
GAO – General Accounting Office
GAS – Group A *Streptococcus*
GB – sarin, a nerve agent
GC – gas chromatography
GD – soman, a nerve agent
GEMS – Global Expeditionary Medical System
GF – cyclosarin, a nerve agent
GLP – Good Laboratory Practices
GMP – Good Manufacturing Practice
GOTS – Government Off The Shelf
GOCO – Government-Owned/Contractor-Operated
GP – glycoprotein
GPFU – Gas Particulate Filter Unit
GPRA – Government Performance and Results Act
GSORTS – Global Status of Resources and Training System(s)

–H–

HAZWARN – NBC Hazardous Warning System
HAZWOPER – Hazardous Waste Operations and Emergency Response
hBuChE – Human Butrylcholinesterase
hCaE – Human Carboxylesterase
HD – sulfur mustard, a blister agent
HEPA – high efficiency particulate
HHA – Hand Held Immunochromatographic Assay
HLA – high level architecture
HMMWV – High Mobility Multipurpose Wheeled Vehicle
HN – Host Nation
HPAC – Hazard Prediction Assessment Capability
HQ – headquarters
HSC/YA – Human Systems Program Office
HSO – Heath and Safety Orientation (Course)
HTA – high threat area
HTH – High Test Hypochlorite
HVAC – heating, ventilation, and air conditioning

–I–

IBAD – Interim Biological Agent Detector
IBMC – Industrial Base Maintenance Contract
ICAD – Individual Chemical Agent Detector
ICAM – Improved Chemical Agent Monitor
ICDS – Improved Chemical Detection System
ID – infantry division
IDE – integrated digital environment
IDLH – Immediate Danger to Life and Health
IEG – Information Exchange Group
IET – Initial Entry Training
IL – Interleukin

IL CBDWS – In-Line Chemical Biological Defense Water System
IM – intramuscular
IMMC – Integrated Materiel Management Center
IMS – Ion Mobility Spectroscopy
IND – Investigational New Drug
IOT&E – Initial Operational Testing & Evaluation
IP – intraperitoneal
IPDS – Improved (chemical) Point Detection System
IPE – Individual Protective Equipment
IMP – Industrial Preparedness Measure(s)
IPP – Installation Protection Program
IPR – In-Process Review
IPT – Integrated Product Team
IR&D – Independent Research & Development
IR-LIDAR – Infrared Light Detection and Ranging
IS – Instrumentation System
ISD – Individual Soldier Detector
ISO – International Standards Organization
ITAP – Improved Toxicological Agent Protective Ensemble
ITS – Individual Training Standard
IVD – Individual Vapor Detector

–J–

JAGG – Joint Air and Ground Glove
JASQ – JSLIST Alternative Source Qualification
JAWG – Joint Assessment Working Group
JB1GU – JSLIST Block 1 Glove Upgrade
JB2GU – JSLIST Block 2 Glove Uprgrade
JBAIDS – Joint Biological Agent Identification and Diagnostic System
JBPDS – Joint Biological Point Detection System
JBREWS – Joint Biological Remote Early Warning System
JBSDS – Joint Biological Standoff Detection System
JBTDS – Joint Biological Tactical Detection System
JCAD – Joint Chemical Agent Detector
JCATS – Joint Conflict and Tactical Simulation
JCBAWM – Joint Chemical Biological Agent Water Monitor
JCBUD – Joint Chemical and Biological Universal Detector
JCHEMRATES – Joint Chemical Defense Equipment Consumption Rates
JCPE – Joint Collective Protection Equipment
JCRS – Joint Canteen Refill System
JCS – Joint Chiefs of Staff
JEM – Joint Effects Model
JETE – Joint Education, Training, and Exercises
JFCOM – Joint Forces Command
JFIRE – Joint CB Protective Firefighter Suit
JFOC – Joint Future Operational Capabilities
JFT – Joint Field Trail
JGEM – Joint Ground Effects Model
JLAS – Joint Land, Aerospace, and Sea Simulation
JMANS – Joint Multimission Advanced NBC System
JMAR – Joint Medical Asset Repository
JMCBDRP – Joint Medical Chemical and Biological Defense Research Program
JMCBRDRP – Joint Medical Chemical, Biological, and Radiological Defense Research Program
JMCBDS – Joint Modular Chemical and Biological Detection System
JMCDRP – Joint Medical Chemical Defense Research Program
JMNBCDST – Joint Medical NBC Decision Support Tool
JMNS – Joint Mission Need Statement
JMPAB – Joint Materiel, Priorities, and Allocation Board
JMRR – Joint Monthly Readiness Review
JNBCDB – Joint NBC Defense Board
JOA – Joint Operations Area
JOEF – Joint Operational Effects Federation
JORD – Joint Operational Requirements Document
JPACE – Joint Protective Aircrew Ensemble
JPO-BD – Joint Program Office for Biological Defense
JPEO CBD – Joint Program Executive Office for Chemical and Biological Defense
JPM IP – Joint Program Manager for Individual Protection
JPS – Joint Portal Shield
JRCAB – Joint Readiness Clinical Advisory Board
JROC – Joint Requirements Oversight Council
JRO-CBRN – Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
JRTC – Joint Readiness Training Center
JSA – Joint Service Agreement
JSAF – Joint Simulated Automated Force
JSAM – Joint Service Aircrew Mask
JSCBIS – Joint Service Chemical Biological Information System
JSFSDS – Joint Service Family of Decontamination Systems
JSGPM – Joint Service General Purpose Mask
JSIG – Joint Service Integration Group
JSIMS – Joint Simulation System
JSIPP – Joint Service Installation Pilot Project (*or,* Joint Service Installation Protection Program)
JSLIST – Joint Service Lightweight Integrated Technology (individual protection)

JSLNBCRS – Joint Service Light NBC Reconnaissance System
JSLSCAD – Joint Service Lightweight Stand-off Chemical Agent Detector
JSMG – Joint Service Materiel Group
JSMLT – Joint Service Mask Leakage Tester
JSNBCDEAP – Joint Service NBCD Equipment Assessment Program
JSNBCRS – Joint Service NBC Reconnaissance System
JSPDS – Joint Service Personnel/Skin Decontamination System
JSSED – Joint Service Sensitive Equipment Decontamination
JSTPCBD – Joint Science and Technology Panel for Chemical/Biological Defense
JSWILD – Joint Service Warning and Identification LIDAR Detector
JTASC – Joint Training and Analysis Center
JTAV – Joint Total Asset Visibility
JTWAG – Joint Training Assessment Working Group
JTC – Joint Training Council
JTCG – Joint Technology Coordinating Group
JTCOPS – Joint Transportable Collective Protection System
JTF – Joint Task Force
JVAP – Joint Vaccine Acquisition Program
JWARN – Joint Warning and Reporting Network
JWARS – Joint Warfighting Simulator
JWFC – Joint Warfighting Center
JWSTP – Joint Warfighting S and T Plan

–L–

L – lewisite, a vesicant agent
LAM – Louisiana Maneuvers
LAV – Light Armored Vehicle
LCBPG – Lightweight CB Protective Garment
LD_{50} – Median Lethal Dose
LDS – Lightweight Decontamination System
LG7 – Land Group 7
LHA – general purpose amphibious assault ship
LHD – general purpose amphibious assault ship (with internal dock)
LIDAR – LIght Detection And Ranging
LLC – limited liability corporation
LLR – Low Level Radiological
LMS – Lightweight Multipurpose Shelter
LMSR – Large, Medium-speed Roll-on, Roll-off Ship
LNBCRS – Light NBC Reconnaissance System
LRBSDS – Long-Range Biological Stand-off Detection System
LSCAD – Lightweight Stand-off Chemical Agent Detector
LSCD – Laser Stand-off Chemical Detector
LSD – landing ship, dock
LSP – Logistics Support Plan
LWRS – Lightweight Reconnaissance System

–M–

M&S – Modeling & Simulation
M&S CA – Modeling & Simulation commodity Area
M&S R&D – Modeling & Simulation Research & Development
MAGTF – Marine Air Ground Task Force
MAJCOM – Major Command
MALDI – Matrix-Assisted Laser Desorption Ionization
MANAA – Medical Aerosolized Nerve Agent Antidote
MANSCEN – Maneuver Support Center
MANTECH – Manufacturing Technology
MARFORPAC – Marine Force Pacific
MASINT – Measures and Signatures Intelligence
MBDRP – Medical Biological Defense Research Program
MBGV – *marburg* virus
MCBAT – Medical Chem-Bio Advisory Team
MCBC – Management of Chemical and Biological Casualties Course
MCHF (LDS) – Marine Corps Heavy Fuel LDS
MCO – Marine Corps Order
MCPE – Modular Collective Protection System
MCU-2A/P – a chemical protective mask
MCWP – Marine Corps Warfighting Publication
MD – methyl dichlorarsine
MDAP – Major Defense Acquisition Programs
MDS – Modular Decontamination System
MED – Medical
MEIR – Medical Effects of Ionizing Radiation
MEPS – Multiplex Electronic/Photonic Sensor
METL – Mission Essential Task List
metL, thrA – methionine biosynthesis
MEU – Marine Expeditionary Unit
MFR – Multi-Function Radiac Set (*or,* Multi-Function Radiation Detector)
MHC – Major Histocompatibility Complex
MICAD – Multipurpose Integrated Chemical Agent Detector
MICAS – Mobility Inventory Control and Accounting System
MIL STD – Military Standard
MIPR – Military Interdepartmental Purchase Request
MITS – Medical Identification and Treatment Systems
MLRS – Multiple Launch Rocket System
MMS – Multimission Sensor (Program)

MNDRP – Medical Nuclear Defense Research Program
MNS – Mission Needs Statement
MOE– Measure of Effectiveness
MOP – Memorandum of Policy
MOPP – Mission Oriented Protective Posture
MOS – Military Occupational Specialist
MOU – Memorandum of Understanding
MPH – miles per hour
MPS – Mission Performance Standard (*also,* Multipurpose Protective Sock)
MPSP – Medical Program Sub-Panel
MRMC – Medical Research and Materiel Command
MS – Mass Spectrometry (*or,* milestone)
MSC – Military Sealift Command or Mesenchymal Stem Cells
MTF – Medical Treatment Facility
MTTP – Multiservice Tactics, Techniques, and Procedures
MTW – Major Theater War(s)
MULO – Multi-purpose Overboot
mCPU – Modified Chemical Protective Undergarment
murE – murein biosynthesis

–N–

NAADS – Nerve Agent Antidote Delivery System
NAAG – NATO Army Armaments Group
NAAK – Nerve Agent Antidote Kit
NAAS – Nerve Agent Antidote System
NAPP – Nerve Agent Pyridostigmine Pretreatment
NATO – North Atlantic Treaty Organization
NAVMED – Naval Medical
NBC – Nuclear, Biological, and Chemical
NBCD – NBC Defense
NBCDT – NBC Defense Training
NBC-E – nuclear, biological, and chemical-environment
NBC-R – nuclear, biological, chemical, and radiological
NBCRS – NBC Reconnaissance System (Fox Vehicle)
NBCRV – (Stryker) NBC Reconnaissance Vehicle
NBCWP – NBC Defense Inter-service Working Party
NCBR(S) – NBC Simulator
NCO – Non-Commissioned Officer
NDA – New Drug Application
NDI – Non-Developmental Item
NEHC – Naval Environmental Health Center
NEPMU – Navy Environmental and Preventative Medicine Unit
NFPA – National Fire Protection Agency
NGB – National Guard Bureau
NGIC – National Ground Intelligence Center
NIAID – National Institute of Allergies and Infectious Diseases
NICP – National Inventory Control Points
NIEX – No-Notice Interoperability Exercise
NIH – National Institute of Health
NIOSH – National Institute for Occupational Safety and Health
NIRF – Nuclear Incident Response Force
NMSO – Nuclear Medical Science Officer
NO – nitric oxide
NSC – National Security Council
NSN – National Stock Number
NSTC – National Science and Technology Council
NTA – Novel Threat Agent
NTC – National Training Center
NTTP – Naval Tactics, Techniques, and Procedures
NYSADC – New York State Academic Dental Centers
NWDC – Naval Warfare Development Command
NWP – Naval Warfare Publication

–O–

O49 – Joint Contact Point and Test Project
O&M – Operations & Maintenance
OAC – Officer Advance Course
OBC – Officer Basic Course
OCONUS – Outside the continental United States
OFW – Objective Force Warrior (Program)
OG – Overgarment
OIPT – Overarching Integrated Product Teams

OPCW – Organization for the Prohibition of Chemical Weapons (in The Hague)
OPLAN – Operational Plan
OPR – Office of Primary Responsibility
ORD – Operational Requirements Document
ORF – Open Reading Frames
OSD – Office of the Secretary of Defense
OSHA – Occupational Safety and Health Administration
OSM3 – oximeter instrument
OT – Operational Testing
OTSG – Office of the Surgeon General

–P–

P3I – Pre-Planned Program Improvement
PA – protective antigen
PACAF – Pacific Air Forces
PACOM – Pacific Command
PAIO – Program Analysis and Integration Office
PAM – Preventative and Aerospace Medicine
PATS – Protective Assessment Test System
PB – President's Budget
PBAS – Program Budget Accounting System

PCC – Premature Chromosome Condensation
PCPS – Portable Collective Protection System
PCR – polymerase chain reaction
PCRA - polymerase chain reaction assay
PCS – Permanent Change of Station
PD – phenyl dichlorarsine
PDDA – Power Driven Decontamination Apparatus
PDM – Program Decision Memorandum
PDRR – Program Definition and Risk Reduction
PE – Program Element
PEO-CBD – Program Executive Office for Chemical and Biological Defense
PF – Positive Force Exercise
PICS – Personal Ice Cooling System
PIP – Product Improvement Program
PL 103-160 – Public Law 103-160, *The National Defense Authorization Act of FY94*
PMCD – Program Manager for Chemical Demilitarization
PMCS – Preventative Maintenance Checks and Services
PMO – Product Management Office
POL – petroleum, oil, and lubricant
POM – Program Objective(s) Memorandum
PPBS – Program Planning and Budgeting System
PQS – Personnel Qualification
PR – Positive Response Exercise
PRD – Presidential Review Directive
PRG – Program Review Group
PROFIS – Medical NBC Professional Filler Course
PSA – Pressure Swing Adsorption

–Q–

QDR – Quadrennial Review
QNFT – Quantitative fit testing
QRR – Qualitative Research Requirements
QSTAG – Quadripartite Standardization Agreement
QWG – Quadripartite Working Group

–R–

R&D – Research and Development
RADIAC – Radiation
RAPID – Ruggedized Advanced Pathogen Identification Device
RBC-AchE – red blood cell acetylcholinesterase
RC – Reserve Component
RDA – Research, Development, and Acquisition
RDD – Radiological Dispersal Device
RDTE (Also, RDT&E) – Research, Development, Test (&) Evaluation
RestOps – Restoration of Operations
RFP – Request for Proposal
RIP – Readiness Improvement Program
RMC – Regional Medical Commands
rPA – recombinant protective antigen
RSCAAL – Remote Sensing Chemical Agent Alarm
RSTA – Reconnaissance, Surveillance, and Target Acquisition
RTP – Readiness Training Plan
RW – radiological/nuclear warfare

–S–

S&T – Science & Technology Base
SACPS – Selected Area Collective Protection System
SAF – Semi-Automated Forces
SAFEGUARD – Scanning Airborne Fourier Emission for Gaseous Ultraspectral Analysis and Radiometric Detection
SAG – Study Advisory Group
SALAD – Shipboard Automatic Liquid Agent Detector
Saratoga – a CB protective overgarment
SASO – Stability and Support Operations
SAT – Systems Approach to Training
SAW – Surface Acoustic Wave
SBA – Simulation Based Acquisition
SBCCOM – Solider, Biological and Chemical Command (U.S. Army)
SCALP – Suit Contamination Avoidance Liquid Protection
SCAMP – Shipboard Chemical Agent Monitor Portable
SCPE – Simplified Collective Protective Equipment
SCUD – surface to surface missile system
SD – Stand-off Detector
SD/ASM – Stand-off Detector for Armor System Modernization
SDD – System Development and Demonstration
SDK – Skin Decontamination Kit
SDS – Sorbent Decon System
SE – *staphylococcal enterotoxins* or status ellepticus
SEA – Staphylococcal Enterotoxin A
SEB – Staphylococcal Enterotoxin B
SECDEF – Secretary of Defense
SERPACWA – skin exposure reduction paste against chemical warfare agents
SFR – System Function Requirement
SGXA – Air Force Surgeon General
SIMBAD – Sensor Integrated Modeling for Biological Agent Detection
SMART-CB – Special Medical Augmentation Response Team-Chemical./Biological
SMART-PM – Special Medical Augmentation Response Team-Preventative Medicine
SNAPP – Soman Nerve Agent Pretreatment Pyridostigmine
SNCO – Staff-Noncommissioned Officer
SOF – Special Operations Forces

SOFCAS – Special Operation Forces Chemical Agent Detector
SOI – School of Infantry
SO/LIC – Special Operations and Low Intensity Conflict
SOMCBD – Special Operations Modular CB Detector
SORTS – Status of Resources and Training System
SOW – Statement (*or,* Scope) of Work
SPA – surface protein antigen
SPOD – Seaport of Debarkation
SRT – Specialty Response Team
STAFFS – Simulation Training and Analysis for Fixed Sites
STANAG – standard agreement
STB – Super Tropical Bleach
STEPO – Self-Contained Toxic Environment Protective Outfit
STEPO-I – Interim Self-Contained Toxic Environment Protective Outfit
STO – Science and Technology Objective
STOM – (Sea Basing) Ship to Objective Maneuver
STRAC – Standards in Training Commission
STRATCOM – Strategic Command
STS – Specialty Training Standard
SUBD – Small Unit Biological Detector
SWA – Southwest Asia

–T–

T&D – Transport & Diffusion

T&E – Test & Evaluation
TAA – Total Army Analysis
TACWAR – Tactical Warfare
TAP – Toxicological Agent Protective boots and gloves
TARA – Technology Area Review and Assessment
TAV – Total Asset Visibility
TB – Technical Bulletin
TBM – Transportation of Biomedical Materials or Tactical Ballistic Missiles
TDA – table of distribution and allowances
TED – Troop Equivalent Dose
TEI – Technical Equipment Inspection
TEMPER – Tent Extendable Modular Personnel
TEU – Technical Escort Unit
TIC – Toxic Industrial Chemical
TIM – toxic industrial material
TM – Transport Molecules
TOF – Time of Flight
TRANSCOM – Transportation Command
TSA – Transition State Analogue
TSG – The Surgeon General
TSP – Topical Skin Protectant
TSWG – Technical Support Working Group
TTP – Tactics, Techniques, and Procedures

–U–

UAV – Unmanned Aerial Vehicle

UCC – Unified Combatant Command(s)
UCP – Upconverting Phosphors (*or,* Unified Command Plan)
UCS – Unified Command Suite
UDP – Unit Deployment Program
UJTL – Universal Joint Task List
UN – United Nations
UNSCOM – United Nations Special Commission
USA – United States Army
USACHPPM – United States Army Center for Health Promotion and Preventive Medicine
USACMLS – US Army Chemical School
USAF – United States Air Force
USAF(SGXR) – USAF Surgeon General
USAMEDDC&S – U.S. Army Medical Department Center & School
USAMMA – U.S. Army Medical Materiel Agency
USAMMDA – U.S. Army Medical Materiel Development Activity
USAMRICD – U.S. Army Medical Research Institute of Chemical Defense
USAMRIID – U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC – U.S. Army Medical Research and Materiel Command
USANCA – United States Army Nuclear and Chemical Agency
USAR – US Army Reserve
USARAK – US Army Alaska
USARJ – US Army Japan
USC – United States Code
USCENTCOM – US Central Command
USD(AT&L) – Undersecretary of Defense (Acquisition Technology & Logistics)
USEUCOM – US European Command
USFK – U. S. Forces, Korea
USG – United States Government
USJFCOM – US Joint Forces Command
USMC – United States Marines Corps
USN – United States Navy
USPACOM – US Pacific Command
USSTRATCOM – US Strategic Command
USTC – US Transportation Command
USUHS – Uniformed Services University of the Health Sciences
UTC – Unit Type Code
UV – ultra-violet

–V–

VCA – Voice Communication Adapter

VCSA – Vice Chief-of-Staff of the Army
VEE – Venezuelan Equine Encephalomyelitis
VERTS – Virtual Emergency Response Training System
VIC – Vector-in-Command
VIG – Vaccinia Immune Globulin
VLP – virus-like particles
VLSTRACK – Vapor, Liquid, and Solid Tracking Model
VNTR – Variable Number Tandem Repeat
VPS – Virtual Prototyping System
VPU – Vapor Protective Undergarment
VTC – Video Teleconference
VVA – verification, validation, and accredidation
VVS – Vehicles, Vans, and Shelters
VX – a nerve agent

–W–

WCF – Working Capital Fund
WDTC – West Desert Test Center
WDTIC – West Desert Technical Information Center
WEE – Western Equine Encephalomyelitis
WG – Working Group
WMD – weapons of mass destruction
WMD-CST – Weapons of Mass Destruction Civil Support Teams
WRAIR – Walter Reed Army Institute of Research
WRM – war reserve materiel
WRSI – War Reserves Secondary Items

–Y–

Y. pestis – *Yersinia pestis* (Plague)