



Department of Defense Chemical and Biological Defense Program



APRIL 2003



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

The information in this report is updated as of February 28, 2003 unless specifically noted otherwise.

Cleared for Public Release.
Unlimited Distribution.

Executive Summary

The DoD Chemical and Biological Defense Program (CBDP) FY 2004 President's budget has been submitted to Congress.¹ In accordance with 50 USC 1523 (Section 1703, Public Law No. 103-160) this annual report on the CBDP is submitted to Congress, and it 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 is provided in two volumes. Volume I provides an assessment of the plans and programs, and Volume II provides a performance plan for the CBDP in accordance with the Government Performance and Results Act.

The DoD CBDP is a key part of a comprehensive national strategy to counter the threat of chemical and biological (CB) weapons as outlined in *The National Security Strategy of the United States of America*, September 2002, and *The National Strategy for Homeland Security*, July 2002. The strategy to counter these threats is further developed in *The National Strategy to Combat Weapons of Mass Destruction*, December 2002. The national strategy is based on three principal 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 CB Defense Program (CBDP) provides research, development, and acquisition (RDA) programs primarily to support the first and third pillars. In support of counterproliferation, the DoD CBDP 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 CB attack against our deployed forces. In support of counterproliferation, the DoD CBDP provides capabilities to respond to the effects of WMD use against our forces deployed abroad, and the homeland. In addition, the DoD CBDP supports the "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 CBDP will support "4-2-1" force planning to accomplish the following:

- "Deter aggression in four critical theaters: Europe, Northeast Asia, the Asian littor, and the Middle East/Southeast Asia" (that is, **4**).
- "Swiftly defeat aggression in any two theaters of operation in overlapping timeframes" (that is, **2**).
- "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**).

¹ Annex G details the CBDP budget and expenditures. For FY04, the total budget request is \$1.105 billion, of which \$0.506 billion is for procurement, and \$0.599 billion is for research, development, test, and evaluation.

The CBDP funds research to exploit leading edge technologies to ensure that U.S. forces are equipped with world class capabilities to defend against CB threats through the far term (FY10–19). This budget includes support of a comprehensive science and technology base program to ensure continued advances in CB defense capabilities. CBDP Basic Research provides core capabilities to ensure U.S. technological advantages through the far term, including research into advanced chemical and biological detection systems, advanced materials for improved filtration systems and protection systems, advanced decontaminants, investigations into the environmental fate of chemical warfare agents, advanced information technologies, medical biological defense research (including diagnostics, therapeutics, and vaccines for viral, bacterial, toxin, and novel threat agents), and medical chemical defense (including investigations of low level chemical warfare agent exposures, diagnostics, therapeutics, pretreatments for classical chemical warfare threats and fourth generation agents.)

The CBDP also supports numerous Defense Technology Objectives (DTOs), which represent the key science and technology base programs for demonstrating advanced capabilities in the near-term (FY03–04) and mid-term (FY05–09). During FY04, DTOs support operational capabilities to **Sense** (Reconnaissance, Detection and Identification), **Shape** (Battlespace Management), **Shield** (Individual & Collective Protection), and **Sustain** (Decontamination and Restoration) U.S. forces for passive defense, force protection, and consequence management missions. Among others, DTOs include capabilities for Automated Genetic Identification, Standoff Biological Aerosol Detection, Detection of CB Contamination on Surfaces, Self-Detoxifying Materials for CB Protective Clothing, Advanced CB Hazard Prediction Modeling, Alternative Delivery Methods for Recombinant Protein Vaccines, advanced medical CB prophylaxes, smallpox therapeutics, and advanced decontamination capabilities.

Technologies currently in advanced development (Budget Activities 4 and 5) provide leading edge systems that will enhance CB defense capabilities for U.S. forces in all CB defense missions in the near-term. As described in the *National Strategy to Combat Weapons of Mass Destruction*, the response to CB threats requires tailored approaches that recognize the fundamental differences between chemical and biological weapons (and even the different types of these threats.) This budget details the comprehensive array of systems under development essential to support principles of contamination avoidance, protection, and decontamination described in Joint Publication 3-11, *Joint Doctrine for Operations in Nuclear, Biological, and Chemical (NBC) Environments*, 11 July 2000. Key systems in advanced development in FY04 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),
- Joint Effects Model (JEM),
- Joint Operational Effects Federation (JOEF), which provide a risk management tool to the warfighter,
- Advanced Concept Technology Demonstrations (ACTDs) to demonstrate CB defense capabilities at fixed sites (Restoration of Operations ACTD and Contamination Avoidance at Sea Ports of Debarkation ACTD),
- Joint Service Family of Decontamination Systems (JSFDS),

- Joint Service Sensitive Equipment Decontamination (JSSED),
- Advanced anti-convulsants and
- Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP),
- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA), a topical skin protectant against chemical agents,
- improved autoinjector system for delivery of nerve agent antidote (ATNAA),
- 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,
- Joint Biological Point Detection System (JBPDS),
- Joint Biological Standoff Detection System (JBSDS),
- Joint Biological Agent Identification and Diagnostic System (JBAIDS),
- Joint Warning and Reporting Network (JWARN),
- Joint Collective Protection Equipment (JCPE),
- Joint Protective Aircrew Ensemble (JPACE),
- Joint Service Aircrew Mask (JSAM), and
- Joint Service General Purpose Mask (JSGPM).

In FY04, the CBDP will start or continue procurement on a variety of CB defense systems intended to provide U.S. forces with the best available equipment to survive, fight, and win in CB contaminated environments. Systems beginning procurement in FY04 include JSGPM, JWARN Block I, and JBAIDS. Continuing procurement includes the Joint Service Mask Leakage Tester (JSMLT), Joint Service Lightweight Integrated Suit Technology (JSLIST), the NBC Reconnaissance Vehicle (NBCRV), Joint Service Lightweight NBC Reconnaissance System (JSLNBCRS), JCAD, JSLSCAD, JBPDS, biological defense vaccines (Anthrax Vaccine Adsorbed and DryVax Smallpox vaccine), the Modular Decontamination System, and the CB Protective Shelter (CBPS).

In addition to efforts described above, the CBDP has significantly strengthened efforts for improving DoD Installation Force Protection against CB threats. DoD has programmed resources to address 200 installations from FY04–FY09. The FY04 increment to support additional procurement of CB defense equipment for force installation protection is \$78 million.

The FY04 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, there have been two significant changes in the management and oversight of the CBDP over the past year to provide a more streamlined and efficient structure. These changes are: (1) the establishment of the Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear (JRO-CBRN) Defense, and (2) the establishment of the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD).

Overall, the FY2004 President's budget achieves a structured, executable, and integrated medical and non-medical joint CB Defense Program that balances urgent short-term procurement needs that include securing the homeland from terrorist attack, and long-term S&T efforts to mitigate future CB attacks. The program supports our commitment to ensure full dimensional protection for all our 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 CBDP 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.

The performance metrics for the Chemical and Biological Defense Program are established in "Volume II: Performance Plan" of this report. The performance plan links performance goals with performance measures in terms of the systems and programs that support warfighter requirements and goals. The performance goals are supported and evaluated by measurable outputs, which are assessed using performance measures. Performance measures quantify the output of the CB defense program for key measures associated with providing a ready force, capable of conducting operations in CB contaminated environment.

OVERVIEW OF THE REPORT

The *Introduction* provides a background of the rationale and purpose of the DoD CBDP. This section summarizes the key counterproliferation priorities and the current CB warfare threats to U.S. forces. Intelligence documents tailored to the threat are essential for developing and updating requirements for CB defense programs. Each CB 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 CBDP management structure that was initiated in 2002 and is being implemented during 2003.

Chapter 2 provides information on medical and non-medical CB 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 Fiscal Year 2001—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 CB defense logistics posture. This analysis shows a continuing trend of maintaining a significant portion of CB defense items at low logistical risk, thus enhancing the warfighters’ abilities to sustain operations in an CB-contaminated environment. The analysis reviews the status of quantities, characteristics, and capabilities and limitations of all fielded CB defense equipment, industrial base requirements, procurement schedules, and problems encountered. Much of the information is based on the model of Joint Chemical Defense Equipment Consumption Rates IV. Additional information is derived from the *Joint NBC Defense Logistics Support Plan*. This chapter reflects the logistics status at the end of FY02 and is based on the FY02 requirement for supporting two nearly simultaneous major theater wars. Assessments are being conducted during FY03 to determine the specific warfighter requirements based on the “4-2-1” force sizing structure and additional mission requirements for force protection, consequence management, and homeland security.

Chapter 4 assesses the status of CB 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 CB warfare defense training activities of the Department of Defense 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 entered into force during 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 E** provide detailed information on Joint and Service-unique NBC defense equipment, including (A) contamination avoidance, (B) modeling and simulation, (C) protection, (D) decontamination, and (E) medical programs. Detailed descriptions are provided for systems and equipment that have been fielded, are in production, or are under development. **Annex F** provides a summary of funds appropriated, budgeted, and expended by the DoD CBDP. **Annex G** provides NBC defense logistics readiness data and a breakout of service war requirements, stocks on hand, and planned acquisitions. This information supplements information in Chapter 3. **Annex H** provides a statement regarding CB 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 I** provides the text of the congressional language requiring this report. **Annex J** provides a list of the many acronyms and abbreviations that are used throughout this report.

(INTENTIONALLY BLANK.)

Table of Contents

Volume I: Annual Report to Congress

	Page
EXECUTIVE SUMMARY	<i>i</i>
INTRODUCTION	1
I Purpose of Report	1
II Government Performance and Results Act.....	1
III The Current Chemical and Biological Warfare Threat.....	4
 CHAPTERS	
1 DOD CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM	
MANAGEMENT AND OVERSIGHT	7
1.1 Introduction.....	7
1.2 Management Implementation Efforts	7
1.3 Key Organizational Relationships, Roles, and Responsibilities.....	8
1.4 Coordination with Related Programs and Initiatives	12
1.4.1 Other U.S. Government Agencies.....	12
1.4.2 International Cooperation	15
1.5 CB Defense Modeling & Simulation Oversight	16
2 CBRN DEFENSE REQUIREMENTS AND	
RESEARCH, DEVELOPMENT AND ACQUISITION PROGRAM STATUS	19
2.1 Introduction.....	19
2.2 CBRN Defense Mission Area Requirements and RDA Summary	21
2.3 Contamination Avoidance (Reconnaissance, Detection, and Identification)	22
2.3.1 Contamination Avoidance Science and Technology Efforts	22
2.3.2 Contamination Avoidance Modernization Strategy.....	24
2.3.3 Joint Service Contamination Avoidance Programs	25
2.3.4 Other Contamination Avoidance Programs	26
2.3.5 Defense Advanced Research Projects Agency (DARPA) Programs.....	26
2.4 Battlespace Management	27
2.4.1 Information Systems Science and Technology Efforts.....	29
2.4.2 Battlespace Modernization Strategy	31
2.5 Restoration	33
2.5.1 Restoration Science and Technology Efforts.....	33
2.5.2 Restoration Modernization Strategy	34
2.5.3 Joint Service Decontamination Programs	35
2.5.4 Other Restoration Programs.....	36
2.6 Protection	36
2.6.1 Protection Science and Technology Efforts.....	37
2.6.2 Protection Modernization Strategy	38
2.6.3 Joint Service Protection Programs	40
2.6.4 DARPA Protection Programs	43
2.6.5 Other Protection Programs.....	44
2.7 Medical Systems	45
2.7.1 Introduction.....	45
2.7.2 Challenges in Medical CBRN Defense Programs	47
2.7.3 Reducing Reliance on the use of Animals as Subject of Research.....	49

2.7.4	Joint Medical Chemical Defense Research Program.....	49
2.7.5	Joint Medical Biological Defense Research Program	51
2.8	Joint Biological Defense Program – Special Report on Anthrax Vaccine Costs, Acquisition Strategy, and Related Issues.....	57
2.9	Operational Testing - Project O49.....	59
2.10	CB Defense RDA Programs Requirements Assessment	61
3	CBRN DEFENSE LOGISTICS STATUS	67
3.1	Introduction.....	67
3.2	CBRN Defense Logistics Management	68
3.3	Quantities, Characteristics, and Capabilities	71
3.4	Logistics Status.....	71
3.5	Peacetime Requirements.....	75
3.6	Funding	75
3.7	Industrial Base	76
3.8	NBC Defense Logistics Support Assessment.....	78
3.9	CBRN Defense Logistics Assessment	78
4	CBRN DEFENSE DOCTRINE, READINESS AND TRAINING	85
4.1	Introduction.....	85
4.2	CBRN Defense Doctrine	85
4.2.1	Joint CBRN Defense Doctrine Program Management.....	86
4.2.2	Joint CBRN Defense Doctrine Development Program	86
4.2.3	Army Medical Doctrine Development Program.....	87
4.2.4	Air Force Doctrine Program	88
4.2.5	Navy Doctrine.....	90
4.2.6	Marine Corps Doctrine	90
4.3	Standards of Proficiency and Currency	91
4.3.1	Army	91
4.3.2	Air Force	97
4.3.3	Navy	100
4.3.4	Marine Corps	103
4.4	CBRN Defense Professional Training.....	105
4.4.1	Joint CBRN Defense Professional Training.....	105
4.4.2	Army CBRN Defense Professional Training.....	105
4.4.3	Air Force CBRN Defense Professional Training	106
4.4.4	Navy CBR-D Defense Professional Training	109
4.4.5	Marine Corps CBRN Defense Professional Training.....	110
4.5	Integration of Realism/Wargames/Exercises	110
4.5.1	Simulations and Wargames	110
4.5.2	Joint CBRN Training/Joint and Combined Exercises	113
4.6	CBRN Defense Training and Readiness Initiatives.....	113
4.6.1	Joint CBRN Defense Training	113
4.6.2	Air Force CBRN Defense Training	115
4.6.3	Navy CBRN Defense Training	116
4.6.4	Marine Corps CBRN Defense Training	117
4.6.5	Emergency Response: Army Medical Response	119
4.6.6	Medical Countermeasures and Surveillance against CBRN and other Battlefield Toxicants and Occupational Health Hazards	122
4.6.7	Air Force Medical CBRN Teams	123
4.7	Readiness Reporting System.....	125

4.8	CB Defense Readiness and Training Assessment	125
5	STATUS OF DOD EFFORTS TO IMPLEMENT THE CHEMICAL WEAPONS CONVENTION	127
5.1	Introduction.....	127
5.2	Department of Defense Implementation of the CWC.....	127
5.3	Safety Orientation for Inspectors	128
5.4	Preparation of Defense Installations	128
5.5	Defense Treaty Inspection Readiness Program	129
5.6	Technical Equipment Inspection Program.....	129
5.7	Article X Assistance and Other Assistance	129
5.8	Arms Control Technology	130

ANNEXES	Page
A Contamination Avoidance Programs.....	A-1
– Automatic Detectors and Monitors	A-2
– Stand-Off Detection and Remote/Early Warning.....	A-16
– NBC Reconnaissance	A-21
– RADIACS.....	A-24
– DARPA Programs.....	A-25
B Battlespace Management Programs.....	B-1
Warning and Reporting.....	B-1
– Hazards Analysis	B-4
– Operational Effects Analysis.....	B-11
– Simulation Based Acquisition Systems.....	B-14
– Training Simulation Systems.....	B-16
C Non-Medical Protection Programs	C-1
– Individual Protection Equipment.....	C-2
– Respiratory.....	C-2
– Ancillary Mask Equipment.....	C-6
– Battlefield Protective Suits	C-8
– Protective Accessories.....	C-11
– Specialty Suits.....	C-13
– Collective Protection Equipment.....	C-15
– Tentage and Shelters.....	C-15
– Collective Protection Systems	C-19
– Generic NBC Filters and Collective Protection Filtration Systems	C-21
D Decontamination Programs	D-1
– Personnel D-1.....	
– Combat Equipment, Vehicles, and Aircraft.....	D-5
E Joint Medical Chemical, Biological, and Nuclear Defense Research Programs.....	E-1
E.1 Medical Chemical Defense Research Program	E-1
E.2 Medical Biological Defense Research Program.....	E-17
F Joint NBC Defense Logistics	F-1
G DoD Joint Nuclear, Biological, and Chemical, Defense Program Funding Summary.....	G-1
H Statement Regarding Chemical and Biological Defense Programs Involving Human Subjects.....	H-1
I Congressional Reporting Requirements: 50 USC 1523	I-1
J Acronyms and Abbreviations	J-1

TABLES

	Page
1	Finalized Geographic CINC Prioritized Counterproliferation Requirements 4
1-1	International Cooperative Efforts in Chemical and Biological Defense 16
2-1	Prioritized CBRN Defense Joint Future Operational Capabilities 20
2-2	Contamination Avoidance Science and Technology Strategy 23
2-3	Contamination Avoidance Modernization Strategy 25
2-4	Information System Science and Technology Strategy 30
2-5	Battlespace Modernization Strategy 32
2-6	Restoration Science and Technology Strategy 34
2-7	Restoration Modernization Strategy 35
2-8	Protection Science and Technology Strategy 37
2-9	Protection Modernization Strategy 39
2-10	Medical Chemical Defense Programs and Modernization Strategy 46
2-11	Medical Biological Defense Programs and Modernization Strategy 46
2-12	Medical Chemical Defense Countermeasures and Diagnostic Techniques 51
2-13	Medical Biological Defense Countermeasures and Diagnostic Techniques 56
2-14	Obligation of Funds for Anthrax Vaccine Adsorbed 58
2-15	Storage and Marketing Costs for Anthrax Vaccine Adsorbed 58
2-16	Anthrax Vaccine Immunization Program (AVIP) 59
3-1	Logistic Risk Assessments: 50 CBRN Defense Items 74
3-2	Protective Essemble Risk Assessment 79
4-1	Core Multi-Service CBRN Defense Publications 85
4-2	Summary of Army Medical CBRN Training in FY02 92
4-3	Total AMEDD Personnel Trained 92
4-4	Air Force CBRN Defense Individual Training 98
4-5	Air Force CBRN Defense Unit Training 98
4-6	Air Force Medical Service (AFMS) Management of Biological and Chemical Casualties Training for Providers 99
4-7	AFMS CBRNE Training for Deployable Personnel 99
4-8	Navy Basic CBR-D Standards 100
4-9	Navy Medical CBRN Defense Training Status 102
4-10	U.S. Army Professional and Initial Entry Training 105
4-11	U.S. Army Specialized Professional Training 106
4-12	U.S. Navy Professional Training 109
4-13	CBRN Capability Current Constructive Simulations 111
A-1	Contamination Avoidance RDA Efforts A-1
B-1	Modeling & Simulation RDA Efforts B-1
C-1	Protection RDA Efforts C-1
D-1	Decontamination RDA Efforts D-1
E-1	Medical Systems RDA Efforts E-1
F-1a	Army Logistics Readiness Data – Non-Consumables F-3
F-1b	Army Logistics Readiness Data – Consumables F-4
F-2a	Air Force Logistics Readiness Data – Non-Consumables F-6
F-2b	Air Force Logistics Readiness Data – Consumables F-7
F-3a	Navy Logistics Readiness Data – Non-Consumables F-9
F-3b	Navy Logistics Readiness Data – Consumables F-10
F-4a	Marine Corps Logistics Readiness Data – Non-Consumables F-12
F-4b	Marine Corps Logistics Readiness Data – Consumables F-13
F-5	Defense Logistics Agency Readiness Data – Consumables F-15

FIGURES

1	Chemical and Biological Defense Program Vision	1
2	Chemical and Biological Defense Program Mission	2
3	Chemical and Biological Defense Program Corporate Goals.....	3
1-1	CBDP Management & Oversight (FY2002).....	8
3-1	War Reserve Requirements and Planning.....	69
3-2	Logistic Risk Assessments: 50 CBRN Defense Items	72
4-1	USMC Individual CBRN Training	103
4-2	USMC Collective Training, CBRN Requirements	104
4-3	USMC Individual Training (Enlisted CBRN Specialists)	110
4-4	USMC Individual Training (Training for CBRN Officers).....	110

Introduction

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 tenth report submitted under 50 USC 1523.*

II. GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

This volume of the Department of Defense (DoD) Chemical and Biological Defense Program (CBDP) Annual Report to Congress provides a performance plan and assessment for the period of FY02–FY04. 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 CBDP can measure the effectiveness of the various projects under the CBDP 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 (FY02) and provides the performance targets against which activities conducted during FY03 and FY04 will be assessed.

VISION, MISSION, AND GOALS OF THE CBDP

Ensure that the Department of Defense has a world class CBRN defense capability that addresses all current and future threats to warfighter and homeland security missions.

Figure 1. Chemical and Biological Defense Program Vision

This vision statement provides focus and direction to chemical and biological defense research, development, and acquisition efforts within the CBDP. The vision statement for the CBDP 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 CBDP 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 I.

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. FY02 requirements are based on supporting the “4-2-1” Force Planning Construct. The **4-2-1 Force Planning** construct replaces the previous force planning construction of two nearly simultaneous Major Theater Wars (MTWs).

This force planning construct calls on DoD to maintain regionally tailored forces forward deployed and stationed in *four (4)* critical regions to assure allies, counter coercion and deter aggression against the United States, its allies, and its friends. U.S. forces will remain capable of undertaking major combat operations (MCOs) on a global basis and will train to be effective across a wide range of combat conditions and geographic settings. For planning purposes, U.S. forces will remain capable of rapidly transitioning from its steady-state condition to conducting an effects-based campaign that aims at swiftly defeating attacks against U.S. allies and friends in any *two (2)* theaters of operation in overlapping timeframes. U.S. forces will retain the capability to decisively defeat an adversary in *one (1)* of the two theaters in which U.S. forces are conducting major combat operations, including the ability to occupy territory or set the conditions for a regime change if so directed by the President. In addition, the new planning approach requires the United States to maintain and prepare its forces for smaller-scale contingency operations in peacetime, preferably in concert with allies and friends.

In order to support the 4-2-1 force-sizing construct and to implement to program vision, **Figure 2** defines the mission for the CBDP. 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 support the 4-2-1 force planning construct are in the process of being defined. Interim planning figures are provided in Chapter 3 and Annex F of this report and will be revised in next year’s report.

Ensure that the U.S. military has the capability to operate effectively and decisively in the face of chemical, biological, radiological or nuclear (CBRN) threats in warfighter missions (passive defense, force protection, and consequence management) and homeland security missions. Advance national interests within the CBRN defense arena by working effectively with other federal agencies, state and local governments, Congress, and the private sector.

Figure 2. Chemical and Biological 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 CBDP, as shown in **figure 3**. Corporate goals provide the broad warfighter requirements for NBC defense operations. These operational goals provide direction for the development, acquisition, and fielding of NBC defense equipment. The CBDP thus develops, acquires, and fields equipment that meets warfighter requirements while reducing acquisition costs and time of development.

- **Goal 1: Develop CB 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 CB defense research efforts.**
- **Goal 3: Oversee DoD CB defense modeling and simulation efforts.**
- **Goal 4: Improve DoD CB defense management practices – become a high performance organization.**

Figure 3. Chemical and Biological Defense Program Corporate Goals

The response to the threat of CB 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 CB agents or weapons provides little or no military advantage. The DoD CBDP continues to work toward increasing the capabilities of Joint Forces to survive and continue their mission during conflicts that may involve the use of CB agents or weapons.

CB defense are capabilities 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 CBDP are highlighted in **bold**.

Table 1. 2002 Combatant Commander Prioritized Counterproliferation Requirements

Rank	Counterproliferation Requirement
1	Detection, identification, characterization, location, prediction and warning of CW and BW agents
2	Enable sustained operations in an NBC environment through decontamination, and individual and collective protection
3	Collection, analysis, and dissemination of actionable intelligence to support CP and counterterrorism
4	Medical protection, training, diagnosis, treatment, surveillance and countermeasures against NBC agents, to include surge manufacturing capability and stockpile availability of vaccines, pretreatments, therapeutics and other medical products
5	Support for Special Operations including WMD and missile 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 NBC/M and related materials, components, and key personnel
10	Target planning for NBC and missile targets
11	Detection, location, characterization, and defeat of NBC/M facilities while minimizing collateral effects
12	Detection, location, characterization, and defeat of hard & deeply buried targets while minimizing collateral effects
13	Prompt mobile target detection and defeat
14	Protection of NBC and missile and NBC and missile-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

* Detecting “employment” refers to the capability to detect prior to actual use.

III. THE CURRENT CHEMICAL AND BIOLOGICAL WARFARE THREAT

Those countries that persist in offensive chemical weapons programs are adding agents and more sophisticated delivery systems. Similarly, the sophistication of CB weapons capabilities is increasing. Proliferation of weapons technology, precision navigation technology, nuclear technologies (medical, power, and industrial applications), and advanced chemical and biological technologies to developing nations presents the United States with a complicated national security challenge. Intelligence efforts include collection and analysis of nations’ dual-use nuclear, chemical, and biological industrial capabilities, and development of the indications and warning of diversion of dual-use capabilities to weapons programs. Tailored intelligence documents are essential for assessing, developing, and updating requirements for CB defense programs. Numerous threat documents tailored to the CB threat have been produced and are updated periodically. The Intelligence Community continues to review U.S. chemical and biological warfare intelligence requirements and assess the adequacy of intelligence assets to execute the required intelligence program.

Chemical and biological weapons are generally easier to develop, hide, and deploy than nuclear weapons and will be readily available to those with the will and resources to obtain

them. More than two dozen states or non-state groups either have, or have an interest in acquiring, chemical weapons; there are a dozen countries believed to have biological warfare (BW) programs, and terrorist groups also are known to be interested in these weapons. The proliferation of chemical and biological weapons is expected to continue, and these weapons could well be used in a regional conflict or terrorist attack over the next 15 years.

The United States faces a number of regional proliferation challenges. Many of these are detailed in the January 2001 report published by the Office of the Secretary of Defense, *Proliferation: Threat and Response*. Additional information is provided by the Central Intelligence Agency (CIA) in the *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 was published prior to OPERATION IRAQI FREEDOM, hence it does not reflect changes in the discovery or destruction of WMD in Iraq since the beginning of that operation.) The report also provides analyses on key supplier countries, including Russia, China, and North Korea. The report also provides an analysis on chemical, biological, radiological, and nuclear (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 continued to rise—particularly in the aftermath of the attacks on 11 September 2001. Several of the 30 designated foreign terrorist organizations and other nonstate actors worldwide have expressed interest in CBRN—although terrorists probably will continue to favor long-proven conventional tactics such as bombings and shootings.

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, Bin Ladin publicly declared that acquiring unconventional weapons was "a religious duty."

Terrorist groups worldwide have ready access to information on chemical and biological, 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 has 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 has been 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

^{*} This report is updated every six months and is available on the internet at http://www.cia.gov/cia/publications/bian/pdfs/721report_jan-june2002.pdf.

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 radiological dispersal devices. In addition, we must be alert to the possibility that al-Qa 'ida or other 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 continue to be more broadly available around the world, new sources of supply are emerging that are making the challenge of stemming WMD 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 expand their chemical industries into pesticide production, they also are advancing toward at least latent chemical warfare capability. Likewise, additional non-state actors are becoming 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 poses the threat of more countries of concern developing longer-range missiles and posing greater risks to regional stability.

In this context, there is a growing concern that additional states that have traditionally been recipients of WMD and missile-related technology may follow North Korea's practice of supplying specific WMD-related technology and expertise to other countries or non-state actors. Even in cases where states take action to stem such transfers, there are growing numbers of knowledgeable individuals or non-state purveyors of WMD-related materials and technology who are able to act outside the constraints of governments. Such non-state actors are increasingly capable of providing technology and equipment that previously could only be supplied directly by countries with established capabilities.

Although Western European countries maintain rigorous and effective export controls on WMD and missile-related goods and materials, proliferators and associated networks nonetheless continue to seek machine tools, spare parts for dual-use equipment, and widely available materials, scientific equipment, and specialty metals. Western countries are also an important source for the proliferation of WMD-related information and training. The relatively advanced research of western institutes, the availability of relevant dual-use studies and information, the enthusiasm of scientists for sharing their research, and the availability of dual-use training programs and education may have shortened development time for some WMD programs, particularly those of terrorist organizations.

Chapter 1

Department of Defense Chemical and Biological Defense Program Management and Oversight

1.1 INTRODUCTION

In accordance with 50 USC 1522, chemical and biological (CB) defense programs within the Department of Defense (DoD) are overseen by a single office within the Office of the Secretary of Defense. Effective oversight and management of the Department's Chemical and Biological Defense Program (CBDP) is critical to fulfilling the program mission, which includes advancing national interests within the chemical, biological, radiological, and nuclear (CBRN) defense arena by working effectively with other federal agencies, state and local governments, Congress, and the private sector. Corporate goals 3 and 4 of the CBDP specifically address the importance of effective oversight and management to fulfilling the program's mission. Section 4.0 of Volume 2: *DoD CBDP Performance Plan* details these management activities. This chapter provides an overview of the processes involved in the oversight, management, and execution of the CBDP.

1.2 MANAGEMENT IMPLEMENTATION EFFORTS

Beginning in 1994, DoD implemented a process to consolidate, coordinate, and integrate the CB defense requirements of all Services into a single DoD CB defense program. Through the 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. The Joint Service Integration Group (JSIG) and the Joint Service Materiel Group (JSMG) served to accomplish the coordinating and integrating function. Two recent changes have been made to provide a more streamlined and efficient oversight and management structure:

- (1) the establishment of the Joint Requirements Office (JRO) for Chemical, Biological, Radiological, and Nuclear (CBRN) Defense, and
- (2) the establishment of the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD).¹

¹ To eliminate redundancy throughout this report, activities and responsibilities that have transferred from the JSIG to the JRO-CBRN Defense are listed as being conducted by the JRO-CBRN Defense, even though activities conducted prior to FY03 were conducted by the JSIG. Similarly, references to management activities conducted by the JSMG are listed as being conducted by the JPEO-CBD, which was approved on April 22, 2003.

Some of the key features of the reorganization include:

- transferring the requirements generation process to a single office within the Office of the Joint Chiefs of Staff (that is, JRO-CBRN Defense).
- establishing the Under Secretary of Defense for Acquisition, Technology, and Logistics, USD(AT&L), as the single Milestone Decision Authority (MDA) for the CBDP.²
- establishing the JPEO-CBD to provide centralized program management and Joint Service acquisition program integration for all delegated non-medical and medical CB defense programs.
- transferring of the management of science and technology base programs to the Defense Threat Reduction Agency (DTRA).

The new processes, roles, and responsibilities are described in Section 1.3.

1.3 KEY ORGANIZATIONAL RELATIONSHIPS, ROLES, AND RESPONSIBILITIES

Key organizational relationships within the DoD CBDP are portrayed in **Figure 1-1**. The organization represents key stakeholders within DoD and provides a balance between operational requirements and RDA programs. This figure does not depict interagency coordination and coordination with related programs within the Department. The CBDP 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, and (3) to *test and evaluate* CBRN defense programs.

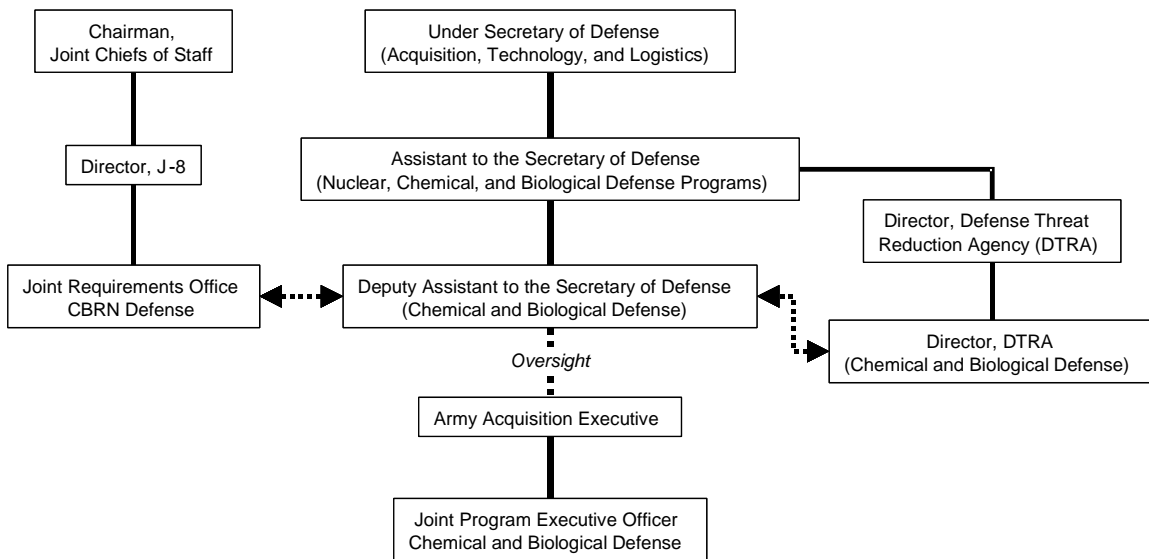


Figure 1-1 CBRN Management & Oversight Structure

This section summarizes selected roles and responsibilities of key individuals and organizations within the CBRN Defense. The JRO-CBRN Defense was formally established on October 1,

² Under the previous structure, nine organizations served as MDAs for different aspects of the CBRN Defense: US Army Soldier, Biological, and Chemical Command (SBCCOM), US Army Program Executive Office for CB Defense (PEO-CBD), US Army Medical Materiel Development Agency (USAMMDA), US Navy Sea Systems Command (NAVSEA), US Navy Air Systems Command (NAVAIR), US Navy Space and Naval Warfare Systems Command (SPAWAR), US Marine Corps Systems Command, US Air Force Materiel Command (AFMC), and the Defense Threat Reduction Agency (DTRA).

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 CBDP, which was approved on April 22, 2003.

1.3.1.1 Under Secretary of Defense for Acquisition, Technology and Logistics, USD(AT&L). The USD(AT&L) serves as the Defense Acquisition Executive (DAE) for the DoD Chemical and Biological Defense Program. As the DAE, he serves as the Milestone Decision Authority (MDA) for overall program and key selected CBD systems—also referred to as “sentinel” programs.³ USD(AT&L) responsibilities include (1) approving Overarching CBDP Strategic Plan, (2) delegating MDA authority to the Army Acquisition Executive (AAE) for selected programs, (3) establishing a CBDP Overarching Integrated Product Team (OIPT) within the Office of the Secretary of Defense, (4) Chair DAE Oversight Reviews for the CBDP, and (5) approve recommended Program Objectives Memorandum (POM) and submit to Secretary of Defense.

1.3.1.2 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 CBDP in accordance with 50 USC 1522. The ATSD(NCB) serves as the permanent chair of the CBDP Overarching Integrated Process Team (OIPT). The OIPT process supports overall CBDP 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 CBDP 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 CBDP 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 CBDP.

The ATSD(NCB) provides technical oversight of all Service and Defense Agency CB defense 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

³ Oversight is tailored by creating an “index of systems” to measure performance of CBDP functional areas based on the criticality, complexity and cost of individual CBDP programs. 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 of the functional area.

or issues related to CB defense S&T. A summary of the FY2002 TARA results is provided in Section 3 of the CBDP Performance Plan included, Volume II of this report.

1.3.1.3 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 will coordinate with the combatant command and Service to develop joint CBRN requirements, and overarching CBRN defense architecture and a joint capabilities roadmap. The JRO-CBRN Defense will define the required system interoperabilities and operational architectures and validate 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 to be responsible for the planning, coordination, and approval of joint CBRN defense operational requirements, medical and non-medical, and to serve 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.

1.3.1.4 Military Departments. Each of the Military Departments—Army, Air Force, and Navy, including the Marines Corps—plan and execute CBRN defense programs. In fulfilling their responsibilities, the Military Departments ensure coordination and integration with other the CBRN defense organizations. Following are selected responsibilities of the Military Departments.

- Validate 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.
- Support development of Service annexes to joint CBRN defense requirement documents.
- Provide acquisition and fielding data for CBRN defense requirements to the JRO during development of the DoD CBDP POM.
- Provide Service Department representatives to all appropriate CBRN defense meetings and organizations.
- Conduct for Service 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 for Joint Programs as assigned by the JPEO-CBD.

1.3.1.5 Army as Executive Agent. In accordance with 50 USC 1522, the Army serves as the Executive Agent for the CBDP and coordinates and integrates research, development, test and evaluation, and acquisition requirements of the military departments for CBRN defense programs of the DoD. Following are selected key responsibilities of Army as the Executive Agent.

- Review all funding for the CBDP.

- Review and recommend approval of the CBDP POM.
- Serve as the Milestone Decision Authority (MDA) for delegated programs, with authority to delegate to the JPEO-CBD.
- Serve as Joint Service Materiel Developer to coordinate and integrate acquisition for the CBDP through the JPEO-CBD.
- Provide Program, Analysis and Integration functions for the CBDP.
- Provide the Test and Evaluation Executive for the CBDP.
- Serve as the Joint Combat Developer for the CBDP through the JRO.

1.3.1.6 Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD).

The JPEO-CBD will serve as the Material Developer and oversee Life Cycle Acquisition Management for assigned system acquisition programs within the CBDP. The JPEO-CBD provides centralized program management and Joint Service acquisition program integration for all assigned non-medical and medical CB defense programs. Following are selected key responsibilities of the JPEO-CBD.

- Serve as the CBDP Milestone Decision Authority for delegated programs.
- Develop and approve program and acquisition strategies.
- Provide the planning guidance, direction, control, and support necessary to ensure systems are developed in accordance with DoD acquisition guidance.
- 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.
- Develop and approve Test and Evaluation Master Plans.
- 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 CB 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.

1.3.1.7 Defense Threat Reduction Agency (DTRA). DTRA will provide funds management functions under the oversight of the ATSD(NCB). DTRA also will manage and integrate CB defense science and technology base (S&T) programs. S&T management responsibilities will include the development and integration of S&T program in response to OSD and JRO guidance. DTRA will provide the necessary programming, planning, and budgeting documentation for CB defense S&T programs. DTRA will work closely with the JPEO-CBD to ensure effective transition of S&T efforts to advanced development. DTRA will also participate in Armed Services Biological Research and Management (ASBREM) Committee meetings to ensure coordination between medical and non-medical S&T programs. Other DTRA responsibilities will include providing a DoD CB defense S&T liaison with various organizations (to include

DARPA, industry, academia, and other government agencies), providing support for Defense CB defense S&T international programs, and providing management and integration of CB defense ACTDs.

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

In support of the CBDP OIPT, the PAIO will provide independent analysis for decision-makers to enable review and recommendations concerning impacts to the overall integrated CBDP. This analysis will include the CBDP oversight process, published plans, and overall programmatic health of the CBDP. The PAIO will review and analyze fiscal programs, requirements, resource planning, and resource allocation for the program years. The office will also maintain the CBDP DoD Future Years Defense Program (FYDP) and will provide 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.

1.4 COORDINATION WITH RELATED PROGRAMS AND INITIATIVES

The DoD Chemical and Biological Defense Program coordinates efforts with other U.S. government agencies and with other nations to achieve its vision to ensure that the Department of Defense has a world class CBRN defense capability that addresses all current and future threats to warfighter and homeland security missions. 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 CB defense technologies. Three organizations with which the CBDP 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), and (4) the Department of Energy (DOE) Chemical and Biological National Security Program (CBNP). With the establishment of the Department of Homeland Security (DHS), the DOE CBNP is being transferred to DHS. An overview of these programs is provided below. There also are other governmental agencies with interest in CB defense related programs with which the CBDP 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 CB 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 the 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 a numerous organizations, including the DATSD(CBD) through regular briefings to the DATSD(CBD) and DTRA(CB) and by participation in the Technology Area Review and Assessment (TARA) process. 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.

As part of the fiscal year 2004 budget request, the DoD CDBP has requested funds to support the transition of technology candidates from the DARPA program into advanced development. Two projects within the Advanced Technology Development funding line (Program Element 0603384BP) support this effort. Within Project CB3, an initiative entitled “technical transition” evaluates candidate non-medical technologies, including mass spectrometers for biological agent detection and other biodetection technologies, and advanced filtration devices for use by the military. In addition, within Project TB3, an initiative entitled “DARPA Program Transition” evaluates candidate medical technologies for potential use by the military, with a focus on developing investigational new drug applications for these products, as appropriate. Medical technologies being evaluated include, among others: (1) small-molecule antibiotic effective against anthrax, (2) B-cell based diagnostic sensor technology, (3) a blood assay for the superantigen toxin antagonists, and (4) DNA vaccines developed from the most cross-reactive antigens, obtained through DNA shuffling, in higher animal species for protection against three encephalitic alphaviruses.

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 chartered 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 CBDP 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 DOE Chemical and Biological National Security Program (CBNP). The CBNP 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 DOE National Laboratories in responding to the threat posed by chemical and biological weapons to U.S. 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 CBDP missions. There are formal agreements between the CBNP and CBDP to ensure that efforts are coordinated and duplication is avoided. Under the CPRC (see section 1.4.1.2) DoD and DOE formally coordinate CB 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, CB Point Detection & Decontamination.* April 2002.
- *Integrated CB Defense RDA Plan for Departments of Defense and Energy, Biological Point Detection,* March 2001.

An integrated report for modeling and simulation technologies, as well as, updates to the CB Point Detection and Decontamination roadmaps is planned for completion during 2003.

1.4.1.5 National Institute of Allergies and Infectious Diseases (NIAID). Until recently, 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, the Medical Biological Defense Research Program (MBDRP) 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 MBDRP has the infrastructure and expertise necessary to support this effort. Furthermore, NIAID's strategic plan overlaps significantly with the MBDRP. To that end, the NIAID and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the lead laboratory for the MBDRP, 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 CBDP participates in efforts to coordinate research, development, and other efforts related to chemical and biological 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 CBDP 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, and (6) Research, Development and Acquisition Memoranda of Understanding (MOU). **Table 1-1** list examples of international cooperative efforts in FY02.

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

<ul style="list-style-type: none"> • Smallpox Vaccine Development and Acquisition. • CB Suit Permeation. • Next Generation Biological Detection Technologies. • Non-incineration Technology for CW Agent Destruction. • 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. 	<ul style="list-style-type: none"> • Ecotoxicology due to CW Agents and Remediation of Soil and Water. • Medical Countermeasures to CB Agents. • Anthrax Letter Tests. • 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.
---	--

During FY02, 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, and (4) three 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 CB defense capability gains from FY98 and through FY01 as a result of international cooperation. During FY02 under the Foreign Comparative Testing (FCT) program, the Canadian Reactive Skin Decontaminating Lotion (RSDL) was successfully tested. The data are being furnished to the Food and Drug Administration for their approval, which must be given before procurement can occur. 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).

1.5 CB 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 use⁴ 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 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.

⁴ 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”).

INTENTIONALLY BLANK.

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 non-medical and medical CBRN defense requirements and how these programs support the needs of U.S. forces. The discussion of requirements and the status of research and development assessments are conducted within the framework of the six operationally oriented commodity areas:

- Contamination Avoidance
- Battlespace Management
- Restoration
- Individual Protection
- Collective Protection
- Medical Systems

These commodity areas correspond to CBRN operational capabilities to sense, shape, shield, and sustain for passive defense, force protection, and consequence management missions. Operational capabilities for *sense* include reconnaissance, detection and identification; *shape* including battlespace management; *shield* includes individual and collective protection, and *sustain* includes decontamination and restoration capabilities.

The threat from the continued proliferation of CBRN weapons creates a continuous need to ensure that U.S. forces can survive, fight, and win in a CBRN-hazard environment. The increasing danger from these weapons demands that we look for every opportunity to avoid technological surprises. Evolving operational requirements demand that the joint program leverage advances in technology to provide the best in CBRN defense equipment and materiel for the forces.

The non-medical research, development, and acquisition (RDA) goal is to equip the joint warfighting forces with sufficient quantities of the best available equipment and in the shortest time possible to win decisively, quickly, and with minimal casualties. The goal of medical RDA is to provide the warfighter with medical protection to prevent, or reduce the effects of exposure to chemical or biological (CB) warfare agents. Products intended for medical protection (vaccines, pre-treatment drugs, post-exposure treatments, diagnostics capabilities) require approval by the Food and Drug Administration (FDA) before they enter the distribution chain. If an item is not approved by the FDA but is considered a necessary medical countermeasure, it will be used in accordance with regulations as an Investigational New Drug (IND) product. The Joint Requirements Office integrates and reviews the DoD CB Defense Program. The results of these reviews, conducted with all Services participating, are documented in the Joint Service Modernization and Joint Service RDA Plans. These documents form the basis for the consolidated Program Objectives Memorandum (POM).

The Services decide if a materiel solution is needed to satisfy a requirement for a war-fighting capability. They first examine doctrinal, training, or organizational solutions (non-materiel solutions), and when these cannot fulfill the need, they seek equipment or materiel solutions through the materiel acquisition process. If a valid need exists, then the research and development modernization process will identify technological approaches that may provide a new system or medical product or upgrade an existing system or medical product.

The JRO documented the Joint Future Operational Capabilities (JFOCs) in an integrated format merging the medical and non-medical needs. The purpose of the JFOCs is to identify and prioritize Joint User (Services and Combatant Commanders) far-term future operational capabilities as expressed in the emerging Joint CBRN Defense Concept. The intent of the prioritized list of JFOCs is to provide enhanced user guidance to the Joint CBRN defense science and technology (S&T) community to assist in S&T program planning and execution and to establish a link between near and long-term Joint CBRN defense research and development efforts and user needs. JFOCs also support the development of CBRN Defense Initial Capability Documents and future Joint Capability Development and Capability Production Documents. **Table 2-1** provides a synopsis of the current (FY03) JFOC priorities, descriptions, and objectives. JFOCs have become an integral part of the Joint Service CBRN Defense Modernization Plan and related S&T plans, specifically the Joint Warfighting Science and Technology Plan (JWSTP) and the Defense Technology Area Plan (DTAP).

Table 2-1. Prioritized CBRN Defense Joint Future Operational Capabilities

<p>1: Battlespace Management— Enhance operational effectiveness and individual and collective protection by providing the critical link between detection and operational decision-making. Commanders at all levels will be provided sufficient, timely CBRN hazard information in conjunction with early and direct warning means; to quickly and effectively quantify the operational and health risks associated with various courses of action; and to simulate the CBRN environment in support of realistic CBRN defense training.</p> <p>2: Contamination Avoidance—Significantly improve tactical, operational and strategic medical and non-medical CBRN Defense situational awareness by rapidly detecting, locating, identifying, quantifying, and confirming CBRN hazards in support of disseminating CBRN hazard information to the joint force.</p> <p>3: Individual Protection— To protect the individual by allowing for the conduct of safe operations, at near-normal levels of effectiveness, while under a CBRN threat or in a CBRN hazard area.</p> <p>4: Restoration— Sustain the joint force by rapidly returning personnel, equipment and the environment to normal operating modes/efficiencies after exposure to CBRN contamination.</p> <p>5: Collective Protection— Protect the joint force, including mission essential resources, and allow the joint force to operate safely, at near-normal levels of effectiveness and efficiency, while under a CBRN threat, or in a CBRN hazard area. Enhance CBRN hazard protection on existing/future joint force mobile and transportable assets and in fixed facilities.</p>

In accordance with the national strategy of achieving and applying technological superiority, several underlying concepts form the foundation of acquisition modernization. The first is the need to reduce cycle time in the acquisition of new systems or medical products or the integration of emerging technologies into existing systems. The use of Advanced Concept Technology Demonstrations (ACTDs), open systems and architectures, along with the new emphasis on commercial standards and practices, allow us 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.

2.2 CBRN DEFENSE MISSION AREA REQUIREMENTS AND RDA SUMMARY

The Services have been increasing jointness in ongoing programs in all commodity areas. This report highlights improvements during FY02 and discusses cooperative efforts for further Joint development of requirements. This section summarizes the requirements in each of the mission commodity areas. This chapter provides a focus on research, development, and acquisition efforts. Issues related to sustainment and logistics of fielded items are discussed in Chapter 3. Detailed descriptions of non-medical equipment can be found in Annexes A, B, C, and D; descriptions of medical systems and research accomplishments are detailed in Annex E.

Sections 2.3 through 2.7 provide an overview of the goals and timeframes, potential payoffs, and major technical challenges for science and technology (S&T) efforts. A detailed account of S&T efforts for all commodity areas is provided in two separate reports: (1) the *Joint Warfighting Science and Technology Plan*, Chapter XII, “Counterproliferation of Weapons of Mass Destruction,” and (2) the *Defense Technology Area Plan*, Chapter II, “Chemical and Biological Defense.” The *Basic Research Plan* also provides descriptions of various supporting sciences—including chemistry, biological sciences, materials science, and others—that support CB defense S&T activities. Within the *Joint Warfighting Science and Technology Plan* and the *Defense Technology Area Plan*, key projects are defined as Defense Technology Objectives (DTOs). A DTO states specific technology advancements to be developed or demonstrated, 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.*, a specific Combatant Commander). DTOs represent high priority projects, consistent with strategy and guidance. DTOs provide a key means for S&T planning and programming and for fulfilling GPRA requirements. DTOs are proposed, reviewed, and updated annually.

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

Investments are being made in the establishment of a comprehensive threat agent infrastructure, to acquire threat agents (both recognized and emerging), using chemical synthesis, biological manipulation, and procurement. Emphasis is placed on the characterization of the properties of threat agents to provide information needed by Joint Service materiel and medical developers. Emphasis is also placed on developing appropriate simulants for use in the RDT&E process. Execution and funding of the work is integrated among DoD and DOE performers and coordinated with the Intelligence Community. Deliverables from this program are threat agents, technical data on threat agents, and simulants for developmental and operational testing.

CW toxicology data support all commodity areas, at all levels, including protection, decontamination, and detection. Primary data gaps include the lack of complete agent dose-

response curves and probit slopes. Secondary data gaps include the toxicology of mixtures found in munitions and of by-products resulting from agent degradation or decontamination.

A multi-year program involving the non-medical and medical communities is currently underway to address the medical and operational issues of low-level exposures to chemical agents. Assessment, prevention, diagnosis, and treatment of possible persistent health effects are central aspects of the medical program. Medical emphasis is on the determination of exposure thresholds for effects from chemical warfare agents. The toxicological emphasis is airborne exposure to low concentrations of agent for exposure durations extending out to several hours, determination of the lowest chemical concentrations that are operationally significant, and characterization of the concentration-time response curve. A new DTO—CB.51, Low-Level CW Agent Exposure: Effects and Countermeasures—was initiated in FY03 to develop data on the toxicological and behavioral impacts of extended exposure to low concentrations of chemical agents. These data may lead to new detector sensitivity and protection factor levels as well as contribute to improved health risk assessments and models of effects of chemical agents on operations.

2.3 CONTAMINATION AVOIDANCE (Reconnaissance, Detection, and Identification)

The operational concept of contamination avoidance includes CBRN reconnaissance, detection, and identification. For fixed sites where contamination cannot readily be avoided and for missions requiring operations in a contaminated environment, reconnaissance, detection, and identification are critical to ensure that forces can (1) assume the optimal protective posture so that they can continue to sustain operations and (2) rapidly identify and decontaminate (if possible) 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 chemical and biological standoff, early warning detection, miniaturization, interconnectivity, improved detection sensitivity, improved interference rejection, improved logistics supportability, and affordability. The following sections detail contamination avoidance science and technology efforts, modernization strategy, and Joint Service programs.

2.3.1 Contamination Avoidance Science and Technology Efforts

2.3.1.1 Goals and Timeframes. The goal of contamination avoidance is to provide real-time capability to detect, identify, characterize, locate, and warn against all known or validated CBRN warfare agent threats (see **Table 2-2**). 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. Research and development efforts seek to optimize and balance system sensitivity, size/weight, cost, power consumption, signature and false alarm rate. Ultimately the goal is direct integration of CBRN detectors as a single system into various platforms, and command, control, communication, computer, and intelligence (C⁴I) networks.

Table 2-2. Contamination Avoidance Science and Technology Strategy

By 2003	By 2008	By 2013
<ul style="list-style-type: none"> • Complete installation of the Joint Portal Shield biological detection network sensor systems at Combatant Command fixed site locations and transition to full production status. • Complete demonstration of integrated point biodetection capability (Advanced Technology Demonstration). • Demonstrate lightweight (30% weight reduction) chemical point detector in the laboratory with a capability to detect and identify a wide range of chemical threat agents and high-threat toxic industrial chemicals. Demonstrate enhanced aerogel-based biological agent sample collection capability. • Initiate development of the Joint Biological Standoff Detection System (JBSDS) Block I. 	<ul style="list-style-type: none"> • Demonstrate Chemical Imaging Sensor for wide area detection. • Complete development of Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD). • Complete development of Artemis (Chemical Agent Standoff Detection System). • Complete development 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. 	<ul style="list-style-type: none"> • 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).

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.

Ongoing DTOs:*

- Automated Genetic Identification
- Stand-off Biological Aerosol Detection
- Chemical Biological Agent Water Monitor
- Activity-Based Detection and Diagnostics
- Terrorist Chemical/Biological Countermeasures
- Integrated CB Standoff Detector
- Lightweight Integrated CB Detection
- Detection of CB Contamination on Surfaces
- Wide Area Aerial Reconnaissance for Chemical Agents

Completed DTOs:

- Biological Warfare Defense Sensor Program
- Force Medical Protection/Dosimeter ACTD
- Chemical Imaging Sensor
- Laser Standoff Chemical Detection Technology
- Chemical Add-On to Airbase/Port Biological Detection ACTD

2.3.1.2 Potential Payoffs and Transition Opportunities. Future CB detection systems will provide the capability to detect, identify in real time, map, quantify, and track all known CB contamination in a theater of operations. This will enable commanders to avoid CB 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

* DTO descriptions are provided in Annex A.

performance degradation and casualties. CB detection technologies have dual use potential in monitoring air pollution, noxious fumes inside enclosed areas, and municipal water supplies.

2.3.1.3 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, and genetic probe development. 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 areas of challenge.

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 trade-offs 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. Further efforts in FY02 and FY03 will begin to validate the feasibility of providing an enhanced level of discrimination of biological material using standoff detection.

2.3.2 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 meet service-specific needs, those in the mid to far-terms demonstrate the increase in joint development and modernization since the founding of the CBDP.

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 threats. Real time detection of biological agents is currently unavailable and is unlikely in the near to mid-term, though investment efforts are reducing detection times. DoD also is on developing lightweight, automated CBRN sensors capable of providing enhanced detection and early warning of all biological and chemical threat agents. To meet the needs in the near to mid term, several stand-alone detectors and sensors are

being developed. Developmental efforts are focusing on system miniaturization, improved sensitivity and specificity, agent characterization and range, decreased false alarm rate, and decreased operation and support costs. This focus will facilitate the integration of chemical detectors into personal warfighter gear, 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.

Table 2-3. Contamination Avoidance Modernization Strategy

	NEAR (FY03-04)	MID (FY05-09)	FAR (FY10-19)
Chemical Point Detection	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Improved surface contamination monitor • Detection of CB contamination in water (Joint Chemical Biological Agent Water Monitor, JCBAWM)
Biological Point Detection	<ul style="list-style-type: none"> • 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) • Navy-Ship based Interim Biological Agent Detector (IBAD) • Army-Biological Integrated Detection System (BIDS) 	<ul style="list-style-type: none"> • 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 (FY06) for Joint Biological Tactical Detection System (JBTDS)– small lightweight biodetector – networked system. Bio/non-bio determination. 	<ul style="list-style-type: none"> • 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) • JBTDS Block 2
CBRN Reconnaissance and CB Remote and Stand-off Detection	<ul style="list-style-type: none"> • Improved CBRN Reconnaissance Vehicle with remote/early warning and data fusion capabilities (M93A1) • Lightweight passive stand-off detection for chemical agent vapors (JSLSCAD) 	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Army-Compact, digital whole body radiation measurement (AN/UDR-13) 		<ul style="list-style-type: none"> • 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.

2.3.3 Joint Service Contamination Avoidance Programs

Since the establishment of the Joint CB Defense Program, 44 separate contamination avoidance developmental efforts have been consolidated into eleven fully coordinated joint projects that meet current multi-Service needs. Table 2-3 above 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.

2.3.4 Other Contamination Avoidance Programs

The Multimission Sensor (MMS) Program uses existing radars to provide early warning of a suspected CB event to allow timely dispatch of a dedicated CB sensor to confirm or deny the existence of the CB 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.

2.3.5 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. 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 will be automated for unattended operations. Detection technologies that provide information on BW agent pathogenicity, antibiotic resistance and viability are also being developed under the DARPA biological detection program.

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.*

2.4 BATTLESPACE MANAGEMENT

The Battlespace Management area seeks to develop the capability to use automatic collection and fusion of medical and non-medical information from all CBRN defense assets throughout the battlespace and integrate that with other relevant battlespace information and C⁴I systems. It will integrate threat information, CBRN sensor and reconnaissance data, protective posture, environmental conditions, 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 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 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 threats. JWARN will be compatible and integrated with Joint/Service C4ISR systems and networks. To improve the prediction of CBRN hazards, JWARN will interface with the Joint Effects Model (JEM) and other high resolution models.

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 is currently finalizing the documentation requirements to achieve a Milestone B decision for Block II. JWARN Block II 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, which can identify and quantify chemical threats, and which are 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 RF. 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 fundamentally 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, simulation based acquisition, and accurate training. Modeling and simulation systems 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 systems 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 combat need. In addition, modeling and simulation information systems aid in the assessment of Joint and Service doctrine, training, materiel development, and equipment design (*i.e.*, Simulation Based Acquisition). They are also used in warfighter training and the training of battle staffs using larger conflict simulations. In the latter aspect, they are used to perform and support analyses of CBD operations within the context of larger military operations. Analytic systems such as models are also critical compo-

nents 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.

2.4.1 Information Systems Science and Technology Efforts

The Information Systems Technology business area includes four sub-areas to fully meet the JFOCs required by the Combatant Commanders. The JFOCs focus on capabilities to provide improved battlespace management, characterization of the CB environment, information systems, and simulation based acquisition. To provide improved characterization of the CB environment, efforts are continuing to provide advanced hazard assessment methodologies, address specific environmental flow regime issues (such as high altitude and urban transport and diffusion (T&D) methodologies) and support first principles 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 collaborate with the 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.]

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

- support the warfighter directly through existing C⁴I networks and information systems,
- support the operational and national command authority with CBD 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 2-4 shows specific efforts supporting these 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 2-4. Information System Science and Technology Strategy

By 2003	By 2008	By 2013
<ul style="list-style-type: none"> • Demo improved VLSTRACK Version 3.1 • Continue efforts with MESO and CBW Computational Fluid Effects (CBW-CFX) technologies • Demonstrate Fixed Site capability: Simulation Training and Analysis For Fixed Sites (STAFFS) • Demonstrate multi-fidelity modeling & simulation (M&S) capability • Initiate Joint Effects Model (JEM) acquisition program • Provide VLSTRACK, HPAC and D2PC methodologies to JEM 	<ul style="list-style-type: none"> • Demonstrate and transition MESO and CBW-CFX methodologies to JEM • Demonstrate and transition STAFFS and NCBR Simulator to Joint Operational Effects Federation (JOEF) • 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 	<ul style="list-style-type: none"> • 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 BE.10, High-Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction.

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 agents or materials within the military context. DTO BE.10 will provide the high-resolution meteorological forecasting capabilities that are only required for CBRN operational decision making processes.

2.4.1.2 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 CBD actions, verify effective deployment of CBD assets and reconstitution procedures, assume the appropriate protection required to continue operations, and sustain their mission with minimal performance degradation and casualties. CB M&S technologies have dual use potential predicting and responding to civil support events such as terrorist activities, air pollution, and toxic industrial chemical (TIC) releases both outside and inside enclosed areas, and municipal water supplies. The key payoffs

of M&S include: (1) commanders and battle staffs better trained and able to analyze alternate courses of action with advanced simulations, (2) less confusion and more consistent decision making via use of a federation of analytical and real time CBD environment M&S tools, (3) CBD systems and operational concepts that match requirements more closely because warfighter feed back is captured earlier in the development cycle under the tenets of SBA, and (4) advanced hazard prediction and human effects modeling that has dual use potential in aiding civilian responders or planners to prepare for or respond to terrorist attacks and industrial accidents.

2.4.1.3 Major Technical Challenges. The major technical challenges for M&S include the following: (1) modeling and validating the effects of complex and urban terrain on CB hazards, (2) modeling and validating high altitude threat intercept effects, (3) modeling and validating human effects and small unit behaviors in a CB 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.

2.4.2 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 CBDP. **Table 2-5** 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 past 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.

Table 2-5. Battlespace Management Modernization Strategy

	NEAR (FY03-04)	MID (FY05-09)	FAR (FY10-19)
Warning and Reporting Systems	<ul style="list-style-type: none"> Automated, standardized warning and reporting (JWARN Block I) MICAD Fox vehicle system Automatic CBRN warning and reporting interoperable with all Services (JWARN Block II) 	<ul style="list-style-type: none"> Integrated and automatic warning and reporting (JWARN Block III) Updated MICAD vehicle system JSLNBCRS embedded JWARN system 	
Hazards Analysis	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Fixed site analysis (STAFFS) Medical resources analysis (CREST) Mobile forces analysis (NCBR Simulator) 	<ul style="list-style-type: none"> Integrated fixed site and medical simulations with JWARS and JSIMS (JOEF Block I) 	<ul style="list-style-type: none"> Mobile forces simulations incorporated into the federation (JOEF Block 2) Automated C4I system integration (JOEF Block 3)
Simulation Based Acquisition Systems	<ul style="list-style-type: none"> Navy-Ship based analysis (CWNavSim) Point and stand-off detector systems (NCBR Simulator) 	<ul style="list-style-type: none"> Detection (VPS Block 1) Biological detection and identification capabilities (VPS Block 2) 	<ul style="list-style-type: none"> Protection and decontamination (VPS Block 3&4)
Training Simulation Systems	<ul style="list-style-type: none"> Virtual Emergency Response Training System (VERTS) 	<ul style="list-style-type: none"> VERTS Capability becomes Training Simulation Capability (TSC) Blocks 1 and 2 Individual and crew training systems (TSC Block 2) 	<ul style="list-style-type: none"> Integrated training systems for battle staffs and commanders (TSC Block 3)

The Joint Operational Effects Federation (JOEF) program achieved Milestone A in February 2002. JOEF will be the acquisition program to address 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 CB 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 CB 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.

2.5 RESTORATION

When contamination cannot be avoided, personnel and equipment may need to be decontaminated to reduce or eliminate hazards after CBRN weapons employment. Decontamination systems provide a force restoration capability for units that become contaminated. Modular decontamination systems are being produced to provide decontamination units with the capability to tailor their equipment to specific missions. Technology advances in sorbents, coatings, catalysis, 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.

2.5.1 Restoration Science and Technology Efforts

2.5.1.1 Goals and Timeframes. The goal of decontamination science and technology is to develop technologies to support two key Joint Future Operational Capabilities (JFOCs)—*Restore (Equipment/Facilities/Large Areas) JFOC*, and *Restore (Logistics) JFOC*. These capabilities will eliminate toxic materials or their effects without performance degradation to the contaminated object, are non-corrosive, environmentally safe, and lightweight (see **Table 2-6**). This area includes decontamination of personnel, individual equipment, tactical combat vehicles, aircraft, facilities, and fixed sites. Decontamination technologies currently being pursued include enzymes, non-chlorine based oxidants, catalysts that improve reactivity, decontaminants that are effective in both fresh and brackish water, improved reactive sorbents, and nanoparticle technology. Supercritical fluid technology, non-ozone depleting fluorocarbons, and solvent wash technologies are being investigated for sensitive equipment decontamination, while thermal approaches, solvent wash technologies, and plasma are among the candidates being evaluated as a decontaminant for interior spaces of vehicles such as aircraft. Enzyme-based decontaminants that are nontoxic, non-corrosive, and environmentally safe were pursued through the recently completed DTO CB.09, Enzymatic Decontamination. 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.

Contamination control involves investigating procedures that minimize the extent of contamination pickup and transfer, and maximize the ability to eliminate the contamination pickup on-the-move as well as during decontamination operations. During the past year, increased emphasis has been 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. I.06), the Contamination Avoidance at Sea Ports of Debarkation (CASPOD) ACTD (DTO I.07), and other DoD sponsored studies.

Table 2-6. Restoration Science and Technology Strategy

By 2003	By 2008	By 2013
<ul style="list-style-type: none"> • Demonstrate improved sorbent delivery systems • Demonstrate Aircraft Interior Decon procedures • Demonstrate Family of Decontaminants 	<ul style="list-style-type: none"> • Demonstrate Sensitive Equipment Decon Systems • Demonstrate concentrated enzymatic and oxidative decontaminants • Demonstrate Family of Applicators • Demonstrate the next generation of reactive sorbent powders 	<ul style="list-style-type: none"> • Demonstrate new self-decontaminating materials • Demonstrate improved thorough decon materials • Demonstrate aircraft and other vehicle interior decontamination • Demonstrate personnel decontaminant

2.5.1.2 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 a 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. Dual use potential for chemical agent stockpile as well as environmental remediation, especially those dealing with pesticide and toxic industrial chemical contamination, is being exploited.

2.5.1.3 Major Technical Challenges. There are two key technical challenges associated with this effort. 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.

2.5.2 Restoration Modernization Strategy

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. 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 2-7** shows the roadmap for modernizing decontamination systems in DoD, 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.

Table 2-7. Restoration Modernization Strategy

	NEAR (FY03-04)	MID (FY05-09)	FAR (FY10-19)
Personal Equipment Decontaminants	<ul style="list-style-type: none"> • More reactive, high capacity adsorbent (M291/M295) • Army-<i>Higher efficiency decon methods (Sorbent Decon)</i> 	<ul style="list-style-type: none"> • Non-caustic, non-corrosive decontaminant for personnel and equipment 	
Bulk Decontaminants	<ul style="list-style-type: none"> • Non-caustic, non-corrosive, easy to store and manufacture multipurpose decontaminants 	<ul style="list-style-type: none"> • Decontaminants for fixed sites • Navy -<i>Less caustic capability</i> 	<ul style="list-style-type: none"> • Mission tailored decontaminants • Navy -<i>Contamination resistant shipboard materials</i> • Army -<i>Environmentally acceptable replacement for DS2</i> • Army -<i>Enzymes for chemical agent decontamination</i>
Expedient Delivery Systems		<ul style="list-style-type: none"> • Auto-releasing coatings; reduces skin contact hazard & labor requirements 	<ul style="list-style-type: none"> • Self-decontaminating, auto-releasing coatings; reduces man-power and logistic requirements eliminates skin contact hazard
Deliberate Delivery Systems	<ul style="list-style-type: none"> • High pressure water wash; improved decontaminant dispenser (increased vehicle throughput) • Army -<i>Rebuild M12A1 Power Driven Decon Apparatus; Replace M17 Lightweight Decon System</i> 	<ul style="list-style-type: none"> • Rapid large scale decon capability for fixed sites; reduced manpower and logistic burden • Non-aqueous capability for electronics, avionics and other sensitive equipment 	<ul style="list-style-type: none"> • Vehicle interior decon capability • Supercritical fluid decontamination apparatus • Army -<i>Waterless decon capability for electronics and avionics</i> • Air Force - <i>Sensitive equipment decontamination system for aircraft interiors</i>

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.

The goal of the CBRN restoration program area is to provide technology to remove and detoxify contaminated material without damaging combat equipment, personnel, or the environment. In FY99 the RDA community worked with the Joint Staff and Services’ operations community and completed a Decontamination Master Plan that provide a roadmap that integrates RDA efforts with non-RDA efforts, including policy, doctrine, standards, and revised tactics, techniques & 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 technologies, 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.

2.5.3 Joint Service Restoration 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. Through the Foreign Comparative Test program, the Reactive Skin Decontamination Lotion was evaluated as a skin decontamination capability, and was approved for use by the FDA in March 2003. In the mid-term, the Joint Service Family of Decontamination Systems (JSFDS) program plans to select an improved skin decontaminant.

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 and Super Tropical Bleach. New technologies, such as reactive decontaminating systems, enzyme-based 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 of under 15 minutes and be effective at a pH below 10.5 in order to eliminate the corrosion risk. 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, peroxy-carboxylic 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. Advancements during the last 18 months in plasma-based systems appear promising for these types of applications. 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 restoration projects is provided in Annex D.

2.5.4 Other Restoration Programs

In the near-term, the Army is rebuilding 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.

2.6 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 that reduce respiratory stress on the user while improving compatibility with weapon sighting systems and reduce weight and cost are being developed. Technology advances are being pur-

sued to produce mask systems that provide fully compatible vision capabilities, laser/ ballistic protection, and further reduction in logistics and physiological burden. Protective clothing and integrated suit ensembles are being developed that will improve protection, reduce the physiological and psychological burden, have extended durability, and have less weight and heat stress burden than present equipment.

- **Collective protection equipment** consists of various types of protective filters, entry/exit, and air movement devices that provide filtered air to a wide range of applications, transportable shelter systems equipped with filtration systems and, in selected cases, environmental control. 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 filtration, environmental control and power generation facilities 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 filtration systems are also being pursued.

2.6.1 Protection Science and Technology Efforts

2.6.1.1 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 CB warfare agents and radiological particles (see **Table 2-8**). 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 to 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 2-8. Protection Science and Technology Strategy

By 2003	By 2008	By 2013
<ul style="list-style-type: none"> • Demonstrate 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 lightweight, low cost materials and advanced closures for shelters 	<ul style="list-style-type: none"> • Investigate reactive materials as a means of self-detoxifying clothing and shelters • Investigate residual life indicators for mask filters, collective protection filters, and clothing • Investigate advanced adsorbents and filter bed configurations to provide protection against a wider spectrum of threats CBRN hazards. 	<ul style="list-style-type: none"> • Investigate membrane/ adsorbent composites for clothing • 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

2.6.1.2 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 the Defense Technology Objective Advanced Adsorbents for Protection Applications.

2.6.1.3 Potential Payoffs and Transition Opportunities. Individual protection investments will result in improved respiratory and percutaneous (skin) protection with reduced physiological and psychological burden to the individual warfighter. Improved air filtration systems or technologies for collective protection applications will allow for extended operation in an CBRN contaminated environment, reduce the logistics burden associated with filter replacement, reduce weight, volume and power requirements, and improve the capability against current and emerging threats. Filtration technology has commercial application to the chemical industry and automotive applications.

2.6.1.4 Major Technical Challenges. Integrating CB 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. CB protective clothing development requires balancing the physiological and psychological burden imposed upon the warfighter with maximum obtainable CBRN hazard protection. 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 systems require tradeoffs with respect to performance, user requirements, size, weight and power constraints, as well as longer life. Addition of threats such as TICs increase the need for additional protection and makes the challenge of reducing physiological performance and size and weight constraints more difficult, requiring threat versus design tradeoffs essential and tailoring of equipment to meet the threat.

2.6.2 Protection Modernization Strategy

Forces cannot always avoid CBRN hazards. Therefore, individual 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 requirements is provided in **Table 2-9**, 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.

Table 2-9. Protection Modernization Strategy

	NEAR (FY03-04)	MID (FY05-09)	FAR (FY10-19)
Individual Eye/Respiratory	<ul style="list-style-type: none"> • Voice amplification; laser/ballistic eye protection; improved decontaminability, improved comfort (M40A1/M42A2) • Army - <i>Aircrew mask compatible with Apache helicopter systems with a significantly lighter motor/blower unit (M48)</i> • Army - <i>Improved compatibility with aviation sighting/night vision systems; reduced logistics burden using non-blower systems, selected for Land Warrior (M45)</i> 	<ul style="list-style-type: none"> • Reduced physiological and psychological burden, improved comfort, enhanced optical and communications, improved compatibility • New mask systems for general purpose and aviation masks (JSGPM, JSAM) • Lightweight CB mask for low threat environments (JSCESM) • Improved mask leakage tester (JSMLT) 	<ul style="list-style-type: none"> • Advanced Integrated Individual Soldier Protection system (Future Soldier System) • Improved multiple agent protection
Individual Clothing	<ul style="list-style-type: none"> • Advanced protective suit technology; lighter, improved agent protection; reduced heat stress integrated with all respiratory systems. <ul style="list-style-type: none"> - Improved foot protection (MULO) - Improved hand protection 	<ul style="list-style-type: none"> • Improved cutaneous protection • Improved protection for aviators (JPACE) • Service Life Indicator • Army - <i>Improved protection for short term use for special purposes (ITAP)</i> 	<ul style="list-style-type: none"> • Integrated multiple threat modular protection (chemical, biological, environmental, and flame) • Self-detoxifying clothing
Collective Protection	<ul style="list-style-type: none"> • Chemically Protected Deployable Medical Systems (CP DEPMEDS) • Chemically Hardened Air Transportable Hospital (CHATH) • Collective Protection for Expeditionary Medical Shelter System (CP EMEDS) • Rapid insertion of technology improvements into existing equipment (JCPE) • Marine Corps - <i>Protection for all combat vehicles and unit shelters</i> • Army <i>CBRN protection for tactical Medical units (CB Protective Shelter, CBPS)</i>. <ul style="list-style-type: none"> - <i>Apply regenerable vapor filter to Comanche,</i> - <i>Apply collective protection to advanced vehicle concepts.</i> • Air Force - <i>Upgrade/install collective protection into existing rest/relief shelters.</i> • Navy - <i>Backfit ships with contamination free protected zones - (Collective Protection System Backfit)</i> 	<ul style="list-style-type: none"> • 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 (JTCOPS) 	<ul style="list-style-type: none"> • 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.

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 fatigue, 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 remove TICs as well as traditional NBC 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 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 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 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 filtration (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 vehicles, vans, shelters, fixed sites, and ships, 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 Comanche, Crusader, Bradley, Breacher, Heavy Assault Bridge, Future Scout and Cavalry System, the USMC Advanced Amphibious Assault Vehicle (AAAV), and other advanced weapons platforms.

2.6.3 Joint Service Protection Programs

Joint programs are shown in **Table 2-9**; Service-unique programs are italicized. A detailed description of Joint IPE and CPE programs is provided in Annex B.

Individual Protection

Eye/Respiratory. The M40 and M42 series masks (for individuals and armored vehicle crewmen, respectively) are undergoing the final stages of fielding to replace their M17, M9 and M25 series counterparts. The new masks offer increased protection, improved fit and comfort, ease of filter change, better compatibility with weapon sights, and a second skin, which is compatible with Army and Marine Corps protective ensembles. The second skin design also is being incorporated by the Navy and Air Force on the MCU-2A/P protective mask. The Army, Marines, and Air Force are also fielding the Protection Assessment Test Systems (PATS) to provide users of the M40, M42, and MCU-2/P series masks with a rapid and simple means for validating the fit and function of the mask to ensure readiness. The Navy is evaluating the use of PATS with its MCU-2/P series mask.

The Navy, in coordination with the Marine Corps, is leading an effort to equip all forward deployed fixed and rotary wing aircrew with improved chemical, biological, and radio-

logical (CBR) protection. The CBR ensembles will feature off-the-shelf items, such as the CB Respiratory System (A/P22-14(V1-4)). The Army, in cooperation with the Marine Corps, recently completed a product improvement program for the M40 series mask that allows ground crew to aircrew communication. The Air Force continues to field Aircrew Eye-Respiratory Protection (AERP) systems to protect aircrews from CBRN hazards. This system complements the recently fielded lighter weight aircrew ensemble. Efforts are planned in the near- to mid-term to develop a Joint Service Mask Leakage Test System as a supplement and/or replacement for the M41 PATS, depending on service specific maintenance concepts.

Mid- and far-term research is focused on improved vapor and particulate filtration technology, and improved masks for light and special operations forces (SOF). Development will be completed in the mid-term for the Joint Service Aircrew Mask and Joint Service General Purpose Mask, which will provide improved eye, respiratory, and face protection against current and future agents. It will maximize compatibility with future weapon systems, be lightweight, and offer modular facepieces to accommodate a variety of mission profiles. A mid-term Joint Service Chemical Environment Survivability Mask (JSCESM) will provide a mask capable of being stowed easily in packs or pocket as an expedient means of CBRN protection in low threat and special operation situations. Future protective mask efforts will focus on integrated mask-helmet systems supporting specific needs of the Joint Services and integrated warrior programs (Land Warrior, Air Warrior, Mounted Warrior, and Force XXI).

Clothing. The JPACE garment ensemble will be used in conjunction with legacy and developmental above-the-neck individual head-eye-respiratory protection by rotary wing and fixed wing aircraft personnel. JPACE will allow aircrew to fly throughout their operating envelope in an actual or perceived CB warfare environment. The ensemble will be suitable for performing all normal and emergency procedures, both in-flight and on the ground. It will provide the ability to fully exploit combat capabilities in a CB environment while reducing heat stress induced by existing aircrew CB garments. The JPACE ensemble will be completed with the addition of the JSLIST Block 2 Glove Upgrade aviation glove and the latest vapor protective socks.

In the far-term, efforts will focus on integrated protection. Next generation technology will be directed toward integrating CBRN protection into a system that will also provide environmental, ballistic, directed energy, and flame protection, as well as reduced physiological and psychological burdens. A strong emphasis on supporting technologies must continue. Materials that detoxify a broad range of chemical and biological agents on contact, which can be incorporated into fibers, nanofibers, fabrics, and selectively permeable membranes, are being developed using biotechnology, electrospinning, and more conventional approaches.

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 agent and allows expansion of protection area and has been fielded. The M28 Simplified CPE has been integrated into CP DEPMEDS and CP EMEDS field hospitals.

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 CB contaminated environment for 72 hours. Chemical protection is integrated into existing Tent Extendable Modular Personnel (TEMPER)-based medical tents and shelters and the Modular, General Purpose, Tent, Extendable System (MGPTS) through addition of M28 Simplified CPE, chemically protected heaters and air conditioners, and alarms. CP DEPMEDS also includes CB protective water distribution and latrine systems. A Milestone C In Progress Review (IPR) was conducted recommending approval. Final approval is in staffing. An urgent operational need is validated to support Operation Enduring Freedom for six systems; new equipment training and fielding was initiated January 2003.

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 CB 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 limited production to meet an urgency of need requirement. Full production approval (Milestone C) was obtained in November 2002. Type Classification Standard decision is in staffing. Currently, an Urgent Operational Need has been validated and 64 systems are being fielded to support Operation Enduring Freedom; new equipment training and fielding was initiated January 2003. 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 filtration, 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 Transportable Collective Protection System (JTCOPS) 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 Comanche, Crusader, USMC AAVV, and U.S. Army advanced vehicle efforts. The USAF is currently undergoing a major upgrade to their mobile and fixed site collective protection capabilities.

2.6.4 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 currently used 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 microfibrinous 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 microfibrinous, 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 has been recently selected by the Joint Service CBRN Defense science and technology program for technology transition funding, and improved prototypes are being developed under U.S. Army SBCCOM'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 CB 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.

2.6.5 Other Protection Programs

Programs supporting requirements of a single service are shown in **Table 2-7** as italicized entries. A detailed description of IPE and CPE projects is presented in Annex C.

Individual Protection

Eye/Respiratory. 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 CB protection without the aid of force ventilated air.

Clothing. 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 will transition to the JCPE in FY03.

2.7 MEDICAL SYSTEMS

2.7.1 Introduction

Many countries and terrorist groups have acquired the means to produce and deliver chemical or biological (CB) 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. Exposure to multiple threats may result in synergistic effects.

Medical CB defense research programs are organized into chemical and biological research. **Tables 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 chemical and biological 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 have been developed. Also being developed are rapid portable diagnostics that will facilitate a quick medical response for exposed warfighters.

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

	NEAR (FY03-04)	MID (FY05-09)	FAR (FY10-19)
Medical Chemical Defense	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 2-11. Medical Biological Defense Programs and Modernization Strategy

	NEAR (FY03-04)	MID (FY05-09)	FAR (FY10-19)
Medical Biological Defense	Joint Biological Agent Identification and Diagnostic System (JBAIDS) Block I (nucleic acid-based analysis) downselect Licensed antibiotic for exposure to anthrax (ciprofloxacin) Anthrax vaccine amendment for new dosing schedule	Licensed smallpox (vaccinia virus, cell culture-derived) vaccine JBAIDS (Block II) (nucleic acid-based analysis and immunodiagnostic platforms) - 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, tularemia, 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 and tularemia

The medical CB defense 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 CB 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 accom-

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

Specific initiatives programmed to improve CB defense medical readiness include:

- Continued emphasis on CB medical countermeasures research.
- 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.
- Cooperative initiative with the U.S. Food and Drug Administration (FDA) for application of the new Animal Rule¹, that 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.
- A prime systems contractor to the Chemical and Biological Medical Systems (CBMS), formerly the Joint Vaccine Acquisition Program) continues its effort to develop, license, produce, and store biological defense vaccines.
- 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).
- Training of health care professionals for the medical management of chemical and biological casualties.

2.7.2 Challenges in Medical CB 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, 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 of 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 CBR 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 Regulation 5000.2-R. In addition to adhering to DoD

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.

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 CB 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) is normally required to conduct the necessary human clinical studies and develop and document the manufacturing processes needed to obtain FDA licensure after an acquisition program has been initiated for a candidate medical countermeasure.

Medical CB 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 CB 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 rule² allows appropriate studies in animals in certain cases to provide substantial evidence of the effectiveness of new drug and biological 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 pyridostigmine bromide to increase survival after exposure to soman nerve gas poisoning. Evidence of the effectiveness of pyridostigmine bromide 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 the neuromuscular disease, myasthenia gravis.

While there are efforts to reduce reliance on animals as subjects of research (see Section 2.7.3.), 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, frequently used and 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 investiga-

² Ibid. Full text of the new rule is Available at <http://www.fda.gov/cber/rules.htm>.

tion is intended to preclude potential resource limitations from slowing the development of medical CBRN defense products.

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

The JMCBDRP utilizes and develops 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.

2.7.4 Joint Medical Chemical Defense Research Program

The mission of the Joint Medical Chemical Defense Research Program (JMCDRP) is preserve the health, safety, and combat effectiveness of warfighters by timely provision of medical countermeasures in response to joint service chemical warfare defense requirements.

2.7.4.1 Goals. The mission-specific goals of the JMCDRP 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.

2.7.4.2 Objectives. The objectives of the JMCDRP 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 enhancing barrier properties and detoxifying any CW agent that penetrates the protective barrier.
- For nerve agents, one objective is the fielding of a safe and effective improved anti-convulsant. 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.

2.7.4.3 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.
- **Active Topical Skin Protectant** – Topical creams that contain reactive moieties that can neutralize CWA as well as act as barriers to skin contact with CWA are being evaluated.
- **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.

2.7.5 Joint Medical Biological Defense Research Program

The mission of the Joint Medical Biological Defense Research Program (JMBDRP) is to develop medical countermeasures to protect U.S. forces and thereby deter, constrain, and defeat the use of biological agents against them. The program is directed against agents of biological origin that are validated military 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.

2.7.5.1 Goals. Mission-specific goals of the JMBDRP include the following:

- Protecting U.S. forces warfighting capability during a biological attack.
- Reducing vulnerability to validated and emerging threats by maintaining a strong technology base.
- Providing consultation medical management of BW casualties.

2.7.5.2 Objectives. In accomplishing the goals of the JMBDRP, 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.

The JMBDRP responds to requirements from the DoD as identified in the Joint Service Agreement on Biological Defense, the Joint Warfighting Science and Technology Plan, the

Defense Technology Area Plan, the Defense S&T Strategy, and DoD Directive 6205.3, “Biological Defense Immunization Program.”

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. These products include multi-agent vaccine delivery capabilities and systems that will reduce costs of vaccine production and simplify immunization schedules, and a common diagnostic system 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. The development of these products, as well as the complementary technology-based research and development to enhance and expand these capabilities and to identify and develop new capabilities, has been supported by collaboration with other agencies, including DARPA and the Department of Energy (DOE).

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 the JMBDRP 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 two years that the DARPA transition initiative has been funded (FY01–FY02), 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 the JMBDRP technology base. The selected programs include:

- Research to develop broad-spectrum vaccines by molecular breeding (gene shuffling) strategies; focuses 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 Program Executive Office for Chemical and Biological Defense (PEO-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) pre-acquisition phase in July 2002. Two other vaccine candidates, a recombinant Protective Antigen (rPA) vaccine candidate and recombinant staphylococcal enterotoxin (SE) vaccine candidates against SEA and SEB, are ready to enter TD in FY03. A decision to approve entry into TD activates advanced development funding in conjunction with technology base research efforts, enabling preparation of an Investigational New Drug application and planning and executing phase 1 human safety trials by CBMS's prime systems contractor, DynPort Vaccine Company (DVC).

Research toward the development of multiagent vaccine platforms under DTO CB.25 was completed in FY02. Similar to the combined measles-mumps-rubella vaccine given to children in the U.S, the technologies explored under this DTO were more advanced, such as the bioengineered vaccine platforms such as viral replicons, naked DNA vaccines, and adenovirus-vectored vaccines. The capability to immunize Service members against multiple BW threats with a single vaccine will reduce the logistical footprint and facilitate force protection. All three vaccine platform technologies were demonstrated as being capable of being utilized in multi-agent vaccine configurations. Proof-of concept in animal system models was obtained. The technologies are not currently ready for development, but are returning to S&T program areas where multiagent vaccine strategies may provide the optimum solution, i.e., protection against multiple types of Marburg viruses, multiple types of protein toxins such as the botulinum neurotoxins, etc.

Research toward development of a common diagnostic system under DTO CB.26, Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases, was completed in FY02. This DTO focused on miniaturized polymerase chain reaction technology for detection and identification of nucleic acids of BW agents and agents causing particular natural infectious disease. Accomplishments included completing system integration and verification of approaches, reagents, and protocols and completing an analysis of alternatives of portable nucleic analysis systems for detecting and identifying nucleic acids from a broad range of biological threat agents in clinical specimens. The program obtained a Milestone A decision in November 2001 and became a candidate for the advanced development program for the JBAIDS. With these capabilities, laboratory-based identification of infections will be made much faster (less than 30 minutes) and farther forward than is now possible.

The JMBDRP 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 of pre-exposure therapy is the production 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 pretreatment therapies, 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 prophylaxes and 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 antibodies in biological materials. The approaches in diagnostic research include the application nucleic acid-based technologies (e.g., polymerase chain reaction analysis), immunodiagnostic platforms, and the use of microarray technologies. 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 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.

2.7.5.3 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 produce genetically engineered threats also

exacerbates the long-lead time between research and development for a medical solution and obtaining FDA licensure for the 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 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.

The current JMBDRP 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.

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

<p>VACCINES</p> <ul style="list-style-type: none"> • <i>Killed</i> – killed or inactivated microorganism that is incapable of replicating but stimulates immunity. • <i>Live, attenuated</i> – live organism, selected not to cause disease but able to stimulate immunity. • <i>Toxoid</i> – toxin protein treated to inactivate its toxicity but retains its ability to stimulate immunity. • <i>Recombinant</i> – 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. • <i>Deoxyribonucleic Acid (DNA)</i> – section of DNA that codes for protein that stimulates specific immunity to a BW agent. DNA produces the desired protein in recipient that stimulates immunity. • <i>Polyvalent/Multivalent/Multiagent</i> – mixture of antigens or vaccine constructs that protect against a number of different BW agents. • <i>Vectored</i> – carrier organism bioengineered to confer immunity against a biological agent or multiple agents. • <i>Replicon</i> – 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. <p style="text-align: center;">ANTIBODY (ANTISERUM, ANTITOXIN)</p> <ul style="list-style-type: none"> • <i>Heterologous</i> – antibodies collected from animals (<i>i.e.</i>, 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). • <i>Homologous</i> – antibodies of human origin (<i>i.e.</i>, same species as the recipient) that provide protective immunity against the BW threat. These antibodies are not prone to stimulating serum sickness. • <i>Monoclonal</i> – a cell culture technique for producing highly specific antibodies against a disease agent. • <i>Bioengineered</i> – 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. <p style="text-align: center;">DRUGS</p> <ul style="list-style-type: none"> • <i>Antibiotics</i> – effective against bacteria • <i>Antiviral compounds</i> – promising drugs in development by the pharmaceutical industry are being evaluated against viral threat agents. • <i>Others</i> – 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.) <p style="text-align: center;">DIAGNOSTIC TECHNOLOGIES</p> <ul style="list-style-type: none"> • <i>Immunological technologies</i> – These tests rely on antibodies for detecting the presence of proteins 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. • <i>Nucleic acid technologies</i> – 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 DNA from the toxin source organism, which would be highly unlikely. • <i>DNA Microarray technologies</i> – 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.
--

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.

2.7.5.4 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 and developing pathogen countermeasures to block pathogen virulence and to modulate host immune response); and Advanced Medical Diagnostics for the most virulent pathogens and their molecular mechanisms.

Medical countermeasures research includes: (1) broad spectrum therapeutics against known, biological warfare pathogens, (2) therapeutics against virulence pathways (mechanisms of disease) shared by broad classes of pathogens and (3) stimulators of innate immunity. Specific approaches include modified red blood cells to sequester and destroy pathogens, development of broad spectrum vaccines, engineering of plants to produce human vaccines and other products, identification of virulence mechanisms shared by pathogens, development of novel therapeutics targeting these mechanisms, and efficacy testing in cell cultures and animals.

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 signs and symptoms (when the pathogen numbers are low).

2.8 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 2-14** identifies all obligations associated with the manufacture of

the Anthrax Vaccine Adsorbed (AVA) as of February 27, 2002. **Table 2-15** identifies storage costs, distribution, and marketing.

Table 2-14. Obligation of Funds for Anthrax Vaccine Adsorbed (\$ in millions)

System Cost Element	FY 01& Prior	FY 02	Total
BioPort Corporation			
Production	54.9	47.4	102.3
Redundancy	4.4	0.0	4.4
Post Approval Requirements	0.0	5.7	5.7
Process Validation/BLA Supplement Approval	68.1	9.7	77.8
Testing, Labeling, Shipping, & Security	9.4	5.2	14.6
Facility Renovation	3.4	1.1	4.5
Camber Corporation	8.0	3.4	11.4
SAIC	1.3	0.0	1.3
Program Management Support	1.3	2.6	3.9
Total	150.8	75.1	225.9

Table 2-15. Storage and Marketing Costs for Anthrax Vaccine Adsorbed (\$ in millions)

AVIP Costs	FY00	FY01	FY02
Contract Personnel/ Support	3.2	3.3	4.5
Vaccine Distribution	0.3	0.4	0.7
Education	1.7	1.1	.5
Program Research and Evaluation	2.6	2.6	4.0
VA-DoD Force Health Protection Initiative	0.6	0.5	3.8
Total	8.4	7.9	13.5

The acquisition of anthrax vaccine adsorbed (BioThrax™) supports the goals and objectives of protection of U.S. forces against anthrax. Total force vaccination against anthrax is being accomplished through the Anthrax Vaccine Immunization Program, as described in **Table 2-16**.

Table 2-16. 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 may be found on the internet at <http://www.anthrax.mil/>.

As of January 6, 2003, 2,305,202 doses of the vaccine have been administered to 619,162 persons. Also, as of this date, 83,826 service members have completed the 6-shot series.

In December of 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. The Secretary of Defense approved the Anthrax Vaccine Immunization Program for the Total Force in May 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. The Services' AVIP plans call for eventual vaccination of the Total Force (active and reserve components) and emergency-essential DoD civilians and contractors. The AVIP plan included three phases. Forces at highest risk were immunized first.

Phase I began in March 1998, vaccinating personnel assigned or deploying to high threat areas (HTAs) of Southwest Asia. 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™).

DoD resumed with a priority execution program, continuing with special mission units, vaccinating forces assigned/deployed to HTAs of (SWA) for more than 15 days (except for naval forces afloat) and expanding the vaccinations to 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.

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 CB 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 recently has upgraded the West Desert Technical Information Center (WDTIC) and coordinated with the Chemical-Biological Information Analysis Center (CBIAC) to vastly improve literature search and analysis capabilities.

Following are summaries of current Project O49 operational tests:

- *Persistent Chemical Agents and Their Reactions with Surfaces* will be conducted during 2003 at the WDTIC at DPG for the U.S. Air Force (USAF). The objectives of this test are to 1) determine the evaporation rate of five different CW agents, neat and thickened, from several warfighting surfaces, 2) determine the transfer hazard of the same CW agents and mixtures from the same surfaces at various times, 3) determine a methodology for extraction of CW agent from concrete and identify various reactions of CW agents in absorbed on or into concrete, 4) determine levels of contamination of CW agents on various surfaces that will result in a contact hazard to personnel, and 5) fully characterize the soil samples used in the previous objectives as to type and world wide incidence.
- *Processing Cargo and Troops Through an Exchange Zone* (Phases I, II) was conducted during 2002 for the Air Mobility Command. The objective of this test was to determine if clean cargo and troops could be processed through an exchange zone without hindering transload operations. Evaluations consisted of attempting to move cargo and troops through the exchange zone without cross contamination. Phases IV, V will be conducted during 2003. This test is a follow-on to Phases I, II, but on a larger scale. Phases IV and V will validate the vapor hazard from a contaminated C-17 after chemical attack using simulants. Phases IV and V will also validate processing cargo and troops in both directions (clean to dirty and dirty back to clean). The final phase (Phase III in FY 04) will validate the C-17 smoke and fume system. The report on Phases I and II is pending.
- *Operation Southern Breeze Field Test (MTMC-Cargo)* 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 is pending. A test to answer the remaining critical operational issues will be conducted in FY03.
- *Operation Southern Breeze Field Test (MSC-Ship)* 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 is pending.
- *Casualty Decontamination* was conducted in November 2002 to field test the Wartime Medical Decontamination Teams Concepts of Operations. The report is pending.

- *Assessment of Live Biological Agents on Material Surfaces* was conducted in February 2002. The test objective is to evaluate the persistence of two high-threat biological agents on various surfaces under diurnal conditions.
- *Large Frame Aircraft Decontamination* simulant methodology was conducted during FY 02. Once a suitable simulant is identified the test will be conducted in FY 03. The objective of this test is to examine decontamination technologies as well as tactics, techniques, and procedures (TTP) to determine the most appropriate means to decontaminate large frame aircraft.

2.10 CB DEFENSE RDA PROGRAMS REQUIREMENTS ASSESSMENT

ISSUE: DoD does not have a current approved mechanism for licensure of chemical and biological defense medical products (i.e., drugs and vaccines) because legal and ethical constraints prevent adequate full testing in humans.

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 to this issue. FDA's Center for Biologics Evaluation and Research (CBER) proposed a rule on October 5, 1999 entitled, "New Drug and Biological Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted". The rule was finalized in May 2002 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.) This process, by which FDA licensure is obtained, is vital to provide military service personnel with products that have been demonstrated to be safe and effective. This rule establishes requirements for licensure and allows the DoD to plan and conduct the appropriate studies to obtain approval for the products planned for production and licensing. Requests for approval of each medical product will be reviewed on an individual basis. 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.

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. For other biological defense vaccines, DoD awarded a prime systems contract to DynPort LLC, now called 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 effort for expanded, pivotal studies. The Centers for Disease Control and Prevention (CDC) will conduct 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 will be 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 anticipated by early 2004 with the completed study in approximately 5 years from initiation.

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

SOLUTION: Beginning in FY96, DoD, in association with the Research Working Group of the Interagency Persian Gulf Veterans' Coordinating Board, dedicated \$5 million to evaluate the chronic effects of low-dose level exposure to chemical agents. Studies have been underway since 1QFY97 to develop highly specific and sensitive assays, preferably forward deployable, to detect and potentially quantify low-level exposure to chemical agents. These ongoing studies may also identify any long-lasting and toxic metabolites of chemical agents that could account for delayed and long-term health consequences. In addition, studies to look at the impact of possible genetic polymorphisms of cholinesterase enzymes upon individual response to nerve agents are underway. Additional funds have been committed and contracts are being awarded to evaluate potential chronic health complaints resulting from exposure to nerve agents. These contracts were begun 1QFY98. In May 1999, the Department of Defense submitted a report to Congress *DoD Strategy to Address Low-Level Exposures to Chemical Warfare Agents (CWAs)*. This report provided a review of the policies and doctrines of the Department of Defense on chemical warfare defense. Based on this review, DoD recommended no modifications to policies and doctrine, and stated that existing efforts were well designed to address the need, based on current scientific information.

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 FY02, continuing research efforts to understand the effects of low level chemical toxicity on the human body and to develop medical countermeasures 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. 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 the new 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: Based on the numerous program test and evaluation issues identified and generated at the Initial CB Defense Program Oversight Executive Summary program review, the need for an effective forum to address these issues was identified. The issues raised included: (1) timely staffing of test planning documentation for milestones decisions, (2) uncertain basis of test costs, (3) unclear test lead authority, (4) utilization of simulants, and (5) program accountability. These test and evaluation issues affect the ability of DoD to adequately equip the warfighting force in a timely fashion to survive and operate in a CB threat environment.

SOLUTION: The OSD CBDP Test and Evaluation (T&E) Integrated Process Team (IPT) was established in accordance with DOD 5000.2R with the purpose of developing recommendations for an adequate CBDP T&E policy and arbitrate issues to improve T&E execution for all CB Defense (CBD) programs. A Kick-off meeting chaired by DATSD(CBD) was held on July 31, 2001 and was attended by representatives of the Services, Joint Staff, Director of Operational Test and Evaluation, and various test agencies supporting the CBDP. The IPT was chartered with following objectives: a) address and resolve numerous systematic T&E issues affecting Joint CBD programs, b) resolve Joint CBD Programs issues to insure test adequacy and alleviate unnecessary programmatic delays, c) recommend changes to existing Memoranda of Agreements and regulatory guidance as appropriate, and d) arbitrate T&E issues affecting current programs. The T&E IPT concluded in January 2003, with ongoing T&E activities to be address by the CBDP T&E Executive as described in Chapter 1 of this report. Key issues addressed by the IPT are the listed below.

1. Testing infrastructure for the CBDP: A comprehensive analysis on CBDP testing infrastructure requirements across all Services, and with the Operational Test Agencies

(OTA) and the Developmental Test (DT) community input, was conducted. The analysis focused on the following issues: current test infrastructure capabilities; identification of capability gaps based on test requirements and whether these capabilities could be re-oriented where they needed to be; and identification of test capabilities that needed to be augmented such as in-house developments, commercial off-the-shelf (COTS) or military construction. Results from the analysis concluded that the current processes for investing, funding, modernizing, and sustaining the CBD Program Test Infrastructure do not provide an integrated strategy to identify and address shortfalls; do not ensure the CBDP can adequately test CBD systems in a comprehensive, dynamic, timely, and cost-effective manner; and that test technologies need to be developed and validated in a process similar to Joint CBD materiel systems. The analysis recommended (a) the establishment of a permanent joint centralized process to define and validate test technology requirements, standardize test methodologies and processes, create common instrumentation, and develop and improve test facilities, and (b) the designation of a single focal point of responsibility for test technology management to meet CBDP TEMP/RDA Plan requirements.

2. Simulant vs. Real Agent testing: DTRA(CB) conducted a study on the effectiveness of using simulants vs. live agent on open spaces. The study's main focus was to review the rationale for use of simulants, the process of simulant selection, and assessment of factors to consider for standoff detection. The study concluded that testing using simulants could provide an acceptable basis for operational testing provided the test complexity is sufficient to emulate the real world environment. Since the results of the study were not conclusive, the IPT requested the National Academy of Sciences (NAS) to conduct an independent assessment of the correlation of live agent testing vs. simulant testing for stand-off detection systems. A testing regime for future systems would then be based on the NAS recommendations. The NAS independent assessment, to be completed in 2003, will address the following:
 - what test protocols should be adopted to ensure that standoff chemical agent detectors will meet operational requirements and why. Consideration should be given to a variety of options to include chamber testing, chamber and simulant testing, and live agent open-air testing.
 - the challenges associated with executing the recommended protocols.
 - the risks associated with not doing open-air testing using live agents.
 - the level of risk in determining the operational effectiveness of standoff systems associated with alternatives to live agent testing.
3. Operational Requirements Document (ORD) Process Requirements: The Joint Requirements Office was tasked to: (a) conduct a comprehensive review of ORD development and review process, (b) enhance testing interface and integration in the CBRN JORD process, (c) ensure early involvement of the Services' Operational Test Agencies in the requirements generation process, (d) coordinate the Service's CBRN experimentation efforts, and (e) develop a methodology to respond to changes in requirements and technology. The Results of the review will be available in 2003.
4. High Wind/Rotorwash (HWRW): There are no current validated tests or models to assess effects of wind-driven agent on CB ensembles. Existing agent penetration data

indicate significant increase with wind speeds well below those measured in rotary wing aircraft downwash and other high wind environments. Existing and developmental CB individual protective ensembles require improved test technologies to address HWRW effects. High winds can be produced by platform (rotorwash, prop wash or jet exhaust), exposure on high speed vehicles (armored vehicles, tanks, trucks), or natural winds. Based on this expected exposures, the IPT tasked the JPEO-CBD to: (a) review all available technical literature on wind-driven CB effects on IPE, including test methodologies, available technologies, and agent physiochemical properties, (b) describe previous work, (c) assess technical strengths and weaknesses, and (d) suggest additional research areas. In addition, the services and the Special Operations Command (SOCOM) were asked to state whether these risks are acceptable and whether there are any doctrine solutions. The JPEO-CBD review of available literature was completed. Based on the information available, it was concluded that additional testing may be required. The Air Force, SOCOM, and the Army believe there is sufficient risk from HWRW to continue to pursue this issue. The Navy and the Marine Corps are willing to accept risk from HWRW, but would support further study to quantify the scope of the potential problem.

ISSUE: The cost for implementing new biosurety and biosecurity requirements will have an as yet undetermined impact on CBDP 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 CBDP 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.

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 Chemical and Biological 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. Consumable CBRN defense items are managed by the Services and the Defense Logistics Agency (DLA). The military departments are responsible for, and have the authority to conduct, all affairs of their respective departments including supplying, researching, developing, maintaining equipment, and training. 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 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 JPEO coordinates CBRN defense logistics issues. The JPEO 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 NBC 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 FY03 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 "4-2-1 construct" 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 a one Major Combat Operation (MCO) scenario is reasonably assured. The ability to support military operations to swiftly defeat the efforts in a second nearly simultaneous MCO scenario 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 MCOs. These requirements have not yet been identified. Contingent upon implementation of the 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.

To address the shortcomings of existing models and to include biological defense, the Joint Requirements Office (JRO) is managing a study, the *Joint Chemical Biological—Quantitative Requirements and Equipment Consumption* (JCB-QREC) study. This study began in FY02 with an identification of user needs and concerns and continues in FY03 with the development of a campaign combat data base for the initial study scenario.

Until the JCB-QREC is complete, the JRO is developing interim requirements based on the 4-2-1 construct for the Services' planning purposes. Since the Services have not had adequate opportunity to assess the impact of the 4-2-1 construct on their requirements, the JRO has recommended in the interim that the DoD CBDP continue using the measure of supporting two nearly simultaneous MCOs—equivalent to the past requirement of supporting two MTWs—until the Services have the opportunity to determine their total Service requirements under the 4-2-1 construct.

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, but is initially hampered by the uneven quality of inventory reporting.

The Services still procure 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 MCO requirements.

The process by which the Services and DLA fund and store war reserve materiel has been hampered by differing definitions, different deployment strategies, and a lack of validated requirements for jointly managed items. The JCB-QREC 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 JSMG initiated its seventh Joint Service NBC Defense Logistics Support Plan (LSP) in August 2002. 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 FY03 LSP was used to develop the findings in this chapter.

3.2 CBRN DEFENSE LOGISTICS MANAGEMENT

CBRN defense logistics management remains in transition. The JSMG (whose responsibilities transferred to the JPEO as outlined in chapter 1) had been charged with coordinating and integrating logistics readiness. They initiated a process to collect data and define requirements to ensure consistency across all planning efforts. The JRO, in coordination with the Services and the JPEO, will provide coordination and integration of joint CBRN defense logistics. The JPEO 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.

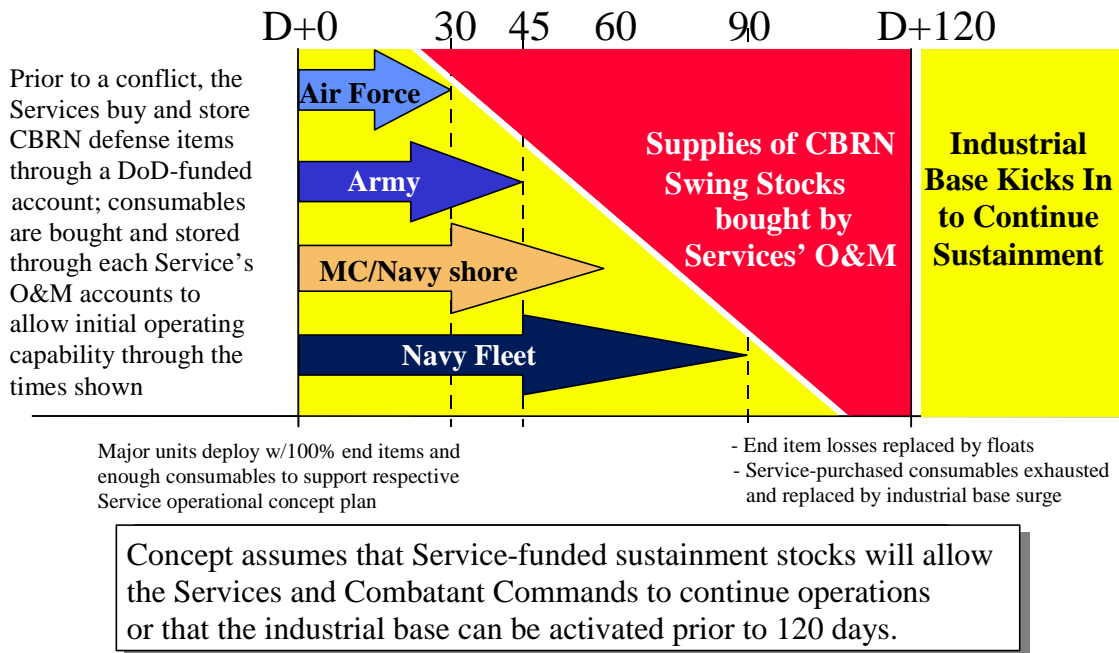


Figure 3-1. War Reserve Requirements and Planning

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, acquisition, 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 (given the post-Cold War environment), 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 will not support sustainment requirements for the entire DoD force during a full two MCO scenario. These numbers are reflected in the tables of Annex F.

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 surveillance Technical Working Group, whose initiatives have been increasing cooperative efforts in surveillance and shelf life programs. The Marine Corps has also begun an CBRN stocks consolidation program and is implementing an 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. Both systems are under consideration for adoption by other Services. The Navy recently began implementing an automated inventory management system called CBR-D Individual Protection Equipment Readiness Enhancement Program (RIP). This program is designed to provide better management and visibility of CBR-D IPE materiel for sailors assigned to afloat platforms, and eventually to ashore sites.

Both DLA and AMC will remain key players in the future CBRN defense logistics management system. The Joint NBC Defense Board, through the JSMG, 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 JCB-QREC study, 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 F-1 through F-5 in Annex F, CBRN Defense Logistics Readiness Data. Tables are included for each of the four Services and the DLA.

3.4 LOGISTICS STATUS

During collection of FY02 data, information on the inventory status of 135 fielded CBRN defense equipment items was compiled. 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 in the assessment process, since they do not reflect wartime service requirements. Quantities required for wartime needs were then compared to quantities currently on-hand. Characteristics and capabilities of selected fielded CBRN defense items are discussed in detail in Annexes A–E of this report.

Among medical consumables, sodium nitrite and sodium thiosulfate are now combined in a single Cyanide Antidote Treatment Kit. The requirements for Pyridostigmine Bromide tablets were adjusted to reflect FDA guidelines, which allows them to be administered for only 14 days, rather than 30 days. 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 two 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 aligns the requirements calculations with those of other commodities such as ammunition.

Two MCO Requirement for Consumables

Previous definition: equal to the greater of JCHEMRATES Initial Issue **or** Consumption
⇒ No inventory remains after 120 days

New definition: equal to JCHEMRATES Initial Issue **plus** Consumption

⇒ Some inventory remains after 120 days

Readiness for the next conflict is enhanced

The current report applies the interim MCO guidance for requirements, while new guidance is being developed that is consistent with the combination of MCOs and lesser contingen-

cies 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.

Of the 135 items reviewed, DoD developed risk assessments for 50 items based on data gathered as of 30 September 2002 (see **Table 3-1**). These items were singled out because of their critical role or their ability to represent the general state of their respective commodity area. While some of the items assessed changed from the previous year's report due to obsolescence, the balance of assessed items among the commodity areas remained as constant as possible to provide for continuity. These items were rated as being in a low, moderate, or high risk category. "Risk" is based on the currently available percent fill of the 2 MCO requirements; the lower this fill the greater the likelihood that such shortages may significantly reduce DoD's ability to respond to a contingency. Shortages for FY02 were calculated by comparing the 2 MCO requirements to on-hand quantities, as shown in Annex F, Tables F-1 through F-5.

RISK ASSESSMENT

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

Table 3-1 provides the results of the assessment. Programs rated as high or moderate risk are discussed in greater detail in Annex F. An eight-year comparison of data assessments is shown in **Figure 3-2**. In comparison to FY01 report data, the percentage of the FY02 items in the low risk category dropped from 62 percent to 48 percent. The percentage of items in moderate dropped from 20 percent to 18 percent, while the percentage of items in the high risk category rose from 18 percent to 34 percent. As shown in the Tables of Annex F, however, several items in the higher risk categories drop to low risk with ongoing purchases in FY03.

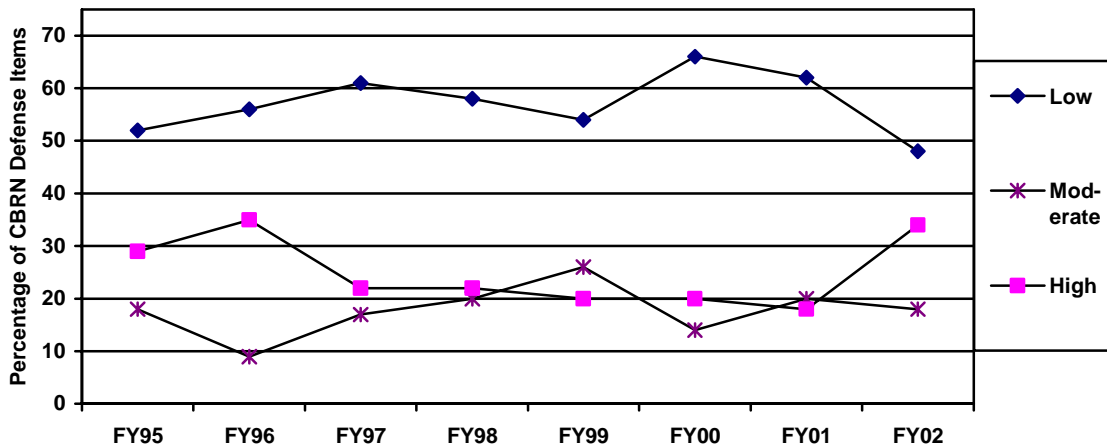


Figure 3-2. Logistic Risk Assessments: 50 CBRN Defense Items

Small changes in the MCO requirements did not significantly affect most of the items that were assessed. Several items remain in the high to moderate risk categories while they are

being fielded. These items will be monitored as continued procurement ameliorates their risk. The following items are highlighted:

- Quantities of BDOs are not adequate to fill the Air Force requirement. The Air Force developed a mitigation plan in concert with procurement of the JSLIST ensembles to minimize risk. The recent plus-up of procurement funds for protective suits has aided in plans to transition to the JSLIST program. Despite the removal of quantities of BDOs from inventory because of defects the overall level of DoD War Reserve Materiel stockage of BDOs remains high, thus the immediate risk is assessed as low. Also, DLA is providing an offset to the Services, based on the value of the defective BDOs, 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 air crew ensemble. It will replace the now obsolete Chemical Protective Undercoverall, and is assessed at moderate risk. Continued planned procurements should correct this assessment in the short term. The Joint Protective Aircrew Ensemble (JPACE), being procured in FY04, 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.
- DS2 requirements, as determined by JCHEMRATES IV, indicated a significant increase in DS2 requirements 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 JCB-QREC study.
- With the expiration of M258A1 decontamination kits in FY99, the status of M291 kits becomes more critical. Present inventory and planned procurements should keep this risk low. Production of M295 kits has improved since last year to lessen their risk.
- Medical chemical defense materiel remains generally in low risk. The shortage of 2-PAM autoinjectors can be supplemented with existing supplies of atropine and Nerve Agent Antidote Kits (NAAK), reducing its risk from moderate to low. 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.

Based on the 2 MCO requirements, the Services continue to exhibit shortages in certain critical areas. Shortages of chemical and biological agent detection systems, collective protection shelters and their respective filters, and biological warfare vaccines 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 4-2-1 construct. The extent of the operational impact of CBRN defense equipment shortages is under review in several classified studies.

Table 3-1. Logistic Risk Assessments (as of 30 September 2002): 50 CBRN Defense Items

Items	Risk Assessment	Remarks	
CONTAMINATION AVOIDANCE/DETECTION EQUIPMENT			
<i>Radiological</i>			
AN/VDR-2 Radiac Set	Low	Low inventory, still fielding	
AN/PDR-75 Radiac Set	Low		
AN/UDR-13 Pocket Radiac	High		
<i>Biological</i>			
Biological Integrated Detection System (BIDS)	Low		
<i>Chemical</i>			
M256A1 Chemical Agent Detector Kit	Low	Shelf life expiration may reduce stocks in future, but has been extended from five to six years	
M8 Detection Paper	Low	Being replaced by M22 ACADA FY03 buys reduce risk	
M8A1 Automatic Chemical Agent Alarm	Low		
M1 Chemical Agent Monitor (CAM)/Improved CAM	Moderate	Low inventory Reduced production	
Improved Point Detection System (IPDS)	Moderate		
AN/KAS-1 Chemical Warfare Directional Detector	Low		
M21 Remote Sensing Chemical Agent Alarm (RSCAAL)	High		
M22 Automatic Chemical Agent Detector/Alarm	High		
M93A1 NBC Reconnaissance System “Fox”	Low		
M272 Water Testing Kit	High		
M274 NBC Marking Set	Low		
INDIVIDUAL PROTECTION			
<i>Masks</i>			
MCU-2/P-series Mask	High	USAF/USN mask, qualifying/procuring second skin (<i>non aircrew</i>)	
M40-series General Purpose Mask	Low	USA/USMC mask (<i>non aircrew</i>)	
M42-series Tank Mask	Low		
M48 Apache Mask	High	FY03 buys reduce risk	
MBU-19/P Aircrew Eye/Resp. Protection (AERP)	High	Replaces MBU-13/P; still fielding	
<i>Suits</i>			
JSLIST protective suits	Moderate	In process of fielding to all Services	
Battle Dress Overgarment (BDO)	Low	No further production – being replaced by JSLIST	
Saratoga Suit	Low	No further production – being replaced by JSLIST	
CWU 66/77P	High	Low inventory	
Mark III Suit, Chemical Protection Overgarment	Low	No further production – being replaced by JSLIST	
Aircrewman Cape	Moderate		
<i>Gloves/Overboots</i>			
Chemical Protective Gloves (7/14/25-mil)	High	Risk is moderate when DLA buys are included	
Green/Black Vinyl Overshoes (GVO/BVO)	Low	Still in production – being replaced by MULO	
Chemical Protective Footwear Covers (CPFC)	Moderate	Replaced by GVO/BVO	
Disposable Chemical Protective Footwear Covers	High		
COLLECTIVE PROTECTION			
Chemical and Biological Protective Shelter (CBPS)	High	Limited fielding in FY03	
M20A1 Simplified Collective Protective Equipment	High	Low inventory, not in production	
M28 CPE HUB	High	Low inventory, still in production	
M48A1 General Purpose Filter	High	Low inventory	
Filter For (M59, M56, Shipboard) (200 CFM)	Low		

Table 3-1. Logistic Risk Assessments (as of 30 September 2002): 50 CBRN Defense Items
(continued)

Items	Risk Assessment	Remarks
DECONTAMINATION EQUIPMENT		
M291 Skin Decontaminating Kit	Low	Quantities cover loss of M258A1
M295 Individual Equipment Decontamination Kit	Low	
DS2, M13 Can	High	Low inventory
M11 Decontaminating Apparatus	Low	
M13 Decontaminating Apparatus, Portable	Low	
M17-series Lightweight Decontamination System (LDS) (to include the A/E32U-8 Decontamination System)	High	Inventory partially supportable
M12A1 Power Driven Decontamination Apparatus (PDDA)	Low	Repair parts only from unserviceable PDDAs
MEDICAL DEFENSE		
Mark 1 Nerve Agent Antidote Kit (NAAK)	High	Risk lowered based on autoinjector stocks
Atropine Autoinjector	Moderate	
2-PAM Chloride Autoinjector	Low	
Nerve Agent Preventative Pyridostigmine (NAPP) Tablet	Low	
Convulsant Antidote Nerve Agent (CANA) Autoinjector	Moderate	
Biological Defense Vaccines	Moderate	Prime contract awarded for development, production, FDA licensure, and storage
Biological Warfare Agent Diagnostics	Moderate	First DoD biological diagnostic effort
BATTLE MANAGEMENT		
JWARN Block 1	Low	

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 wholesale 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 do not track training equipment in their estimates of on-hand requirements.

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 fences 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 stock-piles, 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 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, the new 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, the new Department of Homeland Security, state and local governments and direct sales to concerned citizens have attracted many firms. With the lure of increase 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 these two 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.

Selected CBRN defense items (JSLIST, 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, a “War Stopper” program to sustain key industrial base capabilities, using industrial preparedness funding under PE07080110.

Included in the mission of the Joint Service Integrated Product Team (IPT) for the Logistics Support Plan is an assessment of the Industrial Base. 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 2 MCO 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 IPT is addressing issues from across the Services for more than 141 items/systems and spare parts critical to readiness. The IPT 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. To date, 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 IPT will continue to monitor the industrial base 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 NBC Defense Equipment Assessment Program (JSNBCDEAP) managed 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 is provided in Table 3-2. The risk is presented for each component of a protective ensemble. The quantity of each component is an aggregate of all available fielded items that fulfill that protective function. The requirement is the sum of the former 2 MCO requirements for those items as determined by the JCHEMRATES IV study or those provided by the Services. The overall risk is then determined by the component in shortest supply.

While the risk assessment for JSLIST suits by themselves is currently “moderate,” it is acknowledged that the risk is higher when the entire protective ensemble (suits, gloves, boots, *etc.*) is assessed on the sum of its individual components within each Service. However, as shown in **Table 3-2**, accelerated procurement of all JSLIST components in FY03 will rapidly mitigate this risk, and in the course of any military operations, the Services will take appropriate risk-reduction measures.

3.9 CBRN DEFENSE LOGISTICS SUPPORT ASSESSMENT

ISSUE: The Department of Defense CB Defense Program has a full capability to support and sustain the first of two MCOs. Readiness shortfalls that would preclude full support of a second MCO have been identified. The Services’ modernization efforts and common war reserve requirements will lessen 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 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 *Joint Chemical Biological – Quantitative Requirements and Equipment Consumption* is being conducted in FY02 and FY03 under the auspices of the Joint Requirements Office. The use of this common methodology will allow the presentation of joint service requirements in future reports and facilitate improved joint logistics management.

Table 3-2. Protective Ensemble Risk Assessment

COMBINED SERVICES					
Component	2 MCO Requirement	FY02 On-Hand	FY02 Risk Assessment	FY03 (projected)	FY03 Risk Assessment
Suits ¹	6,420,217	4,955,330	77% Moderate	5,282,592	82% Moderate
Masks	1,819,680	1,413,317	78% Moderate	1,524,431	84% Moderate
Filters	4,388,662	3,359,353	77% Moderate	4,142,578	94% Low
Gloves	9,431,618	5,990,939	64% High	6,037,854	64% ³
Boots	6,078,727	4,530,278	75% Moderate	5,073,132	84% ⁴
Hoods	3,184,423	3,107,716	102% Low	3,169,929	100% Low
			Overall risk is High	Overall risk is Moderate	
ARMY					
Component	2 MCO Requirement	FY02 On-Hand	FY02 Risk Assessment	FY03 (projected)	FY03 Risk Assessment
Suits	2,900,000	2,836,875	98% Low	2,993,394	103% Low
Masks	704,377	757,133	107% Low	798,734	113% Low
Filters	1,367,626	1,325,792	97% Low	2,109,017	154% Low
Gloves	4,634,380	3,583,130	77% Moderate	3,630,045	78% Moderate
Boots	2,899,864	2,235,875	77% Moderate	2,523,729	87% Low
Hoods	1,703,570	1,326,801	78% ²	1,638,841	96% Low
			Overall risk is Moderate	Overall risk is Moderate	
AIR FORCE					
Component	2 MCO Requirement	FY02 On-Hand	FY02 Risk Assessment	FY03 (projected)	FY03 Risk Assessment
Suits	1,224,369	894,218	73% Moderate	971,049	79% Moderate
Masks	395,677	289,801	73% Moderate	296,799	75% Moderate
Filters	1,070,356	1,309,090	122% Low	1,309,090	122% Low
Gloves	2,338,682	1,663,957	71% Moderate	1,663,957	71% Moderate
Boots	714,651	1,333,906	187% Low	1,333,906	187% Low
Hoods	1,057,760	1,832,507	173% Low	1,832,507	162% Low
			Overall risk is Moderate	Overall risk is Moderate	
NAVY					
Component	2 MCO Requirement	FY02 On-Hand	FY02 Risk Assessment	FY03 (projected)	FY03 Risk Assessment
Suits	1,608,242	485,257	30% High	547,865	34% High
Masks	569,626	175,663	31% High	231,994	41% High
Filters	1,590,750	429,503	27% High	429,503	27% High
Gloves	1,666,402	327,167	20% High	327,167	20% High
Boots	1,813,066	280,200	15% High	280,200	15% High
Hoods	2,517	494	20% ²	494	20% ²
			Overall risk is High	Overall risk is High	
MARINE CORPS					
Component	2 MCO Requirement	FY02 On-Hand	FY02 Risk Assessment	FY03 (projected)	FY03 Risk Assessment
Suits	687,606	738,980	107% Low	770,284	112% Low
Masks	150,000	190,720	127% Low	196,904	131% Low
Filters	359,930	294,968	82% Moderate	294,968	82% Moderate
Gloves	792,154	416,685	53% High	416,685	53% High
Boots	651,146	673,598	103% Low	706,598	109% Low
Hoods	343,869	8,560	2% ²	8,560	2% ²
			Overall risk is High	Overall risk is High	

¹ Note: These quantities are reported as of 30 September 2002. Since then, DLA buys of JSLIST Suits have been accelerated such that the total FY03 due-in is 1.2 million suits, and FY04 is 295,000 although additional funding is expected to increase that amount.

² risk is low when suits with integrated hoods are counted

³ risk is moderate when DLA buys are included

⁴ risk is low when DLA stocks are included

ISSUE: DoD continues to lack 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 war time 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 other Services.

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 2.25 per person; masks are issued at

a rate of 1.05 masks per person. The quantities generated by the .25 and .05 values, respectively, cover training needs and size anomalies that may exist at the unit level. Each ship currently maintains this material centrally under control of the Damage Control Officer, but a new procedure (now under development as a pilot program) will issue one clothing set and mask in a carrying bag to each crewmember upon or shortly after deployment while the unit is underway to the operational theater. The material will be returned to ship's custody prior to transfer of the individual.

- b. Inventory Management. Inventory managers issue bulletins regarding eminent 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 has recently instituted a reporting system that involves the automated update of shelf life data via the Internet for use in preparation for deployment. 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 surveil 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) for each deployable Air Force member. Installations procure and maintain NBC IPE for each Air Force military member and emergency-essential civilian in, or deployable to, CB threat areas. Emergency-essential and foreign national citizens 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 Medium Threat Area or High Threat Area. Base supply sustains the wartime contingency mission by maintaining a 10% backup stock for C bags. A smaller stock may be maintained for training operations.

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.

- b. Inventory Management. Some individual units maintain IPE (normally Security Forces) 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.
- c. 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.
- b. Inventory Management. The NBCD 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. Sample of each manufactured lot are received and those assets are stored for future follow on surveillance testing. The DoD NBC Individual Protective Equipment Shelf Life Management System was designed to support Shelf Life Management, surveillance and notification for nuclear, biological and chemical defense (NBCD) protective clothing. Previously, the Shelf Life Management, surveillance and notification processes had been fragmented. The web page above is intended to centralize procedures, ensuring the most comprehensive dissemination of Shelf Life and serviceability data. The Marine Corps managed Joint Service NBC Equipment Assessment Program (JSNBCEAP) and agreed to assume responsibility for Shelf Life Management, surveillance, and notification for all items identified as clothing used for protection for nuclear, biological and chemical warfare agents. 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.
- 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 Joint Service Nuclear, Biological and Chemical Defense Equipment Assessment Program (JSNBCDEAP) is managed by the Marine Corps Logistics Base (MCLB), Albany, Georgia. 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, 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, 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.

The JSNBCDEAP has agreed to assume 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. 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 FY02 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 Marine Corps 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.

Chapter 4

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

4.1 INTRODUCTION

The DoD Chemical and Biological Defense Program (CBDP) builds on the successes of each Service to develop a viable joint orientation to CBRN defense capabilities, which include joint requirements documents; joint doctrine and Tactics, Techniques, and Procedures (TTPs); joint modeling, simulation, and wargaming; and joint professional training.

4.2 CBRN DEFENSE DOCTRINE

Joint Doctrine. Joint Publication 3-11, *Joint Operations in a Nuclear, Biological, and Chemical Environment*, 11 July 2000, provides guidelines for the planning and execution of CBRN defensive operations. Its focus is on the CBRN threat, national policy, and considerations peculiar to the preparation and conduct of CBRN defense. These considerations include principles of theater CBRN defense, logistics support, medical support, training, and readiness.

Multi-Service Doctrine. The Joint Requirements Office (JRO) – for Chemical, Biological, Radiological, and Nuclear (CBRN) Defense is continuing the initiative of working with the U.S. Army Chemical School (USACMLS) to lead the effort in the development of multi-Service CBRN defense doctrine and TTP. The JRO is sponsoring the revision/development of a core list of Service selected multi-Service CBRN Defense publications. This core list provides a framework for CBRN defense multi-Service TTPs (MTTP) that will integrate Service’s TTPs where possible and provide Service-unique TTPs when different. With the U.S. Army Chemical School selected as the lead Service for MTTP development, two CBRN defense publications are planned for revision each year over a five-year cycle. During 2002 the MTTP manual for Biological Defense was approved by the Services and added to the core list. **Table 4-1** lists the revised JRO core multi-Service CBRN defense publications.

Table 4-1. Core Multi-Service CBRN Defense Publications

<ul style="list-style-type: none">• MTTP for NBC Defense of Theater Fixed Sites, Ports and Airfields• NBC Contamination Avoidance• NBC Aspects of Consequence Management• NBC Defense Operations• NBC Decontamination (Restoration) MTTP• NBC Protection MTTP	<ul style="list-style-type: none">• Field Behavior of NBC Agents• Potential Military Chemical/Biological Agents and Compounds• NBC Vulnerability Analysis• MTTP for NBC Reconnaissance and Surveillance• MTTP for Biological Defense
--	--

The 2002 effort consisted of JRO-sponsored initiatives to continue the development of CBRN multi-Service doctrine and TTP. The multi-Service manuals revised during FY02 include: 1. *NBC Vulnerability Analysis*, 2. *Potential Military Chemical/Biological Agents and Compounds*, 3. *MTTP for Biological Defense*. Multi-Service manuals planned for revision in

FY03 are *MTTP for NBC Defense of Theater Fixed Sites, Ports and Airfields* and *NBC Decontamination*.

Multi-National Doctrine. The U.S. Army Nuclear and Chemical Agency (USANCA) has been delegated the lead DoD representative for international standardization of CBRN operational matters. USANCA participates in the following North Atlantic Treaty Organization (NATO) groups:

- NBC Defense Interservice Working Party (NBCWP) under the Military Agency for Standardization
- Land Group 7 (LG. 7)—NBC Equipment, under the NATO Army Armaments Group (NAAG)
- Working Group 2 (LG. 7)—Low Level Radiation in Military Environments
- Challenge Subgroup (LG. 7)—Chemical/Biological Toxicity Challenge Levels
- Technical Subgroup (LG. 7)—Nuclear Weapons Defense
- ATP 45 (NBCWP) NBC Warning/Reporting
- AJP 3.8 Doctrine for the NBC Defense of NATO Forces

USANCA also has been delegated as the representative in the American, British, Canada, Australia (ABCA) Quadripartite Alliance in the Quadripartite Working Group (QWG) for NBC Defense. In that group, USANCA also participates in the Radiation Detection, Indication And Computation (RADIAC) Information Exchange Group (IEG). The USACMLS participates with USANCA to incorporate NBC group agreements in revising existing manuals.

The USACMLS has been delegated as the representative at the NATO Training Group (Joint Services Subgroup) in addition to providing representation and subject matter expertise to support USANCA at NATO/QWG meetings as required. This includes consultation to coordinate the official U.S. position on CBRN defense issues prior to international meetings.

4.2.1 Joint CBRN Defense Doctrine Program Management

The CBDP management strategy described in Chapter 1 provides the mechanism to assist the Joint Staff in the further development of the Joint CBRN defense doctrine program. The JRO coordinates with the Services and combatant commands to ensure the program is realistic and meets the needs of the joint community.

4.2.2 Joint CBRN Defense Doctrine Development Program

The JRO is continuing the initiative to ensure that CBRN defense is addressed appropriately in joint doctrinal materials. Through this program, selected joint publications, either in development or in revision, are reviewed and CBRN defense-related recommendations are provided to the developers. During 2002, the JRO also initiated an effort to analyze Joint, Multi-service, and Service doctrine and TTP against existing and emerging DoD policy that identifies potential deficiencies of current BW defense doctrinal/TTP materials. The scope of materials reviewed will include passive CBRN defense, BW medical defense, homeland defense, consequence management, force protection references, and medical/non-medical information sources. The final results of this analysis are due in 2003 and will provide Joint and Service

doctrine developers with recommendations to address BW defense doctrinal deficiencies in support of existing and emerging DoD policies and warfighter missions.

The U.S. Army Medical Department Center and School (USAMEDDC&S) is the lead agency for Joint Publication 4-02, *Doctrine for Health Service in Joint Operations*, July 2001.

The Air Force was tasked by the Joint Staff to draft Joint Pub 3-40, *Joint Doctrine for Counterproliferation Operations*. This document will set forth the principles to plan for and conduct military activities of counterproliferation operations. One of the key activities of counterproliferation is passive defense. Joint Pub 3-40 will complement joint doctrine promulgated in Joint Pub 3-11, *Joint Operations in a Nuclear, Biological, and Chemical Environment*, 11 July 2000.

4.2.3 Army Medical Doctrine Development Program

Multi-Service Doctrine. The FY02 effort consisted of initiatives to develop new Army Medical Department (AMEDD) CBRN defense doctrine products, provide AMEDD input to other Service CBRN doctrine publications, and provide input to multi-national medical CBRN procedures. FM 4-02.7 (FM 8-10-7), *Health Service Support in a Nuclear, Biological, and Chemical Environment* is being revised and developed as a multi-Service publication. Doctrine for medical aspect of toxic industrial chemicals will be developed and incorporated into current and new manuals as the technology allows. Available material on medical aspects of toxic industrial material will be included in the revision of FM 4-02.7. FM 4-02.285 (FM 8-285)/NAVMED P-5041/AFJMAN 44-149/FMFM 11-11, *Treatment of Chemical Warfare Agent Casualties and Conventional Military Chemical Injuries* is currently under revision. The revision will include new antidote devices, skin protectant, IND protocol requirements, and recognition, medical management, and treatment of selected toxic industrial chemical casualties. A change was made to FM 8-284/NTRP 4-02.23/AFMAN 44-156/MCRP 4-11.1C, *Treatment of Biological Warfare Agent Casualties*, to comply with FDA requirements on use of chemoprophylaxis and IND requirements.

Multi-National Doctrine. HQDA, Office of The Surgeon General, Directorate of Health Care Operations (DASG-HCO) is the Executive Agent for DoD on medical international issues, to include CBRN medical operational issues. DASG-HCO is the US Head of Delegation for the NATO General Medical Working Group and the NATO NBC Medical Working Group (NBC MED WG). OTSG is responsible for coordinating and developing US positions within their respective medical functional area in accordance with the policies and direction established by ASD(HA). OTSG is also responsible for ensuring sufficient and appropriate Joint Staff, OSD, Service, doctrine experts, and key relevant agency representation at all key international meetings. Currently, the US supports the NBC MED WG in developing and validating new concepts and doctrine, which is required for an effective CBRN medical defense response. With the threat of asymmetric warfare and the current trend towards coalition operations and shared risk acceptance cultures, new levels of thinking and close Allied collaboration are required and US DoD and NATO goals and missions must become even more closely aligned.

The NBC MED WG served as the Co-Sponsor with the UK and GE Heads of Delegation in support of the WMD Centre in planning the NATO Medical and Operational Issues in a Biological Warfare Environment Workshop, 11-15 March 02. The purpose of the Workshop was to identify

biological warfare force protection issues from multiple perspectives (operational, medical, armaments and intelligence) focusing on NATO operations in a biological warfare environment with the outcome of identifying and reviewing existing medical and operational capability shortfalls. The outcome from this workshop heavily influenced the Five NBC Defence Initiatives of the NATO Prague Summit, held in November 02. Specifically, the NBC MED WG and the US, per the current international/national focus, 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 2461-2463 AMedP-6 series, Ed.2 - Handbooks on the Medical Aspects of NBC Defensive Operations

The United States has also been instrumental or the custodian for several new STANAG to address doctrinal medical CBRN capability gaps:

- STANAGs 2475-2477, AMedP-8s - Planning Guides for the Estimation of NBC Casualties (US custodian)
- STUDY 2276 - The Development of a NATO Laboratory Response Network (co-sponsor with Italy)
- STUDY 2277 - Health Surveillance System for Data Collection, Analysis, Identification and Dissemination of Info Related to a Bio Outbreak (US custodian)
- STANAG 2491 -Biological Warfare Immunization Programme
- STANAG 2242 - Chemoprophylaxis and Immunotherapy in BW Defense (US custodian)
- STANAG 2474 - Recording Detection of Low Level Radiation for Medical Staffs

The AMEDD participated in numerous NATO medical NBC procedural product reviews, resulting in several NATO Standardization Agreements (STANAGs) being updated. Further, the AMEDD participated in a QWG to develop and update additional Quadripartite Standardization Agreements (QSTAGs), which are medical NBC procedural products. STANAGs and QSTAGs are reviewed for integration of these agreements into Army-specific doctrine literature products as well as multi-Service medical doctrine products for which the AMEDD is the proponent.

The USAMEDDC&S has been designated as the lead agency to revise the “NATO Emergency War Surgery Handbook.” The initial draft for the revision is currently being developed. This draft is projected for completion during FY03.

4.2.4 Air Force Doctrine Program

HQ USAF/XONP has built upon AFDD 2-1.8, *Counter-Nuclear, Biological and Chemical Operations*. It has promulgated an Air Force policy directive, AFPD 10-26, *Counter-NBC Operational Preparedness*. The policy directive establishes the Air Force’s program to plan, organize, train, and equip personnel to survive and fight under threat or attack of CBRN weapons.

Pursuant to the policy directive, the Air Force is undertaking a number of activities. It is developing measurable operational and enabling standards in order to determine the equipment,

training, manpower, and resources needed to conduct and sustain counter-NBC operations. Its concept of operation (CONOP) and other procedural guidance are incorporating counter-NBC considerations, where appropriate. Military, DoD civilian, DoD dependents and contractor personnel are receiving counter-NBC training. The Air Force is also planning, programming and budgeting for counter-NBC preparedness in the areas of training, exercises, evaluations, manpower, and equipment, including medical requirements (in accordance with Title XVII of Public Law 103-160, dated 1994); and, it is improving counter-NBC preparedness in expeditionary operations to take the fight to the enemy.

In order to implement the policy directive, the Air Force published and is coordinating other pertinent instructions. AFI 10-2501, *Full Spectrum Threat Response Planning Operations*, provides policy and guidance to commanders so they may confront the full spectrum of threats and provide for the protection of installation resources. AFI 10-2601, *Counter-Nuclear, Biological and Chemical (NBC) Operations*, Passive Defense will define the passive defense component of counter-NBC operations and will direct the integration of passive defense planning and operations. AFI 10-2601 is in coordination draft.

Among the activities the Air Force undertook in 2002 was the deployment of Operational Effectiveness teams to its bases in southwest Asia and in South Korea. These teams worked with base personnel to update base support plans for counter-chemical warfare. They took the generic Air Force concept of operation for counter-chemical warfare and tailored it to accommodate each bases' resources, infrastructure, missions and conditions. This activity complemented the Air Force's chemical and biological defense training.

To further enhance the credibility of Air Force doctrine toward countering chemical warfare, the Air Force is finalizing a scientific report, entitled *Air Force Hazard Persistence Technical Report*. The report endeavors to characterize the impact of various chemical warfare agents (e.g., VX), delivered by associated means (e.g., theater ballistic missiles), upon a variety of operating surfaces (e.g., asphalt, concrete, painted metal) found at airbases to determine the operational impact of a chemical warfare (CW) attack. It also provides scientifically-derived timelines when commanders can expect to restore operations following a CW attack.

In April 2002, the Air Force published a set of guidelines for its commanders, entitled *Force Protection and Operations in a Biological Warfare Environment*. The guidelines consolidated a baseline of current understanding on BW so that commanders could make informed and reasoned decisions in response to a BW event. The guidelines were the prelude to the next counter-BW initiative pursued by the Air Force, an air base biological defense plan.

The Air Force Chief of Staff approved the establishment of an AF/XO-led Biological Defense Task Force. Its charter is to create a prototype base biological defense plan. The plan will provide commanders with tools to survive and operate in a biological warfare environment. From it, the Air Force will then develop a counter-biological warfare concept of operation and associated doctrine, similar to their work with the Air Force Counter-CW CONOPS.

The Air Force Surgeon General (HQ USAF/SGXR) has been participating with the Army in development of joint and multi-Service medical doctrine and guidance (see paragraph 4.2.3 above). Medical NBC doctrine is included in AFDD 2-1.8, *Counter-Nuclear, Biological and Chemical Operations*, AFDD 2-4.2, *Health Services*, AFTTP 3-42-1, *Medical Command and Control*, AFTTP 3-42.3, *Health Service Support in NBC Environments*, AFTTP 3-42.5,

Aeromedical Evacuation, AFTTP 3-42.6, USAF Medical Support for SOF, AFTTP 3-42.7, Aerospace Medical Contingency Ground Support System, AFTTP 3-42.8, Medical Logistics and Blood Support Operations and AFMS CONOPS, Home Station Medical WMD Response. AFMS published a new AFTTP 3-47.3, Health Service Support in NBC Environments.

4.2.5 Navy Doctrine

The Navy actively participates in all phases of joint, multi-Service and Service-unique Chemical Biological Defense. The Navy Warfare Development Command (NWDC) serves as the lead Navy organization participating in efforts to revise and update all Navy, multi-Service and joint Chemical-Biological Defense publications. Publications completed during FY02 include NWP 3-11 *Multiservice NBC Operations*, NTTP 3-11.24 *Multiservice Tactics Techniques and Procedures for NBC Aspects of Consequence Management*, TACMEMO 3-11.1-02 *Guide to Biological Warfare Defense and Bioterrorism – Afloat and Ashore*, NTRP 4-02.21 *Treatment of Nuclear and Radiological Casualties*, and NTRP 4-02.23 *Treatment of Biological Agent Casualties*. Publications under current revision include NTTP 3-11.25 *NBC Contamination Avoidance and Warning Reporting System*, NTTP 3-11.27 *NBC Protection*, NTTP 3-11.29 *MTTP for NBC Reconnaissance*, NTTP 4-02.7 *Health Service Support in a CBR Environment*, and NTRP 4-02.22 *Treatment of Chemical Casualties and Conventional Military Chemical Injuries*. A new TACMEMO on “Retrograde of Marines in a CBR Environment” is currently under development in conjunction with Commander, Amphibious Group Two and the Marine Corps Combat Development Command (MCCDC). Updates are planned for the Navy publications NWP 3-20.31 *Surface Ship Survivability* and NSTM 470 *Shipboard BW/CW Defense and Countermeasures* to improve interoperability with the USMC during amphibious operations and to revise biological defense procedures.

The Navy Warfare Development Command participates in the following North Atlantic Treaty Organization (NATO) Groups:

- NBC Defense Operations Interservice Working Group (NBC WG) under the NATO Standardization Agency,
- ATP 45 Panel (NBC WG) NBC Warning/Reporting,
- AJP 3.8 (NBC WG) Doctrine for the NBC Defense of NATO Forces.

Naval Sea Systems Command (NAVSEA 05R1) represents the Navy on NATO Land Group 7 (LG. 7)—NBC Equipment, under the NATO Army Armaments Group (NAAG). The Surgeon General of the Navy (OPNAV 093) represents the Navy at the NATO Medical NBC-D Working Group and related medical working groups on behave of NWDC.

4.2.6 Marine Corps Doctrine

The Marine Corps fully participates in all multi-Service doctrine working groups to produce and update jointly funded multi-Service CBRN defense doctrinal publications. The NBC Operational Advisory Group met during FY02 to assess the Marine Corps’ capstone doctrinal manual for NBC Defense, Marine Corps Warfighting Publication (MCWP) 3-37, Marine Air Ground Task Force (MAGTF) NBC Defense Operations. The MCWP will be revised and updated during FY03. This revision and update will better address NBC defense tactics, techniques and procedures for the MAGTF in any expeditionary maneuver warfare (EMW) role.

During November 2001, Navy and Marine Corps representatives met in Quantico to discuss current doctrinal deficiencies in the area of chemical biological defense during amphibious operations. Two Naval publications were considered for possible modification to correct these deficiencies NWP 3-20.1, "Surface Ship Survivability," and NSTM 470, "Shipboard BW/CW Defense and Countermeasures." With the emerging/evolving Marine Corps concepts of Expeditionary Maneuver Warfare (EMW), 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 the Marine Corps Combat Development Command (MCCDC) continue to collaborate on a dual designated publication for release in FY03, that will address the deficiencies.

The NBC Doctrine section of MCCDC is currently preparing a Memorandum of Understanding (MOU) with the Air Force to establish a formal working group of USMC and USAF subject matter experts, who will examine current Air Force Counter Chemical Warfare Concept of Operations (C-CW CONOPS) and their applicability to USMC and Dual USMC/ USAF Airfield Operations. The objective of this working group is to promulgate a dual designated publication on USMC and USAF airfield operations, to include expeditionary airfields. The Marine Corps will attempt to leverage the Air Force's experience and resident knowledge of fixed site (airfield) C-CW CONOPS, ongoing RESTOPS studies and analysis, and current and ongoing 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 Chemical Warfare environment. The proposed publication is to be completed during FY04.

4.3 STANDARDS OF PROFICIENCY AND CURRENCY

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

Unit Training. Each year the Army tests all enlisted soldiers on tasks common to all soldiers. The following CBRN Defense Tasks were tested in FY02.

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
031-503-1017	Respond to Depleted Uranium
031-503-1019	React to Chemical or Biological Hazard or Attack
031-503-1035	Protect Yourself From Chemical and Biological Injury/ Contamination Using Your Assigned Protective Mask
031-503-3005	Submit NBC 1 Report
031-503-2001	Identify Chemical Agents Using M256-Series Chemical Agent Detector Kits

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), U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), 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, and through Distance Learning programs.

Each training modality offers unique advantages. In residence training enables students to use laboratory and field training facilities while maximizing student-instructor interactions. On site training, *i.e.*, courses taken “on the road” and presented at military installations world-wide, 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 4-2**.

Table 4-2. Summary of Army Medical CBRN Training in FY02 (as of 31 Oct 02)

Type of Training	Total Number Trained	Army Trained
AMEDDC&S		
Leader Development (NBC)	3,037	3,037
CBRNE	7,832	7,832
AFRRI		
Medical Effects of Ionizing Radiation (MEIR)	1078	457
USAMRIID/USAMRICD		
MCBC in residence	817	293
FCBC in residence	471	225
On-site to active military	424	283
MCBC Video	91	64
Satellite	10,851	1,059
Regional Medical Command		
CBRNE First Response	1,374	1,374

Approximately fifty percent of Army Medical Department (AMEDD) officers (clinicians and non-clinicians) and twenty percent of the AMEDD enlisted received CBRN training. See **Table 4-3**.

Table 4-3. Total AMEDD Personnel Trained (as of Oct 02)

	Medical Personnel Trained		Percent Trained	
	Clinicians	Non-clinicians	Clinicians	Non-clinicians
Officers	5,222	1,803	50	54
Enlisted	3,261	3,134	19	24
Total	8,483	4,937	30	30

The AMEDD has aggressively incorporated CBRNE 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 chemical and biological 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 CBRN medical readiness and improve training for health care personnel (AMEDD CBRNE Training Strategy) by incorporating CBRN 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. Army Medical Department personnel and selected personnel from all armed services, including the active, reserve and National Guard components. The strategy requires the basic CBRN 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.

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 CBRN training for each specialty.

Leadership Courses. AMEDD leadership courses incorporate targeted instruction in CBRN and Homeland Security. The instruction addresses Antiterrorism/Force Protection, Military Support to Civilian Authorities, Consequence Management, Hospital Emergency Incident Command System (HIECS), DoD Smallpox Response Plan and the leader skills required by the audience. Course materials were specifically developed by the Leader Training Center of the AMEDD Center and School and integrated into the 70 H Course, the BDE/DIV Surgeons Course, The Executive Skills Course and Precommand 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 39 hours of CBRN classroom instruction and 12 hours of NBC field training during the Officer Basic Course (OBC). OBC teaches new AMEDD officer 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 FY02, 2180 students completed OBC.
- The Army Medical Department (AMEDD) 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 CBRN training. In FY02, 460 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 a CBRN environment, decontaminating, managing and treating contaminated casualties, and training non-medical

soldiers in casualty decontamination procedures. In FY02, 1080 NCOs completed the BNCOOC.

- The Principles of Preventive Medicine Course prepares future preventive medicine officers to support medical force health protection programs in CBRN environments. In FY02, 96 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 Army Nuclear Medical Science Officers (NMSOs) during the OBC, OAC and Principles of 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 (RDDs) attacks or releases of radioactive materials from nuclear facilities.

Exercises. The AMEDDC&S hosted a five-day Homeland Security Symposium and Exercise entitled "Pale Horse". The main objectives of this event were to gather information, prioritize requirements, identify shortfalls, communicate, collaborate and synchronize efforts during a catastrophic public health emergency. Its goals were to validate bioterrorism response planning, prepare leaders to respond to a bioterrorism event, prepare military members to assume their role in support to civil authorities. Specific areas of concern were mass care, mental health, logistics, legal, information operations, training, mass fatality, and medical concerns. Over 476 participated in this event, both military and civilians, representing more than 120 agencies. Utilizing a "bottom up" approach, the participants exercised emergency response procedures, strengthened interagency relationships, and identified shortfalls in capabilities as well as strengths and weaknesses.

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. To date over 1400 AMEDD soldiers and DA civilians have taken the review. PPSCP proponents also incorporate course-specific CBRNE instruction into their curricula.

Support To US Army Medical Command (MEDCOM) Homeland Security Initiatives. Training support packages (TSPs) were shipped to all Army MTFs in early January 2002. Technical Support Plans for Special Medical Augmentation Response Teams followed in March 2002. The AMEDDC&S conducted a trainer/evaluator course in San Antonio 20 – 22 February 2002 that included course work on administration and evaluation of in-hospital CBRNE/MASCAL exercises. Two hundred nine military and civilian personnel were trained.

In support of the strategy, AMEDDC&S has conducted or initiated the following actions:

Patient Decontamination Working Group Initiative. The intent is to convene a series of working groups to discuss patient decontamination with the purpose of solidifying current doctrine, developing future doctrine and identifying possible solutions to the CBRNE homeland defense MASCAL decontamination challenges. Deliverable #1 reviews current doctrine, updates it where necessary, and ensures its inclusion in all relevant field manuals; Deliverable #2 analyzes current trends, identifies future needs and capabilities in order to design new methods of patient decontamination; Deliverable #3 develops patient decontamination doctrine for homeland security in response to a CBRNE terrorist incident. Collaboration among the AMEDDC&S, the USACMLS, and other agencies will ensure success in this endeavor. Related homeland security products included the following:

- Delivered a 2-day CBRNE First Responders course to NYC fire fighters, police, Department of Corrections, nurses, physicians, and other clinical care personnel. At the conclusion of this activity, participants should be capable of understanding the medical aspects of CBRNE terrorism and managing CBRNE casualties.
- Developed an individual's pocket guide to Medical Biological and Chemical Defense Materiel. This guide is designed to aid the soldier in the medical decision making process required by a chemical and biological attack.

NBC Sciences Branch Oversight Training Initiative. The NBCSB plans to support CBRNE homeland defense initiatives by traveling to 20 MTFs for FY03 to ensure these facilities are complying with their CBRNE emergency response plans. Active duty soldiers and Department of Army civilians will be involved with this travel, which will occur throughout FY03 at various sites. This improves the AMEDDC ability to quickly respond to a CBRNE event and increase chances of patient survival.

Specialized Army and DoD research laboratories primarily accomplish patient care training of physicians, physician's assistants, and nurses. The laboratories' courses, taught by physicians and scientists from all three armed services, are presented to medical professionals of all armed services. The courses are also generally available to non-DoD agencies and have made significant contribution to Homeland Security initiatives.

USAMRICD and USAMRIID trained 817 medical professionals with the in residence version of the "Medical Management of Chemical and Biological Casualties Course" (MCBC). Sponsored by the AMEDDC&S and the other proponent services, the students attending the in residence MCBC divide their time between USAMRIID, Ft. Detrick, Maryland, and USAMRICD, Aberdeen Proving Grounds, Maryland. The MCBC provides DoD personnel, primarily physicians, nurses, and physician assistants, with an in-depth knowledge of potential chemical and biological weapons and the status and scope of medical defense strategies. It combines classroom instruction and field experience to establish essential skills, instill confidence, and define limitations in therapeutic modalities with each type of medical setting. The course also provides instruction on the use of specialized equipment and skills required for safe, long distance evacuation. Triage, decontamination, and medical operations on the integrated battlefield are stressed. Students are additionally equipped with instructional materials and reach-back assistance to support train-the-trainer activities at their home units. The MCBC awards

continuing education credits to physicians and nurses. During FY02, 29,382 contact hours were awarded to physicians and 21,850 hours were awarded to nurses.

USAMRICD trained 471 corpsmen/medics, first responders, medical planners, and Chemical Corps personnel with the in residence version of the “Field Management of Chemical and Biological Casualties Course” (FCBC). Sponsored by The Army Office of the Surgeon General (OTSG), this 5-day course is held at USAMRICD at Aberdeen Proving Grounds. USAMRIID provides teaching expertise for the biological agent portion of the training. The FCBC provides students with a working knowledge of potential CB weapons and the status and scope of medical defense strategies. It combines classroom instruction and field experience to establish essential skills, instill confidence, and define limitations in therapeutic modalities with each type of medical setting. First-hand experience in triage, decontamination, and medical operations on the integrated battlefield are emphasized. Students are additionally equipped with instructional materials and reach-back assistance to support train-the-trainer activities at their home units.

In FY02, USAMRIID, in collaboration with the Food and Drug Administration, broadcast a live, interactive satellite distance learning course entitled “Biological Warfare and Terrorism: Medical Issues and Response” to 7200 military and civilian health professionals and first responders at 1000 sites across the United States.

The Army OTSG continued funding for USAMRIID and USAMRICD initiatives to exploit the potential of medical CBRN distance learning courses. Distance learning courses, using VTC, satellite broadcasting, videotape series and computer based training programs, offer an alternative to those otherwise unable to attend training. The convenience of distance learning also enables large numbers of medical professionals to attend training.

The Army OTSG maintains the Medical NBC Online Information Server, an Internet web site at: <http://www.nbc-med.org/>. This searchable web site presents medical NBC-related news articles, case studies, congressional testimony, information papers, medical CBRN references, training materials, and the schedule for related conferences and courses. Links are provided to AMEDDC&S, USAMRICD, USAMRIID, and other NBC-related Internet sites offering training documents and software packages. Many references and documents can be downloaded directly from the OTSG site, including the *Medical Management of Biological Casualties Handbook* and *Medical Management of Chemical Casualties Handbook*.

The Field Preventive Medicine and Training Divisions of USACHPPM are currently working with U.S. Army Forces Command to assist field preventive medicine units in assessment of their existing environmental sampling and analysis capabilities and to provide technical training on TIM risk assessment and radiological hazard risk assessment. This training includes orientation and training on existing Table of Organization and Equipment as well as USACHPPM provided equipment and support.

Since 1996, the AMEDD and OTSG have conducted a series of Medical Chemical Biological Awareness Training (CBAT) seminar wargames for U.S. Pacific Command, U.S. European Command, and U.S. Central Command plus two for U.S. Forces Korea. These seminars, for senior and executive level officials, were highly successful and have led to an increase in demand for this type of training. The CBAT games were a predecessor to the current series of Command and Staff Awareness Training (CSAT) seminar games programmed through FY

2004. The purpose of these games is to provide an open forum for commanders and staffs to increase their awareness and explore contemporary issues, concepts, doctrine and policies relating to the medical aspects of chemical and biological defense. Recent exercises include “Crimson Cross” CSAT for Third Medical Command and “Orbit Comet” CSAT for XVIII Airborne Corps & Fort Bragg. “Orbit Comet” involved Pope Air Force Base as well as the communities of Spring Lake and Fayetteville, NC. This seminar wargame considered the operational and medical implications of a terrorist WMD attack on Fort Bragg and the impact on the XVIII Airborne Corps to sustain force projection operations during the response. Subsequent CSAT seminars are currently scheduled for I Corps and III Corps.

Throughout this entire process, a collaborative effort has occurred so that information, plans, training techniques and materials, and subject matter expertise have been freely shared among services, agencies, and educational institutions. The rapidly evolving situation, specifically the threat to the United States at home, required a paradigm shift. 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 that changes to curriculum can be made rapidly. This collaboration has benefited both the Army and the Nation.

4.3.2 Air Force

Air Force policy is to provide initial and annual refresher training to military personnel and emergency essential civilians in or deployable to chemical-biological threat areas, especially personnel in NBC medium and high threat areas (HTAs). The Air Force standards of proficiency are based on two international standardization agreements: NATO Standardization Agreement 2150 (NATO Standards of Proficiency for NBC Defense) and Air Standardization Coordinating Committee (ASCC) Air Standard 84/8 (Initial, Continuation and Unit NBC Standards). Both agreements are currently implemented through AFI 10-2501, *Full Spectrum Threat Response Planning and Operations*. The Air Force ensures proficiencies and currency of NBC warfare defense training through classroom training, unit level training, and exercises. NBC Defense Training (NBCDT) is required only for military personnel and emergency essential civilians in or deployable to NBC threat areas. Major Commands (MAJCOMs), the Air Reserve Component, and Direct Reporting Units may tailor their NBCDT programs to meet their specific mission requirements. The subjects presented in the classroom follow the three principles of NBC defense (avoidance, protection, and decontamination) as identified in Joint Pub 3-11. Unit level training follows the classroom training on wartime mission critical tasks. Supervisors train personnel to complete mission critical tasks while the workers are wearing their full complement of individual protective equipment. Exercises are used for training and evaluation purposes. NBC Defense training instructors at base level receive their professional training through Air Force Apprentice and Advanced courses at Fort Leonard Wood, Missouri.

Individual Training. There are two types of individual training. The first is general equipment and procedures training, which enables personnel to recognize and protect themselves and others from CBRN hazards. The second is individual proficiency training, which enables personnel to perform their wartime tasks in an CBRN-contaminated environment. Detailed training comes with assignment to a threat area or to a deployable unit. CBRN 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 medium or high threat area, as well as any conventional threat areas. Individuals graduating from Air Force Basic Military Training will receive credit for CBRN Defense Initial training. Air Force medical personnel receive CBRN Defense training initially at Commissioned Officer’s Training, or at their technical schools during Basic Expeditionary Medical Readiness Training or Expeditionary Medical Readiness Course. Personnel also receive CBRN defense training in accordance with AFI 10-2501, *Full Spectrum Threat Response Planning and Operations*, as shown in **Table 4-4**. Individual CBRN proficiency training occurs through on the job training and exercise participation. In addition, aircrews are required to conduct a one-time flight while wearing chemical defensive equipment.

Table 4-4. Air Force CBRN Defense Individual Training

AUDIENCE ^{1,2}	TYPICAL INITIAL INSTRUCTION TIME	INITIAL (FREQUENCY)	REFRESHER (FREQUENCY)	REMARKS
Low threat	8 hours	Within 60 days once identified ³	Not to exceed (NTE) 15 months after initial (Within 15 months thereafter)(4 hours)	Allow extra time for quantitative fit testing (QNFT)/ confidence exercise and CCA training.
Medium threat	8 hours	Within 60 days of arrival in MTA	NTE 15 months after initial (Within 15 months thereafter) (4 hours)	See Note 2
High threat	8 hours	Within 30 days prior to arrival in HTA	NTE 30 days after arrival train only theater specific procedures (Annually Thereafter)	See Note 2

1. CBRN Defense Training is required for military personnel and emergency essential civilians in or deployable to chemical-biological medium and high threat areas.
2. Initial training is required if there has been a break of 30 months or more in CBRN defense training.
3. Required for military/emergency essential civilians in or “subject to deploy” or “identified to deploy” to a MTA/HTA.

Unit Training. Units in or deployable to CBRN threat areas conduct the following training:

Table 4-5. Air Force CBRN Defense Unit Training

CB Threat Area	Minimum Exercise Requirements
Low	<p>Annually</p> <ul style="list-style-type: none"> - Conduct attack response exercise implementing the base OPlan 32-1 and other contingency plans (<i>i.e.</i>, CBRN, terrorist, or conventional attack). - Conduct an attack response exercise for units’ mobility commitments based upon the threat at deployment locations.
Medium	<p>Semiannually</p> <ul style="list-style-type: none"> - Conduct attack response exercise implementing the base OPlan 32-1, BSP, and other contingency plans (<i>i.e.</i>, CBRN, terrorist, or conventional attack). One exercise may be satisfied by a tabletop exercise. - Conduct attack response exercise for unit mobility commitments based on the threat at deployment locations. One exercise can be satisfied by a tabletop exercise.
High	<p>Semiannually</p> <ul style="list-style-type: none"> - Conduct attack response exercises implementing the base OPlan 32-1, BSP, and other contingency plans.

Medical Training Initiatives. Following the Air Force Medical Service (AFMS) NBC Warfare Defense Training Workshop in 1998, eleven training initiatives were prepared to meet gaps in Air Force chemical and biological medical defense training. Training tools for the AFMS re-

engineered unit type codes, such as: (1) Patient Decontamination Teams, (2) Collectively Protected Expeditionary Medical Support (CP-EMEDS), (3) Preventive and Aerospace Medicine (PAM) team training, (4) Bioenvironmental Engineering NBC team training, (5) PACAF AFMEDPAC 2000, (6) Continuing Medical Readiness NBC training, (7) NBC CD-ROM Toolkits. The medical NBC CD-ROM Toolkits consist of a field-ready, high-speed laptop computer and a 25 CD medical library. The purpose of the kits is to provide real-time access to critical medical reference material in support of medical contingencies, and to facilitate preparedness training. (8) ACC/ Force Protection Battle Lab Initiative–Bio Agent detection training, and (9) NBC Defense Leadership Skills training were identified for contractor development. The Army (funded by the Air Force) is the office of primary responsibility for the final initiatives: (10) Medical Management of Chemical Casualties, (11) Medical Management of Biological Casualties, and (12) NBC CD-ROMs. The AFMS is participating in satellite-provided Medical Management of Chemical Casualties hosted by USAMRICD/USAMRIID respectively. Additionally, the NBC CD-ROMs were distributed to every AFMS medical treatment facility in FY00. The Air Force Institute for ESOH (*Environmental, Safety & Occupational Health*) Risk Analysis (IERA) trained four students per AEF rotation cycle on PCR-based clinical pathogen diagnosis supporting the Biological Augmentation Team UTC. Care providers who have not been afforded the opportunity to attend the Army MCBC Course will receive an instructor-based course on medical management of chemical and biological casualties training at their units. Overseas locations have priority over CONUS bases for this initiative. In addition, identified medical UTC teams will receive medical reference materials developed by the US Army and civilian contractors for training.

Tables 4-6 and 4-7 provide information on the AFMS Chemical and Biological Defense Training Status as of the end of FY02.

Table 4-6. Air Force Medical Service (AFMS) Medical Management of Biological and Chemical Casualties—Training for Providers¹

# Required	# Trained	% Trained
4,929	4,129	84

Providers are defined as those individuals who have direct patient care responsibilities, who by virtue of their scope of practice, may be called on to clinically manage or assist casualties during a contingency (wartime, humanitarian or disaster response). This includes those designated as “first responders”, including physicians, nurses, physician assistants, and those dentists and medical technicians used in a first response capacity. All providers receive at least 8 hours of training in the identification and management of chemical and biological casualties. The following courses are acceptable methods to meet this training requirement:

- USAMRIID and USAMRICD 12-hour satellite/video/CD training program on CB warfare and terrorism
- USAMRIID and USAMRICD 7-day in-residence course on CB warfare and terrorism

Table 4-7. AFMS CBRNE Training for Deployable Personnel²

# Required	# Trained	% Trained
8,492	7,210	85

² All AFMS personnel assigned to deployable Unit Type Codes (UTCs) are required to complete the following training annually:

- Medical Effects of NBC Warfare (2 hrs): includes the medical effects of NBC warfare, and the medical management of these casualties.
- NBC Defense Training (4 hrs) NBC Defense Training: includes instruction in the proper wear and use of the ground crew ensemble and mask during various MOPP (Mission-Oriented Protective Postures) conditions, as well as an understanding of alarm signals and the use of personal chemical detection kits.
- Individual NBC Defense Task Qualification Training (TQT) (approx. 2 hr): includes, as a minimum, loading and unloading casualties, litter carries, operating communication equipment, and performing self-aid and buddy care.
- Explosive Ordnance Recognition (EOR): includes basic recognition, documentation, and reporting of standard unexploded ordnance.

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.

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 a CBR-D “confidence” chamber exposure. 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 courses. These courses include 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, RI.

Navy medical providers attend the Management of Chemical and Biological Casualties Course at the U.S. Army Medical Research Institute for Chemical Defense and the U.S. Army Medical Research Institute of Infectious Diseases. The Navy Environmental Health Center (NEHC) sponsors a three-day course for providers, and a one-day familiarization/awareness course. Additionally, NEHC is actively developing a “distance-learning,” CNET web-based, provider course expected to be online by June 2002.

Table 4-8. Navy Basic CBR-D Standards

- | |
|--|
| <ul style="list-style-type: none">• Complete Chemical, Biological, Radiological Defense (CBRD) Fundamentals PQS• 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 decon 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. |
|--|

After reporting to designated units, Navy personnel are required to complete basic and advanced CBR-D Personnel Qualification Standards (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 objective of PQS is to standardize and facilitate these qual-

ifications. Basic- and advanced-level CBR-D PQS are contained in NAVEDTRA 43119-H. Basic-level CBR-D PQS, which is required for all personnel assigned to a command and consists of “CBR-D Fundamentals—Watchstation 106” and “Basic CBR-D—Watchstation 306.” (See **Table 4-8**) Advanced level CBR-D PQS is required for personnel assigned to CBR teams, including Detection Teams, Decon Station Teams, Internal/External Monitoring Teams, Decontamination Teams and Team Leaders. Advanced level PQS consists of “CBR Detection Equipment Systems—Watchstation 215” and “Advanced CBR-D Person—Watchstation 309.”

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).

Early in the Basic training phase, a ship is required to conduct a Command Assessment of Readiness and Training (CART), which is a performance-based assessment of a unit’s readiness in each mission area. CART assesses material, administrative, and training proficiency. By the end of the Basic Training Phase, ships are required to be proficient in all mission areas and have demonstrated the ability to sustain readiness through their internal training team organization. Internal CBR training is conducted by the ship’s Damage Control Training Team.

A Final Evaluated Problem (FEP) is the culmination of the Basic training phase and demonstrates the ship’s ability to conduct multiple simultaneous combat missions and support functions and to survive complex casualty control situations under stressful conditions. The conduct of the FEP is dependent upon the ship’s previously demonstrated proficiency and may require the ship to progress through all mission oriented protective postures (MOPP) levels as part of a chemical defense exercise. After completion of the Basic training phase, the completion of a Chemical Defense Drill is a repetitive requirement, conducted every six months.

The Intermediate and Advanced training phases consist of multi-ship and battle group training directed by a numbered fleet commander. Emphasis is placed on integrated watch section training in a fully coordinated multi-threat environment. During the intermediate and advanced phases of the training cycle, combat readiness is reinforced through Composite Training Unit Exercises and Fleet Exercises.

Medical Training. Information on the status Navy CBRN defense medical training as of the end of FY02 is provided in **Table 4-9**.

Table 4-9. Navy Medical CBRN Defense Training Status

	Clinicians ¹			Non-clinicians ²		
	Trained	Total	% Trained	Trained	Total	% Trained
Officers	2,802	3,917	72%	1,874	3,687	51%
Enlisted	267	332	80%	5,754	14,636	39%
Total	3,069	4,249	72%	7628	18,323	42%

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.

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 includes:

- any of the three 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 (NMCS) 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.

4.3.4 Marine Corps

The Marine Corps’ CBRN training focuses on the ability to conduct operations throughout the battlespace with particular emphasis on amphibious deployment, littoral, and air/ground operations. The Marine Corps views CBRN as an environment, similar to daylight/darkness and cold/heat, yet with its own unique challenges.

Training requirements are derived from the Force Commander’s Mission Essential Task Lists, Joint Universal Lessons Learned, Marine Corps Lessons Learned, Mission Need Statements, and Universal Needs Statements. Once validated, the training requirements are introduced into the Systems Approach to Training (SAT) Process. One of the results of the SAT process is the development of training tasks and standards that will fulfill the training requirements. These task lists and standards are incorporated into Individual Training Standards (ITSs) for individual Marines and Mission Performance Standards (MPS) for Marine units. These ITSs and MPSs are published as Marine Corps Orders for standardization and compliance throughout the Marine Corps. During FY02 the Marine Corps began conversion of two ITSs and MPSs related to CBRN defense training to a newer, more effective Training & Readiness (T&R) Manual format. The T&R Manual provides greater specificity in standards and will enhance commanders’ abilities to determine readiness and readiness reporting based on training accomplishments. This conversion will continue through FY03.

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

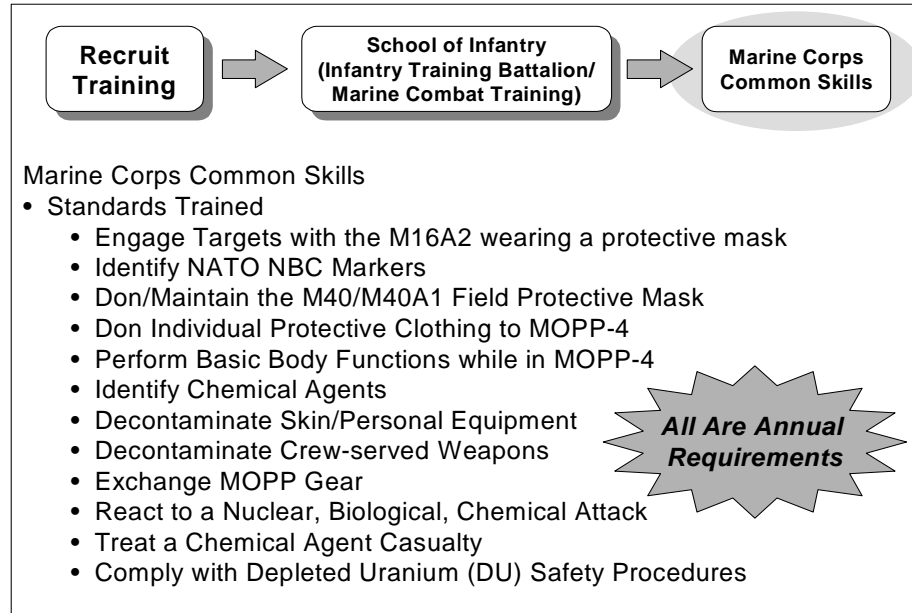


Figure 4-1. USMC Individual CBRN Training

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 and General Grade Officers 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.

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.

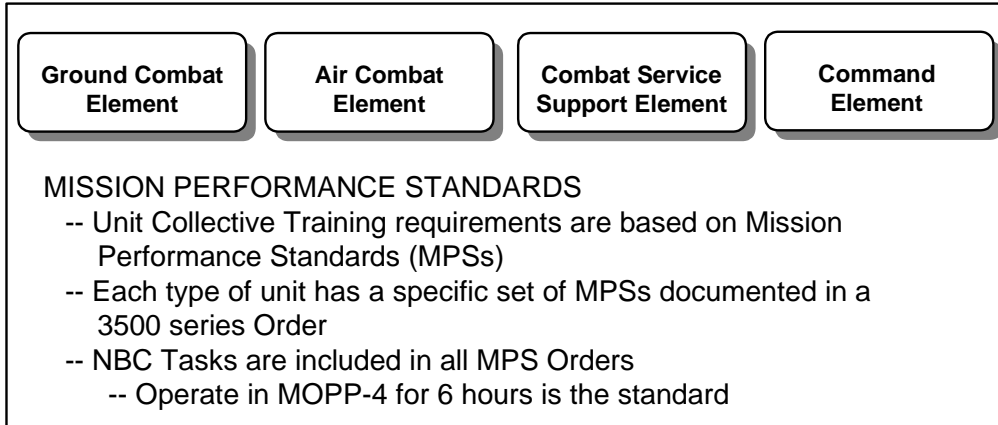


Figure 4-2. USMC Collective Training, CBRN Requirements

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 PROFESSIONAL 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. 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 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 Joint CBRN Defense Professional Training

Joint Professional Military Education, Phases I and II, currently contains a limited degree of CBRN defense considerations and requirements. 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. Section 4.6.1 details a continuing JRO initiative that addresses these short-falls. The JRO also sponsors the Joint Senior Leaders Course at the USACMLS. This course is

targeted at leaders from all Services with the intent of increasing their awareness and understanding regarding CBRN defense issues.

Within the joint medical arena, the U.S. Army Medical Department sponsors the Medical Management of Chemical and Biological Casualties (MCBC) course, which provides training to DoD personnel. All Medical Nuclear Casualty Training has been consolidated under the Armed Forces Radiobiology Research Institute in Bethesda, Maryland, where radiobiology education is made available in a Tri-Service format.

4.4.2 Army CBRN Defense Professional 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 Unit Training (see **Table 4-10**), enlisted soldiers receive training in chemical and biological agent characteristics and hazards, smoke and decontamination operations, chemical and radiological survey procedures, 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 4-10. U.S. Army Professional and Initial Entry Training

Training Command	Type of Training	Training Method	Number of Graduates
USACMLS	Chemical Officer Basic	Resident	157
USACMLS	Chemical Basic Officer Leader	Resident	17
USACMLS	Chemical Captain's Career Course	Resident	62
USACMLS	Chemical Officer Advanced -RC	Resident	66
USACMLS	Chemical Operations Specialist	On Site User Training-Resident	1,484
USACMLS	Chemical Operations Specialist BNCOC	Resident	133
USACMLS	Chemical Operations Specialist BNCOC (RECLASS)	Resident	53
USACMLS	Chemical Operations Specialist ANCOC	Resident	72

- Chemical Corps sergeants attend a two phase (Phase 1: Two week common core; Phase 2: a 9-week, 3-day MOS specific) Chemical Basic Non-commissioned Officer Course (BNCOC), where they are trained to be a CBRN company squad leader and a non-chemical company or battalion CBRN NCO.
- Chemical Corps staff sergeants and sergeants first class attend the two phase (Phase 1: Two week, 2-day common core; Phase 2: a 6-week, 2-day MOS specific) Chemical Advanced NCO Course (ANCOC), where they are trained to be an CBRN platoon sergeant, an CBRN NCO at brigade level, and an CBRN NCO in a division or Corps level CBRN element.
- Chemical Corps lieutenants attend a 19-weeks, 1-day officer basic course, 10 weeks during mobilization. Reserve Component officers must attend the resident course.

- Chemical Corps captains attend the Captain’s Career Course, an 18-week officer advanced course. Extensive use is made of computer simulations to reinforce the application of CBRN assets in support of tactical operations. In the 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), in which they are trained.

Specialized professional training is conducted in standalone courses attended by DoD, Allied, and international students, as shown in **Table 4-11**. All courses use a resident training method and are conducted at the U.S. Army Chemical School.

Table 4-11. U.S. Army Specialized Professional Training

Type of Training	Training Duration	Number of Graduates
Nuclear, Biological, Chemical Reconnaissance	6 weeks	126
Master Fox Scout	3 weeks	29
Biological Integrated Detection SYS (BIDS) SP	4-weeks, 3 days	72
Decontamination Procedures (Non-US)	1 week	197
Radiological Safety (Installation Level)	3 weeks	64
Operational Radiation Safety	1 week	110
WMD Installation Emergency Responder	1 week	189
WMD-CBRN Installation Planner’s Course	1 week	86
Emergency Assessment and Detection Course	3 weeks	140
Chemical Pre-Command & Div/Corps	1 week	15
US Coast Guard Strike Force	1 week	25

4.4.3 Air Force CBRN Defense Professional 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. Further, the Air Force administers a career development correspondence course and two mobile courses in airbase operability and CBRN cell operations. The Air Force courses range from 53 days for the Apprentice course; 10 days for the Craftsman and Readiness Flight Officer Courses; Five days for the CBRN Cell Advanced and Mobile Air Base Operations and Advanced Readiness courses. The Air Force also offers computer based Qualification Training Packages (QTPs) that have been developed for most CBRN Defense Equipment items, and are included as part of professional upgrade training.

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. The following is a synopsis of the CBRN aspects of these courses.

Training for personnel being assigned primary readiness duties includes comprehensive coverage of agent characteristics and hazards (to include determination of incapacitation/ lethality levels); nuclear weapons effects and other specific hazards associated with ionizing radiation; CBRN detection and contamination control and contamination avoidance techniques; plotting and reporting procedures; detailed CBRN persistency and duration of hazard calculations to provide advice on MOPP variations; the inter-relationship between CBRN defense and other

passive defense activities (*e.g.*, camouflage, concealment, and deception, (CCD), dispersal, and hardening, *etc.*); and systematic analysis procedures for assessing hazards identification, vulnerability assessment, and risk assessment and providing credible mission continuation (sortie generation) and force survivability advice to commanders.

Air Force learning theory emphasizes hands-on training, and the school makes extensive use of available training ranges and equipment. The school includes Chemical Defense Training Facility (CDTF) toxic agent training in four of five in-residence courses. Training is provided on every major piece of CBRN detection and decontamination equipment available in the field today, including state-of-the-art items currently being fielded.

The Civil Engineer (CE) Readiness Flight Officer and seven-level Craftsman courses provide flight leaders and mid-level NCOs with the background and technical information that is necessary for effective management of the CE Readiness Flight and contingency response operations.

Readiness is the key to successful Air Force operations. Consequently, the various aspects of CE Readiness Flight operations, including CBRN defense, are also topics of instruction at the Air War College, Air Force Institute of Technology, Air Command and Staff College (ACSC), College for Enlisted Professional Military Education (CEPME), the College for Professional Development, and the Joint Senior Leaders Course. Readiness personnel receive additional training on wartime and contingency aspects of CBRN defense at one of three Silver Flag Exercise sites. These sites are located at Tyndall AFB, FL, Kadena AB, Japan, and Ramstein AB, Germany. Personnel deploy with their complete complement of personal CBRN protective equipment and receive comprehensive training that builds upon their baseline knowledge in the areas of CBRN detection, CBRN reconnaissance, decontamination, warning and reporting and equipment use and inspection. Silver Flag also trains readiness personnel on newly fielded equipment items, new techniques and procedures, and equipment not available at all installations.

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. Bioenvironmental Engineering CBRN Operations provide specialized medical detection, surveillance, and risk assessment training to 88 officers and NCOs per year. Critical Care Air Transport Team training includes movement of CB casualties for 250 students per year. Contingency Public Health Operations course focuses on early recognition, evaluation and control of disease (including CB casualties) through expeditionary preventive medicine. Other specialty courses include Preventive and Aerospace Medicine contingency training, Global Medicine, Military Tropical medicine, and Medical Survival training. The Air Force Institute for Environment, Safety, and Occupational Health Risk Analysis, also at Brooks AFB, teaches PCR-based biological agent clinical diagnosis for members of the Air Force biological augmentation team.

All students who attend Air War College at Air University, Maxwell AFB in Montgomery, Alabama, participate in a three-hour course, entitled DFW 6530, *Emerging CONOPS for Counter-Chemical, Biological and Radiological Warfare*, that is offered by the Warfighting Department. The course provides a comprehensive overview of the CBR threat, analyzes how potential adversaries may employ CBR weapons, enables discussion of the Air Force's emerg-

ing concept of operation and capabilities to respond to CBR attack. Students may elect to take a course, entitled EL 6530, *Chemical and Biological Warfare Issues for the USAF*, which includes classroom lectures/discussions and field trips. The students analyze emerging CB warfare challenges to the USAF, the Homeland, and US allies. They also examine the strategic, operational and tactical uses for these weapons, and learn about the Department of Defense's and USAF counterproliferation efforts.

During ACSC, students are required to participate in a National/International Studies course, entitled NS-533, *Weapons of Mass Destruction*. This course includes a comprehensive overview of the threat, a study of the characteristics of the agents and weapons, and an understanding of the implications for Air Force operations at the operational level. The curriculum includes chemical warfare defense within their capstone Air and Space Exercise. An elective course, entitled EL 664, *WMD - Challenge and Response*, is designed to introduce officers to ways of responding to the challenges of WMD use. Students practice planning using emerging concepts of operation for countering WMD. Finally, the Headquarters Air Force office, XONP, has an initiative to encourage ACSC students to identify research topics related to improving concepts of operation.

The curriculum at the College for Enlisted Professional Military Education provides students with background knowledge of the Air Force's Counter-Chemical Warfare concept of operation. Substantial enhancements to the curriculum are planned for 2003.

At the College for Professional Development, chaplains receive training on chemical warfare defense, and students at the Commander's School receive information on the Air Force's Counter-Chemical Warfare concept of operation for self-paced study.

4.4.4 Navy CBR-D Professional Training

The Navy Construction Training Center Detachment at the U.S. Army Chemical School, 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.

The training, conducted at Fort Leonard Wood, capitalizes on the unique capabilities of the Army Chemical School and makes extensive use of the Chemical Defense Training Facility (CDTF). Approximately 200 students graduate annually from the Detachment's courses. In addition to being fully qualified to conduct training using the Army's facilities, the Navy Detachment actively participates as part of the JAWG.

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 4-12).

Table 4-12. U.S. Navy Professional Training

<u>Course Name</u>	<u>Course Location</u>
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
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
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 Professional Training

The Marine Corps NBC Defense School is a formal Marine Corps 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 U.S. Army Chemical School at Fort Leonard Wood. In addition to professional 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 ITs specified in MCO 1510.71. This course was thoroughly reviewed and updated in FY02 that led to an additional training week. The course not only trains Marines to perform their wartime duties but also provides them with the tools they will need on a daily basis to perform their primary peacetime mission of conducting CBRN defense training for their assigned units. The course is divided into eight blocks of instruction as shown in **Figure 4-3**.

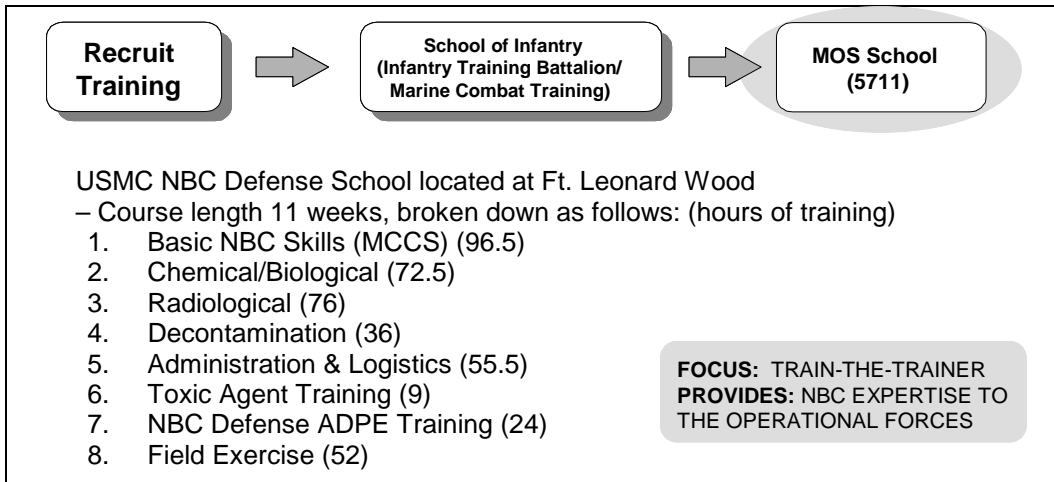


Figure 4-3. USMC Individual Training (Enlisted CBRN Specialists)

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. The NBC Warrant Officer’s course is divided into eight blocks as outlined in **Figure 4-4**.

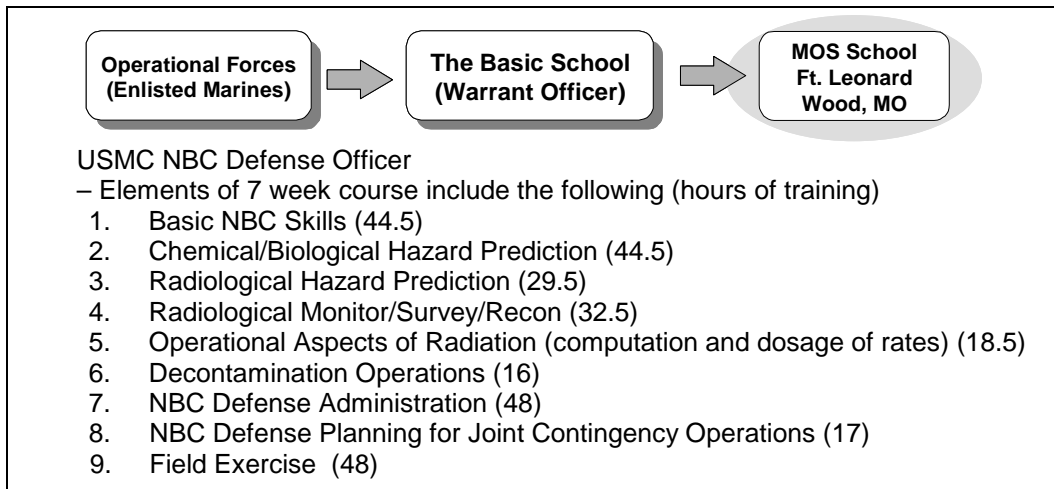


Figure 4-4. USMC Individual Training (Training for CBRN Officers)

4.5 INTEGRATION OF REALISM/WARFIGHTER EXERCISES

4.5.1 Simulations and Warfighter Exercises

There are three types of simulations: live, constructive and virtual. Simulations may also be sub-grouped as training or analytic simulations.

Live simulations involve real people operating real systems. Such simulations are also known as exercises and are discussed further in the next section.

Constructive simulations allow battles to be waged on a synthetic battlefield. They are designed to give commanders and their staffs the opportunity to make decisions during a course of a battle, adjust plans to react to enemy movements, synchronize all available assets and learn, through the After Action Review (AAR) process.

Virtual simulations are designed for training and analysis primarily at the tactical level of war. These simulations are “mock-ups” of actual vehicles and give units an opportunity to train on necessary individual, crew and collective tasks without having to maneuver actual equipment in the field. While the crews maneuver their equipment around the battlefield, the rest of the environment is generated through the use of Semi-Automated Forces (SAF). SAF are computer representations of adjacent elements, the enemy, and the environments upon which the battle is waged. SAF elements not only look like other units they can be programmed to perform tasks/missions autonomously, thus adding to the realism of the training.

There are over 750 virtual and constructive models and simulations in the Army community alone. **Table 4-13** lists the primary battle command simulations in current use throughout the Army and their baseline ability to use CBRN events in their scenarios. However, characterization of CBRN effects in these models and simulations is limited. Very few combat simulations incorporate the effects of CBRN, and none incorporate all aspects.

Table 4-13. Chemical (C), Biological (B), Radiological (R), or Nuclear (N) Capability in Current Constructive Simulations

NAME	USE	FIDELITY	C	B	R	N
Corps Battle Simulation (CBS)	Training	Operational	X		X	X
Brigade Battle Simulation (BBS)	Training	Tactical	X		X	X
Conflict Evaluation Model (CEM)	Analytic	Joint/Strategic	X	X		X
TACWAR	Analytic	Joint/Strategic	X	X		X
Vector In Command (VIC)	Analytic	Operational	X			
Combined Arms and Support Task Force Evaluation Model (CASTFOREM)	Analytic	Tactical	X			X
JANUS	Training/Analytic	Tactical	X			

Current training exercise warfighting simulations have not received sufficient priority or funding to adequately portray CBRN effects and challenge commanders and staffs to apply CBRN defense doctrine and leader-development training strategies to prepare their forces to maintain operational continuity and achieve mission success in a CBRN environment. To be an effective training mechanism, these simulations must challenge training audiences to understand adversaries’ CBRN intent and capabilities. Simulations must also allow players to visualize how CBRN capabilities affect the battle space, friendly courses of action, tactics, techniques and procedures, and operation plans to allow players to apply CBRN defense principles and capabilities to set conditions for mission success against CBRN threats. Warfighting simulations—Joint Warfare System (JWARS), Joint Simulation (JSIMS), and Joint Conflict and Tactical Simulation (JCATS)—are in development to accurately replicate the CBRN hazards of future battlefields and their effects on friendly systems. These warfighting simulations will enable commanders staffs, and soldiers, airmen, and sailors to train and develop required high-order battlefield cognitive skills that will allow for full integration of enemy intent and capabilities, CBRN environment effects, and friendly force capabilities while planning and executing operations.

There is currently no standardized Instrumentation System that can realistically portray all facets of CBRN effects during field training. The U.S. Army Chemical School has developed CBRN Recon training interface devices allowing Multi Integrated Chemical Agent Detector (MICAD) to link the FOX Reconnaissance Vehicle into the Combat Training Center (CTC) instrumentation for the detection and tracking of simulated CBRN contamination at CTCs and home station training areas. Resourcing will be pursued to upgrade the fielded training device interfaces at CTCs and other locations. The upgraded MICADS interface to the Instrumentation System will retrieve, process, and calculate digital contamination data for maneuver units and will also include AAR feedback in the areas of CBRN casualties, change of custody, and reaction procedures during CBRN attacks and operations. This Instrumentation System will provide a realistic replication of CBRN contamination as portrayed on the battlefield.

The requirement to establish a baseline capability within the emerging OneSAF Test Bed version B simulation was completed. This baseline capability is interoperable with high level architecture and works as a CBRN environment and effects model in both constructive and virtual simulations.

The virtual simulation for the M93A1 NBC Reconnaissance System is operational at Fort Leonard Wood, Missouri. Future systems are planned for Fort Hood, Texas (installed in FY02) and Fort Polk, Louisiana (installed in FY03).

A virtual simulation for the P3I BIDS system has been installed at Fort Leonard Wood, Missouri. A portable unit has been installed with the 7th Chemical Company, stationed at Fort Polk, Louisiana.

4.5.2 Joint and Combined CBRN Exercises

Chairman of the Joint Chiefs of Staff (CJCS) Exercise Program. Joint Vision 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 USJFCOM Joint Training and Analysis Center (JTASC). Success for Joint Vision 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 Chairman of Joint Chiefs of Staff 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, and attacking aircraft. Personnel are tasked to perform war skills while in their full complement of protective equipment. 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 defense training may be conducted whether platforms are operating independently or in a group. During scheduled CBR defense training periods, realism is stressed and CBR defense 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).

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.

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.

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.

4.6.1 Joint CBRN Defense Training

The JRO continued a multi-year strategy to address CBRN defense in Joint Doctrine education at the intermediate/senior-level, joint and Service Colleges and training at the Combatant Command staffs. This effort is designed to improve awareness across the entire spectrum of CBRN defense; including doctrine, training, wargames, exercises, and studies. It provides resources to assist in the Joint Doctrinal review and development process by providing CBRN

defense input where appropriate. This JRO effort provides resources to assist Intermediate/Senior-level, joint and Service colleges in reviewing and revising their curriculum for the purpose of incorporating CBRN defense material and providing CBRN experts as guest speakers. It also provides CBRN defense subject matter expert assistance with Combatant Command exercises and with joint staff officer training through a one day Joint CBRN Defense Familiarization Course.

During 2002, the JRO conducted a workshop for the intermediate and senior level colleges to demonstrate the Joint CBRN Faculty and Curriculum Developers Course. This course was developed at the request of the colleges and is intended to educate college faculty in ways to better integrate CBRN defense into their curricula. This course was formally conducted at the Joint Forces Staff College and the Army Command and General Staff College. The JRO provided assistance to three intermediate and senior level colleges with curriculum reviews and recommended CBRN enhancements. The JRO also provided subject matter expert support and assistance with the planning and execution of the Joint Land Aerospace & Sea Simulation (JLASS) conducted by the War Colleges, the Strategic Crisis Exercise at the Army War College and with the OSD Transformation wargames conducted by USJFCOM.

During 2002, the JRO sponsored the development of a Joint Training Development Guide. The purpose of this guide is to provide a training and reference tool than can be used by the materiel developer, the combat developer, and the training developer to develop joint training products during the CBRN defense materiel acquisition process. It is also designed to facilitate the standardization of joint processes, expedite resolution of integrated logistics support and other training development issues, and depict training development procedures for Joint CBRN Defense acquisition programs.

USJFCOM completed the review of the Universal Joint Task List (UJTL) version 4.0 for adequacy in addressing CBD-related tasks, based on input from the combatant commands, combat support agencies, the Joint Staff and the Services, version 4.2 of the UJTL was published in July 2002. USJFCOM is partnering with DTRA in the preparation of lists associated with CBD-related tasks. Additionally, USJFCOM's Joint Training System Support Teams assisted the combatant commands, during their visits to the Combatant Commands in FY01-02, with the preparation/validation of Combatant Commanders JMETLs associated with CB defense. Measures of performance associated with CBD-related tasks will be addressed with the development of UJTL version 5.0, during FY03-05, with the assistance of the Defense Data Manpower Center.

Under the 1999 Unified Command Plan, the Secretary of Defense directed the formation of the Joint Task Force for Civil Support (JTF-CS) within JFCOM to act as the military command and control unit to coordinate the military response in support of the Lead Federal Agency for Domestic CBRNE consequence management response. UCP 2002 created US Northern Command as of 1 October 2002, assigning it responsibility for Homeland defense and as the combatant command designated to provide support to the lead federal agencies for Crisis and Consequence Management (Homeland Security). JTF-CS was assigned as a subordinate command to US Northern Command effective 1 Oct 02.

Modeling. JCATS and JWARS are the future joint models for constructive and virtual combat simulation for training and analysis applications. Plans to incorporate CBRN defense effects

into these models were initiated in FY98. VLSTRACK has been loosely coupled to JCATS to demonstrate the ability to add high-resolution CW effects. JWARS will incorporate a chemical defense capability in release 1.1.

4.6.2 Air Force CBRN Defense Training

The Air Force currently has three training and readiness initiatives underway and continues to improve its professional training.

The Civil Engineer (CE) Readiness Technical School implemented an advanced scenario-driven exercise in the CDTF revolving around a terrorism incident involving chemical munitions. This training is provided to advanced students and differs from the lock step training provided to Apprentice-level students. The scenario will be reviewed/revised annually during the respective course reviews. Air Force instructors are qualified to conduct joint classes at the CDTF and are fully integrated into CDTF operations. Readiness instructors lead Air Force students in four of five resident courses through the training and also assist the other Services with their training requirements. Additionally, they provide an orientation of CBRN defense concepts and toxic-agent training in the CDTF for key Air Force personnel during the semi-annual Joint Senior Leader's Course. The CE Readiness Career Field Education and Training Plan's Specialty Training Standard requires readiness students and personnel to be highly qualified in chemical biological defense operations, including conducting and advising leaders on hazards analysis and the use of emerging detection and plotting technologies.

Air Force Readiness personnel enrolled in correspondence courses for upgrade training to the five skill level will eventually be able to complete a hybrid course, which includes both paper-based and interactive CD-ROM containing full-motion video and sound. The course is presently available only in a paperback version, which will continue to remain available. Interactive courseware development began in FY97 with the goal of developing the entire course on CD-ROM. This initiative was revised in FY00 in favor of the hybrid course. A CE Correspondence course writer at Sheppard AFB, Texas began CD-ROM development in FY01. This product will set the standard for all other CE specialties.

The Air Force has established the Counter Proliferation Integrated Process Team (CP IPT) as the Air Staff focal point for counter-proliferation issues. The CP IPT will also commission working groups as necessary, including a Passive Defense Working Group. The Passive Defense Working Group will:

- Define the end state for future Air Force CBRN operations.
- Focus on near, mid, and far term actions.
- Transform the force while maintaining ability to go to war.
- Identify existing CONOPS for sustaining mission essential tasks under biological and chemical warfare conditions.
- Identify gaps in existing chemical-biological defense (CBD) CONOPS.
- Recommend steps for developing comprehensive and effective CBD CONOPS.
- Identify specific issues and recommend corrective actions.

Additionally, the Air Force Medical Service has initiated, and is in the process of implementing CBRN Defense Training programs for eleven initiatives, which are listed in section

4.3.2. All are being managed by HQ AETC/SGP and HQ USAF/SGX. By 30 April 2003, AFMS will have fully fielded collective protection for its deployable Expeditionary Medical Support System (EMEDS). This will include: 18 EMEDS + 25, 24 EMEDS + 10, and 28 EMEDS Basic.

4.6.3 Navy CBRN Defense Training

Navy initiatives focused on improving CB Defense Readiness, Training, Doctrine and Readiness Reporting across the fleet and also improving coordination of defense actions with other Services and agencies. In addition the Navy has focused on the long term integration of CBR-D, Afloat Anti-terrorism Force Protection, and Homeland Defense initiatives. As a result of an internal re-organization, Navy requirements in these areas are now managed by a single Chief of Naval Operations office.

The Navy maintains a response capability at the Naval Medical Research Center (NMRC). NMRC is primarily a research institute, however, its Biological Defense Research Directorate has developed a capability that consists of a transportable biological field laboratory, expressly for the identification of biological warfare agents. This capability has been utilized extensively by DoD and other government agencies to provide a rapid analysis of biological samples.

To improve Navy readiness to respond to Chemical, Biological, and Radiological events the Navy has conducted an extensive series of CBRD studies. These studies includes:

- “The NBC Warfight” which analyzes operational decision-making within the concept of the Joint CBR Battle Management Cell.
- “Biological Attack on a Pier” which analyzes the consequence management and interagency response to a biological attack on a pier adjacent to a naval base.
- “Shipboard Biological Hoax” which examines the tactical and operational implications of an internal contamination event on a ship.
- “Preparing a Fixed Site for CBR-D” which analyzes basic naval base CBR defensive responses and command and control systems.
- “A Framework for Navy Forward Fixed Site CBR-D Requirements” which examines CBR defense requirements for small, remote facilities, large fixed sites and large fixed administrative sites in peacetime and wartime.
- “Improving CB Defense for Domestic Naval Bases” which focuses on preparedness, point detection requirements, and medical responses to a biological attack at a US Navy base.

To improve Fleet participation in the Joint CBRN Defense Program a successful series of Type Commander CBRD Conferences have recently been convened. These recurring conferences have allowed personnel from the Naval Surface Force, Aviation Force, and Submarine Force Commanders and also personnel from operational units throughout the fleet to actively participate in improving Navy CBRD readiness. The results of these meetings have been used to shape CBRD equipment, doctrine, and training requirements.

To support warfighting and force protection missions, the Navy is assisting the U.S. Coast Guard (USCG) in evaluating requirements and improving capabilities for CBR-D. The

ultimate goal is the integration of the USCG to ensure full interoperability with the Armed Services. The USCG is in the process of upgrading their Naval Operational Capabilities and raising Survivability Standards to include enhanced CBR defense capability for future “Deep-water” assets (new ships and aircraft) and also improving the readiness of current USCG assets.

To improve unit CBRD readiness reporting the Navy has instituted changes to the Status of Resources and Training System (SORTS) reporting process. These changes will improve unit CBR equipment readiness and training readiness reporting procedures. These changes are designed to improve the visibility of CBR readiness issues throughout a naval units entire chain of command.

4.6.4 Marine Corps CBRN Defense Training

During FY02 the Marine Corps Chemical Biological Incident Response Force (CBIRF) continued to refine its tactics, techniques, and procedures to respond to the growing biological and chemical terrorist threat. The CBIRF’s mission focuses on consequence management to terrorist-initiated CBRN incidents. The CBIRF is a national asset, to be globally sourced to Combatant Commanders and the National Command Authority for duties as the President may direct. The CBIRF consists of 360 highly skilled and trained Navy and Marine Corps personnel, organized into three elements: Command Element, Headquarters & Service Company and a Reaction Force Company with three Reaction Platoons. The CBIRF has state-of-the-art detection, monitoring, medical and decontamination equipment and is prepared for operations in a wide range of military-civilian contingencies. In addition to the CBIRF’s capabilities to respond to CB incidents, it also serves as a training asset to the operational forces. The CBIRF can provide mobile training teams to various units to provide advanced consequence management training. This can provide operational forces with the most up-to-date techniques, tactics, and procedures developed by the CBIRF. CBIRF also assists in Unit/Facilities Vulnerability Assessments to enhance force protection. The bottom line is that the CBIRF serves as a force multiplier to the MAGTF.

Marine Corps FY02 Accomplishments:

- Began fielding, training and deployment of the “Enhanced NBC” Force Protection sets for the Marine Expeditionary Units (MEUs) that are forward deployed with the Navy.
- Conducted the Annual CBRN Conference at Fort Leonard Wood, Missouri from 9-10 September 2002. The Marine Corps Conference gathered Marine Corps CBRN Subject Matter Experts for the purpose of refining and defining doctrine, reviewing current CBRN Requirements, and distributing information on programs currently in material development.
- Participated in CENTCOM’s Desert Breeze and CINCUNC/CFC’s Coral Breeze WMD Wargame Seminars. The primary purpose of these seminars was to educate the Combatant Commanders and Component commanders and staffs on implications of the current and emerging WMD threat (MARFORPAC).
- Conducted a comprehensive assessment of USMC vulnerability to WMD within the context of major OPLANs that included gauging adequacy of individual and unit level training (MARFORPAC).
- Provided forces and equipment in support of the Restoration of Operations (RestOps) Advanced Concept Technology Demonstration (ACTD). These forces performed vari-

ous missions, including training and evaluation, toward ACTD objectives (MARFORPAC).

- Marine Forces Reserve (MarForRes) CBRN Defense Single Site Storage Facility (SSSF) became fully operational. This site is located on the Fort Worth Federal Center, Fort Worth, Texas. The SSSF is designed to house, inspect, and maintain all CBRN equipment for MarForRes except for the field protective mask.

Marine Corps FY02 Initiatives:

- Finalized development of a joint Navy/Marine Corps web-based distance-learning course for CBRN Defense Individual Survival Measures co-sponsored by the Marine Corps Institute and the Marine Corps CBRN Defense School for use by all Marines, throughout the Marine Corps.
- The Marine Corps CBRN Defense School remained is actively engaged involved in the JRO Joint Training Sub-Panel activities regarding assistance with identification of training requirements for all joint CBRN defense equipment development programs.
- The Marine Corps Combat Development Command (MCCDC) formed the USMC CBRN Defense Operational Advisory Group (OAG) that is comprised of representation from all Marine Component Commands and their Major Subordinate Commands (MSC). Per the OAG's charter, the purpose of the OAG is to provide a USMC CBRN Defense decision making and guidance forum among the USMC CBRN Defense Specialist Community. The first OAG met from 17–21 June 2002 at Fort Leonard Wood, Missouri.
- In a support role, Marine Force Pacific continued its participation in RestOps. The RestOps ACTD is a USPACOM-USCENTCOM co-sponsored experiment designed to improve actions before, during and after a CB attack. These actions aim to restore operating tempo (OPTEMPO) in wartime mission execution and the movement of individuals and materiel to support combat operations at a fixed site. The ACTD will: identify effective means of pre-attack protection of personnel and critical equipment while maintaining operational agility; identify chem-bio collection, detection, identification and warning that is achievable to reduce vulnerabilities; identify expedient methods of post-attack decontamination of personnel and personal equipment; provide for enhanced decontamination of critical equipment and facilities necessary to restore and sustain operations; provide enhanced ability to determine the extent and location of contamination; and provide for improved post-attack medical treatment to exposed personnel. MARFORPAC participates in this ACTD as a component of both sponsoring Combatant Commands and sits on two of its oversight committees. Also MARFORPAC provides forces and equipment for operational tests and evaluations conducted in support of ACTD objectives. The primary ACTD demonstration site is Osan Air Base, Republic of Korea. Locations for testing and evaluating specific technologies, tactics, techniques, and procedures include the West Desert Test Center, Dugway, Utah, Marine Corps Base Kaneohe Bay, Hawaii, Brooks Air Force Base, Texas, Nellis Air Force Base, Nevada, and Kirtland Air Force Base, New Mexico.
- MARFORPAC sponsored a force protection initiative funded by DTRA. DTRA will conduct an independent assessment of USMC operations in a WMD environment.

4.6.5 Emergency Response: Army Medical Response

The Army Medical Department (AMEDD) continues to support DoD and federal counterterrorism initiatives and contingency operations related to CBRN threat agents, mainly with elements of the Medical Research and Materiel Command (MRMC). 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 Force Protection (AT/FP): Security of Personnel, Information, and Critical Resources from Asymmetric Attacks*, dated 10 September 1998. From this regulation it is assumed that U.S. Army medical treatment facilities and clinics will be called upon to provide assistance 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.

During 2002, MEDCOM will publish Regulation 525-xx, *Medical Emergency Management Planning*, which includes all medical teams and systems that could potentially be available to support civil authorities in the event of a Chemical, Nuclear, Biological, Radiological-Explosive (CNBR-E) event or a terrorist attack with Weapons of Mass Destruction. The regulation also includes the Army policy for fixed facility medical treatment facilities in support of local domestic First Responders.

The AMEDD has formed Specialty Response Teams (SRTs), which in some instances may be designated Special Medical Augmentation Response Teams (SMART). These teams 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 U.S. Army Medical Command (USAMEDCOM) subordinate commands; they are not intended to 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 SRTs using their table of distribution and allowances (TDA) assets. These teams enable the commander to field standardized modules in each of the SRT areas to meet the requirements of the mission. Members of the US Army Reserve (USAR) may be relied upon to provide a variety of functions in support of the various SRT missions. The two SRTs that can most likely to support CBRN are the Special Medical Augmentation Response Team – Preventive Medicine (SMART-PM) and the Special Medical Augmentation

Response Team – Nuclear/Biological/Chemical (SMART-NBC). The following paragraphs describe activities/programs within the Army Medical Command (MEDCOM) that support civil authorities, consequence management, and domestic preparedness.

Medical Capabilities. The U.S. Army Medical Command (MEDCOM) has organized, trained and equipped Special Medical Augmentation Response Teams. Designated MEDCOM 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 43 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) Two 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 contractors of the Department of Defense 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. There are approximately 287 MEDCOM 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 (C/B-RRT) and are ready to deploy worldwide within 4 hours after receiving their orders. The RMC Chemical/Biological SMARTs are trained medical teams located at the RMCs that can deploy in response to a chemical, biological, or radiological 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, C/B-RRT and the Interagency Response Task Force. Both the MCBAT and regional Chemical/Biological 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 RMC Chemical/Biological 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 team is tasked to support each specific mission. Personnel available for deployment consist of physicians, a nurse, toxicologists, veterinarians, and laboratory specialists. These personnel, when coupled with their supporting capabilities, are knowledgeable in the medical effects of a specific chemical warfare agent, 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 casualties, and technical expertise to accomplish mission planning.

USAMRIID has developed the capability to deploy an Aeromedical Isolation Team (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 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 asset that USAMRIID has is the Biological Threat Response Cell (BTRC). The BTRC is designed to respond to any CONUS or OCONUS biological warfare or biological terrorist event. The cell is composed of the Deputy Commander as OIC/POC, the Operational Medicine physicians and the AIT, selected scientists and clinicians, a Biological Safety Officer, a logistician and an engineer. USAMRIID also provides consultants to the Chem-Bio Rapid Response Team as members of the MCBAT.

As a supporting capability, USAMRIID has a 16-bed ward with the capability of isolating (up to 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 requiring this level of containment. 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. An additional supporting capability at USAMRIID is its capacity for medical diagnostic assays for recognized biological agents.

MEDCOM has also taken the initiative to provide a standardized decontamination equipment, documentation, and personnel training package for the command's fixed medical treatment facilities. This equipment and training will provide a decontamination capability at all Army fixed medical treatment facilities for a CBRNE event. The intent is to standardize a minimum level of decontamination capability by providing the same decontamination equipment and training to each medical treatment facility.

4.6.6 Medical Countermeasures and Surveillance against CBRN and other Battlefield Toxicants and Occupational Health Hazards

Historically, most veterans' health and benefit issues are related to service in combat operations. U.S. forces are now more likely to deploy into non-combat environments such as peacekeeping, peacemaking, humanitarian assistance, or training. Presidential Review Directive (PRD)/National Science and Technology Council (NSTC)-5 directs DoD, the Department of Veterans Affairs, and the Department of Health and Human Services to review policies and programs and develop a plan that may be implemented by the Federal government to better safeguard those individuals who may risk their lives to defend our Nation's interests. An NSTC Interagency Working Group oversaw the work of four task forces that focused on (1) deployment health, (2) record keeping, (3) research, and (4) health risk communication.

DoD policy that requires pre- and post-deployment health assessments, screenings, and briefings shall be performed active and reserve component personnel deployed as a result of a Joint Chiefs of Staff/Unified Command deployment order for 30 continuous days or greater to a land-based location outside of the United States that does not have a permanent U.S. military treatment facility. Routine shipboard operations that do not involve field operations ashore for over 30 days are exempt from this policy. The details for completing these assessments are found in JCS Policy Memorandum MCM-251-98, 4 December 1998, subject: Deployment Health Surveillance and Readiness; ASD(HA) Policy Memorandum, 6 October 1999, subject: Policy for Pre- and Post-Deployment Health Assessment and Blood Samples; and DoD Instruction 6490.3, "Implementation and Application of Joint Medical Surveillance for Deployments," August 7, 1997.

Deployment can encompass a wide range of missions in which additional operations in CBRN environments may expose a Joint Task Force to other toxic chemicals, radiological contamination, and environmental contamination from industrial operations within the host nation. Standard U.S. occupational health and environmental standards are not enforceable in a host nation scenario. As a result, the JFC has been confronted with toxic industrial chemicals, radiological hazards, and long-term environmental contamination from industrial operations within the host nation. The Joint Force Commander must utilize organic CBRN reconnaissance and preventive medicine medical surveillance assets to identify host nation occupational and environmental hazards and to determine troop deployment locations that will minimize the short- and long-term health risk during occupation by U.S. forces. This type of information, if not provided by the host nation, is available from the Armed Forces Medical Intelligence Center (AFMIC) and the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). Joint medical surveillance within the theater of operations can identify CBRN related occupational, industrial, and environmental health hazards. Factors to be considered will include the type of contamination and the prevailing wind direction. Proposed planning factors

for downwind hazard distances for some commonly known industrial chemicals are provided in the USACHPPM Technical Guide 230A, “Short-Term Chemical Exposure Guidelines for Deployed Military Personnel”. The technical guide is to be used as a tool to assess potential adverse health impacts resulting from exposure to harmful chemicals as a result of uncontrolled industrial release, sabotage, or from the intentional or unintentional actions of enemy or friendly forces. Preventive medicine assets within the theater can be employed to conduct joint medical surveillance and to provide recommendations to the Joint Force Commander for risk communication to minimize the short-term and long-term health effects of toxic exposures to deployed military personnel. DoD Directives (6055.1 and 6490.2) and Instruction (6490.3) apply to joint medical surveillance and safety and occupational health in a CBRN or otherwise contaminated environment.

The Joint Publication 3-11, *Joint Operations in a Nuclear, Biological, and Chemical Environment* sets forth principles to assist commanders and staffs to plan for and conduct joint, multinational and interagency operations in which their forces may encounter the employment or threat of CBRN weapons and other toxic materials. It has taken into account new DoD and JCS policies, directives, and instructions for joint medical surveillance and risk communication. New DoD standards and guidelines are being developed for accurate risk communication. The Assistant Secretary of the Army for Installations and Environment, ASA(I&E), is the DoD Executive Agent for developing these new DoD nuclear, biological, chemical, and environmental (NBC-E) force health protection policies. ASA(I&E) is staffing a new Army policy entitled “Medical Force Protection: Environmental and Occupational Health Threats Policy.” The need for this new policy was identified during the 1999 Medical Functional Area Assessment and was validated by the Deputy Chief of Staff for Operations, Headquarters, Department of the Army, in a 23 July 1999 memo to the ASA(I&E). This new policy for force health protection is urgently needed to permit the development of appropriate U.S. Army doctrine, detection standards, and risk communication guidelines for use by commanders to protect soldiers from battlefield toxicants and occupational health hazards during deployments.

4.6.7 Air Force Medical CBRN Teams

The Air Force Medical Readiness Re-engineering efforts have created eight specialty teams for CBRN Medical Defense. These teams include (1) Theater Epidemiology Team, (2) Radiological Assessment Team, (3) Wartime Patient Decon Team, (4) Medical NBC Defense Team, (5) Infectious Diseases Team, (6) Preventative Aerospace Medicine Team, (7) Biological Augmentation Team, and (8) In-place Patient Decon Team (USAFE). Following is a brief description of the capabilities provided by these teams.

The *Theater Epidemiology Team* (TET) provides (1) theater medical and environmental threat assessments, (2) theater disease surveillance and disease outbreak investigation, and (3) baseline environmental monitoring. The TET is a theater-level medical asset.

The *Radiological Assessment Team* (AFRAT) is composed of two Nuclear Incident Response Force (NIRF) Teams and one Radio analytical Augmentation Team. The NIRF Teams include health physicists, industrial hygienists, equipment technicians, and bioenvironmental technicians. The AFRAT provides comprehensive radiological monitoring, hazard evaluation, and health physics support in a radiological response operation. The AFRAT is a Service-level asset.

The *Wartime Patient Decon Team* (WMDT) is deployed in direct support of medical treatment facilities operating in CBRN threat environments. They construct and operate decontamination sites and facilities in the vicinity of the supported medical treatment facilities. The WMDT is deployed at the unit level to support a medical treatment facility. Currently, there are 33 complete teams (2 personnel packages and 1 equipment package each) in the Air Force inventory.

The *Medical CBRN Defense Team* consists of bioenvironmental engineering personnel. The team provides increased wing survivability through human health protection, supports medical facility operations, and works to prevent acute or chronic health hazards resulting from operations in a CBRN threat environment. It conducts CBRN surveillance, advises commanders on CBRN health effects, threat impact, protective action posture, recovery activities, and human health risk assessments. It also performs environmental sampling and analysis for force health protection purposes and participates in confirmatory identification process for suspected biological threat agents. Finally, it monitors and documents personnel exposures to CBRN agents.

The *Infectious Diseases Team* provides personnel that augment the capability to identify, control, report, and provide treatment for infectious diseases and biological warfare agents in the deployed theater. The Team is designed to be deployed to facilities with greater than 100 beds where a significant threat for biological warfare casualties or infectious disease exists.

The *Preventative Aerospace Medicine Team*: (PAM) (1) identifies, monitors and prevents disease and non-battle injury (DNBI), (2) performs health threat and risk assessment, such as communicable disease tracking, (3) performs health hazard surveillance, (4) controls health hazards through food, water and field sanitation inspections, and, (5) mitigates the effects and prevents DNBI. PAM teams are an integral to all deployed Air Force medical treatment facilities. There presently are 35 teams in the inventory, and can deploy in increments of two to nine personnel. PAM teams operate at the unit level, while the TET serves as a theater medical asset.

The *Biological Augmentation Team* (BAT) is a two-person team, comprised of a skilled medical laboratory officer and enlisted personnel, which provide rapid pathogen identification using nucleic acid-based identification diagnostic capability. The BAT Team can analyze clinical samples, such as food and water, for pathogens of operational concern. The team is modular so that it may augment other teams, capabilities, and facilities. There are currently 59 approved BATs in the Air Force, of which 35 are fully equipped and trained.

The *In-place Patient Decon Team* supports five U.S. Air Forces in Europe (USAFE) medical treatment facilities (MTF). Nineteen-member teams provide manpower to remove or neutralize, to the extent possible, CBRN agents on wartime casualties prior to being admitted to an MTF. Can decontaminate some medical equipment and perform limited, spot decontamination of medical vehicles.

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 CB defense readiness beginning in July 2001. GSORTS is in place and operational at the Joint level. GSORTS provides information from Unit Commanders on

CB 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 CB 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, the Combatant Commanders of the Unified Commands submit readiness assessments at each Joint Monthly Readiness Review (JMRR). In the JMRR, Combatant Commanders assess the readiness and capabilities of their command to integrate and synchronize forces in executing assigned missions. As needed, Combatant Commanders address CBRN defense readiness and deficiencies as part of the JMRR.

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.

4.8 CB DEFENSE READINESS AND TRAINING ASSESSMENT

ISSUE: The Government Accounting Office (GAO) published a report, *Chemical and Biological Defense: DoD Needs to Clarify Expectations for Medical Readiness*, GAO-02-38, October 2002. The Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) established a tri-Service Integrated Process Team (GAO-IPT) to monitor DoD initiatives to implement the GAO's recommendations. The GAO-IPT continues to report to the OASD(HA) and the Senior Military Medical Advisory Council. 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. OSD(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 CB 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 develop and maintain information management systems to monitor completion of required CB 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 NORTHCOM'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 CB 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, 2003, 148 countries, including the United States, had signed and ratified or acceded to the CWC.

5.2 DEPARTMENT OF DEFENSE IMPLEMENTATION OF THE CWC

Since the CWC entered into force, DoD has hosted more than 390 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 worldwide 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. As of January 1, 2003, 876 USG personnel have 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 and, as of January 1, 2003, the OPCW had conducted 39 inspections.

DoD conducts a Chemical Weapons Agreements Implementation Working Group (CWIWG) to implement the CWC. Through regularly recurring meetings, representatives of the Office of the Secretary of Defense (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 was tasked to destroy all chemical warfare materiel under the Program Manager for Chemical Demilitarization (PMCD). PMCD includes programs for unitary stockpile destruction, destruction of bulk agent by alternative technologies (non-incineration), destruction of other chemical warfare materiel and the destruction of former CW production facilities. There is a separate Army program to demonstrate alternative technologies to destroy assembled CW munitions. The Army coordinates closely with the OSD to ensure that these programs are 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 211 currently assigned OPCW TS inspectors have attended HSO training; 90 of the 211 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 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, 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.

DoD organized a tabletop challenge inspection exercise in 2002. DoD's overall objective was to analyze and improve the processes by which the United States 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. DTIRP provides training and awareness services through such fora as seminars, site assistance visits, mock inspections, mobile training teams, industry associations, national conventions and symposia. DTIRP also publishes various educational products (electronic media and print) and administers electronic bulletin boards to provide information concerning the CWC to government and industry. DTIRP, in close coordination with the Naval Surface Warfare Center at Indian Head, Maryland, has produced and conducted the Chemical Technology Security Course, to train USG personnel and government contractors. As of January 2003, 280 individuals have completed the Chemical Technology Security Course.

The DTIRP has provided, and will continue to provide, arms control vulnerability assessment teams in support of any requirement to assess risks to national security and United States industry and research institutions such as those required under Public Law 106-113, §1124.

The DTIRP also provides the US Army's Soldier and Biological Chemical Command (SBCCOM) with site specific training targeted at the Site/Depot Commander, Treaty Compliance Officers, supervisory personnel, and anyone who performs duties involved with the CWC. This treaty training is designed to be tailored specifically to the nine different declared chemical storage facilities located in the United States to meet their unique requirements. It focuses on transitioning from a preparation mode to a sustainment mode of operation.

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 performs chemical agent monitoring of inbound equipment for all OPCW inspection teams at the Point of Entry to protect U.S. personnel and to prevent inaccurate findings as a result of pre-existing contaminants on the 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

DTRA conducts research, development, test and evaluation (RDT&E) to support U.S. roles in global CW arms control and nonproliferation initiatives. The primary goal of the program is to protect DoD equities and minimize the threat to national security interests posed by U.S. involvement in CW arms control activities. Related objectives are to assist the United States in meeting legal obligations imposed by treaty provisions, support development of U.S. policy, minimize implementation costs, enhance the safety of inspections and conduct research and development (R&D) on enabling technologies for future treaties or nonproliferation initiatives. Current emphasis is on technologies and procedures for on-site analysis under the CWC, development of advanced non-destructive evaluation, and environmental characterization of the emerging CW threat.

DTRA developments to date include analytical software for use in chemical analysis by gas chromatography/mass spectrometry (GC-MS). This software satisfied a critical requirement to prevent the release of potential sensitive or confidential business data during CWC inspections. Additionally DTRA has developed and fielded non-destructive analysis technologies that have been employed as confidence building measures under the CWC. These technologies have also demonstrated their multi-functional role in other nonproliferation related efforts such as United Nations Special Commission (UNSCOM) inspections in Iraq and support to law enforcement agencies at various events. DTRA, in cooperation with Finland, also continues to develop and validate procedures for GC-MS sample preparation and finalized Version 3.0 of these procedures in support of Senate Ratification Condition 18 of the CWC. Finally, DTRA is partnered with the intelligence community in the evaluation of new threat agents and their degradation pathways.

Annex A

Contamination Avoidance Programs

Table A-1. Contamination Avoidance RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN	
Automatic Detectors and Monitors	- M22 Automatic Chem Agent Detection Alarm (ACADA)	Production	Joint	Joint	Joint	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 Point Detection						
	--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		
	-- Block II	RDTE	Joint	Joint	Joint		
	- 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.19 Chemical Imaging Sensor	DTO					
	- CB.35 Standoff Biological Aerosol Detection	DTO					
- CB.49 Integrated CB Standoff Detector	DTO						
NBC Recon	- Joint Service NBC Reconnaissance System (JSNBCRS)	RDTE					
	--NBCRS/CB Mass spectrometer	*	Rqmt		Rqmt		
	--Joint Service Light NBCRS/Lightweight Recon System (JSLNBCRS)	*	Joint	Joint	Joint	Interest	
	- Interim Armored Vehicle-NBC Recon Vehicle (NBCRV Block II)	RDTE	Joint				
- CB.53 Wide-Area Aerial Reconnaissance for Chemical Agents	DTO						
Radiation Detection	- AN/UDR-13 Pocket Radiac	Production	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				
	- ADM-300A	Fielded		Rqmt			

Joint= Joint Service requirement

Rqmt= Service requirement

Rqmt Interest= requirement or interest in sub-product

LRIP= Low Rate Initial Production

Joint*=Draft Joint Service requirement

Interest = Service interest, no imminent requirement

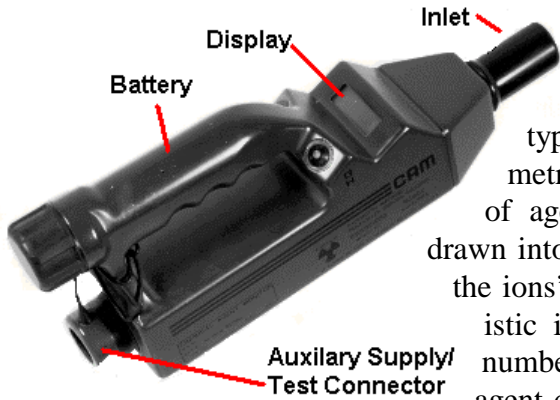
*= Sub-product(s) of a Joint project

DTO=Defense Technology Objective (Science & Technology Base 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.

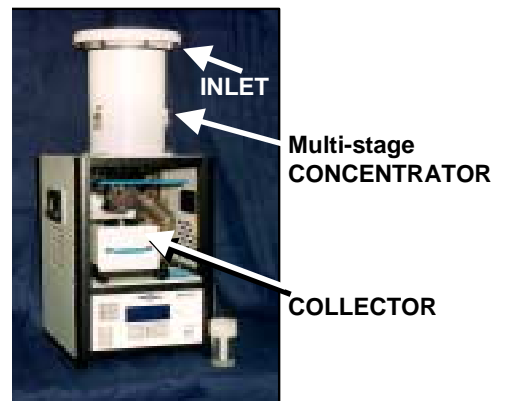
M31 Biological Integrated Detection System (BIDS)

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 (*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), will be fielded at Ft. Hood, Texas.

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 DoD's first networked biological detection system. Portal Shield is a Joint Service capability for biological detection at 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. The Joint Portal Shield (JPS) has been deployed to a total of nine sites in Southwest Asia (SWA) and Northeast Asia (NEA). Initial fielding of twelve additional sites began in FY02. In addition the systems have a chemical sensor interface (M22, M21, M90), which provides an integrated chemical and biological sensor network capability.

The JPS program was initiated in FY96 as an Advanced Concept Technology Demonstration (Air Base/Port Biological Detection ACTD). With a successful Military Utility Assessment (MUA) in FY97, a fielding in FY98 in support of Operation Desert Thunder and a Directed Procurement memorandum from The Office of the Joint Chiefs of Staff, a Milestone III review was held and approved in Jan FY99. The MS III transitioned the program from an ACTD into production and the system was approved for the fabrication, installation, and support at high value fixed sites overseas. The fielding (237 sensors) when completed will provide coverage at 21 fixed sites.

The Commanders of the United States Central Command (CENTCOM) and Pacific Command (PACOM) are the operational sponsors of the JPS program. Contractor Logistics Support person-

nel are on-site at fielded locations in the CENTCOM and PACOM theaters of operation to maintain and repair JPS equipment. In FY02 the Service sites began transition of operations and sustainment (O&S) support from the PEO-CBD to a Service responsibility. In FY03 all O&S support will become a Service responsibility.

Joint Biological Point Detection System (JBPDS), Block I

JBPDS provides point biological detection capabilities for all four services throughout the battlespace. The system, which complements Joint Portal Shield and P3I BIDS and replaces the NDI-BIDS and IBAD, is both more reliable and sensitive than all predecessor systems. The sensor's highly maintainable and modular design detects and presumptively identifies ten BW agents simultaneously in less than 20 minutes. This program is developing 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 Man Portable, the XM97 Shelter, the XM98 Shipboard, and the XM102 Trailer Mounted for airbase, vehicle, surface combatant 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 (by virtue of a parallel Block II Spiral Development effort) with the latest advances in the biological detection/identification, information processing and engineering sciences.



Fielding of JBPDS Block I is scheduled for FY03. In response to the national emergency, a network of 8 JBPDS Block I 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 were deployed in a commercial trailer configuration that was jointly developed and produced by the PM-JBPDS and the Edgewood Chemical/Biological Center (ECBC) of the U.S. Army Soldier, Biological, Chemical Command (SBCCOM).



JBPDS Urban Variant

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, cannot be reused once fluid is applied, and must be disposed of as medical waste. All HHA results must be confirmed by a “Gold Standard” laboratory.



DoD Biological Sampling Kit

The DoD Biological Sampling Kit, 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 4°C, has a one-time use only capability, and is not for diagnostic use. All components of the DoD Biological Sampling Kit must be disposed of as medical waste. All HHA results must be confirmed by a “Gold Standard” laboratory.



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 (*shown*) comes in 4" x 2½" 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 (*shown right*) is rolled into 2-inch wide by 30-foot 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.

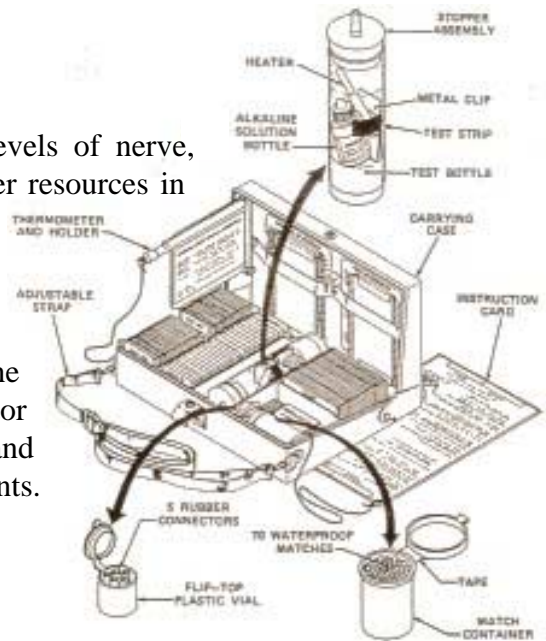


M18A3 Chemical Agent Detector Kit

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 $\frac{1}{2}$ " x 5 $\frac{1}{2}$ " x 11". Using the battery in ground mounted operations adds another 7 $\frac{3}{4}$ " to the height. The M43A1 detector unit uses a radio-isotope 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 $\frac{1}{3}$ ". 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.

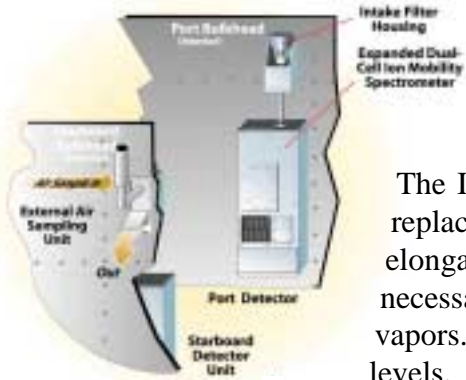
M90 Automatic Agent Detector (AMAD)

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.



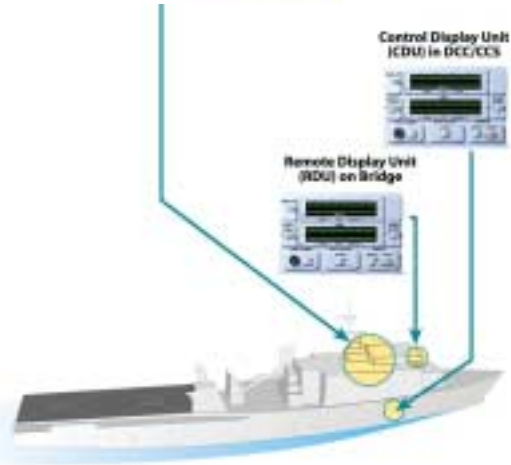
Chemical Agent Point Detection System (CAPDS), MK21, MOD1

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 system has been installed on almost all surface ships.



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 interferent 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.



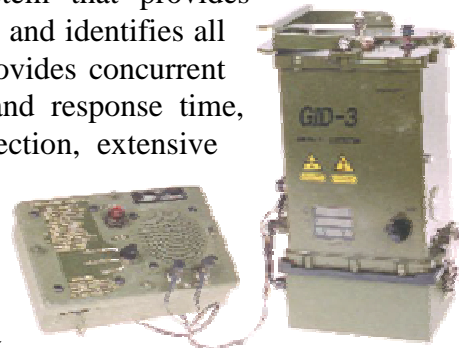
M22 Automatic Chemical Agent Detection Alarm (ACADA)

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.



Shipboard ACADA

The ACADA consists of an off-the-shelf non-developmental item (NDI)—the GID-3 chemical agent alarm. A shipboard version of the ACADA is being built to address the unique interferences 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.



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 DTO 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 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. 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.

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

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

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. While this may or may not be a significant factor for chemical agents, it is extremely challenging for biological agents. Current biological detection technologies rely on analytical techniques, which range in processing times from hours to days. 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.

FY2003: Complete down selection of technology for the detection of chemical agents in potable water. Continue technology development of detection of biological agents in potable water to include sample processing and preparation.

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.

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 (requirements and materiel development lead), 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.

Joint Biological Point Detection System (JBPDS) Block II

Biological Point Detection is a fully cooperative acquisition effort chartered to develop new biological point detectors and detection systems for the four services. The BIDS effort encompasses development of an integrated system as well as several stand-alone biological detectors. In addition, a Joint Biological Point Detection System (JBPDS) is under development. JBPDS will be a system that can stand alone, or be used in a suite of systems.

Rationale:

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

Key Requirements:

- Automatically detect, identify and warn of the presence of biological warfare and produce a sample for transport to and further analysis by designated laboratories.
- Simultaneously identify eight to ten agents with and interchangeable library of assays for all ITF-6 agents.
- Detect cloud concentrations better than Block I and/or militarily significant levels of BW agents at a detection probability of 90% in less than five minutes.
- Provide a common suite of biological detection equipment that can be applied to all four services' designated platforms
- Reliability of 0.92.
- Availability of 0.90.
- Mean Time Between Operational Mission Failure of 288 hours
- Mean Corrective Maintenance Time for Operational Mission Failure Repair of 5 hours or less.

Description:

This operational level biological detection system will provide significant enhancements in number of agents detected and identified with increased sensitivity and lower false positive rates. The system will be smaller and lighter with increased reliability. This developmental system will replace all existing biological detection systems (BIDS, IBAD and the Joint Portal Shield Network System), and complement the JBPDS Block I in the field. It will provide biological detection capabilities for all four services and throughout the battlespace. The Block II JBPDS program will undertake a spiral development process to exploit rapid advances taking place in the biological detection and

identification, information processing and engineering sciences. The Block II Development effort will yield technology advancements and insertions into the Block I Production effort and provide for the fastest possible fielding and upgrade of joint biological detection capabilities. The PM, JBPDS plans to award a Development contract in FY03 for the design, integration and fabrication of Block II JBPDS. Block II Low Rate Initial Production is anticipated to start in FY06, with first unit equipped in FY07.

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), Electrochemilluminescence Assays (ECLAs), Polymerase Chain Reaction Assays (PCRA), 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 PCRA.
- 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, PCRA, 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 12 additional reagents to support the development and fielding of JBPDS Block II and 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 war fighters 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. 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.

FY2003: Conduct Analysis of Alternatives on multiplex/multi-agent (MMA) PCR assays; determine the number of assays needed in a single tube to be cost-effective, the number of assays currently possible in a single tube, and identify the limiting factors. The analysis also includes a multi-variable study on parameters like taggant chemistry, number of gene targets for each agent, compatibility of gene targets between agents, and other factors that can potentially impact the number and choice of gene sequences for multiplexing. Demonstrate current state-of-the-art MMA PCR assay(s).

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.

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 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 also 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.

FY2003: Develop and evaluate technologies, primarily physical methodologies such as optical spectroscopy and other physical approaches. Develop and populate database for downselection criteria.

FY2004: Conduct a Technology Readiness Evaluation (TRE) to obtain and complete information for the downselection database. Downselect to two or three technologies.

FY2005: Transition downselected technology to Advanced Concept Development, design brassboards, and initiate brassboard builds. Complete Milestone A.

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. The successful completion of this DTO 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.

Milestones/Metrics.

FY2003: Perform preliminary down-selection of technologies to include factors such as performance, logistics, platform, operational concerns, maturity, and cost. Initiate construction of breadboard(s) to demonstrate the capability to detect chemical agents at a deposition of 0.5 g/m² and operationally significant biological agent contamination levels to be determined.

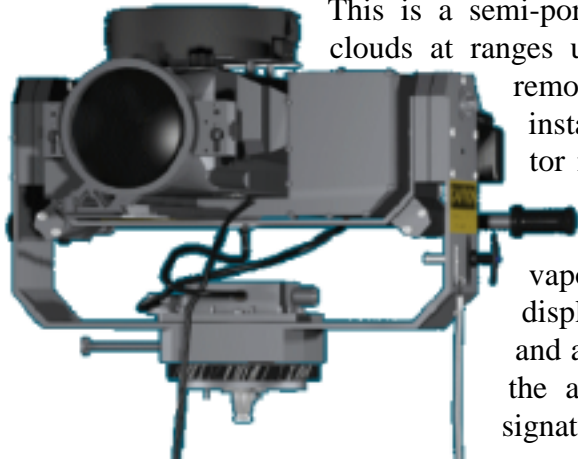
FY2004: Complete construction and conduct initial characterization of breadboard(s) to demonstrate the capability to detect chemical agents at a deposition of 0.5 g/m² and operationally significant biological agent contamination levels. Perform final down-selection.

FY2005: Upgrade and test breadboard(s) based on results of characterization. Demonstrate the capability to detect chemical agents at a deposition of 0.5 g/m² and operationally significant biological agent contamination levels.

STAND-OFF DETECTION AND REMOTE/EARLY WARNING

FIELDDED AND PRODUCTION ITEMS

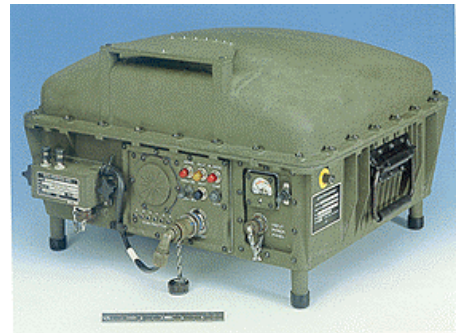
AN/KAS-1/1A Chemical Warfare Directional Detector (CWDD)



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 (requirements and materiel development lead), 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 FY02, DoD initiated a test and evaluation program on the Mobile Chemical Agent Detector (MCAD) as a one-year effort in response to a Congressional request. The program used a sole-source contract to procure existing MCAD prototype in order to determine whether MCAD is 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 (requirements and materiel development lead), 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.

DTO CB.19 Chemical Imaging Sensor

Objectives. The objective of this DTO, which was completed in FY02, was to develop and demonstrate a lightweight wide-area passive standoff imaging detection system. Three significant technical barriers were overcome: high-speed interferometry, imaging chemical detection, and light weight sensor design. The chemical imaging system (CIS) sensor package weighs less than 15 pounds. It was designed using a unique 4-mirror approach that proved to be both rugged and reliable. A focal plane array (FPA) was used in place of the traditional single-pixel element used in commercial fourier transform infrared (FTIR) spectrometers. This gave rise to a high-speed imaging capability. Frame rates were incrementally improved over the course of the DTO beginning at 30 Hz in FY98, to 100-Hz in FY00, and finally 360 Hz in FY02. The final FPA format was a high-sensitivity 2x8 IR element. This provided a unique capability: a high-speed imaging FTIR spectrometer. The advantage to this approach over previous imaging designs is that FTIR provides enhanced detection sensitivity and high spectral resolution. The challenge of multi-element FTIR signal processing was overcome by the development of data acquisition systems that demonstrated the feasibility of real-time signal processing at 100-Hz frame rates. The most obvious payoff is the ability to provide a visual map of a chemical threat over a wide area. At a 1-kilometer standoff range the CIS can see a 50x200 meter image in comparison to current fielded passive standoff technology that is limited to a narrow 25x25 meter cell. The high-speed interferometer technology also provides a payoff in both deployment and operational capability. This lightweight sensor can easily be mounted on a low-altitude airborne platform and provide overhead maps without blurring the image. It can also operate from ground-based platforms and scan fast enough to perform on-the-move detection. The CIS was demonstrated on the ground in fixed-site field experiments and airborne aboard a UH1 helicopter.

DTO CB.49 Integrated CB Standoff Detector

Objectives. This DTO will develop a single technology capable of detecting and discriminating CB aerosols, vapors, and rains at operationally significant concentrations in standoff mode.

Payoffs. The technology will provide an affordable, multi-platform reconnaissance and contamination avoidance capability against airborne CB agents in all physical forms.

Challenges. Significant progress has been made in both the biological and chemical standoff detection arenas. Despite this, significant challenges remain, especially in terms of developing a cost-effective integrated capability, as well as in both arenas individually. Chemical aerosol/rain detection remains a challenge due to the complicating factors of particle size distribution, particle shape, and vapor pressure. Integrated CB detection harbors several additional challenges such as size, weight, power, and developing wide optical bandwidth optics and transmitters.

Milestones/Metrics.

FY2003: Conduct the initial downselection of the potential technologies. The downselection process will include factors such as performance, logistics, platform, operational concerns, maturity, and cost. Initiate the development and testing of higher risk subcomponents of the selected technologies to minimize the risk in the later breadboard development phase phase to demonstrate the capability to detect chemical agents at a concentration of 135 mg/m² and biological agents at a concentration of

DTO CB.49 Integrated CB Standoff Detector

3,000 agent containing particles per liter of air (ACPLA) at a range of 1 km.

FY2004: Complete development and testing of the higher risk subcomponents to project the capability to detect chemical agents at a concentration of 135 mg/m² and biological agents at a concentration of 3,000 agent containing particles per liter of air (ACPLA) at a range of 1 km. Complete the final downselection of the most promising technology(ies). The final downselection will be supported by the results and data obtained in the previous subcomponent development phase.

FY2005: Initiate breadboard construction of the final downselected technology(ies) to demonstrate the capability to detect chemical agents at a concentration of 135 mg/m² and biological agents at a concentration of 3,000 agent containing ACPLA at a range of 1 km.

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 is requirements and materiel development lead)

Key Requirements:

- Detect and track aerosol clouds out to 15 km
- Discriminate biological particles from non-biological particles in aerosol clouds out to 3 km
- Operate at fixed site or in stationary mode from mobile platform
- Operate in conjunction with bio point detectors
- Operationally skin and eye safe

Description:

The JBSDS will be a standoff early warning biological detection system. The system will be capable of providing near real time, on-the-move detection of biological attacks/incidents and standoff early detection/ warning of BW agents at fixed sites or when mounted on multiple platforms, including NBC reconnaissance platforms. It will be capable of providing standoff detection, ranging, tracking, and discrimination (bio vs. non-bio) of BW aerosol clouds for advanced warning, reporting and protection. JBSDS will be employed to provide detection of biological hazards employed by various means and will provide early warning via the Joint Warning and Reporting Network (JWARN). JBSDS will augment and integrate with existing biological detection systems to provide a biological detection network capable of near real time detection and warning theater-wide to

limit the effects of biological agent hazards against U.S. forces at the tactical and operational level of war. JBSDS will have the flexibility to warn automatically or to allow for human intervention in the detection-to-alarm process. JBSDS will be employed in support of various areas of interest (*e.g.*, fixed sites, air/sea ports of debarkation, amphibious landing sites, *etc.*), remotely, in unattended configurations, or on platforms to include vehicles, aircraft, and ships. JBSDS will pass detection information and warnings through existing and planned communications networks (*e.g.*, JWARN). Commanders may integrate JBSDS outputs with information from intelligence, meteorological and oceanographic, radar, medical surveillance, local area operations, and other available assets to increase force protection, mitigate the consequence of biological hazards, and maximize combat effectiveness.

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. 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.

FY2003: Initiate construction and characterization of breadboards to demonstrate the capability to detect and discriminate (bio vs. non-biological agents at a concentration of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km based on the results of the downselect and user input.

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 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. Optimize overall system performance based on test results.

NBC RECONNAISSANCE

FIELDDED 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.



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.

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

NBC Reconnaissance Vehicle (NBCRV) Block II

Rationale:

- U.S. Army and U.S. Marine Corps Requirements

Description:

The Block II modification 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. The NBCRS Block II Program will provide CB Sensor Suites to the NBCRV Program, which 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 and materiel development lead) 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. 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). 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.

FY2003: Perform airborne phenomenology tests with existing hyperspectral imaging sensors (100-Hz, 2x8 TurboFT and 0.3-Hz, 128x128 AIRIS). Complete engineering designs for a 30-Hz, 64-pixel TurboFT, and a 3-Hz, 128x128 AIRIS.

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.

RADIATION DETECTION (RADIACS)

FIELDED AND PRODUCTION ITEMS

AN/VDR-2

The AN/VDR-2 measures gamma dose rates from 0.01 $\mu\text{Gy/hr}$ (micro-Grays per hour) to 100 Gy/hr and beta dose rates from 0.01 $\mu\text{Gy/hr}$ 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 - Production (FUE FY99)

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 -Production



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 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

DTO CB. 38 Activity-Based Detection and Diagnostics

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.

FY2003: Insertion, testing, and evaluation of prototype of high throughput cell based assays for testing the chemical and biological threat list in air, water, and medical samples.

DTO CB.41 Biological Warfare Defense Sensor Program

Objectives. The objective of this DTO, which was completed in FY02, was to develop a fully integrated, well-characterized sensor system for the effective real-time detection of biological warfare (BW) agents to enable pre-exposure detection and discrimination. This DTO will demonstrate advanced warning of specific active exposure to BW agents, and an "all clear" assessment after the use of appropriate decontamination/neutralization countermeasures. The critical challenge is to produce sensor systems that are sufficiently fast and selective to permit an accurate low-false-alarm, high-probability-of-detection decision to be made in a sufficiently timely manner to permit proactive protection of military personnel. To accomplish this task, the fabrication of the first-generation automated time-of-flight mass spectrometer and its characterization for a limited number of BW agents and backgrounds was completed in FY01. In FY02, the characterization will be extended to more species and strains of threat agents, and the optimization of the system to minimize the false alarm rate was investigated.

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:

- Sequencing and analysis of the pathogenic bacteria *Brucella suis*, *Coxiella burnetii*, *Burkholderia mallei*, *Rickettsia typhi*, and several orthopoxvirus variants is nearing completion.
- Random phase sequencing via low-level coverage of *Ochrobactrum anthropi*, a near neighbor of *Brucella suis* was completed.
- Random phase sequencing with high level coverage of *Bacillus cereus* and *Bacillus thuringiensis*, near neighbors of *Bacillus anthracis* was completed.
- Re-initiated sequencing of *Franciscella tularensis* in FY01 with completion in FY02. Sequence information is available via National Library of Medicine for all but *O. anthropi* (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=Genome>).

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 electrochemical 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) -- Multipurpose Integrated Chemical Agent Detector (MICAD)	RDTE/Prod Fielded*	Joint <i>Rqmt</i>	Joint	Joint <i>Rqmt</i>	Joint <i>Rqmt</i>
Hazards Analysis Systems	- Vapor, Liquid and Solid Tracking (VLSTRACK) - Chemical Warfare Naval Simulation (CWNAVSIM) - MESO - CB Warfare Computational Fluid Effects (CBW-CFX) - Hazard Prediction and Analysis Capability (HPAC) - Joint Effects Model (JEM) - CB.42 Environmental Fate of Agents - BE.10 Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction - CB.55 Chemical and Biological Hazard Environment Prediction	RDTE/Fielded RDTE RDTE RDTE Fielded RDTE DTO DTO DTO	Joint* Joint* Joint* Joint* Joint*	Joint* Joint* Joint* Joint* Joint*	Joint* Joint* Joint* Joint* Joint*	Joint* Rqmt Joint* Joint* Joint* Joint*
Operational Effects Analysis Systems	- Simulation Training and Analysis For Fixed Sites (STAFFS) - Joint Operational Effects Federation (JOEF) - Joint Medical NBC Decision Support Tool (JMNBCDST) - CB.43 Chemical and Biological Warfare Effects on Operations	RDTE RDTE RDTE DTO	Joint* Joint* Joint*	<i>Rqmt</i> Joint* Joint*	Joint* Joint* Joint*	Joint* Joint* Joint*
Simulation Based Acquisition Systems	- NCBR Simulator - Virtual Prototyping System (VPS)	RDTE RDTE	Joint* Joint*	Joint* Joint*	Joint* Joint*	Joint* Joint*
Training Simulation Systems	- Virtual Emergency Response Training System (VERTS) - Training Simulation Capability (TSC)	RDTE RDTE	Joint* Joint*	Joint* Joint*	Joint* Joint*	Joint* Joint*

Joint= Joint Service requirement
Rqmt= Service requirement

Joint*=Draft Joint Service requirement
Rqmt = sub-product requirement or interest
DTO=Defense Technology Objective (Science & Technology Base Program)

WARNING AND REPORTING

FIELDDED AND PRODUCTION ITEMS

Joint Service Warning and Reporting Network (JWARN) Block I (FUE FY 99)

Rationale:

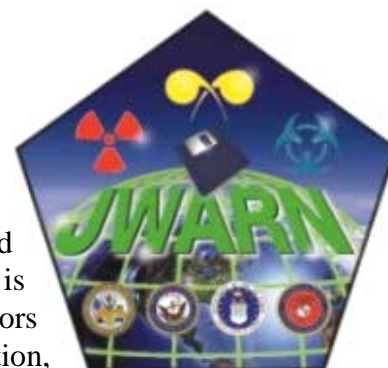
- Army, Navy, Air Force, and Marine Corps requirement

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 (C⁴I²) 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)

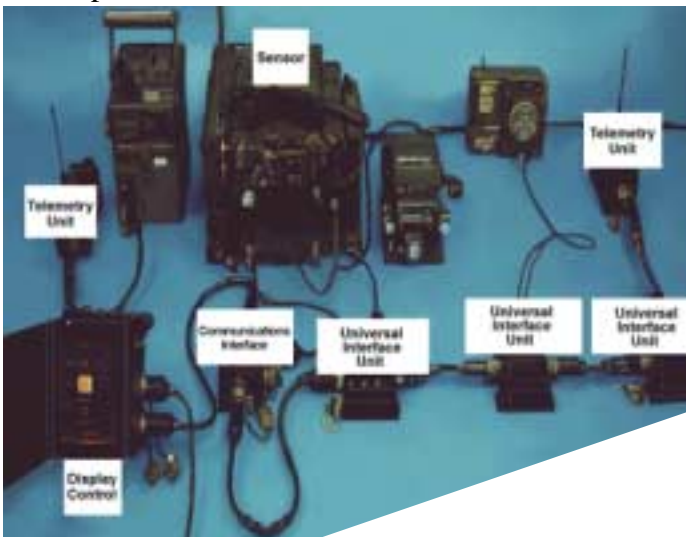
Rationale:

- 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 08)

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

FIELDDED 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. During FY03, 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. During FY03, 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 which 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 develop a validated chemical threat agent fate model that is capable of accurately predicting the persistence of hazard (both contact and inhalation) due to a chemical agent dispersed on surface materials relevant to fixed site operational scenarios.

Payoffs. 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 model 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 master template for addressing persistence analysis for future novel chemical and biological threat agents. Results of this program will directly support numerous decision tools such as the Joint Effects Model (JEM) and Joint Operational Effects Federation (JOEF). During FY02, an initial literature survey was accomplished to collect, evaluate, and rate reports related to agent fate on surfaces testing and modeling capabilities. An existing surface evaporation database was converted to Oracle and expanded to include additional data from wind tunnel tests and field trials. Current modeling capabilities were evaluated via a parameter sensitivity analysis in order to focus data generation efforts. Laboratory, wind tunnel, and outdoor testing facilities were equipped to generate the data needed to develop, calibrate, and validate the target agent fate model. An Oversight Panel of experts evaluated the Agent Fate Research Program and provided documented recommendations for improvement.

Challenges. Formulation, standardization, and dispersing techniques for thickened agents are major technical hurdles. Determining and measuring processes within a porous surface requires new equipment and analytical techniques. Wind tunnel test conditions must be related to outdoor conditions that would exist on the fixed site.

Milestones/Metrics.

FY2003: Complete literature survey, produce bibliography report, and establish on-line reference tool. Complete construction of test matrix. Add data on painted and military materials to surface evaporation database. Determine VX (and variants) fate on/within concrete under laboratory conditions. Complete and document GD, HD, thickened GD, and thickened VX on concrete wind tunnel tests and field trials. Correlate wind tunnel and field trial characteristics using neat and thickened GD on a non-porous surface. Develop baseline model incorporating concrete results, wind tunnel-field trial correlation, and contact hazard capability.

FY2004: Perform and document neat and thickened GD and VX on asphalt tests on all scales and neat and thickened GD and VX on live grass wind tunnel tests and field trials. Refine model structure to include humidity, temperature, contact hazard, droplet spread, and droplet absorption data.

FY2005: Perform and document neat and thickened GD and VX on soil laboratory studies. Perform and document GD, HD, and VX on brackish water wind tunnel tests and field trials. Tests on painted surfaces may also be done, pending results from the literature survey. Refine model to utilize data from additional agent-surface combinations, and document final model methodology and capabilities.

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) have 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 will be determined. In cases where there is a significant disagreement in a value and no clear indicator which is the more valid, the parameters will be identified as an estimate used pending further experimentation or investigation.

DTO BE.10, Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction

Objectives. The objective of this DTO 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.

Payoffs. Current operational atmospheric observation and prediction systems do not have sufficient resolution, speed, geographical coverage, or altitude range needed to provide a robust, accurate, validated operational capability to predict the effects of chemical and biological agents over the range of militarily significant time and space scales. Lack of near-real-time high-resolution weather support means that fast response hazard predictions essential for contamination avoidance, protective posture, and consequence management have high uncertainty at the time they are most critical, i.e., at the time of an incident and shortly thereafter. Deficiencies in atmospheric modeling systems will be addressed by: increasing vertical resolution near the surface (approx.-3X) and at high-altitudes, i.e. above 30 km for theater ballistic missile threat application (past practice is to use climatology above 30km which can be quite different from current conditions); improving dispersion physics near the surface under stable night-time conditions and in complex terrain (both conditions are poorly handled at the current resolution of mesoscale models); assimilating on-scene observations into mesoscale forecasting systems to more accurately blend current conditions with modeled fields; increasing resolution and parameterization of radiation, turbulence, and precipitation physics (factors that affect agent fate and persistence); and utilizing high-resolution surface and terrain data. 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. A set of optimal engineering and operational practices will be developed to operate within the limits of available computing resources, and the modeling system will be verified and validated against field trial data for a realistic range of applications. The enhanced Nowcast system will provide forward-deployed land- and sea-based units with an organic capability to continuously update a local web-enabled JWARN (Joint Warning and Reporting Network) simulation using the latest available on-scene meteorological information. Nowcast provides the on-scene meteorological information by fusing the latest observation data (surface, upper air, aircraft, satellite, and radar) with objective analyses and short-range mesoscale weather predictions to maintain a time-varying, high-resolution, three-dimensional database of the environment. The environmental database is then sampled to provide the input wind, density, cloud, terrain, and precipitation fields for the Hazard Assessment and Prediction (HPAC) and Vapor, Liquid, Solid Tracking (VLSTRACK) models in JWARN. The user interface will be a simple JAVA applet with pull down folders to fully describe a simulated chemical or biological attack. JWARN will then run automatically when the database is updated through Nowcast.

Challenges. In the coupled (meteorological and dispersion) system, the primary challenge lies with the representation of realistic mesoscale meteorological fields in a consistent fashion at the appropriate

DTO BE.10, Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction

scales. A multisensor/multiscale approach is required in order to provide localized, on-scene weather information at tactical-scale spatial resolution. Additionally, as time-critical decisions are necessitated, the forecast capability should be tied to real-time observational nowcast and battlefield management systems (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 interferences 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.

FY2003: Demonstrate coupled CB agent dispersion models driven by high-resolution mesoscale wind fields and incorporate application in Nowcast system.

FY2004: Demonstrate improved turbulent parameterization and complex terrain methodology of CB dispersion models. Demonstrate improvement (approx. twofold) 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 (JEM), the next-generation CB hazard model.

DTO CB.55 Chemical and Biological Hazard Environment Prediction

Objectives. This DTO aims 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.

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

DTO CB.55 Chemical and Biological Hazard Environment Prediction

hazard prediction tools.

Milestones/Metrics.

FY2003: Transition VLSTRACK Version 4 capabilities to the JEM Block I and JOEF programs. Continue development of advanced predictive capabilities (MESO). Enhance the ability to analyze transport and flows over complex terrain and around structures such as ships (enhancements include addressing biological agent slurry transport, dusty agent behavior, and complex agent sources and sinks).

FY2004: Transition advanced predictive capabilities (MESO) 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 models such as MESO, CONTAM (an interior zonal model), and CBW-CFX. Incorporate methodologies for agent fate and persistence developed under DTO CB.42.

Joint Effects Model (JEM)

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)

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. 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 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.

FY2003: Preparation for transition of the fighterbase and casualty modules to Joint Operational Effects Federation (JOEF) program to support Block 1 Demonstration. Complete the first phase of independent verification of software by NSWC. Baseline RESTOP ACTD results as model validation. Deliver OSAN Airbase representation module and generic airbase module to DTRA/CB and DTRA/TD. Specific capability milestones and metrics: Fighter sortie scheduling and generation. Post-attack recovery CONOPS. Comprehensive chem-bio effects on personnel. Multiple-trial and multiple-case

DTO CB. 43 Chemical and Biological Warfare Effects on Operations

(batch) execution capabilities. Transportation route network capability.

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:

- Joint Army, Navy, Air Force, and Marine Corps requirement

Key Requirements:

- Evaluate proposed, prototyped, and fielded CB defense equipment (CBDE) via a simulation capability that accurately represents the contamination and operational environments for which they are intended.
- Represent standoff and point detection systems on stationary and mobile platforms in urban, rural, and littoral terrains.
- Detector representations will be reconfigurable and responsive to design and operations changes.
- Immersive simulation capability will allow evaluation of operator interfaces.
- Represent individual and collective protection systems in operational environments.

Description:

The VPS will provide the immersive capability to evaluate how the operating characteristics of proposed or developmental CBDE will affect the performance of the overall system. VPS will enable materiel developers to assess how proposed CB defense systems will provide increased capabilities. At a more detailed level it will allow system designers to assess the impact that design changes have on the overall system performance. The virtual immersive capability will enable human factors evaluations of operator interfaces long before the first prototype units of the developmental CBDE are built in hardware. All of these capabilities address the basic Simulation Based Acquisition tenet of enabling early and sustained user feedback throughout the system design process.

Performance assessments and evaluation will be enabled at the engagement and engineering levels of simulations. The trade space for evaluating technical options for system and component alternatives will be expanded. That evaluation will take place in a realistic synthetic or virtual operating environment. Human and live system in-the-loop capability will exist. Development will be based on current proof-of-concepts simulation used to support developmental, analysis, training and testing efforts. The envisioned simulation system will be able to operate at specific sites for focused evaluations or distributed to many sites for robust Joint Task Force (JTF) engagement assessments of engineering alternatives.

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 C⁴I²RS 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 (C⁴I²RS) 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.

(INTERNATIONALLY BLANK.)

Annex C

Non-Medical Protection Programs

Table C-1. Protection RDA Efforts

Category	Nomenclature	Status	USA	USAF	USMC	USN
Eye/ Respiratory Protective Masks	INDIVIDUAL 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	Production		Rqmt		Rqmt
Ancillary Equipment	- Joint Service Aircrew Mask (JSAM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service General Purpose Mask (JSGPM)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Protection Assessment Test System (PATS)	Production	Rqmt	Rqmt	Rqmt	Interest
	- Voice Communication Adapter	Production	Rqmt	Rqmt	Rqmt	Rqmt
Battlefield Protective Suits	- Joint Service Mask Leakage Tester	RDTE	Interest	Rqmt	Rqmt	Rqmt
	- CB.36 End-of-Service-Life Indicator for NBC Mask Filters	DTO				
	- CB Protective Overgarment Saratoga	Fielded	Interest		Rqmt	Interest
	- Chemical Protective Undergarment (CPU)	Fielded	Rqmt		Int-NIR	
	- Modified CPU (mCPU)	Production	Rqmt			
	- CMU-34P and CMU-35P (USN modified CPU)	RDTE				
	- Joint Service Lightweight Integrated Suit Technology				Rqmt	Rqmt
	-- Overgarment	Prod.*	Rqmt	Rqmt	Rqmt	Rqmt
	-- Boots (MULO)	Prod.*	Interest	Rqmt	Rqmt	Rqmt
	- Battledress Overgarment (BDO)	Fielded	Rqmt	Rqmt	Rqmt	Rqmt
- Battledress Overgarment (BDO)	RDTE	Rqmt	Rqmt			
- Joint Protective Aircrew Ensemble (JPACE)	RDTE					
- 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			
Tentage and Shelter Systems	COLLECTIVE PROTECTION:					
	- M20A1/M28 Simplified 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		Rqmt
	- CP Expeditionary Medical Shelter System (CP EMEDS)					
	- Joint Transportable CP System (JTCOPS)	Production	Rqmt	Rqmt	Rqmt	Rqmt
Collective Protection (CP) Systems	- CB.08 Advanced Adsorbents for Protection Applications	RDTE				
	- Shipboard Collective Protection System (CPS)	Production	Interest	Interest		Rqmt
	- Modular Collective Protection System (MCPE)	Fielded	Rqmt	Interest		Interest
	- M8A3 GPFU	Fielded	Rqmt			
	- M13A1 GPFU	Fielded	Rqmt	Rqmt		Rqmt
Generic Filters	- Joint Collective Protection Equipment (JCPE)	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- CB.40 Immune Building Program (DARPA)	DTO				
	- M48/M48A1 (100 cfm)	Fielded	Rqmt		Rqmt	Rqmt
	- M56 (200 cfm)	Fielded	Rqmt	Rqmt	Interest	Rqmt
	- Fixed Installation Filters	Fielded	Rqmt	Rqmt		Rqmt

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

RESPIRATORY

FIELDDED AND PRODUCTION ITEMS

M17A2 Protective Mask

The M17A2 Protective Mask consists of a natural blend rubber face piece; two activated charcoal filters mounted within cheek pouches; a voicemitter to facilitate communications, a drinking tube; eyelens outserts to protect the mask's integral eyelens and reduce cold weather fogging; an impermeable hood; and a carrier for the mask, its components, and medical items (such as the Nerve Agent Antidote Kit). The Army and Marine Corps are replacing this mask with the M40 series protective masks. The Navy has replaced the M17A2 protective mask with the MCU-2/P. The Air Force replaced it with the MCU-2A/P, but retained limited quantities of extra small M17A2s for those situations where the MCU-2A/P small size is too large.



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.



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 over-



garments, 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.

M43 Protective Mask

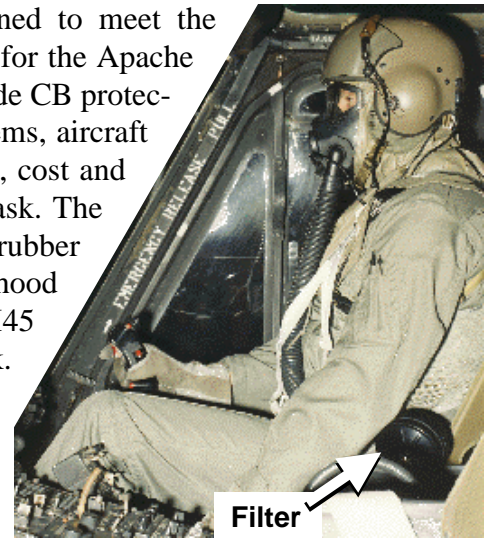


The M43 Aviator Mask consists of a form-fitting face piece with lenses mounted close to the eyes; an integral CB hood and skull-type suspension system; an inhalation air distribution assembly for air flow regulation, lenses and hood; and a portable motor/blower filter assembly that operates on either 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 aviators 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)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.



RESPIRATORY

RDTE ITEMS

Joint Service General Purpose Mask (JSGPM)

Rationale:

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

Key Requirements:

- 24-hour CB protection
- Lower breathing resistance
- Reduced weight and bulk

Description:

The JSGPM 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 future threats. The mask components will be designed to minimize the impact on the wearer's



performance and to maximize the ability to interface with future Service equipment and protective clothing.

Joint Service Aircrew Mask (JSAM)

Rationale:

- Joint Army, Navy (requirements lead), Air Force (materiel development lead), 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.

Joint Service Chemical Environment Survivability Mask (JSCESM)

Rationale:

- Joint Army (SOCOM), Air Force (requirements lead), Marine Corps, Navy (potential) requirement

Key Requirements:

- One size fits all
- For low threat area usage
- Limited protection (6 hours, limited agent concentrations)
- Small, lightweight
- Drinking capability



Description:

The JSCESM (*concept illustration shown*) is intended to 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.

ANCILLARY MASK EQUIPMENT

FIELDDED AND PRODUCTION ITEMS

M41 Protection Assessment Test System

The M41 Protection Assessment Test System (PATS) enhances operational capability by validating proper fit of the mask to the face of the individual. PATS provides a simple, rapid, and accurate means of validating the face piece fit and function of protective masks.



Voice Communication Adapter

The Voice Communication Adapter (VCA) is a low risk program providing additional capability to the M40/42 mask. The VCA is a joint program between the USMC and US 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. Both Services developed prototype designs and, after field user and human engineer testing, the Marine Corps design was selected. The Air Force is developing a second skin for the MCU-2A/P.

ANCILLARY MASK EQUIPMENT

RDTE ITEMS

Joint Service Mask Leakage Tester

The Joint Service Mask Leakage Tester (JSMLT) will be a man portable test system capable of checking the serviceability of a protective mask in the field. 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. The U.S. Marine Corps is the lead service for requirements.



Defense Technology Objective (DTO) CB. 36 End-of-Service-Life Indicator for NBC Mask Filters

Objectives. This DTO increases warfighter readiness and survivability through improved protection and sustainment. 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 the design concept with target challenge agents.

Payoffs. This effort alerts the user that a mask filter has been contaminated 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 FY02, completed screening evaluations of top candidate colorimetric indicator technologies to assess range of sensitivity against target chemical warfare agents and select high-priority toxic industrial vapors/gases.

Challenges. Development of an ESLI to detect such a wide range of chemical warfare agents is considered moderate to high 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 nonspecific colorimetric indicator technologies could be used to target key organic vapor and acid gas contaminants of concern. This DTO will focus on passive indicator technologies capable of detecting a select range of key chemical warfare and toxic industrial agents.

Milestones/Metrics.

FY2003: Evaluate leading candidate technologies and downselect best candidate technology(ies) for integration into viable ESLI mask filter prototypes. Enhance ESLI baseline design and determine optimum location of indicator(s) in filter sorbent bed based on specific target challenge agent.

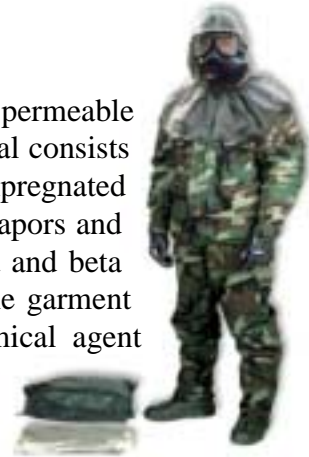
FY2004: Conduct demonstration testing of ESLI filter prototype(s) to verify ESLI is a reliable indicator of sorbent depletion for key target agents (i.e., GB, HD, CK, AC and CG). Assessments will include determining the effects of common environmental factors (heat, humidity, ozone, etc.) that may impact ESLI performance and evaluating the effects of rough handling and long-term storage.

BATTLEFIELD PROTECTIVE SUITS

FIELDIED 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.

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.



BATTLEFIELD PROTECTIVE SUITS

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 (materiel development lead), Air Force (requirements lead), and Marine Corps Requirement (Navy lead)

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. This effort improve warrior protection and sustainment. 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 reduces the probability of skin, eye, or respiratory contact with CB agent hazards. This DTO will 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. In FY02, 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 hyperbranched materials was demonstrated in coatings. Undergarments were treated with N-chloramine to decontaminate biological warfare agents.

DTO CB. 45 Self-Detoxifying Materials for Chemical/Biological Protective Clothing

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 extra weight added to the garments. 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. In general, biocides are more universal in their activity.

Milestones/Metrics.

FY2003: Scale-up electrospinning to manufacturing speeds of 1,000 m²/day. Select process for reactive membrane manufacturing with costs not to exceed \$20/yard. Expand cotton fabric treatment chemistry with N-halamines to further include nylon/cotton fabrics, polyesters, and polyurethane coatings. Demonstrate catch and kill mechanism of aerosol threats for antimicrobially treated electrospun fibers. Demonstrate the processability and good dispersion of reactive nanoparticles into fibers and fabric coatings.

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 2 mg agent/1cm²/day. Demonstrate effectiveness of scaled-up N-halamine treated materials against significant biological **Challenges.** Demonstrate nanoparticle reactivities in excess of 2 mg agent/1cm²/day in both fiber and coating form. Downselect most reactive, cost-effective nanoparticle compositions and optimize.

FY2005: Demonstrate reactivity stability to realistic time, temperature, and use conditions. Demonstrate, durability and overall cost effectiveness of scaled-up electrospun self-detoxifying membranes, N-halamine treated textiles, and materials containing reactive nanoparticles. Fabricate prototype garments. Demonstrate activity, durability, and user acceptance of garments. Transition technologies to end-item development programs.

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 like 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 an 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 over-cape should be worn if aircrews have to walk around liquid contaminated areas and if aircraft are not sheltered. If worn, the over-cape is removed before entering the aircraft.



SPECIALTY SUITS

FIELDDED 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/m² 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, CO₂, aircraft POL), and (5) is capable of being donned in 8 minutes.

Suit Contamination Avoidance Liquid Protection (SCALP)

The SCALP 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 to 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/m² 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.

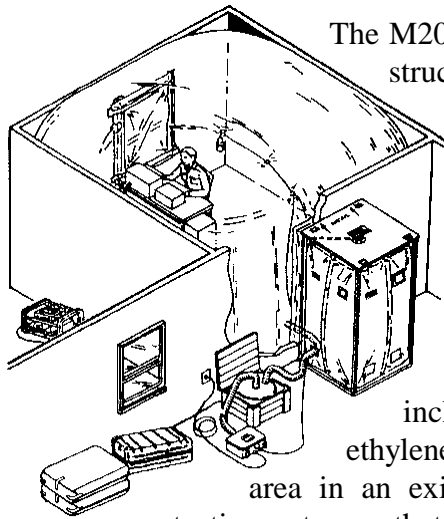
The ITAP fabric is self-extinguishing meeting NFPA 1991. The fabric is also static dissipative and does not hold a charge sufficient to set off munitions and explosives in accordance with current Explosive Safety Board requirements. The fabric is light in color to reduce operator solar heat load, and 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 Protective Equipment



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 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 (C³), medical treatment, and soldier relief functions. M20A1 is a room liner for existing shelters. 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 Simplified CPE (SCPE)



The M28 SCPE is a low cost method of transforming a room of an existing structure into an NBC collective protection shelter for command, control and communication (C³), medical treatment, and soldier relief functions. M28 is a liner for the TEMPER tent. 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 (P³I) program to the M28 SCPE provides liquid agent resistant liners, protective liners for tents, interconnectors, and an interface with environmental control units. The improved SCPE also allows more people to enter at one time, and protects hospitals under tents.

The improved SCPE also allows more people to enter at one time, and protects hospitals under tents.

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 operation 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 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. Also, the following capabilities are 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) – Production

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 Multipurpose 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 limited production.

TENTAGE AND SHELTERS

RDT&E ITEMS

Joint Transportable Collective Protection System (JTCOPS)

Rationale:

- Joint Service requirement (Air Force is lead service for requirements, Army is lead service for materiel development)

Key Requirements:

- Protection against chemical and biological agents, toxic industrial materials, and radiological particulate matter
- Use as a stand-alone structure or within existing structures
- Ability to process personnel through a contamination control area to a contamination-free area

Description:

The JTCOPS program will use new technology to provide relief from psychological and physiological stresses during sustained operations in a contaminated environment due to wearing full Individual Protection Equipment. JTCOPS will be a modular shelter system that will provide the ability to process contaminated personnel through a Contamination Control Area into a Toxic Free Area, and will be expandable to meet changing mission needs. It will allow collective protected vehicles/vans to be connected for safe personnel ingress/egress. The system will include air filtration, environmental control, and power generation elements. JTCOPS will be used for a variety of mission scenarios to include command and control, rest and relief, billeting and medical treatment.

DTO CB. 08 Advanced Adsorbents for Protection Applications

Objectives. This DTO 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. 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

DTO CB. 08 Advanced Adsorbents for Protection Applications

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. 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.

FY2003: Identify at least one adsorbent bed composition that provides the level of protection required by the JTCOPS program (ca. six 2,000 CT attacks) for all agents and at least 90% of the threshold TICs. Provide at least one adsorbent bed composition that provides effective TSA system performance (at the level stated in JTCOPS requirements) for all chemical warfare agents and all high-priority TICs.

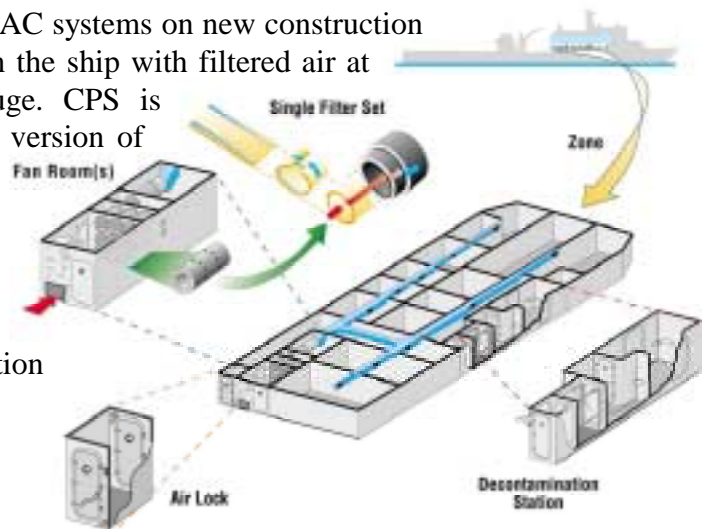
FY2004: Evaluate impregnation formulations as intercalated adsorbent preparations. Further modify ASZM-TEDA carbon to remove at least one additional (total of two) hard-to-remove TIC compounds. Construct composite vapor-aerosol media for reduced pressure drop with a target pressure drop of that of the adsorbent alone. Develop adsorbents for improved temperature performance under cyclic conditions by increasing high-temperature performance duty by 50%.

COLLECTIVE PROTECTION SYSTEMS

FIELDIED 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 a Navy-improved version of the 200 cfm M56 filter. 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 will transition to the JCPE program in FY03.

Joint Collective Protection Equipment (JCPE)

Rationale:

- Joint Service requirement (Navy lead service for requirements and materiel development)

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. 40 Immune Building Program (DARPA Program)

Objectives. The objective of this DTO is to 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 (1) protect the 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.

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.

FY2003: Evaluate strategies and architectures in full-scale testbed. Results will be used for design and optimization of complete building protection systems.

FY2004: Design and optimize system for demonstration at a military installation.

FY2005: Conduct full-scale demonstration at military installation.

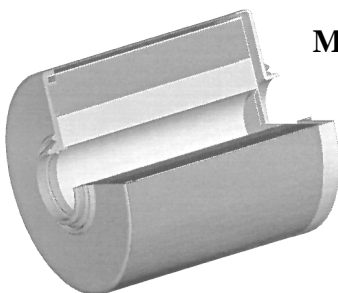
GENERIC NBC FILTERS AND COLLECTIVE PROTECTION FILTRATION SYSTEMS

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

The 100 cubic foot per minute (cfm) filter is used in the M1A1/A2 Abrams tank, M93 Modular Collective Protection Equipment (MCPE), CB Protected Shelter, and Paladin Self Propelled Howitzer.

M56

The 200 cfm filter is used as the basic filter set in the MCPE and in Naval applications. It can be stacked to obtain filtration of higher air flow rates.



600 cfm and 1200 cfm Stainless Steel Fixed Installation Gas Filters

These filters are used in fixed site applications where high volumes of air flow are required. They can be stacked to provide higher NBC filtered air flow rates. Particulate filter would be procured separately.

GENERIC NBC CP FILTRATION SYSTEMS

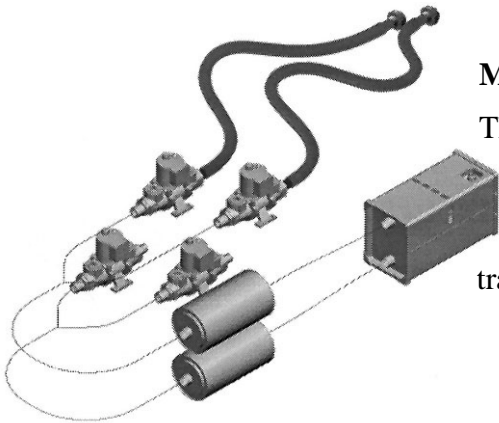
The following are modular NBC CP filtration systems which are applied to a wide variety of applications. They consist of an NBC filter, motor/blower unit, housings, and integration housings/ductwork. Some can be integrated into environmental control equipment.

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, 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 M48 NBC filter in the 100 cfm system and the M56 NBC filter in the others.

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
	- CB.09 Enzymatic Decontamination	DTO				
	- 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
	- Modular Decontamination System (MDS)	Production	Rqmt	Int-NIR	Int-NIR	Int-NIR
	- Joint Service Sensitive Equipment Decon	RDTE	Rqmt	Rqmt	Rqmt	Rqmt
	- Joint Service Family of Decontamination Systems	RDTE		Rqmt	Rqmt	Rqmt
	- I.06 Restoration of Operations ACTD**	DTO				
	- I.07 Contamination Avoidance at Seaports of Debarkation (CASPOD) ACTD**	DTO				

Rqmt = Product Requirement

Interest = Product Interest

Int-NIR = Product Interest, No Imminent Requirement

** These ACTDs support more than the decontamination functional area, but are placed in only one annex to prevent redundancy.

* = sub-Product(s) of a Consolidated Joint Service Project

Rqmt, Interest = Sub-Product Requirement or Interest

Defense Technology Objective (Science & Technology Base Program)

PERSONNEL

FIELDDED 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.

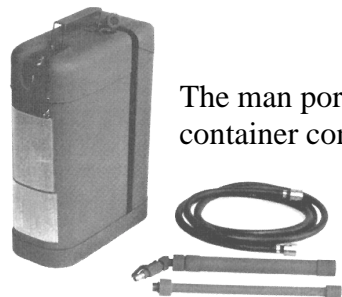
ABC-M11 Portable Decontaminating Apparatus

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



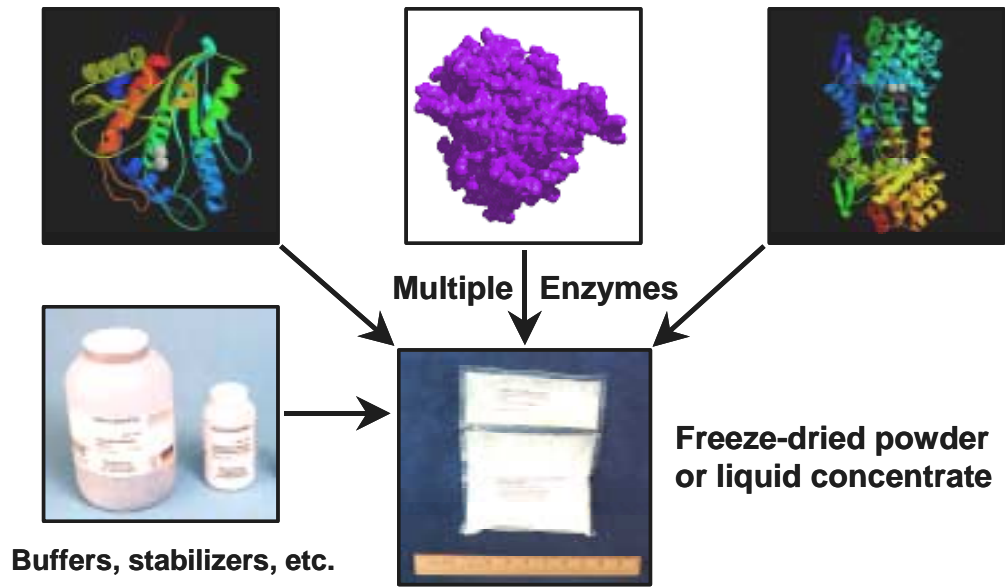
can decontaminate 1,200 square feet per fluid container. The combination of spray pump and brush allows personnel to decontaminate hard to reach surfaces, and remove thickened agent, mud, grease and other material.

PERSONNEL

RDT&E ITEMS

Defense Technology Objective (DTO) CB.09 Enzymatic Decontamination

Objectives. The objective of this DTO, which was completed in FY02, was to increase protection offered by the licensed topical skin protectant (TSP), Skin Exposure Reduction Paste against Chemical Warfare Agents (SERPACWA), by incorporating an active moiety that will neutralize nerve agents and sulfur mustard. This DTO was successful in the identification of compounds that will augment the barrier properties of SERPACWA by neutralizing (i.e., decontaminating) all chemical warfare agents, liquid or vapor, which could be absorbed through the skin. Decision tree network (DTN) evaluation models were modified to improve discrimination between SERPACWA and candidate active TSP formulations. Fifty-one new active moieties were identified for developing an active TSP. Acute eye and skin irritation safety evaluations were performed and efficacy studies were completed of candidate active TSP formulations in two animal species challenged with estimated battlefield levels of nerve agents and sulfur mustard as liquids and vapors. Significantly improved efficacy was demonstrated by 17 active moieties against sulfur mustard and 15 against nerve agent. The best candidate active TSP formulations were selected for transition out of the technology base. Polyamine was identified as the lead active candidate with demonstrated efficacy against sulfur mustard and nerve agent in both in vitro and in vivo models.



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. 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 peroxy carbonate-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.

Milestones/Metrics.

FY2003: Downselect peracid systems that meet preliminary efficacy requirements. Determine whether efficacy of the peroxy carbonate candidate meets efficacy requirements on painted surfaces. Determine if candidate systems meet efficacy requirements on an expanded test bed of agents. Investigate catalytic buffering approach for potential formulations and determine suitability for peroxide-based systems.

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

FIELDIED 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 dismantled 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 watertank or natural water resource.

COMBAT EQUIPMENT, VEHICLES, AND AIRCRAFT

RDTE ITEMS

Joint Service Sensitive Equipment Decontamination (JSSED)

Rationale:

- Joint Service requirement (Air Force is lead service for requirements; Army is lead service for materiel development)

Key Requirements:

- Non-aqueous based decontamination systems for sensitive equipment and vehicle 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 Family of Decontamination Systems (JSFDS)

Rationale:

- Joint Service requirement (Air Force is lead service for requirements; Marine Corps is lead service for materiel development)

Key Requirements:

- Provide restoration capability at fixed site locations
- Provide improved/state-of-the-art NBC decontamination equipment
- Provide non-hazardous and environmentally safe NBC decontaminants

Description:

The JSFDS program is a joint effort. The system will provide the warfighter with a family of decontaminants and applicator systems to decontaminate personnel, equipment, ships, ports, airfields, rear-area supply depots, and key command and control centers. Decontaminants will be less corrosive and hazardous than existing decontaminants. Personnel decontaminants will be approved by the Food and Drug Administration. Application systems will reduce the manpower intensive decontamination processes.

DTO I.06 Restoration of Operations ACTD

Objectives. This DTO supports the QDR Transformation Operational Goal for Protecting Bases of Operation by demonstrating 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.

FY2003: Conduct the final demonstration. Determine technologies to be recommended for transition to core acquisition program. Initiate residual support activities.

FY2004: Conclude interim capability support period.

DTO I. 07 Contamination Avoidance at Seaports of Debarkation (CASPOD) ACTD

Objectives. The CASPOD ACTD focuses on chemical and biological (CB) defense at OCONUS seaports during the early stages of power projection operations at seaports in theaters where there is limited U.S. presence. CASPOD will identify the before, during, and after attack actions necessary to minimize the effects of a CB attack on force flow and operating tempo in support of contingency operations or theater war.

Payoffs. Potential payoffs include providing the in-theater enhanced capabilities to protect against, immediately react to, and minimize the impact of a CB attack at seaports, thereby maintaining the critical flow of forces and materiel into any theater worldwide.

Challenges. Emerging technologies being identified as candidates for the CASPOD ACTD will be leveraged from both the Seaport Protection Analysis (SPPA) program and the RestOps ACTD. Subject matter expertise will need to be incorporated to resolve port defense and logistics/concepts of operation (CONOPS) in a CB environment. The greatest technical risk will be integrating these technologies so that they perform synergistically while configured as a "deployable package" to maintain or return a seaport of debarkation to near-normal levels immediately following a CB attack. An additional risk will be the identification and training of appropriate personnel (organized and trained for CB defense operations and available for deployment during an overseas contingency) to operate the equipment provided in the "flyaway" or transportable equipment package.

Milestones/Metrics.

FY2003: Conduct CASPOD baseline activities. Develop ACTD transition plan and integrated assessment plan. Establish CASPOD quantified baseline. Conduct technical testing and CONOPS development of CASPOD material and nonmaterial solutions to support Limited Utility Assessments of selected CASPOD items. Refine CONOPS and material in preparation for the preliminary demonstration. Conduct preliminary demonstration.

FY2004: Refine material and CONOPS solutions. Finalize transition plan and ensure transition support for FY07 ACTD technologies identified for transition to acquisition. Identify policy and doctrine issues with recommended solutions. Assess and incorporate appropriate new technologies not available or the preliminary demonstration. Conduct pre-final demonstration readiness activities. Conduct final demonstrations and military assessments.

FY2005: Commence interim capability support phase.

Annex E

Joint Medical Chemical and Biological Defense Research Programs

The Joint Medical Chemical and Biological Defense Research Programs are addressed in two sections of this annex. Section E.1 addresses medical chemical defense research, and section E.2 addresses medical biological defense research.

Table E-1. Medical Chemical and Biological 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 Pyridostigmine Pretreatment	Fielded	Joint	Joint	Joint	Joint
	- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA)	Production	Joint	Joint	Joint	Joint
	- Active Topical Skin Protectant	RDTE	Joint*	Joint*	Joint*	Joint*
	- Chemical Agent Prophylaxes	RDTE	Joint*	Joint*	Joint*	Joint*
	- CB.28 Chemical Agent Prophylaxes II	DTO				
	- CB.29 Active Topical Skin Protectant	DTO				
	- 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				
	Medical Biological Defense	- Anthrax Vaccine Adsorbed	Fielded	Joint	Joint	Joint
- 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.25 Multiagent Vaccines for Biological Threat Agents		DTO				
- CB.26 Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases		DTO				
- CB.31 Medical Countermeasures for Brucellae		DTO				
- CB.32 Alternative Delivery Methods for Recombinant Protein Vaccines		DTO				
- CB.33 Recombinant Protective Antigen Anthrax Vaccine Candidate		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					

Joint= Joint Service requirement

Joint*=Draft Joint Service 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 (CANAA), 1991
- Medical Aerosolized Nerve Agent Antidote (MANAA), 1994
- Soman Nerve Agent Pyridostigmine Pretreatment, 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 FY02 are grouped by the major medical chemical defense strategy areas, which are:

- *Pretreatments/Prophylaxes.*
- *Therapeutics.*
- *Diagnostics.*

Today's chemical threat, however, 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 FY02:

Research Category: Pretreatments/Prophylaxes

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of pretreatments are outlined below.

Countermeasures:

- Improved Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) by incorporation of active moieties that detoxify the chemical agents.
- Pretreatment regimen that protects against rapid action and incapacitating effect of nerve agents and non-traditional agents.
- Pharmaceutical and biological pretreatments, treatments, antidotes, decontaminants and protectants.

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.
- Lack of a capability to provide forensic diagnostics for chemical threats.

Accomplishments:

The detailed accomplishments that follow are drawn from the basic research, applied research, and concept exploration investments in research on CWA pretreatments. They are organized under major research thrust areas that comprised the medical chemical defense research portfolio in fiscal year 2002.

Research thrust: *active Topical Skin Protectant (aTSP) to augment currently fielded SERPACWA*

- Modified Decision Tree Network (DTN) evaluation models to improve discrimination between SERPACWA and candidate aTSPs.
- Evaluated over 500 candidate formulations in the aTSP DTN.
- Initiated efficacy studies of candidate aTSP formulations in three animal species and performed challenges with both vesicants and nerve agents in order to identify and down select candidates with optimum performance characteristics.
- Identified polyamines as the lead active candidates with demonstrated efficacy against sulfur mustard (HD) and nerve agent GD (soman) in both in vitro and in vivo models.
- Initiated modeling studies to estimate potential beneficial impact of using SERPACWA and aTSP with various levels of military-oriented protective posture (MOPP) gear.
- Completed initial safety evaluations on all lead formulations.
- Elucidated the mechanism of $H_5PV_2Mo_{10}O_{40}$, a metal oxide catalyst identified as ICD# 3647, under aerobic oxidation of half-mustard and HD under aerobic/ liquid phase conditions by applying different state-of-the art spectroscopic techniques, i.e., nuclear magnetic resonance, electron paramagnetic resonance, and UV-VIS spectroscopy. The findings are important and relevant for processing any potential candidate with similar chemical/physical properties that may eventually be submitted for FDA approval in an aTSP formulation.
- Established a commercially available cell proliferation assay for cell viability, cell proliferation, and drug intervention studies. This clonogenic assay is an easy-to-use, rapid, and reliable resource in the aTSP research effort.
- Received nine patents describing aTSP development that were filed in FY01 and filed one new provisional patent application for polyamines.

Defense Technology Objective (DTO) CB.29 Active Topical Skin Protectant
--

Objectives. The objective of this DTO, which was completed in FY02, was to develop and demonstrate a new chemical agent decontaminant based on multiple catalytic enzymes. Eventually, other enzymes would be added to the formulation to provide biological agent capability. An enzyme-based decontamination system will be non-toxic, non-corrosive, non-flammable, environmentally safe and lightweight (dry concentrate). It has the potential to reduce the logistical burden by 25-50 fold. It will require no specialized equipment and can be used with any spray or foam systems available to the user (military or civilian). Although the enzymes require water, they will actually save water since they do not need to be rinsed off after application. Enzymes with highly efficient activity against G-agents and wide variety of organophosphorus pesticides have been identified, well characterized and their genes cloned and expressed. Several enzymes with low activity against V-agents have been identified and significant improvement in activity achieved (~10 fold increase). The most difficult problem was dealing with sulfur mustard. Initial efforts were aimed at using mild oxidants to convert HD to its sulfoxide and then enzymatically dehalogenating it. Such an HD sulfoxide dehalogenase has been identified. In the last year of the DTO, a microbial dehalogenase enzyme capable of directly attacking HD was identified. The enzyme system is a candidate for transition to the JSFDS program as a product improvement. There is also interest in the system at stockpile demilitarization sites. A commercial version of the system is being pursued with private industry. Tests with single enzymes in foams and sprays were conducted at Dugway Proving Ground and, under the auspices of NATO Project Group 31, in France, Germany, and the UK. Tests with the combined formulation are being completed at ECBC.

Research thrust: *nerve agent bioscavenger (chemical warfare agent prophylactic):*

- Identified human butyrylcholinesterase (h-BuChE) as the lead candidate stoichiometric bioscavenger based on the results of research studies performed through fiscal year 2002.
- Isolated and purified sufficient h-BuChE for animal safety and efficacy proof-of-concept.
- Partnered with MedImmune Corporation for production of the h-BuChE scavenger under current Good Manufacturing Practice (cGMP) conditions in sufficient quantity for future phase I safety trials in human subjects.
- Sequenced genomic Es-1 carboxylesterase gene as a prelude to making a construct for knockout mouse development for use in bioscavenger research.
- Expanded physiological based pharmacokinetic modeling efforts to include effect of bioscavenger on GD toxicokinetics.
- Developed protocols to complete efficacy testing of h-BuChE in two animal species in support of consideration for Investigational New Drug (IND) status under Food and Drug Administration (FDA) regulations.
- Focused basic research on studies to advance a next generation nerve agent bioscavenger that has catalytic as opposed to stoichiometric capabilities. Current candidates are human paraoxonase – 1 (h-PON-1) and human carboxylesterase (h-CaE) enzymes.

DTO CB.28 Chemical Agent Prophylaxes II

Objectives. The objective of this DTO, which was completed in FY02, was to demonstrate improved medical protection against nerve agents by developing a prophylactic that can detoxify nerve agents at a rate sufficient to protect the warfighter from exposure of up to five median lethal doses (5LD₅₀). This research effort is intended to yield a nerve agent prophylactic that will improve the current medical regimen for nerve agent intoxication. The current therapeutic approach is successful, but the warfighter always suffers a toxic insult that must then be reversed. An effective prophylaxis for chemical warfare nerve agents will increase the ability of U.S. forces and allies to sustain operational tempo, provide full-dimension protection, reduce reliance on MOPP gear, and discourage the use of nerve agent by the enemy. The DTO was successful in the development of human butyrylcholinesterase (h-BuChE) as a stoichiometric biological scavenger that will provide a capability for extended protection against a wide spectrum of nerve agents without causing side effects, behavioral effects, or the need for extensive post exposure therapy. Sources of h-BuChE for purification were identified and sufficient amounts of purified h-BuChE were prepared to test efficacy in two animal models. The effects of pretreatment with h-BuChE scavengers on the toxicokinetics and binding of chemical warfare nerve agents in guinea pigs and marmosets were evaluated. Preparation of a technical data package to address Food and Drug Administration (FDA) requirements for an Investigational New Drug (IND) application and that supports transition of the bioscavenger candidate out of the technology base was initiated.

Research thrust: *vesicant pretreatment*

- Determined that ethachrynic acid, a stimulator of glutathione-S-transferase, had minimal protective effect against HD cytotoxicity in human epidermal keratinocytes (HEK) and observed that this effect is not related to the transferase but to a small increase in glutathione.
- Observed that exposure of keratinocytes to HD in culture reduced oxidative glutamate metabolism.
- Observed that mitochondrial membrane potential is lost within three hours of mustard exposure, thus adversely affecting cellular energy metabolism.

Research Category: Therapeutics/Diagnostics

The countermeasures, technical barriers, and accomplishments in the medical chemical defense research category of therapeutics/diagnostics 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 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 antidotes that are deployable.
- Lack of appropriate experimental model systems for treatment efficacy and safety in

- humans.
- Need for detailed molecular model of non-traditional agents to understand the origin of their unique chemical properties.
 - Lack of simple and sensitive field-portable diagnostic assays for CWA exposure.

Accomplishments:

Research thrust: *medical countermeasure (treatment) for vesicant exposure*

- Completed all phases of colony stimulating factor (CSF) studies in African Green monkeys and confirmed efficacy by CSF against the HD-induced leukopenia.
- Established via the modified mouse ear drug screening model, that combining molecular scavenger candidates and anti-inflammatory drugs is the lead therapeutic approach for treatment of vesicant injury.
- Determined that the Fas/Fas ligand pathway is directly associated with cell death and tissue injury following exposure to HD.
- Determined that proteomic analysis of cellular proteins following in vitro exposure to HD is able to detect discrete classes of altered proteins.
- Confirmed the lack of phospholipase A2 involvement in arachidonate release following exposure of cells to mustard agent.
- Observed that cytokine IL-8 activity is a useful indicator of the protective effects of several pharmacological classes, to include cannabinoids, poly(ADP-ribose) polymerase inhibitors and phosphodiesterase inhibitors.
- Demonstrated that three specific commercially available inhibitors of caspases were able to eliminate the in vitro toxicity of mustard as demonstrated by a vital dye staining assay.
- Determined that half-mustard induces acantholysis in the epidermis through reduced expression of structural proteins and initiation of apoptosis.
- Demonstrated that, within one hour of mustard exposure, multiphoton fluorescence microscopy can detect basolateral displacement of integrins, reduction of integrins and laminin 5 and destruction of the receptor-ligand organization that supports dermal-epidermal attachment.
- Determined that cytokines/chemo-attractants such as interleukin-1 (IL-1), tumor necrosis factor – alpha (TNF- α), IL-6, and IL-8 are good biomarkers of cutaneous lesions caused by vesicant agents.
- Identified and characterized that the cytokine, human TNF- α , is a good biomarker to distinguish between sulfur mustard (HD) or Lewisite (L) exposure.

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 tech base.

Payoffs. Currently, medical management of the injuries produced by blister agents is 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

DTO CB.30 Medical Countermeasures for Vesicant Agents II

among exposed soldiers, with concomitant reductions in the medical logistic burden. In FY02, 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. Also, began pharmacokinetic and formulation studies on selected candidates and determined the window of opportunity for administration of therapy(ies) for HD exposure.

Challenges. Challenges include developing therapeutic measures with minimal adverse effects, demonstrating safety and efficacy, developing formulations, and extrapolating test results from animals to humans.

Milestones/Metrics.

FY2003: Perform preclinical studies of selected candidate compounds that best meet the goal of preventing or decreasing by 80% the severity of blister injuries. Complete downselection. Prepare a technical data package that addresses FDA Investigational New Drug requirements and that supports transition of the best candidate out of tech base.

Research thrust: effective methods for removing chemical warfare agents from exposed skin surfaces

- Continued to optimize solutions used for polyurethane sponges for removing the nerve agent GD. Tested high (350 mM) and medium (150 mM) concentrations of 2-PAM in conjunction with tetraglyme and found that both of the higher concentrations were inferior to the 50 mM concentration currently used. Two polyamines that have been investigated in the aTSP research program were also tested, one of which gave promising results.
- Tested the effectiveness of two halogenated hydrocarbon solvents (1-bromoperfluorooctane and HFE-7200) at removing GD from skin; neither proved as effective as aqueous decontaminating solutions.
- Tested the ability of Sandia foam MDF-100 to neutralize GD and VX on guinea pig skin; MDF-100 was very effective at protecting against exposure to both and is the best decontaminating solution tested to date against GD exposure.
- Conducted six HD exposures where the ideal amount and length of exposure to liquid HD was determined. The ideal exposure produced moderate lesion area, moderate edema weight change and moderate histopathological change. Once exposure amount and length was determined, it was demonstrated that decontamination using polyurethane sponges treated with 2-PAM and tetraglyme gave significant benefit by reducing lesion size, edema and sub-cellular damage.

Research thrust: medical countermeasures for non-traditional chemical threat agents

- Demonstrated persistence of compounds representing non-traditional chemical agents in the blood.
- Screened FDA-licensed anticonvulsants against seizures induced in guinea pigs by non-traditional chemical agents and identified anticonvulsants that terminated seizures.
- Identified midazolam as the anticonvulsant with the broadest window of time for effective administration against seizures induced by non-traditional chemical agents.
- Screened oximes in guinea pigs against lethality induced by non-traditional chemical agents.

- Developed and validated a physiological pharmacokinetic model for use in non-traditional chemical agent research studies.
- Identified a number of lead candidate drugs to improve medical countermeasures against non-traditional chemical agents. These lead compounds have suggested other drug analogues that are currently being synthesized for further testing against non-traditional chemical agents.

Research thrust: *development of an Advanced Anticonvulsant*

- Determined that two person-equivalent doses of 10 mg midazolam, delivered 10 minutes apart, successfully terminated soman-induced seizures in greater than 90% of the non-human primates tested. Observed that seizures terminated rapidly (median ~ 35 minutes) and animals regained consciousness within 1 hour.
- Determined that blood levels of midazolam produced by the divided dose (10 mg midazolam delivered 10 minutes apart) were equivalent to those demonstrated to produce an anticonvulsant effect when given as a bolus dose.
- Demonstrated that the proposed advanced anticonvulsant system will control nerve agent-induced seizures when given in the doses proposed for field use and in accordance with current anticonvulsant treatment doctrine.
- Observed that a scopolamine dose of 0.2 mg/kg body weight, rapidly (<10 min) terminated soman-induced seizures in non-human primates. The treated animals regained consciousness within 20 minutes.
- Demonstrated that a potent centrally acting anticholinergic drug can control nerve agent seizures in a non-human primate model faster than currently available benzodiazepine drugs.
- Tested drug combinations of benzodiazepine and anticholinergic for improved efficacy against nerve agent-induced seizures. It was observed that combinations of diazepam or midazolam plus scopolamine were quite effective in terminating soman-induced seizures and that the effects of the drugs were additive. It was also noted that there were no differences in speed of seizure control with the drug combinations when compared to the most effective drug in the combination.
- Determined that combinations of benzodiazepine and anticholinergic drugs may provide improved anticonvulsant action against nerve agent-induced seizures especially if treatment is delayed >30 minutes from seizure onset.
- Tested higher doses of benzodiazepine anticonvulsants for improved incidence and/or speed of seizure control. It was observed that higher doses of diazepam and midazolam were successful in treating 100% of animals with seizures induced by the nerve agent soman. It was also observed that seizure control by midazolam was produced at a significantly lower dose and was significantly more rapid than that produced by diazepam.
- Observed that lorazepam (Ativan®) was significantly less potent and slower acting than either midazolam or diazepam.
- Determined that the dose of diazepam provided by the approved Convulsant Antidote for Nerve Agent (CANA) injector needs to be significantly increased (300-400%) in order to successfully and rapidly control nerve agent seizures.

Research thrust: development of a neuroprotectant to protect from exposure to nerve agents

- Conducted evaluation of seed extracts of the medicinal herb, *Celastrus paniculatus* (CP), for the treatment of neurodegenerative diseases and observed that methanol extracts exert free radical and anti-oxidant scavenging effects.
- Evaluated water soluble and organic soluble extracts derived from CP-seeds for neuroprotective effects.
- Pretreated neuronal cells with the extracts and then with glutamate to evaluate protection afforded against excitatory amino acid-induced toxicity or hydrogen peroxide to evaluate anti-oxidant scavenging ability. The criteria for neuroprotection was based on alterations in morphology of the cultured cells and effective concentration 50% (EC₅₀) values obtained for glutamate-induced toxicity. Found that pretreatment of neuronal cells with many of the CP seed extracts attenuated glutamate- and hydrogen peroxide-induced neuronal death. Specific extracts (e.g., ethanol extract) were more effective in protecting mature neuronal cultures than younger ones.
- Observed that the activity of extracellular acetylcholinesterase (AChE) was not affected by the CP extracts.
- The natural alkaloid, huperzine A (HupA), exhibits a unique dual pharmacology and acts as a neuroprotective agent. Demonstrated that part of HupA pharmacological and neuroprotective action resides in its ability to non-competitively inhibit the passage of calcium ions through n-methyl-D-aspartate (NMDA) ion channels. It was also observed that cholinesterase inhibitors such as tacrine, physostigmine, or E2020 showed little effect in displacing radiolabeled MK801 (³H-MK801), an NMDA ion-channel blocker. This observation provides additional evidence that the neuroprotective effects of HupA are separate from cholinesterase activity.
- Observed that HupA exhibited antagonism of central benzodiazepine receptors measured with tritiated (i.e., radiolabeled) RY-80 (³H-RY-80), although it was less effective than that observed with tritiated ³H-MK801.
- Determined binding competition by enantiomers of HupA and dimethylhuperzine (DMH). Similar results were observed for the (+) stereoisomer of HupA, which exhibits markedly reduced anticholinesterase activity.
- Demonstrated that the (+) HupA isomer exhibits more than 100-fold lower AChE inhibition while maintaining equivalent neuroprotective effects, both in the primary cell culture model for protection against excitatory amino acids (EAA)-induced toxicity and in binding studies.
- Installed telemetry probes in animals to monitor brain activity (EEG), heart rate, respiratory rate, body activity, ratio, and body temperature in ongoing neuroprotection studies.
- Evaluated seizure protection by (-) HupA enantiomers and DMH in guinea pigs against seizures induced by 2LD₅₀ of soman (GD). Data indicated that DMH is tolerated better than the parent compound HupA and also offered equivalent protection against GD-induced seizures and morbidity.
- Observed that neurotoxicity is time- and concentration-dependent, suggesting that neurons die by apoptosis.
- Determined that MK801 enhances the toxicity of paraoxon, suggesting that NMDA receptors are not involved in paraoxon-mediated neurotoxicity. The results also suggest

that NMDA receptors may be protective since more toxicity was observed in the presence of MK801.

- Observed that the PI 3-kinase inhibitor, LY294002, also enhances paraoxon-mediated neuronal cell death, suggesting that this signal transduction pathway is protective.
- Determined that the muscarinic antagonist atropine (100 μ M) and a non-selective muscarinic agonist do not affect paraoxon-mediated neurotoxicity, suggesting that muscarinic receptors do not play a role in the neurotoxic effect.
- Determined that pretreatment with a maximum subtoxic concentration of NMDA protects all of vulnerable neurons against paraoxon-mediated neuronal cell death.
- Determined that the addition of a maximum neuroprotective concentration of NMDA added 3 hours after the addition of a neurotoxic concentration of paraoxon protects almost all of the vulnerable neurons against the neurotoxic effects of paraoxon. The result strongly suggests that, if the intracellular mechanism of NMDA-mediated neuroprotection against paraoxon toxicity can be determined, this should lead to an effective treatment in an animal model.
- Determined that paraoxon, an AchE inhibitor, is neurotoxic to cultured cerebellar granule cells.
- Observed no effect of ECGC, a major component in green tea that has been found to be protective against several neurotoxins.
- Observed a small protective effect of the alpha-2-beta-4-nicotinic agonist against paraoxon-mediated neurotoxicity.
- Observed that a muscarinic 4 antagonist exerted no effect on paraoxon-mediated neurotoxicity.
- Observed that protein kinase C inhibition is protective against paraoxon-mediated neurotoxicity. Alternatively, reagents that enhance protein kinase C activity increase neuronal cell death mediated by paraoxon.
- Determined that the window of opportunity for neuroprotection following soman-induced seizures is brain region specific.
- Determined neither diazepam nor dantrolene provide protection from seizure-induced brain damage when given 40 min after onset of seizures. However, it was observed that coadministration of diazepam and dantrolene/mannitol at 40 min after seizure onset is synergistic and protects against brain damage.
- Middle Cerebral Artery Occlusion (MCAO) Brain Injury Studies - Completed time-course of apoptosis (comet analysis, caspase-3 activation and pulse-field gel electrophoresis, PFGE) and inflammatory gene regulation (using QRT-PCR) studies following brain injury in rats produced by non-agent measures (focal ischemia insults using the MCAO method).
- While both comet and PFGE analysis documented significant DNA degradation in only the ischemic hemisphere at 15 and 24 hr post-MCAO), no significant change in caspase-3 activity was evident at any time intervals. The findings support the hypothesis that ischemia-mediated neuronal degeneration is comprised of a large component of apoptosis-mediated cell death. Understanding the contribution of apoptosis in ischemia- or agent exposure-mediated neuronal cell death may be useful in the development of anti-apoptotic strategies for neuroprotection against agent-induced brain damage.

- Expression profiles of several important genes associated with inflammation were measured at various time-intervals (3, 6, 12, 24, 72 h) after MCAO using QRT-PCR. The results are consistent with the pro-inflammatory properties of the induced molecules, which are involved in the initiation of the inflammatory cascade, and may thus contribute to secondary cellular responses that lead to further brain damage.
- Initiated a time-course study of cellular changes associated with brain injuries produced by soman exposure (1.5 LD₅₀ at 2, 6, 24 and 48 hr post-exposure). Apoptosis and inflammatory gene regulation studies are ongoing. A time-related increase in caspase-3 activity was observed with maximal activation in the three brain regions being observed at 2 hr post-soman exposure. The thalamus appears to be most sensitive.
- Examined the capacity of α -phenyl-N-tertbutylnitron (PBN) to protect cultured neurons in vitro from 3 different types of insult - hemoglobin, hydrogen peroxide, or glutamate, all of which can induce oxidative stress. Observed that 10 mM PBN was protective against all three insults with greatest protection evident when given immediately following the insult.
- Conducted a study using PBN to protect rats from neurotoxicity secondary to soman-induced seizures but found no evidence of protection against neuronal damage.

DTO CB. 48 Improved Oxime

Objectives. Medical protection via therapeutics for treating exposures to chemical nerve agents supports the QDR operational goals for Protecting Bases of Operation and Projecting and Sustaining U.S. Forces. 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 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 defining 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.

FY2003: Drawing from an array of promising compounds already identified, initiate assay development for oximes in biological fluids, stability studies, and studies to identify a surrogate marker for efficacy. Continue efficacy studies in guinea pigs. Initiate discussions with Food and Drug Administration (FDA) and begin down selection process. Synthesize appropriate quantities of each oxime for required studies.

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. Continue discussions with FDA. Continue the downselection process.

DTO CB. 48 Improved Oxime

FY2005: Complete 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 a technical data package that supports requirements for an Investigational New Drug application and for transition of the best candidate improved, broad-spectrum candidate oxime(s) out of the technology base.

Research thrust: *develop chemical diagnostic technologies:*

- Established a new biotechnology (fluorescence spectroscopy) capable of analyzing multiple biomarkers in a single sample. The versatility of this biotechnology to measure up to 25 relevant biomarkers simultaneously in small sample volumes of many tissue fluids including serum, plasma, and cerebral spinal fluid, makes it the method of choice for the development of a rapid screen for the insult of human cells exposed to various CWAs. The time and labor required to generate results are significantly less than standard biotechnologies. These efficiencies lead to lower costs per result while hastening the collection of data. This is critical to diagnose individuals exposed to CWAs. This biotechnology could be useful in the medical management of military and civilian personnel exposed to CWAs.

Research thrust: *Low-Level CW Agent Exposure: Effects and Countermeasures:*

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. Specific accomplishments are listed following the DTO.

DTO CB. 51 Low-Level CW Agent Exposure: Effects and Countermeasures

Objectives. This DTO supports the QDR Transformation Operational Goals for Protecting Bases of Operation and Projecting and Sustaining U.S. Forces by delivering data sets on operationally relevant health effects of exposures to sub-lethal concentrations of CWAs, which support 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 defensible 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.

DTO CB. 51 Low-Level CW Agent Exposure: Effects and Countermeasures

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 routes 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.

FY2003: Complete inhalation data set to define longer-time, lower level operational effects for GB in swine and GF in rats that refine operational human health risk assessments. Deliver assessments of short-term behavioral and physiological effects of GB in rodents following low-dose exposures of varying durations and their potential impact on operational readiness in humans.

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.

- Determined maximum doses of the major nerve agent threats sarin (GB), cyclosarin (GF), soman (GD), VX, and VR that can be absorbed daily in male and female guinea pigs without lethal effects, histopathological lesions, or clinical signs of toxicity.
- Determined the doses of the nerve agents GB, GD, and VX that change basic behavioral indices, such as startle responses, in two species of rodents repetitively exposed to low-level chemical warfare nerve agents.
- Tentatively identified changes in rodent behavior that are altered 2-3 months following 2 weeks of repeated GB exposures.
- Identified gene transcription products that are either enhanced or depressed in the brain following low-level chemical warfare nerve agent exposures to GB, GD, or VX.
- Measured inhibition and recovery of brain acetylcholinesterase activity in various brain regions with low-dose nerve agent exposures and compared these values to acetylcholinesterase inhibition in blood.
- Identified functional changes in synaptic connections between brain neurons following acute exposure to low-dose VX, GB, and GD as well as determining the ability of pretreatment compounds to reverse such effects.
- Developed a computer model of electrical flow in the heart to predict nerve agent induced cardiac arrhythmias and identified a putative physiological mechanism of nerve agent-induced cardiotoxicity.

- Identified alterations in peripheral lymphocyte DNA after repeated GD exposures in rodents.

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 medical R&D process links the materiel developers (tech base research via the U.S. Army Medical Research and Materiel Command; advanced development via the U.S. Army Medical Materiel Development Activity) with the combat and training developer (U.S. Army Medical Department Center and School, AMEDD C&S) and the logistician (U.S. Army Medical Materiel Agency, USAMMA) in addressing the threat and JMCDRP requirements. In FY03, advanced development of medical chemical countermeasures will be managed by Chemical Biological Medical Systems (CBMS), the project management office under the Program Executive Office for Chemical and Biological Defense. In addition, requirements and user representation will change from AMEDD C&S to the Joint Requirements Office, reflecting 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 scaleup approved by FDA.

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.
- The FDA issued an approval letter for the New Drug Application (NDA) on 17 January 2002.
- A Transition Planning and Tracking Group formed.
- Successful Full Rate Production Integrated Product Review (FRP IPR) 4QFY02 with fielding of ATNAA.

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 (CANAN) 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 one medical materiel solution (Anthrax Vaccine Adsorbed, trade name BioThrax™) is fully licensed by the Food and Drug Administration (FDA) and available for use. 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)
- 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)
- New smallpox vaccine (Vaccinia Virus, Cell Culture-derived) (IND #4984)
- 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)

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 FY02 are grouped by the following overarching medical defense strategic areas against biological threats (bacteria, viruses, and toxins):

- Vaccines against bacterial agents.
- Therapeutics for bacterial agents.
- Vaccines against viral agents.
- Therapeutics for viral agents.
- Vaccines against toxin agents.
- Therapeutics for toxin agents.
- Diagnostics.

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 FY02. Current Defense Technology Objectives (DTOs) associated with the strategic areas are described following the FY02 accomplishments in the following sections. Also, DTOs that were started in FY03 are also listed.

Bacterial Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of bacterial agents are outlined below.

Countermeasures:

- Vaccines for immunity against bacterial threat agents.
- Therapeutics for treatment of bacterial diseases.

Technical Barriers:

- Developing genetic information for all of the bacterial threat agents.

- Lack of 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 products.
- Difficulty in field testing rapid identification 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 and antibody therapies for bacterial agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new, emerging, and genetically engineered bacterial threats.

Vaccines Accomplishments:

Research thrusts: *Understand the pathogenesis of diseases caused by Burkholderia species and to develop vaccines against Burkholderia mallei and B. pseudomallei, causative agents for glanders and melioidosis, respectively:*

- Performed studies to evaluate inactivated (heat-killed or irradiation inactivated), whole cell *Burkholderia mallei* candidate vaccines in animal models.
- Completed initial studies of the effect of interleukin-12 on the murine immune response to *B. mallei* candidate cellular vaccines.
- Completed construction of a plasmid (pGSV3BmaroA) to disrupt the *B. mallei* *aroA* gene in order to create an auxotrophic strain of glanders (a *B. mallei* *aroA* mutant) to enable the organism to proliferate only when the culture medium is supplemented with some specific substance not required by the wild-type organism.
- Began creating the *B. mallei* *aroA* mutant by conjugating the pGSV3BmaroA plasmid from the *E. coli* host to the *B. mallei* wild-type recipient.
- Cloned the *B. mallei* *hsp70* gene into plasmid pET15b, sequenced the *B. mallei* *hsp70*, and overexpressed the protein produced by the gene.
- Determined that the *B. mallei* *hsp70* gene is approximate 66% homologous with the *E. coli* DnaK gene and is 98% homologous with the same gene in *B. pseudomallei*.
- Completed the construction of pGSV3 vectors containing parts of the *B. mallei* *hsp60* and *hsp70* genes to make mutations in the respective *hsp* genes of *B. mallei* to create potential candidate vaccines.
- Standardized a procedure to isolate the capsular polysaccharide, the exopolysaccharide, and lipopolysaccharide (LPS) in milligram quantities from *B. mallei* and *B. pseudomallei* strains. Established a standard protocol to determine the carbohydrate composition of these polysaccharides to investigate polysaccharide conjugates as candidate vaccines for glanders and melioidosis. In addition, standardized a method employing high performance liquid chromatography (HPLC) to purify the polysaccharides.
- Standardized an electrochemical detection method for separating oligosaccharides based on their molecular charge.
- Completed a study on the murine aerosol model of melioidosis and confirmed that the aerosol lethal dose 50% (LD₅₀) using BALB/c mice was approximately 100-fold less than that observed with *B. mallei*, the causative agent of glanders.

- Determined that aerosol exposure of mice with *B. pseudomallei* resulted in systemic infection of the mice and found residual challenge organisms in a variety of organs.
- Observed that pathologic changes in mice infected with *B. pseudomallei* were more severe than those observed with *B. mallei* in mice, suggesting greater pathogenicity of *B. pseudomallei* in mice.
- Inoculated mice and hamsters and boosted them intramuscularly and intradermally (using a gene gun) with 55 preparations containing segments of the *B. mallei* genome to assess the feasibility of a glanders DNA vaccine. Observed that, in five of the test groups, a single hamster in each group survived aerosol challenge with *B. mallei*. Residual microorganisms were not detected in the spleens of the surviving animals.
- Tested *B. pseudomallei* auxotrophic mutants as potential vaccines against *B. mallei*. The vaccine preparations protected the animal against death when the challenged intraperitoneally. Animals that were challenged via aerosol did not survive.
- Developed seven monoclonal antibodies that react with *B. mallei* and not *B. pseudomallei* when assessed by enzyme-linked immunosorbent assay (ELISA). The antibodies will be used in a competitive ELISA in an effort to increase the specificity of the assay.
- Evaluated two preparations of the oligonucleotide immunoenhancer, CpG, for the ability to protect mice exposed to aerosol challenge with virulent *B. mallei* and determined the optimal CpG dose and schedule. Results demonstrated that 100 µg of CpG was more efficacious than lower doses used in this study and that the intraperitoneal route was superior to the subcutaneous route of administration.
- In an effort to understand the mechanism of *B. mallei*-induced cell death, studies were performed to titrate the effective range of infection (i.e., bacterial cell number) and optimum infection time for bacterial replication using the J774.1 and MH-S (resistant), and AMJ2 and J774.1-dnMKK4 (sensitive) macrophage cell lines.
- Observed that macrophages are capable of clearing infection when approximately 5–10 x 10⁷ viable *B. mallei* or *B. pseudomallei* cells per milliliter (cells/ml) are used to infect the macrophages. Determined that, when infectious doses greater than 1x10⁹ viable cells/ml are used, the infected macrophages remain viable for up to 4-8 hr post-infection, but are killed by 24 hr post-infection.
- Observed that macrophage cell lines from BALB/c mice are more sensitive to *B. mallei* and *B. pseudomallei* infection than cell lines from the C57BL/6 strain of mouse.
- Determined that cell lines derived from alveolar macrophages are less permissive for bacterial growth than those derived from peritoneal macrophages.
- Observed that macrophages exposed to killed *B. mallei* and *B. pseudomallei* or infected in vitro with the bacteria respond with a strong inflammatory response with significant expression of the cytokines, IL-1b and TNF-a.
- In preliminary studies of the effects of acyl homoserine lactones (AHL) expressed by *B. mallei* and *B. pseudomallei*, on macrophage and T-cell lines, results suggest a decrease in the viability of the treated T-cells but not in the macrophages.
- Analysis of T-cell lines Hut-78 and H-9 treated with irradiated *B. mallei* and *B. pseudomallei* suggests that the mechanism of cellular toxicity results from apoptosis.
- Successfully generated a panel of monoclonal antibodies (MAbs) specific for *B. mallei*. Preliminary immunoblot assays indicate that the majority of the MAbs react with lipopolysaccharide moieties of *B. mallei*.

- Developed four individual anti-*B. mallei* MAb-based competitive inhibition ELISAs for use in vaccine studies.
- Examined the role of dendritic cells (DC) and innate immune components such as γ/δ T-cells after challenge with *B. mallei* or *B. pseudomallei*.
- Isolated peripheral blood mononucleocytes (PBMC) from random healthy donors by Ficoll-Hypaque centrifugation and screened the PBMCs for reactivity to γ/δ T-cell antigen by culturing them with or without inactivated *B. mallei*. Expanded PBMCs responding to inactivated *B. mallei* by 5- to 30-fold using flow cytometry with TCR V gene-specific monoclonal antibodies. Tested γ/δ T-cells obtained via flow cytometry for the expression of TOLL-like receptors (TLR - key components of innate immune responses) and found many of the TLRs were substantially modulated in the *B. mallei*-treated group as compared to those in untreated control cells.

Research thrust: *Reverse genetic identification of Burkholderia pseudomallei and B. mallei virulence determinants to identify the virulence determinants of B. pseudomallei and B. mallei:*

- Purified genomic DNA from *B. pseudomallei* (DD503), *B. mallei* (GB8), and *B. thailandensis* (DW503) for PCR amplification by using a commercially available DNA purification kit according to the manufacturer.
- Amplified target genes and internal gene fragments for disruption constructs by polymerase chain reaction (PCR) using primer pairs designed from the *B. pseudomallei* NCTC 4845 genome project.
- Created six GB15 quorum mutants that disrupt the *bmI1* and *bmI2* AHS alleles in addition to four (*bmR1*, *bmR3*, *bmR4*, and *bmR5*) transcriptional regulator mutants.
- Disrupted the complete quorum network in DW503 and found that it consists of three AHL synthase genes (*btI1-I3*) and five cognate AHL receptor proteins (*btR1-R5*).
- Achieved successful mutations in the *bpmI1*, *bpmI3*, *bpmR2* and *bpmR3* genes.
- Measured siderophore production by *Burkholderia* strains DD503, GB15, and DW503.
- Determined that strains DD503, GB15, and DW503 synthesize both N-hexanoyl-L-homoserine lactone (HHL) and N-octanoyl-homoserine-L-lactone (OHL).
- From lipid extracts from strain DW503, showed that *B. thailandensis* synthesizes a rhamnolipid similar to *B. pseudomallei*.
- Determined that all of the *B. mallei* quorum mutants exhibited a significant reduction in the ability to disseminate and colonize the spleens of BALB/c mice.

Research thrust: *develop vaccines against Yersinia pestis, causative agent for pneumonic plague:*

- Determined the effect of CpG 10105 (an oligonucleotide immunoenhancer) when used in combination with the recombinant plague vaccine candidate (F1-V fusion antigen) in BALB/c mice. Results indicated that survival is enhanced as the dose of the vaccine increases.
- Found that CpG 10105 resulted in an increase in the amount of immune globulin IgG above that observed in mice immunized with the vaccine candidate alone. The observation was consistent across the F1-V vaccine doses used in the study.
- Determined that the relationship between the level of IgG and the immunomodulator was inverse – the 5 μ g dose of CpG 10105 stimulated higher amounts of IgG than the higher doses (10 and 25 μ g) used in the study.

- Determined that the F1-V vaccine candidate stimulated a high IgG1 subclass response and a very low IgG2a subclass response.
- Initiated cloning of the fusion protein hsp 70-V to use as a candidate vaccine for plague and cloned the *Y. pestis* hsp 60 gene into pET15b.
- Analyzed total cell protein and culture supernatant of *Yersinia enterocolitica* cultures by two-dimensional electrophoresis (2-DE). Documented notable differences in the membrane protein proteome between wild type and mutant strains of the microorganism. Compiled lists of mutant-related proteins for further processing by mass spectroscopy for protein identification.
- As part of preclinical research leading to the development of the F1-V fusion antigen recombinant plague vaccine candidate, performed an efficacy bridging study with a laboratory-prepared lot of the plague vaccine candidate and a pilot lot produced by a commercial manufacturer. The study found comparable protection against moderate aerosolized encapsulated challenge between both vaccine lots at the test dose 10 µg delivered one time). Performed serological analysis and found no statistically significant differences in mean titers to F1 or V between the vaccine lots.
- Performed a preliminary experiment, under a Collaborative Research and Development Agreement (CRADA) with ID Biomedical, comparing immunogenicity and efficacy versus route of inoculation and adjuvants in mice with the plague vaccine candidate. Found that intranasal inoculation with proteosome-formulated F1-V vaccine provided enhanced immunogenicity and efficacy against 200 LD₅₀ of aerosolized CO92 plague vs. Alhydrogel/F1-V vaccine given intramuscularly. Selected one (IVX-908) of three proposed adjuvant formulations for future studies based on superior efficacy and immunogenicity in the preliminary studies.
- Completed three anti-F1-V passive transfer experiments in the mouse with immune nonhuman primate serum. The data suggest that antibody is sufficient to protect naive animals from plague and that this protection may be dose dependent. Additional studies are underway to confirm this hypothesis.
- Purified naïve and immune IgG fractions for future studies.
- Conducted nonhuman primate serological analysis to assist in determining the association between total IgG or IgG1, IgG2 or IgG3 and protection.
- Initiated a CRADA with the Trudeau Institute and provided protein to map “protective” F1-V T-cell epitopes.
- Provided F1-V under a CRADA with the National Institutes of Health (NIH) to evaluate the F1-V vaccine candidate in the flea-bite model for plague infection (bubonic form of plague).
- Screened several anti-V antigen monoclonal antibodies for concentration and binding before performing studies to assess protection in a mouse passive transfer study.
- Demonstrated a statistically significant correlation between anti-F1 antibody levels in mice vaccinated with recombinant F1 (rF1) and protection against a subcutaneous (s.c.) challenge. Extended this observation to include recombinant F1-V-vaccinated mice challenged either s.c. or by whole-body exposure to the challenge strain.
- Tested the sera of a group of cynomolgus macaques vaccinated with recombinant F1-V vaccine candidate and challenged with *Y. pestis* in the anti-F1 competitive inhibition

ELISA. The results suggest an association between high serum levels of anti-F1 antibodies in the macaques with survival from a lethal *Y. pestis* challenge.

- Generated and tested five anti-V monoclonal antibodies in passive transfer experiments using the mouse model of pneumonic plague to determine their ability to provide protection.
- Established Th1 and Th2 cytokine profiles of spleen cells obtained from mice vaccinated with either recombinant F1 (rF1), recombinant V (rV) or recombinant F1-V (rF1-V) and stimulated in vitro with either rF1, rV or rF1V. Found that cytokines of both the Th1 and Th2 types were expressed.
- Performed studies to establish the aerosol LD₅₀ for *Y. pestis* strain CO92 in the cynomolgus macaque. Results indicate the LD₅₀ to be 400 CFU inhaled organisms.
- Completed a challenge study in cynomolgus macaques with the F1-V vaccine candidate combined with Alhydrogel. Animals were challenged with 100 LD₅₀ of *Y. pestis* strain CO92 six weeks after the third dose. Eight of 10 immunized animals (80%) survived challenge. All control animals died.
- Determined the absolute mass of F1-V and its subcomponent proteins by high performance size exclusion chromatography (HP-SEC) coupled with detection/analysis by multi-angle laser light scattering (MALS), together referred to as SEC-MALS) in aqueous solution at physiological conditions. Determined that purified F1-V protein exists as a polydisperse population in phosphate-buffered saline at 37° C.
- Developed several assays to characterize the F1-V plague vaccine candidate, including SEC-MALS, sodium dodecylsulfate – polyacrylamide gel electrophoresis (SDS-PAGE), western blot, reverse-phase HPLC (RP-HPLC), and high performance size exclusion chromatography (HP-SEC). Comparative characterization of F1-V protein in research-grade lots and two commercially prepared pilot lots via these assays indicated equivalence in biochemical structure.
- Determined that the Pestoides group of *Y. pestis* strains is the missing link between *Y. pestis* and *Y. pseudotuberculosis*. Data indicate a stepwise evolution for *Y. pestis*.
- Determined that the Angola strain, part of the Pestoides group, appears to be the closest link to *Y. pseudotuberculosis* and is the most ancient of *Y. pestis* strains identified to date, while other Pestoides-type strains fall between Angola and typical *Y. pestis* strains.
- Preliminary results from invasion assays with the HeLa cell line suggest that Pestoides F more closely resembles the attenuated Pla- derivative of *Y. pestis* strain CO92 in invasive ability than the fully virulent CO92 parental strain. Preliminary evidence indicates that Pestoides F, which lacks plasmid pPst, may differ from typical strains in its ability to maintain certain replicons.
- Determined that the unique *Y. pestis* plasmid pJARS is readily transferred to an *E. coli* K12 arsB strain by conjugation with selection for arsenic resistance, suggesting a mechanism for acquisition of the plasmid by Java 9 (interspecies transfer).
- Identified a source of recent Tanzanian isolates of *Y. pestis*.
- Collaborated with Lawrence Livermore National Laboratories (LLNL) for whole-genome sequencing and genetic analysis of diverse *Y. pestis* strains. Collaborated with Northern Arizona University and LLNL to create new methods for genetic analysis.

- Undertook a study to determine which adjuvant (CpG, MPL-AF, LT-192) would be most appropriate for use in formulating an inhalational F1-V vaccine against *Yersinia pestis*. Mice were vaccinated either intranasally or intramuscularly with the F1-V protein formulated with CpG, MPL-AF, or LT-192 adjuvants. The control group received intramuscular vaccination with F1-V protein formulated with Alhydrogel. Groups vaccinated by intranasal administration of F1-V were not protected against pneumonic plague challenge, regardless of the adjuvant used. Determined that both CpG and LT-192 performed as well as or better than Alhydrogel in animals vaccinated intramuscularly, suggesting potential use as alternative adjuvants.
- Demonstrated that treating *Y. pestis* with well-defined antibodies (rabbit polyclonal anti-V IgG or monoclonal antibody 7.3) both specific for V and protective against plague in vivo, protected J774.A1 macrophages from *Y. pestis*-induced cell death.
- Compared sources/stocks of the J774 macrophage cell line for consistent performance over time with control samples and determined that the source of the macrophages had no apparent effect on assay performance, provided the cells were used within 48 hr of seeding and were morphologically and functionally viable. Found that the attenuated derivative of strain C092 (C092/pgm- pPst-), performed more consistently than a similar derivative (C092/pgm- Pla-) and performed comparably in the macrophage assay to the strain used originally to develop the assay (strain C092/pgm-). Also determined that inconsistency in growth of the infecting strain of *Y. pestis* was likely a major source of inter-experimental variability. To alleviate this problem, a master seed stock of multiple single-use vials of the infecting strain of *Y. pestis* was prepared to facilitate assay consistency and reproducibility.
- Initiated tests to assess the correlation between in vitro cytotoxicity neutralizing activity of sera from vaccinated animals and protection from lethal challenge.
- Used several variations of the yeast two hybrid (TH) system to detect protein interactors and identified eight gene products as candidate V-interacting proteins. These included sequences with homologies to entities such as a protein tyrosine phosphatase, proteases, and amino acid synthetases, the IgM constant region H chain, cyclin I, and a fatty acid-binding protein.
- Performed a study to search for V-interacting proteins in two new cellular DNA libraries (human fetal lung and mouse spleen) with the BacterioMatch™ bacterial TH system and identified library clones potentially able to interact with V and sequenced the target protein genes.
- Prepared 25 signature-tagged mutant pools of *Y. pestis*. Exposed mice to aerosols of three of the pools and collected tissue samples as preliminary steps to identify genes important for aerosol pathogenicity caused by *Y. pestis*.

DTO CB. 34 Recombinant Plague Vaccine Candidate

Objectives. The objective is to complete the preclinical development of the recombinant F1-V fusion protein plague vaccine candidate.

Payoffs. Infection induced by inhalation of *Yersinia pestis* represents a serious biological warfare threat. The resultant disease, pneumonic plague, is associated with an incubation period of 2-5 days and an untreated mortality of nearly 100% within 1-3 days after onset of illness. The previously licensed

DTO CB. 34 Recombinant Plague Vaccine Candidate

plague vaccine is no longer available and provides poor protection against aerosolized *Y. pestis*. The recombinant F1-V fusion protein has shown excellent protection against aerosolized *Y. pestis* in rodents, and partial protection in a preliminary nonhuman primate (NHP) study. Additional preclinical studies in animals are required to define optimal dosing schedules, long-term immunogenicity, and duration of protection. Additionally, in vitro correlates of protective immunity must be established to obtain FDA licensure. A strong correlate of immunity with an associated assay could potentially replace older animal-based efficacy testing for vaccine potency. The vaccine candidate should also be assessed against a variety of strains of virulent *Y. pestis*. Well-established mouse and NHP aerosol models will facilitate completion of these goals. An effective FDA-licensed vaccine against aerosolized plague will enhance force protection and strategic mobility. **In FY02**, performed vaccine efficacy studies in two NHP species to resolve the most appropriate model for demonstrating protection with the vaccine candidate. Also, continued expanded studies in NHPs for immunogenicity and passive protection and to establish a correlate of immunity. Advanced the vaccine candidate to a Component Advanced Development (CAD) review in July 2002, engaging the advanced developer in executing Milestone B entrance criteria and facilitating transition out of tech base.

Challenges. Major technical challenges include identification of the most appropriate in vitro correlates of protective immunity against aerosolized plague, establishment of a surrogate efficacy model for F1-V immunity, and the time required to assess the duration of protection offered by the F1-V vaccine candidate.

Milestones/Metrics.

FY2003: Complete expanded NHP studies for immunogenicity and efficacy, including the evaluation of long-term immunity, correlates of immunity, and range of protection against other virulent strains of *Y. pestis*.

Research thrust: *develop a vaccine against Bacillus anthracis, causative agent of anthrax:*

- Selected 19 target open reading frames (ORF) by using the available *B. anthracis* preliminary sequence database from the The Institute for Genomic Research (TIGR) website. Also searched a subset of ORFs. The non-redundant list obtained from these searches comprised approximately 1400 ORFs.
- Obtained primer/probes for the plasmid ORFs and confirmed their functions by using *B. anthracis* genomic DNA.
- Developed a TIGR microarray consisting of three-fourths of the ORFs in *B. anthracis*.
- Successfully generated a *pagA* gene knockout mutant that produces only edema factor (EF) and lethal factor (LF) and created four additional gene knockout mutants. Tested the five mutants using approximately 20 LD₅₀ of each to challenge guinea pigs and determined that four of the mutants were as virulent as wild-type Ames strain of *B. anthracis* in these animals.
- Established a detailed plan for plate design for a quantitative reverse transcriptase-polymerase chain reaction (RT-PCR) assay.
- Initiated studies to determine the optimal conditions (time and amount of tissue) for extracting mRNA from *B. anthracis*-infected tissues in various organs and determined the conditions for optimal mRNA extraction for in vitro-grown organisms using 16sRNA probes.

- Conducted an accelerated potency stability study of the recombinant protective antigen (rPA) vaccine candidate to facilitate transition to advanced development. Also, initiated a long-term efficacy study in rabbits immunized with the rPA vaccine candidate.
- Collected preliminary information required for later formulation studies with the rPA vaccine candidate and began the planning process to test several options for alternative adjuvant/stabilizer/physical forms for improving the rPA vaccine candidate.
- Analysis of the rPA in a vaccine pilot lot produced under current Good Manufacturing Practices (cGMP) conditions by an enzyme-coupled HPLC assay revealed the presence of modified amino acids, including de-amidated asparagines.
- Demonstrated >90% survival in animals challenged with virulent anthrax with a 100 µg rPA dose in the rPA vaccine candidate. Statistical analysis of the data showed that ELISA titer and concentration level significantly influenced survival. Data obtained with the toxin neutralizing assay (TNA) suggest that the upper plateau titer response in rabbits is greater than the highest rPA vaccine dose tested thus far (100 µg of rPA). Statistical analysis of the data suggests a significant correlation between the effective dose 50% (ED₅₀) and relative ED₅₀ (RED₅₀) titers at all weeks. Cox Proportional Hazards Model survival analysis showed that the ED₅₀ and RED₅₀ titers significantly influenced survival when concentration level was factored in.
- Observed a 3.13-fold and 2.33-fold increase in odds of survival per log₁₀ increase in week 2 geometric mean ED₅₀ titer and RED₅₀ titer, respectively. Also measured similar odds of survival for weeks 3 and 4. Observed no significant correlations between TNA assay titers and ELISA titers at each week.
- Found that two doses of rPA vaccine at 0 and 4 weeks induced a graded response against challenge with a targeted aerosol dose of 80 LD₅₀ Ames spores. Survival analysis by the Cox Proportional Hazards Model showed that ELISA titer at each week tested significantly influenced survival.
- Evaluated Alhydrogel adjuvant in rPA vaccine preparations in New Zealand white rabbits. After two doses of 50 µg of rPA with Alhydrogel, 100% of the animals were protected against a targeted aerosol dose of 80 LD₅₀ Ames spores compared to 91% of the animals dosed with rPA vaccine without Alhydrogel.
- Demonstrated passive protection in CBA/J mice with rabbit anti-AVA serum (50% protection) and rabbit anti-rPA (45% protection) against a B. anthracis Vollum 1B strain challenge (combined results from three separate experiments). Determined there was no protection provided with human anti-AVA serum as measured by affinity-purified anti-PA IgG.
- Determined that the immunological response of female A/J mice to inoculation with a single dose of rPA in Alhydrogel resulted in a linear dose response between 100 µg and 0.1 µg of rPA as measured by a quantitative anti-PA IgG ELISA using polyclonal antibody as a standard. Week 5 quantitative anti-PA ELISA IgG titers were the best predictors of ELISA titer from concentration.
- Demonstrated that female A/J mice were completely protected against 10LD₅₀ B. anthracis Sterne strain spores after subcutaneous (sc) inoculation with as little as 0.032 µg of rPA containing Alhydrogel. Protection was only partial with a 100 LD₅₀ Sterne spore challenge and with a 10LD₅₀ sc Vollum B spore challenge.

- Determined that two doses of rPA with Alhydrogel at 0 and 4 weeks resulted in about a 10-fold increase in geometric mean quantitative anti-PA IgG ELISA titers two weeks after the week 4 booster inoculation for all five groups tested.
- Observed that A/J mice inoculated with four half-log serial dilutions of rPA vaccine from a fixed protein and Alhydrogel concentration (31.6 µg of rPA) had a linear response between anti-PA IgG ELISA titer and vaccine dose.
- Found that the immunological response of CBA/J mice to inoculation with rPA as measured by anti-PA IgG ELISA titers differed from that of A/J mice.
- Determined that CpG oligonucleotides enhance non-specific (innate) immunity to anthrax spore challenge in mice and found that they also enhance specific, vaccine-induced protection in guinea pigs.
- Determined in rhesus monkeys that CpG oligonucleotides administered with rPA plus Alhydrogel or AVA resulted in anti-PA ELISA titers that were higher, longer lasting, and higher in avidity than in control animals that were not administered the CpG along with the vaccines.
- Inserted various promoters, designed from a search of the *B. anthracis* genome for highly expressed genes, in front of the protective antigen (PA) gene (*pagA*) in an attempt to elevate expression of PA.
- Inserted various antigen genes downstream of *pagA* in an operon structure for co-expression of the antigens (LFnV, LF, and Hly).
- Deleted sufficient portions *pagA* to inactivate it and prevent toxin formation in the case of the downstream insertion of the lethal factor gene (*lef*) and in an attempt to elevate expression levels that might be affected by the presence of excessive proteins (PA) destined for secretion.
- Showed that including a *B. anthracis* *prsA* homologue resulted in an increase in protein secretion levels, which was consistent with the observation that *prsA* increased the synthesis rates of secreted proteins in *B. subtilis*, a related organism.
- Observed a range of expression levels in vitro and in vivo for nine different promoters tested. Mice from which the anti-PA titers were obtained were challenged with *B. anthracis* Sterne strain spores as well, showing levels of protection comparable to that of rPA.
- Found and isolated a spontaneous deletion in one of the promoter plasmids, in which the entire *pagA* gene was lost by recombination between the second *pagA* codon and the second codon of the green fluorescent protein (*gfp*) gene, by its higher fluorescence relative to that of the background parent strain. Determined that spores produced by *B. anthracis* strains Δ ANR, Sterne, and Sterne hly- that harbored the mutant plasmid were also fluorescent.
- Found several potential spore coat proteins during analysis of the TIGR *B. anthracis* DNA sequence data.
- Analyzed data from the complete DNA sequence of the chromosome of *B. anthracis* for determining possible virulence factors that will be studied by real time PCR.
- Obtained a preliminary annotation of the *B. anthracis* genome from TIGR and used it to complement the analysis.
- Examined the *B. anthracis* cholesterol-dependent cytolysin gene (*hly*). Determined that the function of homologues of this protein from bacterial pathogens is the formation of

large pores in eucaryotic membranes, allowing bacterial escape from phagolysosomes and from the cytoplasm, and is thus a potential virulence factor in *B. anthracis*.

- Deleting the gene in Δ ANR and Sterne resulted in no noticeable loss in virulence in mice nor in survival in macrophages, suggesting that this protein is not an essential virulence factor or that *B. anthracis* produces other proteins with redundant capabilities.
- Tested 32 *B. anthracis* isolates obtained from diverse geographic locations in AVA-immunized guinea pigs and, in an adjunct study, tested ten of the isolates in rPA-vaccinated guinea pigs. Five of the isolates were determined to be more virulent in the inoculated guinea pigs than the *B. anthracis* Ames strain
- Grew several of the isolates in both a complete and minimal medium to determine differences in growth rates and found that there were differences in growth rates among the isolates. The differences in growth rates did not correlate to the differences in virulence exhibited by inoculated guinea pigs.
- Identified an isolate of *B. anthracis* that spontaneously lost its capsule when incubated on capsule agar in the presence of 5% CO₂ in air. This loss of capsule was concomitant with the loss of plasmid pX02 as confirmed by PCR.
- Tested all isolates for hemolysin and protease production by standard assays and found that all isolates produced hemolysin on washed sheep blood agar plates. Determined that four of the isolates did not produce protease on casein agar.
- Found that treating spores with anti-PA antibodies was associated with increased phagocytosis, greater rate of intracellular germination, and enhanced killing by the macrophage.
- Developed a quantitative, semi-automated procedure for detecting germination by using a microtiter kinetic reader for fluorescence spectrophotometry. Demonstrated that anti-PA antibodies inhibit *in vitro* germination. Performed regression analyses of the germination data obtained with the reader. Results yielded parameters (i.e., the difference between the baseline and maximal fluorescence values (a coefficient) and the area under the curve) that revealed significant differences between spores pretreated with anti-PA or non-immune IgG or antiserum.
- Developed protocols that allow germination to be measured either continuously or at defined intervals upon exposure to the germinant.
- Initiated peritoneal chamber implantation experiments to model spore germination *in vivo* and to determine if intracellular localization (i.e., residence within macrophages) is required to induce germination of *B. anthracis* spores in mice and guinea pigs. Initial results of chamber experiments suggest that spores cannot germinate readily *in vivo* in the absence of host blood cells (presumably mononuclear and/or polymorphonuclear phagocytes). Hypothesized that germination of spores *in vivo* by *B. anthracis* requires their exposure to the intracellular environment, i.e., the spores must be in contact with or phagocytosed by host cells.
- To understand the role of the *B. anthracis* capsule in immunity, utilized spores to purify each *B. anthracis* strain (Δ ANR, Δ Ames, Δ ANR-pPA102, and Δ Ames-pPA102) that will be used to vaccinate and challenge rabbits in future studies.
- Developed procedures for producing highly purified *B. anthracis* capsule and confirmed that humans produce an immune response to the capsule. Also created a non-polar capA mutant and developed a shuttle vector containing capA and constructed a depA mutant

and found that conjugating capsule to bovine serum albumin and PA increased its antigenicity.

- Determined in preliminary experiments that *B. anthracis* capsule may have minor adjuvant properties.
- Initiated experiments with blocking monoclonal antibodies to known receptors on macrophages to determine if masking a known receptor inhibits spore binding and confirmed that the antibodies were truly bound to murine peritoneal macrophages.
- Constructed mutants in the putative adherence genes, *adcA* and *orf168* of the *B. anthracis* Ames strain.
- Characterized a *B. anthracis* mutant in a rhamnose biosynthesis gene, *spsI*. Analyzed spores made from this mutant strain by transmission electron microscopy and found that most spores of the *spsI* mutant lacked an exosporium. In contrast, the exosporium was present on all spores from the Ames wild-type strain. Analyzed the carbohydrates of both the *spsI* mutant and Ames wild-type strains and found rhamnose in the exosporium from the Ames strain but not in the exosporium of the *spsI* mutant.
- Examined the interaction between *B. anthracis* spores and macrophages and recovered fewer colony-forming units (CFU) from the mutant strains than from the wild-type strain.
- Challenged 10 guinea pigs intramuscularly with 2000 spores of the mutant or the Ames wild-type strain but failed to observe any differences in survivability between the wild-type strain and mutant.
- Performed preliminary experiments to determine if anthrax spores are able to adhere A549 cells, a Type-II lung carcinoma line and found that spores adhered to the pneumocytes. Transmission electron microscopy suggested that a specific receptor exists for binding the spore to the pneumocyte. Defined this receptor by using lectin-coated cells, which showed a dramatic increase in spore adherence.

DTO CB.33 Recombinant Protective Antigen Anthrax Vaccine Candidate

Objectives. The objective of this DTO, which was completed in FY02, was to characterize a recombinant protective antigen (rPA) anthrax vaccine candidate, to include preliminary development of an appropriate in vitro correlate of PA-induced protective immunity against *Bacillus anthracis* aerosol exposure. Obtaining an alternative for the currently licensed anthrax vaccine would provide DoD with additional options in obtaining force protection against anthrax. The program produced a pilot lot of the rPA vaccine candidate consistent with current Good Manufacturing Practices for use in phase 1 clinical trials, demonstrated efficacy of the candidate against aerosol challenge with virulent anthrax in rabbits and non-human primates, demonstrated surrogate efficacy in guinea pigs and rabbits and, based on studies with licensed anthrax vaccine in animal models, proposed Toxin Neutralizing Antibody (TNA) as a surrogate marker for immunity. The program evaluated the requirement for formaldehyde to obtain stable vaccine preparations, continued to develop a potency assay and the determination of the in vitro correlate of immunity, developed antibodies to rPA in higher animal species to support passive immunity studies, and optimized proposed manufacturing procedures. Efficacy of the *B. anthracis*-derived rPA vaccine candidate was compared to rPA derived from *E. coli*. Technical summaries were provided to the Next Generation Anthrax Vaccine Integrated Project Team to support entry of the rPA vaccine candidate into Component Advanced Development (CAD), planned for the first quarter FY03. Entry into CAD engages the advanced developer in executing Milestone (MS) B entrance criteria and marks a successful conclusion of the DTO.

Research thrust: *develop a vaccine against Brucella melitensis*:

- Re-characterized a vaccine candidate described in FY01 as a new single deletion mutant and found that the mutant is attenuated and immunogenic in nonhuman primates. This vaccine candidate is currently the lead candidate for transition to advanced development.
- Demonstrated the antibacterial effects of immunization with the single deletion mutant in mice over a 6 month period.
- Initiated immunization and a Brucella challenge study with the single deletion mutant in nonhuman primates.
- Found that subcutaneous and intranasal immunization with lipopolysaccharide (LPS)-based vaccines LPS and LPS-GBOMP (Group B meningococcal outer membrane protein) were equivalent in providing protection from disseminated infection after intranasal challenge of mice with virulent Brucella.
- Found that passive transfer of immune serum markedly reduced bacteremia in nonhuman primates challenged with virulent brucellae, but did not affect intensity of infection of other elements of the mononuclear phagocyte system. These studies suggest use of this model as a potential in vitro correlate of vaccine-induced immunity that could be performed with serum from human vaccinees.
- Found that a double deletion mutant vaccine candidate that is attenuated and immunogenic after oral administration to mice is not attenuated in nonhuman primates. This study demonstrates the need for testing candidate vaccines in more than one mouse strain. Confirmed usefulness of conjunctival challenge route in nonhuman primates as a reproducible model of brucellosis, reducing the need for complex and expensive aerosol challenge models for intermediate studies.
- Established improved fermentation conditions for newly characterized live, attenuated Brucella vaccine candidate and determined stability of fermented vaccine candidates in several freezing media using FDA-approved excipients.
- Performed dose ranging studies for intranasal challenge of mice with Brucella suis and Brucella abortus and initiated immunization and challenge studies on B. suis.
- Found that antigen-stimulated spleen cells from mice immunized with a protective live, attenuated Brucella vaccine accumulated messenger RNA (mRNA) for 12 different cytokines and chemokines and correlated mRNA expression with protein secretion. These studies provide further support for a multiplex analysis of immune response using gene array
- Developed selective human cellular DNA (cDNA) slide arrays and established methods for analysis of antigen-stimulated nonhuman primate samples.
- Demonstrated anti-brucella activity using passive transfer of immune serum in nonhuman primates. Found that IgG from Brucella-immune mice protected C57BL/6, but not Rag-1 mice, from dissemination of intranasally administered virulent B. melitensis strain 16M, but reduced spleen infection in both mouse strains when animals were challenged with the purine auxotrophic strain WR201. These data suggest that B and/or T cell activity is required for antibody to protect against virulent brucellae, but not to protect against a purine auxotroph, further emphasizing the safety of a purine auxotroph as a live, attenuated vaccine candidate.

- Found that infection of human mononuclear phagocytes with “rough” Brucella (i.e., a brucella mutant that does not have long-chain O-polysaccharide molecules on its cell surface) enhances production of proinflammatory cytokines.
- Demonstrated high efficiency of human monocyte-derived macrophage transfection with heat shock protein-70 and inhibition of B. melitensis LPS-induced cytokine production in transfected cells. These studies lay the groundwork for development of nonspecific medical countermeasures against Brucella.
- Cloned green fluorescent protein (GFP) downstream from strong and weak Brucella promoters and demonstrated differential expression of GFP in vitro. Also expressed Bacillus anthracis protective antigen on a Brucella plasmid and adjusted codon usage to enhance expression. Heterologous antigen expression on the Brucella platform demonstrates that the platform may provide another multi-agent vaccine strategy.

DTO CB. 31 Medical Countermeasures for Brucellae

Objectives. The objective is to develop a genetically characterized live attenuated vaccine that elicits cellular and humoral immunity against the biological warfare threat of Brucella capable of protecting 90% of vaccinated warfighters against disease after aerosol exposure.

Payoffs. Brucella melitensis, B. abortus, and B. suis are closely related biological warfare threat agents that are highly infectious by aerosol and cause severely incapacitating illness. B. canis can also cause disease, but is less threatening. Protective strategies that rely on antibiotic prophylaxis or treatment may not be adequate (a multidrug-resistant strain of B. abortus is known to exist). Live attenuated vaccines have proven highly successful in controlling brucellosis in livestock, but none is suitable for human testing. A live, single deletion mutant vaccine candidate developed by USAMRMC between 1993 and 1999 was shown to be attenuated in mice and nonhuman primates (NHP) and highly efficacious in a pulmonary challenge model in mice. A vaccine that is efficacious against aerosol challenge in NHPs should protect humans against infection with all pathogenic species of Brucella. Such a vaccine would benefit warfighters at risk of exposure to this biological threat agent. **In FY02**, demonstrated that vaccine candidate MNPH 1 is more attenuated than the previously developed live attenuated mutant, WR201. Antibiotic resistance was also removed from the MNPH1 candidate, an important feature for manufacturing and for eventual use in humans. In addition, a freezing/lyophilization process with FDA-approved excipients was developed for MNPH1. The resulting vaccine preparation is proposed for use in future phase 1 clinical trial.

Challenges. Major technical challenges include defining the most appropriate in vitro correlates of protective immunity, and defining the best criteria for demonstration of efficacy. The limited availability of nonhuman primates for research also presents a challenge.

Milestones/Metrics.

FY2003: Demonstrate proof-of-concept for protective efficacy of candidate vaccine in the NHP conjunctival challenge model against Brucella melitensis, which is regarded as the most virulent for humans of the four pathogenic strains. Prepare a technical data package supporting FDA requirements for an Investigational New Drug application and transition of the candidate vaccine out of tech base.

Therapeutics Accomplishments:

Research thrust: identify and characterize therapeutics for bacterial BW agents:

- In support of research to identify and characterize antibiotics against aerosolized, Y. pestis, obtained a digital radiographic system to be used inside BSL-3 containment

suites and reagents to assay utility of gentamicin safety and efficacy in African green monkeys. Also obtained training to insert a chronic, indwelling, central intravenous line in African green monkeys to support conduct of pharmacokinetic and pathophysiological studies.

- Determined that 27 antibiotics evaluated thus far had positive activity against *B. anthracis*, *Y. pestis*, and the *Burkholderia* spp. while four compounds had no antibiotic activity against these agents.
- Determined the minimal inhibitory concentration (MIC) for 62 antibiotics against 22 strains of *B. anthracis* and determined MICs at two temperatures (37°C and 28°C) for 62 antibiotics on eight *Y. pestis* strains.
- Utilized the aerosol model for anthrax challenge in mice and evaluated LD₅₀ doses for Ames spores in four strains of mice in support of bacterial therapeutic research studies.
- Correlated antibiotic efficacy for ciprofloxacin and doxycycline in mice to data in the nonhuman primate model. Collected histopathology and tissue bacterial burden data for the mouse model and tested three additional antibiotics (levofloxacin, ampicillin, and ampicillin/sulbactam) in the mouse model.
- Identified potential target sites to screen for small molecule compounds that will inhibit anthrax toxin assembly and activity.
- Designed and established an in vitro peptide based plate assay to screen for inhibitors of anthrax toxin lethal factor (LF) activity. Also performed high-throughput screening of a diversity set obtained via collaboration with the National Cancer Institute (1990 compounds) using a fluorescence-based plate reader assay. Designed a HPLC-based assay for validating compounds that were positive in the plate reader assay. Validated the compounds that showed greater than 75% inhibition in plate reader assay.
- Tested 3,000 natural extracts against anthrax LF activity in a peptide-based cleavage assay. Developed a pharmacophore hypothesis and structure-activity relationship using molecular modeling and target-structure based approach in support of research toward development of therapeutics against *B. anthracis*. Screened 500 congeners of the lead compounds to identify compounds that exhibit increased specificity, affinity, and bioavailability. Tested some of the lead compounds of in vitro cell-based toxicity assays. Initiated testing of 5,000 natural compounds against anthrax toxin LF activity.

Toxin Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of toxins 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 Barriers:

- Develop 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 and antibody therapies for toxin agents of interest.
- Necessity to establish and maintain capabilities to assess threats and provide countermeasures for new and emerging toxin threats.

Vaccine Accomplishments:

Research thrust: *develop recombinant Staphylococcal enterotoxin (SE) vaccines:*

- Established a standardized assay for use in assessing human immune responses to the SE serotype B (SEB) vaccine candidate.
- Performed a study to infect CTL (cytotoxic T lymphocyte) targets with VEE replicons expressing the SEB subunit vaccine.
- Completed determination of SE serotype A (SEA) vaccine structure by x-ray crystallography.
- Continued long-term stability testing of the SEB vaccine candidate pilot lot via the standardized protocol and found no indications of variance from designated tolerances.
- Obtained SEA vaccine reference standard from a commercial source and biochemically characterized it for identity, purity, and comparison to the laboratory standard. Results were comparable to the standard.
- Purified additional SEB vaccine (6 g) from the production lot produced under cGMP conditions via contract arrangement for use in research studies.
- In support of research to develop an inhalationally delivered SE vaccine, established the aerosol LD₅₀ for SEB in transgenic MHC-II mice and also established immunological, toxicological, and histopathological parameters in the mice. Established the efficacy of inhaled SEB vaccine in transgenic and BALB/c strains of mice.
- Demonstrated in passive transfer studies that 70% of mice injected with sera from other mice receiving the SEB vaccine candidate formulated with the immunomodulator CpG survived an intraperitoneal challenge.
- Tested an aggregated form of the SEB vaccine candidate in mice for immunogenicity and developed a hypothesis that derivatives of superantigen vaccines engineered to assemble into aggregates would be able to induce immunity when administered intranasally.
- Created a mutant version of the existing SEB vaccine candidate with cysteine residues at the N and C termini (SEBv-2C) and observed that this protein forms fibrous aggregates via electron microscopy.

- Performed three experiments in which Balb/c mice were given three doses (100 µg) of SEBv-2C protein intranasally at 2-week intervals. Preparations of the SEBv-2C vaccine containing a mixture of insoluble aggregate and soluble monomeric protein produced substantial seroconversion after three doses while the originally formulated SEB vaccine without adjuvant failed to elicit seroconversion. After challenge with 10 µg of SEB + 75 µg of lipopolysaccharide (~30 LD₅₀), mice vaccinated with SEBv-2C were only partially protected. Higher levels of survival were observed when cholera toxin subunit was administered as adjuvant, which was consistent with observed serum antibody titers.
- Determined from intranasal and intramuscular studies using the recombinant SEB vaccine candidate, that the cholera toxin subunit (for intranasal inoculations) and Alhydrogel (for intramuscular inoculations) were more effective than alpha-2-M as adjuvants for antibody induction.
- Evaluated intradermal and transdermal devices from a commercial pharmaceutical manufacturer in research studies to develop transdermal immunization with protein subunit vaccines. Initiated formulation studies for with SEB and recombinant protective antigen (rPA) vaccines for compatibility with trans- and intradermal devices.

DTO CB. 32 Alternative Delivery Methods for Recombinant Protein Vaccines

Objectives. The objective is to develop alternatives to the injection of recombinant protein-based vaccines that result in mucosal and systemic immunity to these agents.

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. **FY02** accomplishments included a proof-of-concept study for transdermal and intranasal vaccine delivery with the recombinant protective (rPA) vaccine candidate, downselection to one lead from several intranasal adjuvant candidates with the recombinant F1-V plague vaccine candidate, and a comparison of immunomodulators and other adjuvants/activators with intranasal delivery of a recombinant ricin vaccine candidate.

Challenges. Major technical challenges include defining quantifiable immunological end-points indicative of protection, producing stable vaccine formulations, selecting practical and efficacious route(s) of administration, and protecting vaccinated individuals from lethal and incapacitating toxin challenges. In addition, the limited availability of nonhuman primates for study presents a challenge.

DTO CB. 32 Alternative Delivery Methods for Recombinant Protein Vaccines

Milestones/Metrics.

FY2003: Demonstrate efficacy of needle-less monovalent vaccines. Propose formulations for intranasal/inhalation and transdermal delivery. Conduct baseline studies in animal models.

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. Complete program studies and prepare a technical data package that addresses FDA requirements and that supports transition of the needle-free delivery technology out of tech base.

Research thrust: *develop vaccines against botulism:*

- Demonstrated that various parts of the recombinant botulinum neurotoxin protein, not previously developed as vaccine candidates, can elicit a protective immune response in mouse models.
- Completed scale-up process development for the recombinant botulinum neurotoxin (rBoNT) type E heavy chain (Hc) vaccine candidate. The vaccine candidate was determined to significantly protected mice from challenge with BoNTE.
- Developed antibody reagents for use in ELISA and western blots for research studies with recombinant botulinum types A, B, C, E, and F vaccine candidates.
- Determined that the rBoNT type A(Hc) vaccine candidate elicited protection against both A1 (Hall strain) and A2 (honey/Kyoto strain) types of BoNT type A.

Research thrust: *development of a recombinant ricin vaccine:*

- Demonstrated a dose response in mouse antibody titers after two and three vaccinations with recombinant ricin vaccine candidate RTA198/33.
- Continued passive transfer protection studies with deglycosylated ricin A chain to develop a surrogate model for testing ricin vaccine candidates RTA198 and RTA198/33.
- Completely re-sequenced yeast-optimized genes for RTA198 and RTA198/33 proteins in order to demonstrate the genetic stability of the gene sequences. Obtained E. coli-optimized genes for RTA198 and RTA198/33.
- Confirmed dynamic light scattering experiments that suggested that RTA 198/33 is a monodisperse monomer in buffer and determined the molecular radius and confirmed the molecular weight of 19,300 daltons on a standard curve of globular proteins. Also obtained thermal melts of lead vaccine candidate RTA198/33, which showed it to be more stable than the previously developed chemically-derived ricin toxin A-chain (RTA) vaccine candidate. In addition, characterized the RTA198/33 vaccine candidate by circular dichroism and near and far UV absorption. Initiated chemical denaturation studies with RTA198/33 to understand why it is more stable than RTA.

DTO CB. 46 Recombinant Ricin Vaccine

Objectives. The objective 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.

FY2003: Perform scale-up process development for lead immunogens and qualify an analytical test for stability. Test immunogens in an in vitro vascular leak model. Downselect the lead immunogen. Initiate formulation and stability studies and a potency assay for the lead immunogen. Finalize studies to determine adjuvant requirements for a proposed vaccine. Perform abbreviated efficacy studies to bridge to data generated with an earlier ricin vaccine candidate (deglycosylated ricin toxin A-chain). Develop a small animal passive transfer model.

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.

Therapeutics Accomplishments:

Research thrust: evaluate therapeutics against *Staphylococcal enterotoxins (SE):*

- Determined that aerosolized SEB was lethal to HLA transgenic mice. This demonstrates the potential of this “human-like” animal model for application to the development of vaccines against “superantigen” molecules such as the SEs.
- Determined that aerosolized SEB induced high levels of inflammatory cytokines in the lungs and spleens of HLA transgenic mice. Studies using human MHC class II transgenic mice showed inhibitors of signal transduction such as PLC inhibitors may be useful for SE-toxicity. Also determined that aerosolized SEB induced lung lesions in the HLA transgenic mice, similar to SEB lesions induced in nonhuman primates.
- Tested several “statin” compounds in vitro for therapeutic activity against SEs and determined that lipid raft microdomains may play a crucial role in SE toxicity, suggesting that these microdomains could be targeted in therapeutic activity studies.
- Tested two “statin” compounds in transgenic mice and demonstrated that they reduced SE induced cytokine gene expression and protein induction. Pre-treating the transgenic mice with statin compounds protected HLA-DR3/DQ8 transgenic mice against SEB challenge.

- Created 528 transgenic mice and tested them for expression of HLA-DQ and DR genes. Also monitored human MHC class II protein on mononuclear cells obtained from the transgenic mice.
- Obtained a trimeric peptide, which was shown to inhibit SE toxicity in BALB/c mice, for future testing in transgenic mice.
- Screened over 4000 compounds for SE therapeutic potential (2000 against SEB and 2000 against SEA) from a diversity set obtained from the Developmental Therapeutics Program (DTP) of NCI. The compounds were assessed for inhibition of binding of fluorescent SEA or SEB to MHC molecules expressed on the surface of LG2 cells. Identified 19 of these compounds as potential candidate therapeutics against SEB. Screened 500 congeners of the lead compounds to identify those that exhibited increased specificity, affinity, and bioavailability, and tested some of them by flow cytometry.
- Identified two drugs, baicalin and pirfenidone, capable of blocking SEB-induced cytokine (IL-1b, TNFa, IL-6, IFNg, MCP-1, MIP-1a and MIP-1b) release and T cell proliferation in vitro. Determined that biacalin, a flavonoid from a medicinal herb, delayed death and prevented lethal effects in DQ8 transgenic mice exposed to SEB aerosol in preliminary experiments. Found that baicalin inhibited SEB-induced cytokines and chemokines at the transcriptional level.

Research thrust: *develop therapeutic strategies against botulinum neurotoxins:*

- Provided a free-energy profile for complex formation between botulinum neurotoxin type B and synaptobrevin fragment.
- Completed gene encoding a mutated non-toxic botulinum neurotoxin (BoNT).
- Produced purified recombinant light chains (rLC) for BoNT serotypes A, B, and C1.
- Developed chimeric and human monoclonal antibodies with a high capacity for neutralizing BoNTA.
- Developed and tested rapid assays for use with non-toxic recombinant light chain of several BoNT serotypes for therapeutic research studies.
- Improved a microtiter plate assay by eliminating the final transfer step and permitting real-time velocity tracings during the assay.
- Collaborated with the Mayo Clinic to identify, synthesize, and test BoNT inhibitors.
- Screened a database of 2.5 million unique chemical structures based on structure-function predictions in support of research toward development of botulinum therapeutics.
- Analyzed L-chain and substrate vesicle-associated membrane protein (VAMP) fragments with mass spectroscopy (MS) as part of a research effort to assess the structural stability of the L chain of BoNTB. Developed an additional hydrogen-deuterium (H-D) approach to provide more detailed MS information.
- As part of a research effort to develop immunoliposomes for BoNT type A heavy chain targeted for receptor-specific delivery of anti-BoNT chemotherapeutic agents, prepared batches of liposomes to select the composition most suitable for film formation and for rehydrating the liposomal vesicles. Determined that the best phospholipid composition was hydrogenated soy-bean phosphatidyl cholin (HSPC):cholesterol:maleimide-derivatized disteoyl-phosphatidyl-ethanolamine (DSPE) and the best molar ratio was

determined to be 2:1:0.1. Accomplished the size reduction of the liposomes by serial extrusion through polycarbonate filter of various sizes.

- Examined conformational change in BoNT A Hc fragment at various pH levels using hydrogen/deuterium exchange mass spectrometry (MS) and established a procedure that is applicable to almost any protein. Examined the fluorescence of BoNT A holotoxin at different pH values. Used multilamellar vesicles (MLVs) of different phospholipid composition to evaluate membrane topology of botulinum neurotoxin A at pH values of 7 and 5. Observed BoNT A-mediated calcein release from asolectin liposomes after pH reduction. Initiated crosslinking reactions on BoNT A solutions and used gel electrophoresis and MS to monitor the reactions as part of ongoing immunoliposome studies.
- Used nerve growth factor-differentiated and non-differentiated PC-12 cells to assess BoNT A, tetanus toxin, and diphtheria toxin binding and organization. Observed ganglioside and phospholipid binding to tetanus Hc fragment using MS.
- Performed preliminary experiments using nerve growth factor-differentiated PC-12 cells to test if the initial binding of BoNT A uses lipid raft membrane microdomains as organizing centers for binding and internalization.
- Synthesized and tested substrates of varying lengths and sequences for the proteolytic activities of types D and F botulinum toxins (BoNTs D and F) in HPLC-based assays. Found differences in the substrate binding and catalytic requirements of BoNTs D and F, and identified a potential allosteric site for BoNT F activity.
- Developed a sensitive and efficient quenched-fluorescence (FRET) substrate for BoNT A and F proteolytic activity.
- Developed and tested recombinant BoNT protease substrates in solid-phase assays.
- Constructed, expressed, and purified a recombinant substrate for the protease activities of BoNTs B, D, F, and G. Determined that BoNTs B, D, and F readily cleaved the substrate. Successfully produced a recombinant substrate for BoNTs A and E.
- Obtained libraries of compounds from the NCI repository and from a commercial source, and tested 2,800 compounds for inhibition of both BoNT A and BoNT B by solid-phase assays. Compounds that inhibited in the initial high-throughput screen were retested in an HPLC-based assay. To date, 17 compounds that exhibit significant inhibition have been identified. These are being further evaluated.

Research thrust: *develop therapeutics for ricin toxin:*

- Completed statistical and data mining analyses of the cellular DNA array data for ricin-exposed lungs and determined that, out of the 1,178 murine mRNA species investigated, 35 genes had statistically significant changes in gene expression.
- Successfully tested commercially available plastic arrays as a replacement for nylon arrays. This improvement will query 5,000 gene transcriptions for mice and 12,000 transcriptions for human and nonhuman primates. Selected software for statistical evaluation of the data.
- Evaluated the gene expression profile of murine alveolar macrophages exposed to ricin in vitro by cellular DNA microarray analysis. Found that two anti-inflammatory drugs, D609 and TJU103, were able to inhibit ricin-induced cytotoxicity in the murine alveolar

macrophage cell MHS. Further investigated D609 and showed it able to inhibit ricin cytotoxicity in other cell types (Jurkat, EL-45, and MOLT).

- Obtained and evaluated the gene expression profile for MHS cells exposed to ricin and treated with D609. D609 was unable to inhibit the ability of ricin to block protein systems in vitro.

Viral Agents

The countermeasures, technical barriers, and accomplishments in the biological threat category of viral agents are outlined below.

Countermeasures:

- Vaccines for 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).
- Need for 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 for which efficacy data from human clinical trials is impossible to obtain.
- Need for 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 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.

Vaccine Accomplishments:

Research thrust: *develop vaccine against filoviruses (Marburg and Ebola viruses):*

- Prepared sequences of the variable regions obtained for three monoclonal antibodies to be humanized and identified additional monoclonal antibodies that compete with the same epitopes. Identified a potential filovirus glycoprotein (GP)-specific monoclonal antibody.
- Tested peptides predicted to be cytotoxic T lymphocyte (CTL) epitopes recognized by mice and tested overlapping peptides for filovirus GP and nucleoproteins (NP).
- Identified several new T-cell epitopes in GP, NP, viral proteins (VP) VP24 and VP35 by chromium release assays, intracellular cytokine staining, and ELISpot assays.
- Sequenced mouse-adapted challenge viruses and deposited the sequences at GenBank to ensure retention of CTL epitopes in the mouse-adapted challenge virus.
- Confirmed that one new NP epitope is protective in adoptive transfer studies.

- Evaluated a cocktail of VEE replicon particle vaccine constructs (four to six constructs) in mice and demonstrated efficacy with no significant interference observed.
- Utilized gene microarray technology to assist in elucidating the mechanisms of Ebola and Marburg virus pathogenesis. Printed and tested 8,000 and 20,000 gene arrays for microarray analyses.
- Optimized methods for RNA amplification, cellular DNA labeling, hybridization, and array-wash techniques. Using improved methods of standardization for probe synthesis, implemented a protocol for tracking labeling efficiency. Created a data-tracking database to catalog microarray images, microarray analysis results, and RNA samples.
- Designed and acquired primers for sequencing the entire genomes of Marburg and Ebola viruses.
- Completed nucleotide sequencing of 99% of the genomes of a guinea pig-lethal Marburg Musoke virus, a guinea pig-attenuated Marburg Musoke virus, Marburg Ci67 virus, and Marburg Ravn virus.
- Completed nucleotide sequencing of 80% of the genome of Ebola Zaire 1995 virus, and started sequencing the genomes of Ebola Sudan Boniface and Ebola Ivory Coast viruses.
- Tested gene gun vaccination of Ebola virus (EBOV) GP and NP lysosome-associated membrane protein (LAMP) and ubiquitin chimeras in mice and measured T helper and cytotoxic T cell responses.
- From results of studies in cell culture or in guinea pigs, found that the proteins were targeted appropriately to subcellular compartments, but that the constructs were not clearly better at eliciting protective immunity than the DNA vaccines alone. Found that the control gene differed from GP in that it still had a portion of the LAMP sequence, but not the portion that was responsible for targeting. Found that the LAMP and ubiquitin chimeric-gene approach was very successful in enhancing DNA vaccines in mice for the lymphocytic choriomeningitis virus.
- To determine if the prime boost strategy would work for EBOV in guinea pigs, prepared baculovirus recombinants expressing the GP, GP with the carboxy terminal anchor sequence deleted (GPanch-), or NP genes of EBOV and tested them in a prime-boost vaccine regimen. Results indicated that this prime-boost regimen was not more efficacious than the individual vaccines.
- Performed a study in rhesus macaques to more fully evaluate the DNA-prime-baculovirus GP protein boost for MBGV and found that only the DNA vaccine conferred protective immunity to monkeys. Determined from these experiments that the DNA prime-baculovirus protein boost approach does not appear to be a method to improve the DNA vaccine strategy.
- Determined that the baculovirus-expressed EBOV GP could stimulate CTL responses in human dendritic cells, thus providing evidence that both cell-mediated and humoral responses to the expression product might be elicited.
- Constructed, isolated, and replicated prototype adenovirus recombinants expressing EBO-Zaire 95 GP or NP, or EBO-Sudan GP to high titer in cell culture.
- Constructed chimeric Ebola/Marburg GP molecules, and performed a preliminary evaluation of their protective efficacy in guinea pigs challenged with either Marburg or Ebola virus. Determined that a single chimeric molecule was able to protect against both agents. Found that construction of further chimeric molecules will help define the

region(s) in which protective epitopes reside, and may lead the development of a bivalent Marburg/Ebola vaccine strategy. This strategy will also be applied to the problem of lack of cross protection between divergent MBGV isolates by creating MBGV Musoke/MBGV Ravn chimeric GP molecules.

- Examined humoral and cell-mediated responses of nonhuman primates which were vaccinated with admixture of Musoke and Ravn GP and those animals vaccinated with Ci67 GP. Found that magnitude of the humoral response did not correlate with protection in the nonhuman primates vaccinated with the admixture.

Research thrust: *develop alphavirus vaccines:*

- Tested three cleavage-deletion vaccine candidates for western equine encephalitis (WEE) virus and determined that one met the operational requirements threshold for efficacy in onset and duration of immunity studies.
- Determined that Venezuelan equine encephalitis virus (VEE) replicons individually expressing the WEE glycoproteins provided threshold-level protection in mice. Developed a CRADA with a commercial entity to evaluate proprietary replicons that co-express both glycoproteins.
- Initiated a study evaluating a vaccine construct expressing VEE IA glycoproteins in mice.
- Determined via cross-protection studies with the V3526 infectious clone (originally developed against VEE subtype 1A/B) vaccine candidate that it provided insufficient mucosal protection from EEE and WEE challenge. These results suggest that EEE and WEE vaccine components will be required in a multivalent equine encephalitis (VEE, WEE, and EEE) vaccine candidate.
- Testing of murine sera after vaccination with live virus candidates indicated the induction of type-specific neutralizing antibodies. In order to obtain neutralizing monoclonal antibodies to WEE and EEE viruses, performed fusions with the spleens of mice vaccinated to WEE or to a South American EEE.
- Identified and characterized protective monoclonal antibodies with varying plaque-inhibiting capabilities.
- Identified an attenuated cleavage deletion mutant of EEE by using a novel approach to generate live mutant viruses. Tested the EEE mutant for attenuation in young chicks and found that it elicited immunity against a lethal challenge. Demonstrated, in equivalent studies in mice, that the virus was not protective against aerosol challenge with the EEE virus.
- Identified an attenuated strain of WEE. The strain is being evaluated to determine the durability of the immunity induced by this strain.
- Tested a vaccine candidate for VEE virus subtype IE (1150), which was found to meet operational requirements document (ORD) objectives for efficacy in onset and duration of immunity studies. Found no major pathological findings resulting from the VEE IE vaccine candidate in subcutaneously vaccinated mice.
- Tested three vaccine candidates for VEE virus subtype IIIA in mice; two reproducibly demonstrated short-term efficacy that meets the operational requirements objectives.
- Demonstrated that co-administration of the VEE IA/B and IE candidates indicated possible interference with the IA/B responses in mice.

- Evaluated the cross-protective efficacy of the V3526 vaccine candidate and the VEE subtype IE vaccine candidate (IE 1150) to heterologous VEE virus subtypes IE and IIIA. The studies demonstrated that the V3526 vaccine candidate is capable of meeting the operational requirements objective for VEE IE and VEE IIIA protection in mice and that the VEE IE candidate (IE 1150) does not meet the operational requirements objective for VEE IA/B protection in mice, but may meet the threshold.
- Testing serum from mice vaccinated with IE and IIIA candidates indicated the induction of type-specific neutralizing antibodies. Determined that V3526 vaccination induced low titers of IE- or IIIA- neutralizing antibodies.
- Determined that passive transfer of neutralizing MAbs to epitopes conserved on VEE virus subtypes IA/B and IE, or all three VEE virus subtypes, protected at least 80% of mice against aerosol challenge.
- Constructed replicons expressing the GP equivalents of cleavage deletion mutants for WEE and EEE viruses for evaluating efficacy in eliciting protective immune responses in mice.
- Completed safety assessment studies on western equine encephalitis viral vaccine candidates WE2102 and WE2130 and found the desirable results, i.e., both candidates replicated poorly in mosquitoes, did not revert to virulence after mosquito passage, and induced sterile immunity in chickens 2 weeks after vaccination.
- Initiated studies with the RPE.40 passage 23 strain of the EEE virus and demonstrated that this strain induced a low level viremia in 1-day-old chickens and that it remained avirulent after passage in chickens.
- Inoculated *Aedes albopictus* mosquitoes with the RPE.40 passage 23 strain of EEE virus and several related strains to determine a growth curve for these viruses.
- Inoculated additional mosquitoes to determine the potential for viral transmission to chickens.
- Determined median effective dose for both VEE-IE and VEE-III A by using a staircase approach exposing one nonhuman primate at a time and moving up or down in dosage depending on outcome.
- Demonstrated protection with V3526 and IE 1150 candidate vaccines in nonhuman primates against VEE-IE aerosol challenge. Based on results from these studies and mouse studies, the VEE virus IA/B infectious clone vaccine candidate V3526 is the lead VEE vaccine candidate for transition advanced development.
- Completed a study to demonstrate efficacy of candidate vaccines (including V3526) against a VEE-III A aerosol challenge of nonhuman primates. Preliminary analysis of the data indicates that V3526 cross-protects nonhuman primates against aerosol challenge with VEE-III A. This strengthens the position of the V3526 vaccine candidate as the lead candidate that offers protection against the pathogenic VEE virus subtypes and points to the potential that a multivalent VEE vaccine may only require a single vaccine component.

DTO CB. 24 Medical Countermeasures for Encephalitis Viruses

Objectives. The objective is to perform research leading to the development of medical countermeasures against the BW threat of the Venezuelan equine encephalitis (VEE) viruses (referred to as alphaviruses). Recombinant vaccine technology will be exploited to provide effective vaccine candidates.

Payoffs. The VEE group of viruses are important BW threats because they are very stable when freeze-dried and highly infectious when transmitted by aerosol. There are currently no FDA-licensed vaccines for protection from VEE viruses, and current investigational vaccines are inadequate because they do not provide protection across the full spectrum of VEE strains and have adverse effects. Improved vaccines will decrease the threat of BW and enhance strategic mobility. Under this DTO, vaccine components necessary to protect against genetically divergent VEE viruses will be constructed and evaluated. This DTO demonstrated in FY02 that V3526 (VEE virus subtype IA/B vaccine component) is as effective as a homologous VEE IE vaccine candidate in protecting nonhuman primates against challenge with VEE virus subtype IE. A single vaccine component that protects against 2 of 3 VEE pathogenic subtypes will simplify a multivalent VEE vaccine to no more than 2 components. This finding served as a basis for presenting the V3526 vaccine component for entry into Component Advanced Development in July 2002, facilitating transition out of the tech base. Also, initiated studies comparing the efficacy of a VEE IIIA vaccine candidate with the V3526 candidate in small animals and nonhuman primates.

Challenges. Major technical challenges include developing appropriate animal model systems for investigational purposes, and determining expression vectors for recombinant products.

Milestones/Metrics.

FY2003: Complete potency and stability studies on the VEE vaccine components. Define surrogate protection marker. Complete formulation and vaccine component interference studies. Prepare a technical data package that addresses FDA requirements for an Investigational New Drug application and that supports transitioning out of the tech base a multivalent vaccine candidate against pathogenic VEE viruses.

Research thrust: *develop an orthopox vaccine:*

- Cloned several vaccinia virus genes that are potential targets of protective immunity and sequenced genes A14L, A13L, F9L, I5L, L5R, and G9R. Evaluated the expression of these genes by using mouse hyperimmune ascites fluid, human vaccinia immune globulin (VIG), and mouse monoclonal antibodies of unknown specificity. Determined that A14L expressed the correct sized protein. Specificities of the other genes remain unknown.
- Determined that vaccinating mice with H3L and F13L genes elicited antibody responses and that the A13L gene elicited a response in one mouse.
- Demonstrated that vaccinating mice with A27L plus B5R vaccinia virus genes protected them from a lethal challenge with vaccinia virus.
- Tested a four-gene-combination vaccine (L1R+A33R+B5R+A27L) prepared by precipitating the plasmids on different gold beads and then combining the gold beads in the same gene gun cartridge. The combination vaccine protected 100% of the vaccinia virus-challenged mice.

- Cloned and sequenced the monkeypox virus strain Zaire 79 orthologs of the vaccinia L1R, A27L, A33R and B5R genes and expressed monkeypox L1R, A27L, A33R, and B5R orthologous proteins in cell culture.
- Determined that A33R-specific monoclonal antibody 1G10 bound the vaccinia virus A33R ortholog but did not bind the monkeypox A33R ortholog.
- In the first of three experiments, determined that a high dose of monkeypox virus was lethal in rhesus monkeys. Determined that a dose 100-fold lower still caused severe, but nonlethal, monkeypox in the recipient animals.
- In the third experiment, challenged a control monkey and a smallpox vaccine (Dryvax)-scarified monkey with a challenge dose. The scarified monkey exhibited no disease, whereas the control monkey developed extremely severe monkeypox disease.
- Vaccinated three monkeys with L1R alone and determined that a neutralizing antibody response was elicited.
- Re-cloned genes, sequenced, and constructed double-promoter VEE replicon constructs expressing smallpox proteins L1R (premier target of IMV-neutralizing antibodies) and A33R. Results of studies in rabbits suggest that VEE replicons may be ineffectual (as immunogens) in this species.

Research thrust: *develop a multiagent vaccine against BW agents:*

- Determined that single promoter replicons expressing heavy chain (Hc) of botulinum serotypes A (A/Hc), B (B/Hc), C (C/Hc), or F (F/Hc) protected mice from challenge with homologous botulinum neurotoxins (BoNT).
- Initiated cloning a BoNT serotype D/Hc VEE replicon.
- Evaluated a triple promoter replicon expressing A/Hc, B/Hc, and C/Hc and a quadruple promoter replicon expressing F/Hc, E/Hc, A/Hc, and B/Hc in animals. The experiment failed to demonstrate protection from a BoNT serotype A challenge.
- Determined that mice inoculated with two double promoter replicons, A/Hc-B/Hc and E/Hc-F/Hc, were 40% protected from a BoNT A challenge.
- Found that mice inoculated with a double promoter replicon, A/Hc-B/Hc, were completely protected from consecutive BoNT A and then BoNT B challenges.
- Demonstrated that vaccinating mice with a *Y. pestis* V antigen VEE replicon construct or with a F1-V fusion protein VEE replicon construct resulted in 50% and 80% protection, respectively in mice from subcutaneous challenge with *Y. pestis*.
- Determined that mice inoculated with a mix of F1- and V- expressing VEE replicons or an F1-V fusion VEE replicon were 60% or 80% protected, respectively, from an aerosol challenge.
- Used a double promoter VEE replicon vaccine expressing botulinum serotype A/Hc and recombinant SEB vaccine component to vaccinate mice and found that the vaccine protected 80% of the mice from a BoNT A challenge. Mice inoculated with a mixture of A/Hc and SEB VEE replicons were completely protected from a BoNT A challenge.
- Observed that mice vaccinated with multiagent formulations consisting of single promoter replicons expressing botulinum A/Hc, MAT PA, and Marburg virus glycoprotein (MBGV-GP) were 100% protected from a BoNT A challenge. Also found that mice vaccinated with either a mix of A/Hc and MAT PA or A/Hc and MBGV-GP were 100% protected from a BoNT A challenge.

DTO CB.25 Multiagent Vaccines for Biological Threat Agents

Objectives. The objective of this DTO, which was completed in FY02, was to demonstrate proof-of-concept for a vaccine delivery approach that could be used to concurrently immunize the warfighter against a range of biological warfare (BW) threats. Obtaining the capability to immunize warfighters against several biological threat agents with one vaccine would facilitate force protection and help to minimize the logistical footprint. The effort exploited bioengineering and recombinant vaccine technologies (naked DNA vaccines or VEE replicon vaccines). This research effort successfully produced VEE replicon vaccine constructs for botulinum toxins (A, B, C, and F), anthrax, plague, Marburg virus, and staphylococcal enterotoxin (SEB) and tested them in small animal models. DNA vaccine constructs for smallpox using genes from the closely related vaccinia virus were successfully produced and tested in small animal and higher animal species. Foreign genes of interest were added to the VEE replicon vaccine platform, individually and in combination, and evaluated for efficacy in animal models. Combined vaccine components were also evaluated for immunogenicity and interference effects. The DTO research program determined that the VEE replicon platform was the most promising approach for a combined vaccine against biological threats and met its final milestone/metric by demonstrating proof-of-concept in animal models with a vaccine delivery platform containing up to 3 vaccine components against biological threat agents.

Therapeutics Accomplishments:

Research thrust: *develop therapeutic strategies for orthopox viruses:*

- Synthesized light and heavy chain cellular DNAs from total RNA prepared from peripheral blood lymphocytes of a vaccinia virus (VACV)-immune human donor who exhibited a high neutralizing antibody titer.
- Used 22 different primer sets for reverse transcriptase-polymerase chain reaction TR-PCR_analysis, allowing for amplification of lambda and kappa light Fab (an immunoglobulin fragment) genes in addition to heavy chain cellular DNAs.
- Successfully cloned heavy chain (Fd) genes derived from the VACV-immune donor into phagemid (a phage whose genome contains a plasmid that can be excised by co-infection of the host with a Helper phage) vector pComb3.
- Initiated efforts to obtain peripheral blood lymphocytes from individuals who recently received the smallpox vaccine and exhibited prominent inflammation at the injection site. Obtained blood from two donors enrolled in this protocol and purified the peripheral blood lymphocytes.
- Converted a Fab clone into a full-length monoclonal antibody by stable transformation of insect cells using a cassette vector system.
- Evaluated the biological functions of these full-length monoclonal antibodies by ELISA with VACV antigen and by immunoprecipitation with radiolabeled VACV-infected cell lysates or radiolabeled VACV proteins prepared from cells transfected with naked DNA vectors expressing individual VACV genes. Examined the neutralizing capabilities of these monoclonal antibodies by plaque reduction neutralization (PRNT) of the VACV Connaught human vaccine strain and found that only one antibody had neutralizing properties.
- Successfully generated a recombinant baculovirus capable of expressing a full-length human monoclonal antibody derived from the Fab clone.

- Cloned and sequenced regions of the polymerase gene (E9L) from 35 variola isolates, as well as cidofovir-resistant vaccinia, cowpox, monkeypox, and camelpox viruses.
- Continued sequencing on the drug-resistant viruses and found several mutations.
- Completed sequencing specific genes from approximately 20 strains of variola and observed mutations in a few strains.
- Determined the 50% inhibitory concentration (IC₅₀) of cidofovir and 3-hexadecyloxy-1-propanol (HDP)-cidofovir against 40 strains of variola, monkeypox, cowpox, and vaccinia. All viruses appeared to respond essentially equally with no major differences in IC₅₀ in LLC-MK2 or Vero cells.
- Tested six different orally active prodrugs of cidofovir in vitro against a panel of orthopoxviruses at USAMRIID and variola at the Centers for Disease Control and Prevention (CDC). Determined that each prodrug had an IC₅₀ value for each virus approximately tenfold lower than the IC₅₀ value for cidofovir.
- Tested four of the prodrugs in the mouse cowpox model and found that HDP-cidofovir was orally active in cowpox-infected mice; treatment with 10 mg/kg/day completely protected the animals for 1 to 5 days. Determined that there was a dose effect, with lower doses less protective.
- Found that cidofovir given orally offered no protection but when given intraperitoneally at 100 mg/kg in a single dose on day 0, it was completely protective.
- Evaluated the dose response of cynomolgus monkeys given monkeypox virus to establish a model of severe poxvirus illness. Found that monkeys infected with 10⁵, 10⁶, 10⁷, and 5 x 10⁸ plaque forming units (PFU) intravenously developed progressively more extensive and severe lesions with increasing dose, but ≥ 10⁷ PFU produced lethal disease. Animals infected with 10⁷ or more PFU met the WHO criteria for “grave” with > 250 lesions. Found that the distribution and timing of development were consistent with human monkeypox and variola and the rash progressed through all stages of development. The rash lesions were beginning to scab and appeared to be resolving when animals died, just as in human cases. At necropsy, found that the animals had lesions compatible with coagulopathy, lymphocyte apoptosis, virus-induced visceral degeneration and necrosis, and generalized, centrifugally distributed virus-induced exanthem and enanthem. Fibrin deposition and thrombi, and systemic lymphoid apoptosis involving secondary lymphoid organs were also present. Found that distribution of viral antigens by immunohistochemistry correlated well with replicating virions and pathologic lesions.
- Successfully lethally infected cotton rats with cowpox administered intraperitoneally (i.p.) and intranasally (i.n.) and with monkeypox administered i.p. (75% lethal) and i.n. (75% lethal).
- Began sequentially passing camelpox in cotton rats to establish an additional rodent model of poxvirus disease.
- Screened approximately 200 new compounds against variola, monkeypox, camelpox, and vaccinia in two cell lines.
- Tested ribavirin 4275, 303, HDP-cidofovir against all 40 strains of Variola virus. Found that all viruses responded equally with no major differences on LLC-MK2 cells.
- Worked with the former Soviet biowarfare facility VECTOR under the CTR program to establish a drug-screening program. This program has now tested over 3000 compounds

and identified one significant new lead compound. Activity of that lead was confirmed at USAMRIID.

- Used green fluorescent protein (GFP)-expressing vaccinia to successfully test antiviral drugs (cidofovir, ribavirin, 303, 4275, cyclic -cidofovir, HDP-cidofovir). Determined that approximately 1×10^5 PFU/well yielded easily detectable fluorescence as well as IC₅₀ values.
- Compared drug activity by neutral red, GFP-expression, LacZ production, and plaque reduction assays and found that all methods yielded approximately the same IC₅₀ values for all drugs.
- Successfully completed transfection and coinfection tests. Determined that adenosine-N1-oxide analogs that inhibit variola and other orthopoxviruses fall into two groups, which are synergistic and may have two different mechanisms of action.
- Found that two compounds that were very active in vitro were not active in the cowpox mouse model due to toxicity that precluded achieving the minimal effective concentration in mice.

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 a lead candidate. 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.

Challenges. Developing appropriate model systems that emulate human aerosol exposure and intoxication—if such a demonstration can be made, it can be substituted for a human efficacy clinical trial by using the FDA animal model 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 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, which is currently experiencing ongoing civil strife, thus limiting the possibility of clinical trials.

Milestones/Metrics.

FY2003: Determine optimum dose of cidofovir in the cynomolgous monkey model using both the lethal pulmonary and lesional infection models with monkeypox. Characterize pathogenesis of both models. Complete required studies utilizing the cowpox mouse model. Refine the cynomolgous monkey variola model to establish a standard challenge dose and characterize the disease pathogenesis.

DTO CB. 54 Therapy for Smallpox and other Pathogenic Orthopoxviruses

Establish therapeutic window in this variola model. Begin assessment and development of clinical study site where sufficient monkeypox exists naturally to characterize the clinical course and pathogenesis of monkeypox.

FY2004: Complete drug efficacy evaluation in the various animal models. Perform a comparison of the variola animal model with the monkeypox animal model and with human monkeypox in order to extend understanding of the disease pathogenesis. Complete preclinical virology studies, including animal efficacy studies, to obtain data on the optimum therapeutic approach for this class of drug in treating orthopoxvirus disease. If political situation in Congo permits, initiate human clinical study.

FY2005: Compile technical data necessary to support consideration of the drug candidate for licensure for use as a smallpox therapeutic.

Research thrust: *develop therapeutic strategies for filoviruses (Marburg and Ebola viruses):*

- Vaccinated immunoglobulin heavy-chain $\gamma 1$ antibody-producing Xenomice by either gene gun vaccination (vaccinia B5R, A27L or L1R), gene gun vaccination followed by multiple booster vaccinations with a) Venezuelan equine encephalitis (VEE) virus replicons expressing various filoviral proteins b) VEE replicons expressing viral proteins (Lassa-Josiah GP or vaccinia L1R, A33R, or D8L) or c) replication-defective recombinant adenoviruses expressing Ebola-Sudan GP.
- After fusion of spleen and lymph node cells from $\gamma 1$ antibody-producing Xenomice primed by gene gun inoculation of the above viruses, isolated eight ELISA and indirect fluorescent antibody (IFA)-positive (putative) EBO-Zaire GP-specific human monoclonal antibodies and four ELISA and IFA-positive (putative) MBG-Musoke GP-specific human monoclonal antibodies.
- Fusion of spleen and lymph node cells from $\gamma 1$ antibody-producing Xenomice primed by gene gun vaccination with plasmid DNA expressing either EBO-Zaire GP or MBG-Musoke GP and multiply boosted with the appropriate VEE replicons resulted in the isolation of seven ELISA and IFA-positive (putative) EBO-Zaire GP-specific human monoclonal antibodies and one ELISA and IFA positive (putative) MBG-Musoke GP-specific human monoclonal antibody.
- Fusion of spleen and lymph node cells from $\gamma 1$ antibody-producing Xenomice multiply vaccinated with VEE replicons expressing MBG-Ravn GP resulted in the isolation of two putative MBG-Ravn GP-specific human monoclonal antibodies, which were positive by ELISA, did not cross react by ELISA with purified irradiated EBO-Zaire, MBG-Musoke, or MBG-Ci67 virus, and specifically immunoprecipitated radiolabeled MBG-Ravn GP as analyzed by SDS-PAGE and autoradiography.
- Observed that none of the aforementioned ELISA and IFA-positive (putative) EBO-Zaire GP-specific human monoclonal antibodies cross-reacted with MBG-Musoke antigen by ELISA, and vice-versa.
- Obtained DNA from four Ebola virus-convalescent rhesus macaques, tested it for safety, and submitted it to the Wisconsin Regional Primate Center for MHC testing.
- Submitted DNA from over 20 colony rhesus macaques for MHC testing.
- Completed in vitro experiments to determine if available Ebola virus monoclonal antibodies have infectivity-enhancing qualities, which may exacerbate disease in vivo. None was found.

- Used an anti-Ebola monoclonal antibody, developed from convalescent human peripheral blood mononuclear cells, in an Ebola guinea pig model. Found that passive transfer of this antibody protected guinea pigs from lethal Ebola challenge.
- Assessed passive transfer of the monoclonal antibody in four rhesus monkeys; results indicated only a beneficial but not a protective effect.
- In collaboration with CDC, successfully constructed and sequenced genomic fragments of the Ebola virus containing the GFP gene, as an extra gene. This work will lead to an Ebola containing the reporter molecule GFP for use in higher volume drug screening.
- Used the mouse model to test several compounds (amantadine, adenosine antagonist, interferons α and β , indomethacin, and polyIC) and interferon. Interferon inducers showed activity in the model.
- Identified three new molecular targets: Ebola virus suppression of the cellular interferon mediator/inducer IRF-3, requirement for the cellular protein VSP4 for viral assembly, and Ebola virus VP24 protein function as an ion channel.
- Generated a phage display library by using total RNA obtained from lymphocytes purified from the spleen of a cynomolgus monkey that was vaccinated with a Marburg-Musoke GP replicon and subsequently survived challenge with Marburg-Musoke and Marburg-Ravn viruses. Conducted a genetic analysis to confirm the presence of light and heavy chain Fab genes.
- As part of research to develop a drug screening assay for filovirus therapeutics, cloned VP35 and VP30 genes downstream of the T7 promoter and demonstrated that both were expressed at very high levels in bacteria. Made a construct that expressed VP35 with a 10 histidine tag at its N-terminus. Cloned the VP35 gene into pET16b via NdeI/BamHI digestion. Sequenced the VP35 insert and determined it to be identical to the published VP35 sequence of Ebola Zaire (Mayinga).
- Demonstrated that the pET16b construct produced large amounts of tagged VP35 and purified it to > 95% homogeneity.
- Cloned Ebola Zaire (Mayinga) L and NP into transfer plasmids to create recombinant baculoviruses expressing these proteins.
- Amplified by RT-PCR the genes from Vero cells infected with Ebola Zaire (Mayinga) and cloned them into pCR0-Blunt II-TOPO vector.
- Subcloned the EBOV genes into the baculovirus transfer vector, pBlueBac4.5.
- Sequenced the plasmids to confirm that both NP and L were in proper orientation and identical to the published sequences of Ebola Zaire (Mayinga) NP and L. Transfected the plasmids into the Sf9 insect cell line (used in baculovirus expression vector production systems) in the presence of linearized, triple-cut viral DNA.

Diagnostic Assays for Biological Warfare Threat Agents

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.

Accomplishments:

Research thrust: *develop technologies (reagents, assays, devices) suitable for a rapid, portable diagnostic capability for BW agents:*

- Validated the performance of two rapid gene amplification systems developed to identify *Bacillus anthracis*, *Yersinia pestis*, *Clostridium botulinum* and Venezuelan equine encephalitis virus.
- Demonstrated that rapid gene amplifications in comprehensive trials were 100 % specific for the detection of *Bacillus anthracis* and *Clostridium botulinum* gene targets.
- Demonstrated limits of detection (LOD) and limits of quantification (LOQ) equal to 100 femtograms (fg) by using two rapid gene amplification systems for the detection of *Bacillus anthracis* and *Clostridium botulinum* gene targets.
- Demonstrated the detection of 10 to 50 colony forming units of *Yersinia pestis* collected on swabs by using two rapid gene amplification systems.
- Demonstrated the detection of 10 to 50 colony forming units of *Clostridium botulinum* on swabs by using two rapid gene amplification systems.
- Demonstrated low variation (1 log or less in the limit of quantification) or no variation for the identification of *Bacillus anthracis* on 3 consecutive days of testing using two different rapid gene amplification systems.
- Demonstrated LOD and LOQ equal to 1000 plaque forming units by using two different rapid gene amplification systems for the detection of Venezuelan equine encephalitis virus.
- Demonstrated that only SmartCycler rapid gene amplification systems could simultaneously detect RNA gene targets and DNA gene targets in the same sample run.
- Demonstrated the simultaneous detection of 8 biological threats on a single rapid gene amplification system.
- Obtained, purified, characterized and archived over 553 bacterial strains for use as diagnostic standards for regulated evaluation trials.
- Established bacteriological preparations that will serve as reference standards for evaluating diagnostic and detection systems.
- Obtained 10 strains of *B. pseudomallei*, 10 strains of *B. mallei*, and 31 strains of *B. thailandensis* for use in diagnostics research studies. Analyzed 16S rRNA genes by HPLC and DNA sequencing to determine if the proposed point mutation difference could be confirmed between *B. pseudomallei* and *B. mallei*. Found that data indicated this mutation did not consistently distinguish the two species. Therefore, three

additional genes were identified as potential targets. For the secretion gene, developed a *B. pseudomallei* specific primer set (does not amplify *B. mallei* or *B. thailandensis*).

- Developed two non-specific primer sets. Developed primer sets that amplify the insert element ISO470A. Found that for the resistance gene, two of these primer sets amplify the region spanning a point mutation at basepair (bp) 240. Amplified one primer set for both *B. mallei* and *B. pseudomallei*, despite having the mutation located within the primers. Designed FRET and Taqman probes against the 240 bp and 600 bp mutations. Designed Taqman probes to contain the mutation, which will hopefully provide an assay specific for *B. mallei* and *B. pseudomallei*. Developed a Taqman assay for the insertion element (IS407A).

Research thrust: *develop new targets and real-time technologies for nucleic acid detection of natural infectious diseases and BW agents:*

- Successfully developed and used a functional multiplex assay for pX01 and pX02 used on the Cepheid Smart Cycler™ and MX4000 real time PCR platforms.
- Optimized assays for BW agent targets on both the R.A.P.I.D. and Smart Cycler™.
- Accomplished multiplex of *Yersinia pestis*, *Francisella tularensis*, and the internal positive control the MX4000. Found the limits of detection of the multiplexed assays to be identical to the assays run as single reactions.
- Designed FRET (Fluorescent Resonance Energy Transfer) assays for *Burkholderia* and initiated evaluation of assays.
- Designed and evaluated an assay specific internal positive control for *B. anthracis* protective antigen gene.
- Multiplexed a novel internal positive control with the following assays: *Bacillus anthracis* (pX01-PA, pX02-capB, chromosome-vrrA), *Y. pestis* (plasminogen activator, pesticin), *F. tularensis* (TUL4, FOPA), *Clostridium botulinum* neurotoxin serotype A, *Brucella* sp. (OMP25), and *Vaccinia/Variola* HA gene
- Purified DNA was made from six type A and one type B *F. tularensis* isolates, including the highly virulent Schu4 strain, five isolates from cottontail rabbits, and one presumptive Type B isolate from a 1991 human case of tularemia in Alabama. Produced the DNAs under approved protocols, tested for limit of detection using available primer sets for a universal bacterial gene target as well as the *tul4* gene, and all seven DNAs gave very robust signals and good limit of detection. Found preliminary results showing that type A and type B strains of *F. tularensis* can be differentiated by using HPLC to analyze PCR products from amplicons produced from the 16SrRNA gene,
- Designed, optimized, and evaluated two new primer and probe sets (*tul4* and *fopA* gene targets) on both the Smart Cycler™ and R.A.P.I.D. Determined that both assays have a limit of detection of 10 fg of genomic DNA and do not cross-react with 100 pg (picograms) of genomic DNA from any of the strains from the DNA reference panel. Both primer-optimized assays were transitioned to sample testing laboratories and were used extensively during Operation Noble Eagle.

Research thrust: *develop TaqMan™/FRET assays for various biological threats:*

- Validated several previously developed TaqMan™ assays by using thousands of environmental samples.

- Determined two *Brucella* genes (OMP2b and OMP25) to be the most feasible sequence targets for designing TaqMan™ and FRET assays. Determined that the level of detection in both chemistries was 100 fg of total pure genomic DNA (<100 copies).
- Found that the TaqMan™ Omp2b assay was capable of detecting all *B. melitensis*, *B. suis*, and 10/12 *B. abortus* samples tested. Preliminary results indicate that the 291 basepair (bp) amplicon FRET assay was far superior and is in the process of being optimized.
- Determined that two *F. tularensis* genes (Tul4 and FopA) were the most feasible sequence targets for designing TaqMan™ and FRET assays. Determined the level of detection (LOD) of this primer/probe pair to be 10 fg of genomic DNA (similar to the LOD of the Tul4 TaqMan™ assay) and no cross-reaction was found with using the USAMRIID DNA panel.
- Designed ten sets of primers which excluded these regions of the insertion sequence element of *C. burnetti* DNA and Sybr™ Green 1 on the LightCycler system.

Research thrust: *develop diagnostics for toxin threat agents using electrochemical luminescence (ECL):*

- Successfully installed ECL analyzer, trained technicians, and synthesized one batch of labeled substrate for BoNT B. Developed a cleavage assay for BoNT B. Demonstrated specificity and inhibition by specific antibodies and by zinc chelators. Demonstrated cleavage of BoNT A by HPLC.
- Developed and optimized an antibody-based assay for BoNT F. Determined the sensitivity to be about 1 ng/ml and total assay time to be about 1 hr.
- Developed an antibody-capture assay for ricin.

Research thrust: *develop immunodiagnostic assays and reagents:*

- Vaccinated mice with *Yersinia pestis* and Pla antigens to generate antibodies for use in immunodiagnostic assay research.
- Evaluated additional ricin and Rift Valley fever virus monoclonal antibodies.
- Obtained large numbers of monoclonal antibodies for orthopox viruses, *Brucella* sp., *Bacillus anthracis* capsule antigen, and *Y. pestis* F1 antigen. Produced polyclonal goat and rabbit sera to *B. anthracis* protective antigen (PA).
- Replaced botulinum (BoNT) serotype A capture antibody with a newly identified antibody.
- Improved immunodiagnostic assay sensitivity for BoNT serotypes A, B, and E targets.
- Identified large quantities of polyclonal *C. burnetti*, phase I antigen, rabbit antibody, and *F. tularensis* goat antibody.
- Transitioned StabilCoat to preserve ECL ruthenium activity and a lab-prepared buffer for preservation of antigen to the Program Executive Office for Chemical and Biological Defense for use in FASTube production. Used four ECL FASTube assays to examine over 30,000 samples.
- Developed positive and negative controls as well as a testing strategy.
- Transferred *B. anthracis* PA, SEB, ricin, BoNT A/B/E and *Brucella* sp. ECL assays to the division training branch for use in training specialists in diagnostic procedures.

- Evaluated fluorogenic probe PCR and ECL assays at a field site endemic for anthrax and brucellosis. Established a field laboratory in the Wood Buffalo National Park (WBNP) in the Northwest Territory of Canada to facilitate both studies.

Research thrust: *develop and evaluate simplified, automated procedures for preparing nucleic acid for enzymatic amplification:*

- Demonstrated, in preliminary evaluations of the Autolyser Model 303 (single-site machine), that the endpoint detection limit is approximately equivalent to the Modified Qiagen DNA Mini Kit. Found that results were reproducible and consistent across most sample matrices, with approximately the same endpoint detection limits for buffer, plasma, or serum.
- Tested Hand-held Manual Extractor and determined that it has an endpoint detection limit much higher than meets operational requirements. Testing for PCR inhibition revealed the reagents and procedures were not interfering with nucleic acid amplification.
- Evaluated the manual IsoCode Stix procedure for multiple agents in varying matrices and found comparable results to the Modified Qiagen DNA Mini Kit for *Bacillus anthracis* vegetative cells in buffer, serum and blood; *Yersinia pestis* in buffer and serum; *Clostridium botulinum* in buffer; *Burkholderia pseudomallei* in buffer; *Francisella tularensis* in buffer; and *Vaccinia* in buffer. Initiated studies with *Brucella melitensis*, *Burkholderia mallei*, and *B. anthracis* spores.
- Tested LINK cartridges with agent in standard buffers and preliminary results show a similar detection limit to that of the Modified Qiagen DNA Mini Kit. GeneXpert studies with *B. anthracis* spores in buffer produced a limit of detection comparable to that of the Modified Qiagen DNA Mini Kit.

Research thrust: *Animal studies for the collection of biological specimens for development, validation, and fielding of diagnostic assays for BW agents:*

- Completed evaluation of samples obtained during a primary Venezuelan equine encephalitis (VEE) study and determined that virus appears in nasal swabs immediately after exposure and disappears very quickly, depending on the dose of virus. Also, determined that virus could be found in throat swabs and/or serum as early as 24 hr after exposure. Found virus in throat cultures as late as 10 days post-exposure and observed a close relationship between dose of virus administered and duration of virus shedding in the throat.
- Demonstrated that VEE virus-specific IgM first appears in serum at day 7 post-exposure regardless of dose and lasts until approximately 90 days post-exposure.
- Determined that VEE virus-specific IgG did not appear until day 14 post-exposure and observed that titers had not peaked at day 112 post-exposure, when the experiment was terminated.
- Completed evaluation of samples obtained during a secondary anthrax-exposure study in nonhuman primates. Observed the minimum duration of detectable anthrax in samples acquired during that study by three different detection methods (antigen detection, PCR, and culture).

Research thrust: *genomics and diagnostics:*

- Designed primers for linear polymerase chain reaction (LPCR) amplification of camelpox, cowpox, monkeypox and variola viruses. Completed sequencing of A14L, A26L, A27L, A28L, A34R, A36R, A37R, A40R, A47L, A48L, B9R, B10R, B19R, B20R, B22R, C7L, D8L, D9L, D10L, D16L, D17L, D18L, F8L, G1R, I5R, J6R, and M1R open reading frames (ORFs) from camelpox Somalia, cowpox Brighton and monkeypox Zaire. The total number of nucleotides sequenced was about 360 Kb.
- Cloned and sequenced A25R, B8R, E9L, G2R, J7R, L2R and L6R from variola strain BSH 1995.
- Developed a highly sensitive and specific assay for real-time detection of smallpox virus DNA on the SmartCycler platform. By using genomic DNA purified from variola Bangladesh 1975 virus, determined the LOD to be approximately 25 copies. Evaluated the assay in a blinded study with 322 coded samples that included genomic DNA from 47 different isolates of variola; 18 different strains and isolates from camelpox, cowpox, ectromelia, gerbilpox, Herpes, monkeypox, myxoma, rabbitpox, raccoonpox, skunkpox, vaccinia and varicella viruses and two rickettsial species, at concentrations ranging from 1-1000,000 fg/uL. Observed that the overall specificity of the assay was 98.7 %; the analytical sensitivity was 96.1%. Of the 43 samples that contained purified variola virus DNA ranging in concentration from 1-1000,000 fg/uL, the assay correctly detected all 43 samples.
- Developed a multiplex assay based on the hemagglutinin antigen (HA) gene for simultaneous detection of variola virus species and Orthopoxvirus genus in the same tube in real time. The assay has been optimized and is ready for evaluation with genomic variola and Orthopoxvirus samples at CDC.

Research thrust: *detection of Burkholderia mallei for medical diagnostic applications:*

- Infected Balb/c mice by aerosol with capsule-proficient and capsule-deficient strains of Burkholderia. Isolated total splenic RNA and synthesized, labeled, and hybridized it to mouse Atlas cDNA expression arrays.
- Examined five strains of *B. thailandensis* for the production of *B. mallei*-specific bacteriophage. Strains E264 and E251 were isolated from soil in central Thailand and strains E275, E202 and E125 were isolated from soil in northeast Thailand. Found that all of the strains, with the exception of E251, spontaneously produced bacteriophage that formed plaques on *B. mallei* ATCC 23344.
- Observed that strain E264 produced two bacteriophages that formed distinct plaques on *B. mallei* ATCC 23344. Tested the bacteriophages for their ability to form plaques on 52 different strains of Burkholderia and found that all of the bacteriophages formed plaques on *B. mallei* strains NCTC 10248, NCTC 10229, NCTC 10260, NCTC 10247, ATCC 23344, NCTC 3708, NCTC 3709 and ATCC 10399.
- Sequencing results demonstrated that the *B. mallei* ATCC 23344 genome is 5.8 million bases (Mb) and contains two circular chromosomes (3.5 Mb and 2.3 Mb).
- Collaborated with TIGR to construct a whole genome DNA microarray for *B. mallei* ATCC 23344.

Research thrust: *develop improved immunodiagnostic platforms for the identification of BW agents:*

- Successfully transitioned the electrochemiluminescence (ECL) immunodiagnostic technology to the advanced developer of biological detectors (Program Executive Office for Chemical and Biological Defense (PEO-CBD), formerly the Joint Program Office for Biological Defense) for non-medical applications. The transition package included 14 assays directed against ten potential biological weapons. Also developed standard operating procedures for systems operation and reagent development and transferred these to PEO-CBD for use by contractors to produce and operate the assays.
- Transferred a program for operator training to the Field Training and Operations Branch, USAMRIID, to train DoD operators in ECL systems operation.
- Completed a proof-of-concept assay for antibody detection and completed the preliminary evaluation of two other detection systems (Bera and CANARY biosensors).

Research thrust: *Development of methods for immunodiagnostic reagent production using recombinant DNA technologies:*

- Cloned the Marburg glycoprotein (GP) into Promega PinPoint Xa vector for expression in *E. coli*. Demonstrated by restriction enzyme mapping and sequencing of the Marburg gene cloned into the expression vector that the gene is present with no mutations and in the correct reading frame. Evaluated expression of the glycoprotein.
- Identified Baculovirus constructs for expression of Ebola and Marburg viruses.
- Initiated characterization of VEE hybridoma, 1A4A, a stable and high producing cell line into which all homologous recombinations will be made, to facilitate faster and more efficient homologous recombinations.
- Evaluated recombinant *C. botulinum* (BoNT) serotype A and B monoclonal antibody-producing cell line. Determined sequences of heavy and light chains transfected into 1A4A for each of five clones. Recombined BoNT heavy chain into the 1A4A genome, but did not replace the endogenous heavy chain gene. Recombined BoNT light chain to replace the endogenous light chain gene in four of five clones. Determined sequences flanking 1A4A heavy and light chain gene regions to design improved primers for homologous recombination. Designed 3' heavy chain PCR primers with additional flanking sequence to improve targeting.

Research thrust: *Isolation and characterization of the outer cell membrane proteins, including porin, from *Burkholderia thailandensis* (Component of research effort to develop diagnostic reagents for glanders):*

- Tested purified porin of *B. thailandensis* by sodium dodecyl sulfate-capillary electrophoresis (CE-SDS) and identified it by its migration.
- Further characterized the porin protein by HPLC-techniques (reverse phase and size exclusion methods) and confirmed the characterization using SDS-PAGE procedures.
- Identified purified porin by molecular weight standards and confirmed *B. mallei* porin proteins in the preparation by western blot analysis, with polyclonal antibody (rabbit serum) against whole cells.
- Cultured three hybridoma cell lines to produce monoclonal antibodies against bacterial peptidoglycan membrane proteins. Characterized and stored peptidoglycan monoclonal antibody against membrane proteins for neutralization studies both in animals and in cultured cells. Developed an ELISA with peptidoglycan monoclonal antibody against

membrane wall. Determined that although *B. thailandensis* porin had a weak response against polyclonal *B. mallei* antibody, it had high activity against monoclonal peptidoglycan (HB-8511) antibody as verified by ELISA.

- Found that neither LPS nor porin from *B. thailandensis* caused hemolysis.
- Found that cytokines effected a remarkable increase in bacteria-treated cells but not in control macrophages.

DTO CB.26 Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases

Objectives. The objective of this DTO, which was completed in FY02, was to develop technologies (platforms/devices) capable of diagnosing biological warfare (BW) and infectious disease agents in clinical specimens. The devices are intended for preventive medicine personnel for disease surveillance and monitoring and for medical laboratory personnel for the diagnosis of disease due to natural and BW threat agents. The research effort focused on miniaturized polymerase chain reaction technology for detection and identification of nucleic acids of BW agents and natural infectious disease. Accomplishments during the 5-year course of the DTO include completing system integration and verification of approaches, reagents, and protocols and completing an analysis of alternatives of portable nucleic analysis systems for detecting and identifying nucleic acids from a broad range of biological threat agents in clinical specimens. A technical data package was prepared to support transitioning the common diagnostic systems technologies out of technology base and for eventual preparation of a medical device application to the Federal Drug Administration (FDA). The program obtained Milestone A decision in October 2001. The technologies (reagents, protocols, device assessments) developed under this DTO are under consideration, along with other technologies, for incorporation into the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Block I. The MS B In Process Review for JBAIDS Block I is managed by the Program Executive Office for Chemical and Biological Defense and is planned for late FY02-early FY03. These achievements mark the successful conclusion of this DTO research program.

DTO CB. 47 Improved Immunodiagnostic Platform

Objectives. Medical protection facilitated by rapid, deployable medical diagnostic systems against biological threats supports the QDR operational goals for Protecting Bases of Operation and Projecting and Sustaining U.S. Forces. 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.

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

DTO CB. 47 Improved Immunodiagnostic Platform

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.

FY2003: Conduct comparative evaluation trial of at least four diagnostic technologies that have a high probability of meeting DoD requirements for improved immunodiagnostics used in medical diagnostic applications. Prepare technical data package detailing results of trial. Identify the top two performing immunodiagnostic platforms from results of evaluation trial. Obtain a Milestone A in process review of the improved immunodiagnostics technologies.

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.

Research thrust: *Reducing Reliance on the use of Animals as Subjects of Research:*

- Tested the numerical accuracy of implicit solvent models versus explicit calculations for modeling protein surface loop reorganization and provided a free-energy profile for complex formation between botulinum neurotoxin type B and synaptobrevin fragment.

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 infections; 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. The objective of this DTO is 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 agents is of concern. 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 immunosuppression, further increasing both the risk from biological threats and the need for robust immune defenses.

Milestones/Metrics.

FY2003: Develop testing and evaluation architectures for operational force protection efficacy.

FY2005: Transition of lead therapeutic candidates to USAMRMC for continued development.

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, the sole manufacturer of BioThrax™, obtained FDA approval for their renovated facility on December 27, 2001. There have been a series of issues that have delayed efforts to resume full production. Regulatory reform initiatives implemented in the mid-1990s led to changes in FDA regulation of biologics. More stringent Good Manufacturing Practices to validate production have extended this process at BioPort. However, since March 2001, BioPort has submitted 18 regulatory submissions to the FDA including its final supplement for its renovated facility and the supplement for their contract filler. On January 31, 2002, the FDA announced that it approved license supplements for BioThrax™, allowing lots from the renovated facility to be released and distributed. BioPort received approval January 2002 for the use of their contract filler Hollister Stier and has distributed over 2.1 million doses of BioThrax™ to the DoD.

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, a product required by the FDA as a potential adjunct to smallpox vaccine used to treat 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.
- (SE) Toxicity testing and preparation of Investigational New Drug Application required for clinical trials for staphylococcal enterotoxin vaccine.
- (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

- Cambrex Bioscience of Baltimore, MD, a subcontractor to DynPort Vaccine Company, completed a manufacturing process.
- Defined optimum formulation, fermentation and lyophilization parameters for cGMP manufacturing of the vaccine.
- Work continued on animal models for safety and manufacturing lot consistency evaluations at Defense Science Technology Laboratory (DSTL) (UK).

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 Venezuelan Equine Encephalitis Vaccine

- Completed cGMP pilot lot manufacturing.
- Began stability and lot release testing of pilot lot.
- Initiated neuro-virulence test on pilot lot.
- Initiated equine safety and cross protection study with pilot lot.

E.2.4.6 Recombinant Botulinum Toxin Vaccine

- Began formulation to adjuvant process development, Diosynth, Cary, NC.
- Completed cGMP manufacture of bulk serotype B at Cambrex, Hopkinton, MA.
- Began animal efficacy testing, cGMP bulk lot potency testing, Battelle, West Jefferson, OH.

E.2.4.7 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 new CANUKUS CBR MOU permits full cooperative research and development of vaccines. Negotiations are underway to develop a Project Arrangement for cooperative research and development of a smallpox vaccine.
- In addition to the Vaccinia Virus Vaccine Project Arrangement development, the JVAP is exploring opportunities for CANUKUS development of new vaccines against anthrax, plague, and brucellosis.

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 confirm and identify 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 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. Block II will focus on automation of the sample preparation process, inclusion of new technologies for toxin identification, reductions in size, weight, and 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.

Annex F

NBC Defense Logistics Readiness Data

F.1 BREAKOUT OF SERVICE WAR REQUIREMENTS, STOCKS ON-HAND, AND PLANNED ACQUISITIONS

The following tables (Tables F-1 through F-5) display NBC defense equipment total Service requirements, their wartime requirements, FY02 stocks on-hand quantities (as of 30 September 2002), and FY03–04 planned procurements for each of the four Services and Defense Logistics Agency. As described in Chapter 3, the Major Combat Operations (MCO) requirements for consumables and for end items (non-consumables) are based on the interim JRO guidance that they remain equal to the 2 Major Theater War (MTW) requirements already established through the JCHEMRATES Study until the Services have had the opportunity to assess the new requirements that are being developed to meet the operational needs of the 4-2-1 force planning construct.

It should be emphasized that the JCHEMRATES IV study's two MTW requirement was not and should not be considered the total procurement target. This study did not fully consider air transport into theaters of conflict or Navy fleet requirements for ships at sea. While the Services agreed with the methodology and intent of the study in general, it would require further refinement prior to becoming a fully accepted planning tool. The JCHEMRATES MTW requirement did not consider peacetime training requirements, sizing requirements, or full procurement for the entire active and Reserve forces and critical operational personnel. The MTW requirement did denote a minimum planning number, which if the total DoD inventory dropped below, may represent a critical shortfall for that particular item, which should be immediately addressed to avoid diminishing the force's NBC defense capability.

The JCHEMRATES IV study also did not consider the requirements of units specifically identified to provide domestic CBRNE consequence management support. Units such as the Army CB-RRT, SMART and WMD CSTs, the Navy NMRC, the Marines Corps CBIRF, and the Air Force Medical NBC Teams will require individual and collective protection, detection, and decontamination equipment. Since domestic CBRNE consequence management response is not regarded as a mission of the 4-2-1 force planning construct, these requirements are not included in the following tables.

Because of the limitations in the study, the Services have identified their total Service requirements as their procurement targets, while acknowledging that JCHEMRATES-type requirements modeling is a necessary step in joint service management of the NBC defense program. The Services continually 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 FY03 Joint Service NBC Defense Logistics Support Plan to update all figures and to provide 100% of the information required for logistics readiness and sustainment assessments.

The items listed under “**NOMENCLATURE**” in Tables F-1 through F-5 are 135 NBC defense items that are currently fielded in the Services. “**TOTAL SERVICE REQUIREMENTS**” include the quantity required for the entire Service (to include active and reserve forces), and includes peacetime replacements (wear and tear) and training requirements, but do not include requirements for Homeland Security. “**2 MCO REQUIREMENT**” is the interim requirement recommended by the JRO, and is based on the existing 2 MTW requirement. Note that materiel requirements for training, sizing variations and peacetime replacements are *not* included in the wartime requirements (**2 MCO REQUIREMENT**). This number represents an average expenditure of chemical defense equipment, adjusted to the missions of the 4-2-1 force planning construct.

The “**STOCKS ON-HAND**” represents the total of all serviceable NBC 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). 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 FY02, but has not received the requisitioned items are included in FY03. Finally, the quantities depicted as “**PROJECTED DUE-IN**” are quantities the Services plan to buy to replace peacetime consumption of NBC 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.

Table F-1a. Army Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN						
					FY03	FY04	FY05	FY06	FY07	FY08	FY09
INDIVIDUAL PROTECTION COMMODITY AREA											
CB MASK											
MASK, CB, M17A2	4240-01-143-2017-20	0	0	241,944*	0	0	0	0	0	0	0
MASK, CB, M40/M40A1	4240-01-258-0061-63	957,624	610,506	1,095,343*	29,301	0	0	0	0	0	0
MASK, M24, AVIATOR	4240-00-776-4384	0	0	4,195*	0	0	0	0	0	0	0
MASK, M25A1, TANK	4240-00-994-8750-52	0	0	45,406*	0	0	0	0	0	0	0
MASK, M42, TANK	4240-01-258-0064-66	84,742	69,015	119,863*	140	0	0	0	0	0	0
MASK, M43, APACHE	4240-01-208-6966-69	0	0	2,678*	156	0	0	0	0	0	0
MASK, M45, AVIATOR	4240-01-414-4034-35/-4051-52	20,156	20,156	14,766*	7,500	0	0	0	0	0	0
MASK, M45, LAND WARRIOR	4240-01-447-6987-9, 8967				904	9,995					
MASK, M48, APACHE	4240-01-386-0198/-4686/-0201/-0207	3,877	1,609	2,355*	3,600	0	0	0	0	0	0
MISC PROTECTION											
PATS, M41	4240-01-365-8241	14,763	11,790	6,617	1,000	1,420	1,420	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA											
NUCLEAR DETECTION EQUIPMENT											
AN/PDR-75	6665-01-211-4217	5,445	5,445	5,477	521	0	0	0	0	0	0
AN/PDR-77	6665-01-347-6100	532	532	797	110	0	0	0	0	0	0
AN/UDR-13	6665-01-407-1237	51,918	51,918	21,632	6,202	0	0	0	0	0	0
AN/VDR-2	6665-01-222-1425	35,950	35,950	32,181	403	0	0	0	0	0	0
BIOLOGICAL DETECTION EQUIPMENT											
BIDS, M31	6665-01-392-6191	76	76	76			0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT											
ACADA, M22	6665-01-438-6963	31,830	31,830	15,080*	1,198	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	28,000	28,000	28,000*	499	0	0	0	0	0	0
CAM/ICAM	6665-01-357-8502	19,595	19,595	16,079*	4,119	0	0	0	0	0	0
M21 RSCAAL	6665-01-324-6637	191	191	156*	2	0	0	0	0	0	0
NBC RECON SYS, M93A1	6665-01-372-1303	110	110	123*		0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA											
DECON APPAR, M11	4230-00-720-1618	40,998	40,221	61,486	25	0	0	0	0	0	0
DECON APPAR, M13	4230-01-133-4124	112,900	112,001	137,342	863	457	458	456	456	456	456
DECON APPAR, PDDA, M12A1	4230-00-926-9488					0	0	0	0	0	0
L/WT DEC SYS, M17A1	4230-01-303-5225	129	129	452	151						
		2,516	2,516	2,055	538	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA											
CP DEPMEDES (HUB, CP, M28)	4240-01-395-5179	23	23	12*	6	6					
SHELTER, CB PROTECT	5410-01-441-8054	779	779	95*	113	22	32	31	31	28	48
SHELTER, CP, M20/M20A1	4240-01-166-2254	2,019	1,747	1,223*	90	93	92	91	92	92	92
SHELTER, M51	4240-00-854-4144			4*							
MEDICAL COMMODITY AREA											
LITTER, DECONTAMINABLE	6530-01-380-7309	7,320	5,148	6,738	0	0	0	0	0	0	0

*Data for these selected Class VII major end items is as of March 31, 2003.

Table F-1b. Army Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
CHEM PROT UNDERGARMENT TOP	8415-01-363-8692-00		0	3,413	42	
CPU DRAWERS	8415-01-363-8683-91	431,564	431,564	3,433	10,042	
JSLIST (ABDO) 45 DAYS	SEE NSNs IN TABLE F-5	3,300,000	2,900,000	660,000	156,519	115,101
SCALP (TAN AND GREEN)	8415-01-333-0987-89		0	8,380		
	8415-01-364-3320-22	151,490	151,385	6,934		
SUIT, CP CAMO (BDos)	8415-01-137-1700-07		0	2,176,875	0	
OVERBOOTS/GLOVES						
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85		0	2,102,091	264,166	0
	8430-01-049-0878-87	2,899,864	2,899,864	110,540	23,688	0
CP FOOT COVERS	8430-01-021-5978	71	0	23,244		0
CP GLOVES 7 MIL	8415-01-138-2501-04	154,612	154,612	101,385	180	0
CP GLOVES 14 MIL	8415-01-138-2497-00	618,448	618,448	170,692	5,910	0
CP GLOVES 25 MIL	8415-01-033-3517-20	3,861,320	3,861,320	3,311,053	40,825	0
MISC PROTECTION						
2D SKIN, M40 SERIES	4240-01-413-1540-43	691,040	691,040	262,137	80,888	56,000
BATTERY, BA-5800 (PRO MASK)	6665-99-760-9742	61,052	61,052	8,745	859	
CP HELMET COVER	8415-01-111-9028	1,605,279	1,605,279	2,704,505	185,939	
FILTER CAN, C2A1	4240-01-361-1319	1,367,626	1,367,626	1,008,365	781,732	432,000
FILTER CAN, M10A1	4240-00-127-7186	0	0	15,720	1,493	
FILTER ELEMENT, M13A2	4240-00-165-5026	0	0	301,707		
HOOD, M40	4240-01-376-3152	1,703,570	1,703,570	1,249,127	310,473	119,000
HOOD, M5 (FOR M25A1)	4240-00-860-8987	0	0	42,721	1,455	
HOOD, M6A2 (FOR M17)	4240-00-999-0420	0	0	12,628	10	
HOOD, M7 (FOR M24)	4240-00-021-8695	0	0	22,325	102	
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, ACADA BA-5590	6135-01-036-3495	110,000	110,000	12,073	714	
BATTERY, BA-3517	6135-00-450-3528	52,645	52,645	3,728	16	
BATTERY, ICAM BA-5800	6665-99-760-9742	52,645	52,645	Included with ProMask		
BATTERY, M42 BA3030	6135-00-930-0030	220,000	220,000			
DET KIT, M256A1	6665-01-133-4964	48,027	48,027	72,286	64,283	25,400
DET PAPER, M8	6665-00-050-8529	2,169,231	2,169,231	1,367,052	280,269	123,000
DET PAPER, M9	6665-01-226-5589	2,023,873	2,023,873	1,073,984	128,397	165,000
MAINT KITS, M293/M273	5180-01-379-6409		0	13,595	148	
	5180-01-108-1729	41,106	41,106	2,430	7	
NBC MARK SET, M274	9905-12-124-5955	9,906	9,906	27,761	1,788	
WATER TEST KIT, M272	6665-01-134-0885	9,580	9,580	5,308	1,271	894
DECONTAMINATION COMMODITY AREA						
DECON KIT, M291 (Box of 20)	6850-01-276-1905	183,382	183,382	501,511	81,139	16,000
DECON KIT, M295 (Box of 20)	6850-01-357-8456	166,892	166,892	305,976	80,659	45,177
DS2, 1 1/3 QT	6850-00-753-4827	192,388	192,338	30,361		
DS2, 5 GAL	6850-00-753-4870	226,163	226,163	62,143	23	
DS2, M13 CAN	6850-01-136-8888	369,535	369,535	56,034	296	

Table F-1b. Army Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
STB, 50 LB	6850-00-297-6653	10,628	10,628	38,592	68	
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP, M12A2 (M14 GPFU)	4240-01-365-0981	12,816	12,816	3,748	778	383
FILTER, CP, M13 SERIES (M14 GPFU)	4240-00-368-6291	12,816	12,816	2,830	600	742
FILTER, CP, M18A1	4240-01-365-0982	60,580	60,580	17,252	2,476	5,189
FILTER, CP, M19	4240-00-866-1825	44,971	44,971	9,188	698	833
FILTER, GP, M48A1	4240-01-363-1311	15,930	15,930	5,951	4,901	2,805
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	1,167	1,167	2,793	1,530	3,246
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	115,000	115,000	1,955,608		
ATROPINE AUTOINJ	6505-00-926-9083	1,115,000	1,115,000	1,265,690		
CANA AUTOINJ	6505-01-274-0951	1,554,920	1,554,920	1,292,409		
NAAK, MKI	6705-01-174-9919	2,281,312	2,281,312	447,573	1,376,028	
PYRIDOSTIGIMINE TAB	6505-01-178-7903	288,000	288,000	671,981		
SODIUM NITRITE INJ (300 MG) KIT	6505-01-206-6009	69,000 kits	69,000 kits	1,697		
Sodium Thiosulfate INJ (12.5 G) KIT	6505-01-206-6009			74		
Sodium Thiosulfate INJ (50 ML Ampule)	6505-01-334-8781			40		
ATROPINE 1MG/ML 1 ML VIAL, 25s	6505-00-957-8089			78		
ATROPINE 2MG/ML 25ML VIAL	6505-00-299-9673		108	30		
POTASSIUM IODIDE TABS 14's BTL	6505-01-116-8198			550		
POTASSIUM IODIDE TABS 14's IS	6505-01-496-4916	48,000	48,000	9,609		
PATIENT WRAPS	6530-01-383-6260	18,900	18,900	3,274		
ATROPINE SULFATE AEROSOL	6545-01-332-1281	2,238	2,238	2,418		
OTHER TREATMENTS						
CIPROFLOXACIN (500 mg tabs 50s)	6505-01-272-2385			2,029,150 tablets		
(500 mg tabs 100 IS)	6505-01-273-8650			1,070,900 tablets		
(500 mg tabs 100s)	6505-01-333-4154	1,881,870 tablets	1,881,870 tablets	0		
(500 mg tabs 30 IS)	6505-01-491-2834			3,334,650 tablets		
DOXYCYCLINE CAPS (100 mg tabs 500s)	6505-01-153-4335	72,000,000 tablets	7,200,000 tablets	5,391,500 tablets		
(100 mg tabs 30s)	6505-01-491-5506			7,053,810 tablets		
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-143-4641			247		
	6505-01-457-8901			1,235		

1

Table F-2a. Air Force Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIRE- MENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN							
					FY03	FY04	FY05	FY06	FY07	FY08	FY09	
INDIVIDUAL PROTECTION COMMODITY AREA												
<i>CB MASK</i>												
MASK, A/P22P2	NOT ASSIGNED	14,810	14,810		0	0	0	0	0	0	0	
MASK, AERP	8475-01-339-9782(S)	32,864	29,879	16,450	892	0	0	0	0	0	0	
MASK, CB, M17A2	4240-01-143-2017-20	5,132	5,132	491	0	0	0	0	0	0	0	
MASK, M45, AVIATOR	4240-01-414-4034-35/- 4051-52				6,998							
MASK, MCU-2/P,	4240-01-415-4239-41	574,372	345,856	223,659	0	0	0	0	0	0	0	
MASK, MCU-2A/P	4240-01-284-3615-17			16,425	0	0	0	0	0	0	0	0
MASK, MCU-2A/P (WR) USAF	4240-01-327-3299-01			32,776	140,000	50,000	0	0	0	0	0	0
<i>MISC PROTECTION</i>												
PATS, M41	4240-01-365-8241	1,208	1,208	82	6	0	0	0	0	0	0	
CONTAMINATION AVOIDANCE COMMODITY AREA												
<i>NUCLEAR DETECTION EQUIPMENT</i>												
ADM 300 - A KIT	6665-01-363-6213NW	300	1,800	49	0	0	0	0	0	0	0	
- B KIT	6665-01-342-7747NW	800		98	0	0	0	0	0	0	0	
- C KIT	6665-01-320-4712NW	750		196	0	0	0	0	0	0	0	
- E KIT	6665-01-426-5071NW	250		56	0	0	0	0	0	0	0	
<i>CHEMICAL DETECTION EQUIPMENT</i>												
ACADA, M22	6665-01-438-6963	3,521	3,521		0	0	0	0	0	0	0	
ALARM, CAA, M8A1	6665-01-105-5623	423	331	81	0	0	0	0	0	0	0	
CAM/ICAM	6665-01-357-8502	0	0	57	0	0	0	0	0	0	0	
	6665-01-199-4153	1,960	1,960	73	0	0	0	0	0	0	0	
M90 CHEM WARFARE ALARM	6665-01-408-5108	65	58	22	0	0	0	0	0	0	0	
DECONTAMINATION COMMODITY AREA												
A/E32U-8 DECON SYS	4230-01-153-8660	175	0	1	0	0	0	0	0	0	0	
L/WT DEC SYS, M17	4230-01-251-8702	299	0	14	0	0	0	0	0	0	0	
L/WT DEC SYS, M17A1	4230-01-303-5225	50	0	5	0	0	0	0	0	0	0	
L/WT DEC SYS, M17A2	4230-01-349-1778	324	324	10	0	0	0	0	0	0	0	
COLLECTIVE PROTECTION COMMODITY AREA												
CHATH (HUB, CPE, M28)	NOT ASSIGNED	21	20	0	0	0	0	0	0	0	0	
MEDICAL COMMODITY AREA												
LITTER, DECONTAMINABLE	6530-01-380-7309	28,225	26,770	6,786	0	0	0	0	0	0	0	

Table F-2b. Air Force Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
AIRCREWMAN CAPE	8415-01-040-9018	290,014	283,502	194,578	0	0
CLOTHING TEST KIT	6630-00-783-8192	200	167		0	0
CP UNDERCOVERALL	8415-01-040-3136-44	75,000	67,376	3,091	0	0
EOD HGU-65P HOOD	4240-01-338-1646	225	192	38	0	0
EOD M-3 TAP	8415-00-099-6962/68/70 8415-01-105-2535	312	176 0	9	0	0
EOD TAP BOOTCOVER	8430-00-820-6295-6306	275	199	38	0	0
EOD TAP GLOVES	8415-00-753-6550-54	500	375	38	0	0
JSLIST (ABDO) 45 DAYS	SEE NSNs IN TABLE F-5	1,914,572	1,224,369	271,377	62,608	46,040
M-2 APRON	8415-00-281-7813-16	225	198	44	0	0
M3 COOLING HOOD	8415-00-261-6443	350	308	9	0	0
M3 COOLING SUIT	8415-00-264-2929	200	170	9	0	0
SUIT, AIRCREW, CWU-66/77P	8475-01-328-3434-57	150,000	126,000	51,669	14,233	0
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	0	0	507,134	0	0
SUIT, CP CAMO-DESERT 3 clr	8415-00-327-5347-53	0	0	53,492	0	0
SUIT, CP CAMO-DESERT 6 clr	8415-01-324-3084-91	0	0	10,546	0	0
OVERBOOTS/GLOVES						
JLIST MULO	8430-01-464-9453-84	1,914,572				
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85		0	887,040	0	0
GVO	8430-01-049-0878-87	1,175,090	528,880	295,752	0	0
CP FOOTWEAR COVERS	8430-01-118-8172		0	1,059	0	0
	8430-01-021-5978	154,802	0	600	0	0
CP GLOVES 7 MIL	8415-01-138-2501-04	2,350,181	1,057,760	148,565	0	0
CP GLOVES 14 MIL	8415-01-138-2497-00		1,257,871	1,513,672	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20		23,051	1,720	0	0
CP SOCKS	8415-01-040-3169	200,056	170,768	75,209	0	0
DISP FOOTWEAR COVER	8430-00-580-1205-06	201,980	185,771	149,455	0	0
GLOVE INSERTS	8415-00-782-2809 (S)	2,350,181	1,057,760	1,553,929	0	0
				0	0	0
MISC PROTECTION						
FILTER CAN, C2/C2A1	4240-01-119-2315 / -361-1319	2,350,181	1,057,760	1,260,655	0	0
FILTER, GP	4240-01-161-3110	2,090	1,750	667	0	0
FILTER ELEMENT, M13A2	4240-00-165-5026	12,596	12,596	48,435	0	0
HOOD, M6A2 (FOR M17)	4240-00-999-0420	0	0	1,206	0	0
HOOD, MCU-2/P	4240-01-189-9423	2,350,181	1,057,760	1,831,301	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, ACADA BA-5590	6135-01-036-3495	46,331	46,331	904	0	0
BATTERY, BA-3517	6135-00-450-3528	880	0	263	0	0
BATTERY, ICAM BA-5800	6665-99-760-9742	67,295	67,295	516	0	0
DET KIT, M18A2	6665-00-903-4767	100	0	266	0	0
DET KIT, M256A1	6665-01-133-4964	50,123	1,292	625	0	0
DET PAPER, M8	6665-00-050-8529	293,773	132,220	1,049,857	0	0

Table F-2b. Air Force Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
DET PAPER, M9	6665-01-049-8982 6665-01-226-5589	293,773	0 132,220	106,829 284,298	0 0	0 0
MAINTENANCE KIT, M293	5180-01-379-6409	90	0	45	0	0
NBC MARK SET, M274	9905-12-124-5955	725	517	386	0	0
WATER TEST KIT, M272	6665-01-134-0885	764	764	112	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	625	625	0	0	0
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439			2		
DECON KIT, M291	6850-01-276-1905	58,755	26,444	24,863	0	0
DECON KIT, M295	6850-01-357-8456	29,378	13,222	20,510	0	0
SODIUM HYPOCHLORITE	6810-00-598-7316	100	0		0	0
STB, 50 LB	6850-00-297-6653	517	517		0	0
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP M13 SERIES (M14 GPFU)	4240-00-368-6291	0	0	5,565	0	0
FILTER, GP M48A1	4240-01-363-1311	8	8	0	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	540,000	354,796	706,962		
ATROPINE AUTOINJ	6505-00-926-9083	540,000	354,796	633,489		
CANA AUTOINJ	6505-01-274-0951	180,000	113,323	265,938		
NAAK, MKI	6705-01-174-9919	140	0	160	0	0
PYRIDOSTIGIMINE TAB	6505-01-178-7903	36,000	23,460	52,470	0	0
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-143-4641	167 kits	167 kits	84 kits		
ATROPINE 1MG/ML 1ML VIAL, 25s	6505-00-957-8089			27,858		
ATROPINE 2MG/ML 25ML VIAL	6505-00-299-9673			2,337		
POTASSIUM IODIDE TABS 14's BTL	6505-01-116-8198	2,700		1,263		
OTHER TREATMENTS						
DOXYCYCLINE TABS, 100 MG, 500s + 100 MG, 50s +	6505-01-153-4335 6505-01-095-4175	16,200,000 tablets	16,200,000 tablets	1,681,000 tablets 0	0 0	0 0
CIPROFLOXACIN 500 MG TAB 100s IS+ 500 MG TAB 100s BTL+	6505-01-273-8650 6505-01-333-4154	10,800,000 tablets	3,351,500 tablets	6,775,500 tablets 945,000 tablets	0 0	0 0

Table F-3a. Navy Logistics Readiness Data - Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN							
					FY03	FY04	FY05	FY06	FY07	FY08	FY09	
INDIVIDUAL PROTECTION COMMODITY AREA												
CB MASK												
MASK, A/P 22P-14(V)2	NOT ASSIGNED	11,067	11,067	3,718	0	0	0	0	0	0	0	
MASK, A/P 23P-14(V)2	NOT ASSIGNED	(22&23)	(22&23)		0	0	0	0	0	0	0	
MASK, CB, M40/M40A1	4240-01-258-0061-63	26,400	26,400	1,426	34,000	0	0	0	0	0	0	
MASK, M45, AVIATOR	4240-01-414-4034-35/-4051-52	3,177	1,909	702	1,268	0	0	0	0	0	0	
MASK, MCU-2/P	4240-01-173-3443	530,250	530,250	92,829	0	0	0	0	0	0	0	
MASK, MCU-2A/P	4240-01-284-3615/17			19,942	0	0	0	0	0	0	0	0
MASK, MCU-2A/P (WR) USN	4240-00-327-4148-50			57,046	21,063	16,263	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA												
NUCLEAR DETECTION EQUIPMENT												
AN/PDR-27	6665-00-543-1435	4,176	4,176	3,566	0	0	0	0	0	0	0	
AN/PDR-43	6665-00-580-9646	2,628	2,628	3,587	0	0	0	0	0	0	0	
AN/PDR-56	6665-00-086-8060	1,286	1,286	1,327	0	0	0	0	0	0	0	
AN/PDR-65	6665-01-279-7516	716	716	619	0	0	0	0	0	0	0	
CP-95	6665-00-526-8645	1,607	1,107	5,478	0	0	0	0	0	0	0	
PP-4276	6665-00-489-3106	3,277	3,277	656	0	0	0	0	0	0	0	
IM-143	6665-00-764-6395	23,229	23,229	7,899	0	0	0	0	0	0	0	
DT-60	6665-00-978-9637	344,944	344,944	144,642	0	0	0	0	0	0	0	
AN/PDQ-1 MFR	6665-01-435-0127	12,019	12,019	9,038	400	494	361	546	528	572	400	
OA-9449/PDQ	6665-01-435-0131	6,262	6,262	6,262	0	0	0	0	0	0	0	
BIOLOGICAL DETECTION EQUIPMENT												
IBAD	NOT ASSIGNED	25	25	19	0	0	0	0	0	0	0	
CHEMICAL DETECTION EQUIPMENT												
ACADA, M22	6665-01-438-6963	444	444	388	0	0	0	0	0	0	0	
ACADA, SHIPBOARD	6665-01-484-7823	774	774	233	491							
ALARM, CAA, M8A1	6665-01-105-5623	Incl in M22	Incl in M22	109	0	0	0	0	0	0	0	
CAPDS	6665-01-294-2556	incl in IPDS	incl in IPDS	65	0	0	0	0	0	0	0	
CHEM AGENT MONITOR/ICAM	6665-01-199-4153	1,008	1,008	873	0	0	0	0	0	0	0	
CWDD, AN/KAS-1	5855-01-147-4362	401	401	644	0	0	0	0	0	0	0	
IMP POINT DETECTION SYSTEM	6665-LL-HAL-5532	254	254	175	48	32	0	0	0	0	0	
DECONTAMINATION COMMODITY AREA												
DECON APPAR, M11	4230-00-720-1618	224	224	220	0	0	0	0	0	0	0	
L/WT DEC SYS M17A3 DIESEL	4230-01-346-3122	412	412	169	0	0	0	0	0	0	0	
COLLECTIVE PROTECTION COMMODITY AREA												
SHELTER, CP, M20/M20A1	4240-01-166-2254	7,311	7,311	27	0	0	0	0	0	0	0	
MEDICAL COMMODITY AREA												
LITTER, DECONTAMINABLE	6530-01-380-7309	1,200	1,200	90	0	0	0	0	0	0	0	

Table F-3b. Navy Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
APRON, TAP	8415-00-281-7813-16	110	110	108		
JSLIST (ABDO) 45 DAYS	SEE NSNs IN TABLE F-5	1,608,242	1,608,242	414,095	62,608	46,040
SUIT, TAP 3	8415-00-099-6962/68/70 8415-01-105-2535	1,800	1,800	1,660		
SUIT, CP, OG MK3	8415-01-214-8289-92	Incl w/ JSLIST	Incl w/ JSLIST	27,000		
SUIT, CP, SARATOGA	8415-01-333-7573-76	Incl w/ JSLIST	Incl w/ JSLIST	44,122		
SUIT, CP SARATOGA-DESERT	8415-01-333-7577-80	Incl w/ JSLIST	Incl w/ JSLIST	40		
OVERBOOTS/GLOVES						
JLIST MULO	8430-01-464-9453-84					
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85	Incl w/ CP FOOTWEAR COVERS	Incl w/ CP FOOTWEAR COVERS	93,804	0	0
GVO	8430-01-049-0878-87			0		
CP FOOTWEAR COVERS	8430-01-118-8172 8430-01-021-5978	1,608,242	1,608,242	186,396	0	0
CP GLOVES 14 MIL	8415-01-138-2497-00	58,160	58,160	61,128	0	0
CP GLOVES 25 MIL	8415-01-033-3517-20	1,608,242	1,608,242	266,039	0	0
CP SOCKS	8415-01-040-3169	204,824	204,824		0	0
DISP FOOTWEAR COVER	8430-00-580-1205-06	204,824	204,824		0	0
GLOVE INSERTS	8415-00-782-2809	4,824,726	4,824,726	167,430	0	0
MISC PROTECTION						
CP HELMET COVER	8415-01-111-9028	450	450	574	0	0
FILTER CAN, C2/C2A1	4240-01-119-2315	1,590,750	1,590,750	429,503	0	0
HOOD, MCU-2/P	4240-01-189-9423	2,517	2,517	494	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
DET KIT, M256A1	6665-01-133-4964	11,400	11,400	8,290	0	0
DET PAPER, M8	6665-00-050-8529	111,707	111,707	60,655	0	0
DET PAPER, M9	6665-01-226-5589	50,803	50,803	25,334	0	0
NBC MARK SET, M274	9905-12-124-5955	1,859	1,859	349	0	0
TUBE PHOSGENE	6665-01-010-7965	1,280	1,280	1,113	0	0
WATER TEST KIT, M272	6665-01-134-0885	280	280	265	0	0
DECONTAMINATION COMMODITY AREA						
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	10,626	10,626	13,773	0	0
CALCIUM HYPOCHLORITE (100 lb)	6810-12-132-2439			0		
DECON KIT, M291	6850-01-276-1905	34,500	34,500	121,853	0	0
DECON KIT, M295	6850-01-357-8456	9,049	9,049	5,195	0	0
DS2, 5 GAL	6850-00-753-4870	42	42	62	0	0
SODIUM HYPOCHLORITE	6810-00-598-7316	400	400	375	0	0
STB, 50 LB	6850-00-297-6653	1,718	1,718	322	0	0

Table F-3b. Navy Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIRE- MENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, GP, M48A1	4240-01-363-1311	258	258	0	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533	Installed, not spared	0	0	0	0
PRE-FILTER, SHIPBOARD CPE	4240-01-348-8785	2,499	2,499	411	0	0
LP Filter		1,049	1,049	0		
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	1,515,000	1,515,000	240,357		
ATROPINE AUTOINJ	6505-00-926-9083	1,515,000	1,515,000	280,681		
CANA AUTOINJ	6505-01-274-0951	505,000	505,000	22,842		
NAAK, MKI	6705-01-174-9919	6,000	6,000	6,143		
PYRIDOSTIGIMINE TAB	6505-01-178-7903	505,000	505,000	173,562		
ANTIDOTE TREATMENT KIT, CYANIDE	6505-01-143-4641			11		
ATROPINE 1MG/ML 1ML VIAL, 25s	6505-00-957-8089			4,939		
ATROPINE 2MG/ML 25ML VIAL	6505-00-299-9673			400		
POTASSIUM IODIDE TABS 14's BTL	6505-01-116-8198			48,310		
POTASSIUM IODIDE TABS 14's IS	6505-01-496-4916	49,000	49,000	735		
TETRACYCLINE	6505-00-655-8355	1,212,205	1,212,205			
OTHER TREATMENTS						
CIPROFLOXACIN	6505-01-273-8650			90,600 tablets		
	6505-01-333-4154	100,472 tablets	100,472 tablets	97,100 tablets		

Table F-4a. Marine Corps Logistics Readiness Data – Non-Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN						FY09
					FY03	FY04	FY05	FY06	FY07	FY08	
INDIVIDUAL PROTECTION COMMODITY AREA											
CB MASK											
MASK, CB, M40/M40A1	4240-01-258-0061-63	227,069	150,000	186,826	6,184	9,222	4,611	0	0	0	0
MASK, CB, M17A2	4240-01-143-2017-20	0	0	2,042	0	0	0	0	0	0	0
MASK, M24, AVIATOR	4240-00-776-4384	0	0	80	0	0	0	0	0	0	0
MASK, M42, TANK	4240-01-258-0064-66	0	0	1,590	0	0	0	0	0	0	0
MASK, MCU-2/P, -2A/P	4240-01-284-3615-17	0	0	182	0	0	0	0	0	0	0
MISC PROTECTION											
MASK COMM ADAPTOR	5996-01-381-9012	50,000	50,000	17,890	0	0	0	0	0	0	0
PATS, M41	4240-01-365-8241	469	469	363	0	0	0	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA											
NUCLEAR DETECTION EQUIPMENT											
AN/PDR-75	6665-01-211-4217	1,203	1,203	684	0	0	0	0	0	0	0
AN/VDR-2	6665-01-222-1425	1,182	1,182	2,255	0	0	0	0	0	0	0
CHEMICAL DETECTION EQUIPMENT											
ACADA, M22	6665-01-438-6963	762	762	578	0	0	0	0	0	0	0
ALARM, CAA, M8A1	6665-01-105-5623	28	28	0	0	0	0	0	0	0	0
CAM 1.5	6665-01-359-9006	1,854	1,565	0	0	0	0	0	0	0	0
CAM 2.0	6665-99-725-9996	1,528	875	2,747	0	0	0	0	0	0	0
M21 RSCAAL	6665-01-382-1968	151	151	0	0	0	0	0	0	0	0
NBC RECON SYS, FOX	6665-01-372-2582	0	0	6	0	0	0	0	0	0	0
DECONTAMINATION COMMODITY AREA											
DECON APPAR, M11	4230-00-720-1618	21,050	7,235	44,719	0	0	0	0	0	0	0
DECON APPAR, M13	4230-01-133-4124	16,913	16,913	6,084	0	0	0	0	0	0	0
L/WT DEC SYS, M17A1	4230-01-303-5225	344	0	71	0	0	0	0	0	0	0
HEAVY FUEL DECON	4230-01-470-5288			647					0		
L/WT DEC SYS, M17A3	4230-01-346-3122	1,570	1,570	274	0	0	0	0	0	0	0
COLLECTIVE PROTECTION COMMODITY AREA											
* SHELTER, CP, PORTABLE	4240-01-346-2564	0	0	57	0	0	0	0	0	0	0
MEDICAL COMMODITY AREA											
LITTER, DECONTAMINABLE	6530-01-380-7309	0	0	24	0	0	0	0	0	0	0

* - Note: The Marine Corps is using the Portable Collective Protection System for training purposes.

Table F-4b. Marine Corps Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIREMENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA						
OVERGARMENTS						
JSLIST (ABDO) 45 DAYS	SEE NSNs IN TABLE F-5	853,176	687,606	132,779*	31,304	23,020
SUIT, CP CAMO (BDO)	8415-01-137-1700-07	0	0	312	0	0
SUIT, CP, SARATOGA	8415-01-333-7573-76	596,131	596,131	525,427	0	0
SUIT, CP SARATOGA-DESERT	8415-01-333-7577-80	50,000	50,000	80,774	0	0
OVERBOOTS/GLOVES						
JLIST MULO	8430-01-464-9453-84			249,000**	255,000	223,077
BLK/GRN VINYL O/BOOTS BVO	8430-01-317-3374-85		0	223,943		
GVO	8430-01-049-0878-87	654,000	651,146	33,703		
CP FOOT COVERS	8430-01-021-5978		0	166,952		
CP GLOVES 25 MIL	8415-01-033-3517-20	792,154	792,154	416,685		
MISC PROTECTION						
2D SKIN, M40 SERIES	4240-01-413-1540-43	277,069	183,684	472,931	0	0
FILTER CAN, C2/C2A1	4240-01-119-2315		0	236,513		
	4240-01-361-1319	554,246	359,930	58,195	0	0
FITLER CAN, M10A1	4240-00-127-7186	2,468	0	230	0	0
FILTER ELEMENT, M13A2	4240-00-165-5026	27,766	0	30	0	0
HOOD, M40	4240-01-376-3152	343,869	343,869	8,560	0	0
HOOD, M5 FOR M25A1	4240-00-860-8987	867	0	0	0	0
HOOD, M6A2 FOR M17	4240-00-999-0420	0	0	0	0	0
HOOD, M7 (FOR M24)	4240-01-021-8695	323	0	0	0	0
CONTAMINATION AVOIDANCE COMMODITY AREA						
CHEMICAL DETECTION EQUIPMENT						
BATTERY, BA-3517	6135-00-450-3528		0	0	0	0
BATTERY, ICAM BA-5800	6665-99-760-9742	27,136	27,136	0	0	0
BATTERY, ACADA BA-5590	6135-01-036-3495	20,706	20,706	0	0	0
DET KIT, M256A1	6665-01-133-4964	30,547	30,547	5,665	0	0
DET PAPER, M8	6665-00-050-8529	272,770	272,770	55,357	0	0
DET PAPER, M9	6665-01-049-8982		0	8,660		
	6665-01-226-5589	380,949	380,949	51,614	0	0
NBC MARK SET, M274	9905-12-346-4716	2,286	2,262	0	0	0
WATER TEST KIT, M272	6665-01-134-0885	3,159	1,115	591	0	0
DECONTAMINATION COMMODITY AREA						
DECON KIT, M291	6850-01-276-1905	408,220	33,067	128,940	0	0
DECON KIT, M295	6850-01-357-8456	29,244	29,244	13	0	0
DS2, 1 1/3 QT	6850-00-753-4827	1,006,813	1,006,813	1,229	0	0
DS2, 5 GAL	6850-00-753-4870	253,837	2,919	5,451	0	0
DS2, M13 CAN	6850-01-136-8888	32,451	0	1	0	0
NITROGEN CYLINDERS	4230-00-775-7541	27,993	27,993	7,685	0	0
STB, 50 LB	6850-00-297-6653	7,410	1,264	4,566	0	0

Table F-4b. Marine Corps Logistics Readiness Data – Consumables

NOMENCLATURE	NSN	TOTAL SERVICE RQMTS	2 MCO REQUIRE- MENT	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
					FY03	FY04
COLLECTIVE PROTECTION COMMODITY AREA						
FILTER, CP, M12A2 (M14 GPFU)	4240-01-365-0981	1,108	1,108	136	0	0
FILTER, CP, M13 SERIES (M14 GPFU)	4240-00-368-6291	1,122	1,122	332	0	0
FILTER, CP, M18A1	4240-01-365-0982	3,236	3,236	228	0	0
FILTER, CP, M19	4240-00-866-1825	1,674	1,674	331	0	0
FILTER, GP, M48A1	4240-01-363-1311	644	644	254	0	0
FILTER SET FOR (M59, M56, SHIPBOARD)	4240-01-369-6533		0	0	0	0
MEDICAL COMMODITY AREA						
2-PAM CHLORIDE AUTOINJ	6505-01-125-3248	500,505	500,505	280,925		
ATROPINE AUTOINJ	6505-00-926-9083	500,505	500,505	346,081		
CANA AUTOINJ	6505-01-274-0951	142,481	142,481	85,111		
PYRIDOSTIGIMINE TAB	6505-01-178-7903	289,075	289,075	68,485		
ATROPINE 1 MG/ML, 1ML VIAL, 25s	6505-00-957-8089	42,672		19,906		
CIPROFLOXACIN 500 MG TAB 100s IS+	6505-01-273-8650	530,000 tablets	530,000 tablets	369,200 tablets		
500 MG TAB 100s BTL+	6505-01-333-4154			162,300 tablets		
OTHER TREATMENTS						
DOXYCYCLINE CAPS, 500s	6505-00-009-5063	8,400,240 tablets	8,400,000 tablets	10,662,000 tablets		

* Includes SOF, Training, Chemical Testing, and Surveillance

** Includes Joint Service stocks held for all Services prior to fielding

Table F-5. Defense Logistics Agency Logistics Readiness Data - Consumables

NOMENCLATURE	NSN	FY02 STOCKS ON HAND (as of 30 Sept 02)	PROJECTED DUE IN	
			FY03	FY04
INDIVIDUAL PROTECTION COMMODITY AREA				
OVERGARMENTS				
CAPE, AIRCREWMAN	8415-01-040-9018	6,717	171,000	
CHEM PROT UNDERGARMENT TOP	8415-01-363-8692-00	10,996	0	
CPU DRAWERS	8415-01-363-8683-91	15,400	0	
EOD M-3 TAP	8415-00-099-6962/68/70	5,963	530	
	8415-01-105-2535			
EOD TAP BOOTCOVER	8430-00-820-6295- 6306	7,288	12,082	
EOD TAP GLOVES	8415-00-753-6550-54	22,820	14,130	
JSLIST SUITS *				304,096 **
Wood - Coat	8415-01-444-1163/-1169/-1200/38/49/65/70	0	100,000**	
Wood Trousers	8415-01-444-1435/39/-1613-/2308/10/25/38	0	100,000**	
Desert Coat	8415-01-444-5902/05/13/26/-6116/31/38	0	505,634**	
Desert Trousers	8415-01-444-5417/5504/06/-5892/93/98/-5900	0	505,634**	
OVERBOOTS/GLOVES				
JLIST MULO	8430-01-464-9453-84	0	0	0
BLK/GRN VINYL O/BOOTS	8430-01-317-3374-85	85,476	449,978	0
CP GLOVES 7 MIL	8415-01-138-2501-04	345	138,453	0
CP GLOVES 14 MIL	8415-01-138-2497-00	9,443	654,648	0
CP GLOVES 25 MIL	8415-01-033-3517-20	36,112	993,975	0
CP SOCKS	8415-01-040-3169	37,128	300,000	0
DISP FOOTWEAR COVER	8430-00-580-1205-06	6,699	20,760	0
MISC PROTECTION				
CP HELMET COVER	8415-01-111-9028	30,496	415,800	0
CONTAMINATION AVOIDANCE COMMODITY AREA				
CHEMICAL DETECTION EQUIPMENT				
BATTERY, BA3517	6135-00-450-3528	3,321		
TUBE, DET, PHOSGENE GAS	6665-01-010-7965	73		
DECONTAMINATION COMMODITY AREA				
CALCIUM HYPOCHLORITE (6 oz)	6810-00-255-0471	106,200		
STB, 50 LB	6850-00-297-6653	11,611		
MEDICAL COMMODITY AREA				
2-PAM CHLORIDE, AUTOINJ	6505-01-125-3248	95,508	403,024	0
ATROPINE AUTOINJ	6505-00-926-9083	163,226	716,937	0
CANA AUTOINJ	6505-01-274-0951	75,623	433,000	0
NAAK, MKI	6705-01-174-9919	158,164	1,467,752	0
PYRIDOSTIGIMINE TABLETS	6505-01-178-7903	39,232	45,000	0
LITTER, DECONTAMINABLE	6530-01-380-7309	6,167	1,640	0
ATROPINE SULFATE AEROSOL	6545-01-332-1281	0		0
ANTIDOTE TREAT KIT, CYANIDE	6505-01-457-8901	0	2,000	0

* DLA purchases JSLIST suits for the Services. Projected Service allocations are included in the individual Service totals.

** These quantities are reported as of 30 September 2002. Since then, DLA buys have been accelerated such that the total FY03 due-in is 1.2 million suits, and FY04 is 295,000 although additional funding is expected to increase that amount.

F.2 FIELDDED NBC DEFENSE ITEMS - ISSUES AND CONCERNS

NBC 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.

F.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 NBC 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 appear in the moderate and high risk categories, but their risk will improve with continued procurement in coming years.

Current numbers 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 are insufficient as measured against the MCO requirements. Automatic biological agent point detectors and stand-off detectors are currently in development, and will not be deployed in significant numbers prior to FY03. 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, Marine Corps will not have that capability either. The Navy is fielding the DFU, which is a commercially available system. 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 sample solution is analyzed via hand held assays (HHAs) for the detection and identification of biological agents.

The combined total of chemical agent detection systems remains at moderate risk, but will improve slowly as the M22 Automatic Chemical Agent/Detector (ACADA) supplements the M8A1 Automatic Chemical Agent Alarm. 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 places them in the low risk category, which reflects the success of refurbishment actions that were completed during FY02, and planned buys in FY03.

The M21 Remote Sensing Chemical Agent Alarm (RSCAAL) is at high risk compared with MCO requirements. The M93A1 NBCRS is currently fielded at its projected requirements. 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 available in sufficient quantities to meet wartime requirements. Some shortages 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 the MCO average 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 in sufficient quantities through the depot system. The Navy has small quantities of older RADIACs still in the inventory, which will be replaced through a modernization program currently underway. 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 requirements, and the remaining procurement of the AN/PDQ-1 is currently fully funded and programmed to be completed in FY08. The Marine Corps has sufficient AN/VDR-2s and over half of its AN/PDR-75s as compared to the MCO requirements, 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.

F.2.2 INDIVIDUAL PROTECTION

Currently fielded protective suits and masks are designed to protect against all known CB threat agents. 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. Fielding of the M40/42 protective masks, JSLIST protective suits and the MULO boot has begun to resolve many of these former challenges.

F.2.2.1 Protective Ensembles

The Services are continuing acquisition of the Joint Services Lightweight Integrated Suit Technology (JSLIST) suits as a replacement for the 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 will produce more than 128,000 suits per month beginning in April 2003. In addition, DLA/DSCP will expand the base by having two additional contractors on line and in production during September 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 FY03, the total Services' inventory of protective suits is at high risk of not meeting projected average MCO 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 Battle Dress Overgarment (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 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 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.

Armor crews and aircrews require special protective ensembles to integrate with their weapon systems. Services 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 Underoverall, which is now obsolete. For the USAF, it is replaced by the CWU-66/77, which remains low in inventory resulting in a moderate risk rating. The USN and USMC aircrew are now using the CMU-34P and CMU-35P (formerly known as Navy modified Chemical Protective Undergarment) in conjunction with the flyer's Summer Coverall for adequate protection. To protect armor crewmen when they exit their vehicles, the Services have developed the Suit Contamination Avoidance Liquid Protection (SCALP), which is available in sufficient quantities to meet MCO requirements.

The Services will have adequate stocks of 14 and 25-mil chemical protective gloves in FY03 for contingency use. Currently, 7-mil gloves are 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.

Chemical Protective Footwear Covers, also known as the "fishtail" boot, 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 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.

F.2.2.2 Eye/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 are replacing the M17 and M25-series masks, respectively. Some Navy shore activities are also using the M40 masks. 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 at low risk, as the combined numbers of all aviator masks on hand 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 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 eyelens-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-2A/P mask is designed to meet the needs of the Air Force ground crews, Navy shipboard and shore-based support missions, and Marine Corps rotary wing forces. The number of these masks on hand generally meets the requirement, although increased Navy requirements have resulted in localized shortfalls, particularly in size large. The USAF has some shortages in masks. Second skins, which provide complete personal protection, are currently in First Article Testing (FAT) in preparation for production. The MCU-2A/P mask will continue to be the mainstay of these units until the Joint Service General Purpose Mask 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.

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 rated as low risk. The MCU-2P hood is at low risk with an abundant inventory. Second skins for the MCU-2P are in development and will be issued beginning in FY03. 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. The Chemical Protective Helmet Cover is also available in sufficient quantities.

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 masks. The number on hand falls short of the MCO requirements as a moderate risk. The M13A2 filter element exceeds requirements, but will be leaving the inventory with the retirement of the M17-series mask. The M10A1 filter canister used on the M24/25 is short of the requirement, but these masks will also leave the inventory and will not be a readiness problem.

F.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 in short supply due to low peacetime demand and low production quantities. The increased emphasis on procuring individual protection and contamination avoidance equipment has resulted in a corresponding decrease in procurements of shelters and large collective protection filters.

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 ship-board collective protection filter requirements and the Army and Marine Corps traditional integrated vehicular systems and tactical shelter requirements, the near-term MCO requirements for large carbon-based filters have outpaced current inventories even aided by industrial surge capability. As a result, much of this sector is 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 Defense Planning Guidance. CPBS will experience a break in production in FY04 and FY 05 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 chemically protected heaters and air conditioners initiated production in FY99. Procurement and production of CP DEPMEDS components has initiated. All components will be assembled into CP DEPMEDS sets at depot. The budget supported the

production of 12 the 18 CP DEPMEDS sets identified by Defense Planning Guidance (DPG). No additional funding 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 initiated for remaining M28 CPE, CB protected water distribution and latrine systems, CB ISO Shelter Seals and Low Pressure Alarms.

The M20-series Simplified CPEs are used to provide a contamination-free, environmentally controlled work space 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. This leads to an assessment as high risk. Current policy is that the M20/M20A1 Simplified CPE is a free issue item with no requirement to stock other than spares replenishment. 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 stand-alone shelter outside of the medical community in the inventory.

The Services have continued to improve integrated collective protection systems in armored vehicles and vans. 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 chaises. 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 MTW requirements has not been initiated for all filters. 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 are being procured in sufficient quantities. Continued difficulties in obtaining a strong industrial base in this field compounds the issue of fielding and sustaining these items.

F.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. While the M11 is assessed as posing low risk, there are insufficient quantities of the M13 DAP as measured against the MTW requirements. 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 are expected to be available for purchase 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 a moderate 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 assessed as high risk. The maintenance requirements due to the age of this item limit its full utilization and increases its risk. The Modular Decontamination System will displace 200 M12A1 PDDAs over the far term, resulting in a high-low mix of technology. By FY03, the on-hand quantities of the MDS will help satisfy the two MCO requirement. Additionally, the Marine Corps is replacing their M12A1 PDDAs with the M17-series LDS.

The Army and Marine Corps plans for stocking containers of DS-2 (5-GAL and M13 Can) are below the MCO requirements expected for decontamination operations. The situation is compounded by a 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 meets average MCO requirements, but 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 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 the MCO and total 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 2006. In the meantime, an interim replacement is nearly ready and a back-

up 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 puts it in a low risk category when compared with MCO requirements. 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.

F.2.5 MEDICAL

Medical NBC 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 and present overall low risk. Quantities of Nerve Agent Antidote Kits (NAAK), and Atropine and 2-PAM Chloride Autoinjectors now fall short of MCO requirements. Convulsant Antidote Nerve Agent (CANA), and Nerve Agent Pyridostigmine Pretreatment (NAPP) Tablets (also known as PB Tablets) are 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 NAPP for the Military, in Jan 2003, for the use as a nerve agent pre-treatment for Soman. The use of NAPP 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 NAPP.

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, Autoinjector (ATNAA), which is a multi-chambered injector that began procurement in FY03.

Patient Chemical Wraps have not been procured since 1991 and are made of a special five –layer material that is no longer produced. OTSG and USAMMA with SBCCOM 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 can 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 has centrally programmed and funded the Army's Medical Chemical Defense Materiel since 1994. USAMMA has procured, stored and main-

tained this materiel for the Army in strategic locations for early deployers and forward deployed forces Deployable Force Packages (DFP), which will support various sizes 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. That status and schedule of the anthrax vaccination program is provided in Table 2-16 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.

OSD 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 remarks the materiel and maintains it with the unit. The Marines remark the materiel at its centralized storage locations. JRCAB is currently looking at other alternatives, similar to the Army's, the replace pen and ink changes. The DoD/FDA Shelf Life Program has saved an average of \$118.50 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.

Annex G

DoD Joint Service Chemical and Biological 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 (CB) 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. 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 G-1 (and Figure G-1) provides a summary of appropriated and requested funding from FY1996–FY2009. Detailed funding request for FY 2004–2009 are provided separately in the President's FY2004 Budget Submission. 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. Much of the growth in program funding between FY1996 and FY1997 resulted from the transfer of funds between existing accounts rather than real growth in the overall DoD CB Defense Program.

Table G-2 (and Figure G-2) provides a summary of expenditures by the DoD Chemical and Biological 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 G-2 will be updated in following years to show total expenditures of appropriated funds.

Table G-1. Chemical and Biological Defense Program Appropriations Summary

Program Element PE (\$ in millions)	FY02‡	FY03**	FY04**	FY05**	FY06**	FY07**	FY08**	FY09**
0601384BP – Basic Research	43.986	54.829	35.831	36.769	37.946	41.001	43.863	42.341
0602384BP – Applied Research	145.706	173.362	106.451	104.385	101.916	88.711	86.059	85.014
0603384BP – Advanced Tech. Dev.	80.198	107.763	103.725	98.843	85.019	89.626	89.870	86.800
Science & Technology Base Subtotal	269.89	335.954	246.007	239.997	224.881	219.338	219.792	214.155
0603884BP – Advanced Component Development and Prototypes	122.210	89.925	162.142	79.195	86.063	75.045	61.941	49.932
0604384BP – System Development and Demonstration	168.081	172.262	148.017	83.325	72.900	58.252	93.541	114.357
0605384BP – Management Support	34.091	35.889	39.345	42.652	47.462	45.107	40.167	37.774
0605502BP- Small Business Innovative Research (SBIR)	9.300	0.000	0.000	0.000	0.000	0.000	0.000	0.000
0607384BP – Operational Systems Development	0.000	0.000	3.442	3.428	1.949	0.000	0.000	0.000
RDT&E Subtotal	603.572	634.03	598.953	448.597	433.255	397.742	415.441	416.218
0208384BP – Procurement Subtotal	513.943	436.639	505.737	639.884	758.061	805.227	859.996	862.670
CB Defense Program Total	1117.515	1070.669	1104.69	1088.481	1191.316	1202.969	1275.437	1278.888

‡ Total Obligation Authority (TOA) ** Estimated [from FY2004/2005 President's Budget Request]

Table G-2. Chemical and Biological Defense Program Expenditures Summary

Program Element (PE) (\$ millions)	FY96†	FY97†	FY98†	FY99†	FY00†	FY01†	FY02†
RDT&E, Defense-Wide	251.160	287.378	332.736	330.673	375.598	348.154	266.076
Procurement, Defense-Wide	134.210	230.795	227.952	291.229	333.256	367.485	280.637
CB Defense Program Total	385.370	518.173	560.588	621.902	708.854	715.639	546.713

† Expenditures as of September 30, 2002.

Table G-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	161.956	137.254	138.533	139.975	147.104	145.888	145.745

‡ Total Obligation Authority (TOA) ** Estimated [from FY2004/2005 President's Budget Request]

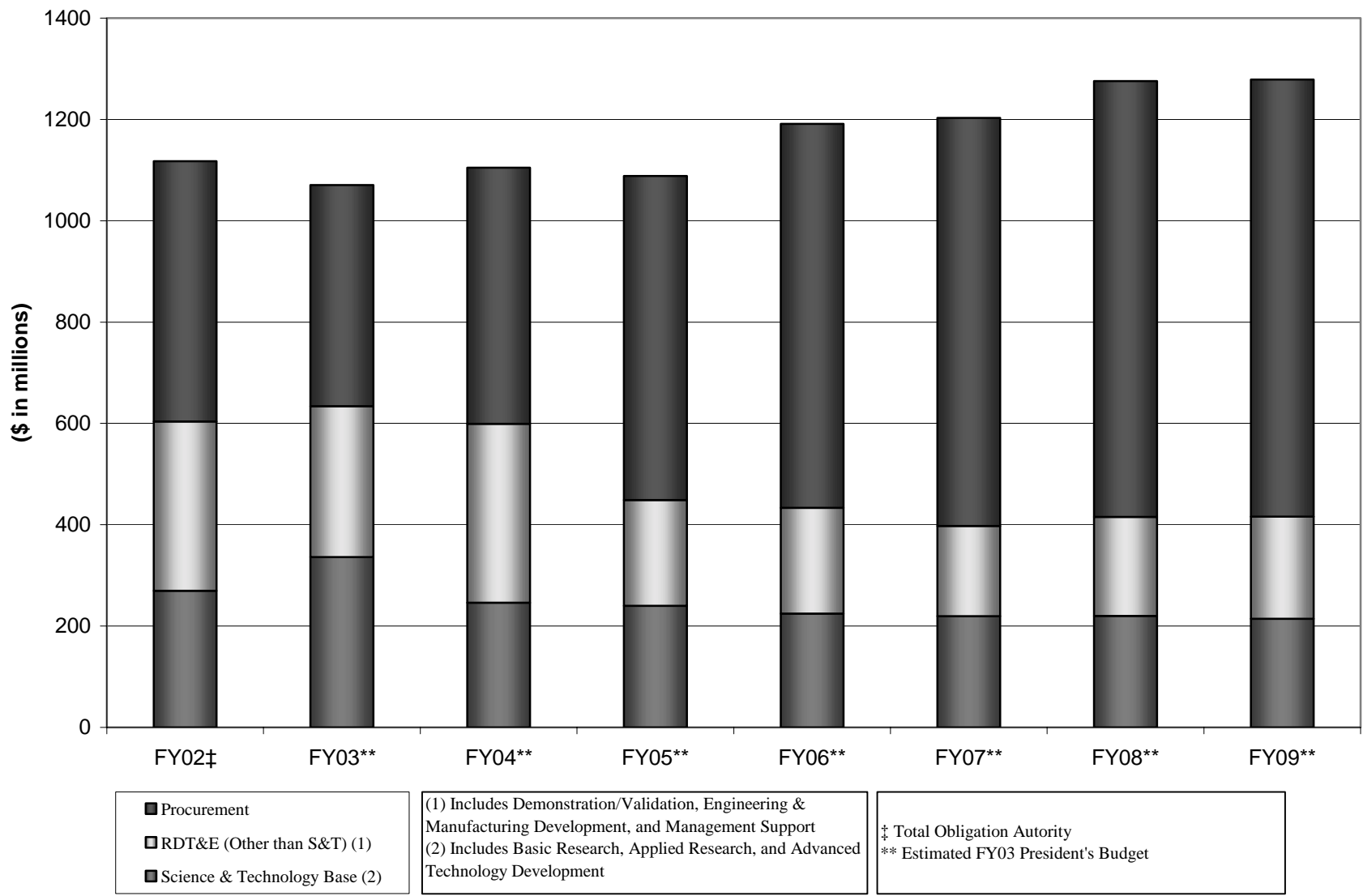
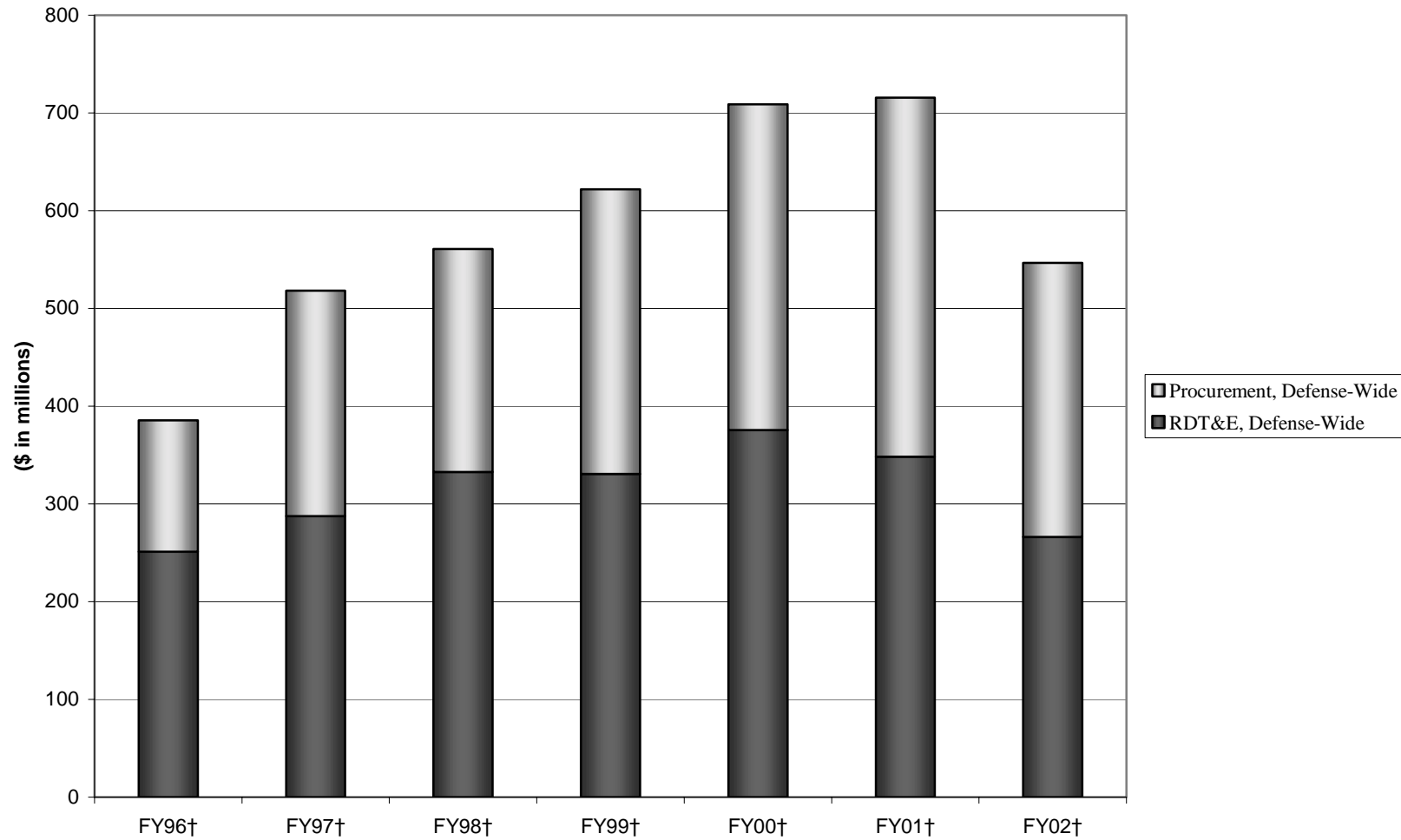


Figure G-1. Chemical and Biological Defense Program Appropriations Summary



†as of September 30, 2002

Figure G-2. Chemical and Biological Defense Program Expenditures Summary

Annex H

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 H-1 provides a summary of prior and planned tests conducted by the Department of Defense, both directly or 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 H-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 which involve the exposure of human subjects to chemical or biological agents.

As part of the DoD Chemical and Biological 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 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.

Annex I

Congressional Reporting Requirement: 50 USC 1523

<p style="text-align: center;">Text of Public Law Mandating Report on The Department of Defense Chemical and Biological Defense Program</p>
--

**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 J

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 may 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 and 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
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
ALSA – Air Land Sea Application
AMAD – Automatic Mustard Agent Detector
AMC – U.S. Army Materiel Command
AMEDDC&S – Army Medical Department Center and School
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 and 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)
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–

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, Radiological Defense
CBRNE – Chemical, Biological, Radiological, Nuclear, and High-Yield Explosives
CBRNC – Chemical, Biological, Radiological & 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 Dynamics
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)
CPE – Collective Protection Equipment
CPO – Chemical Protective Overgarment
CPRC – Counterproliferation Review Council
CPS – Collective Protection System
CPU – Chemical Protective Undergarment
CRDA – Cooperative Research & Development Agreement
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
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
CWCW – 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 and Engineering
DEA – Data Exchange Agreement
DEPMEDS – Deployable Medical Systems
DEST – Domestic Emergency Response Team
DHHS – Department of Health and Human Services
DLA – Defense Logistics Agency
DMMP – Dimethyl Methyl Phosphonate
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
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 – electrochemilluminescence assay
ECU – Environmental Control Unit
ECV – Expanded Capacity Vehicle
ED – ethyl dichlorarsine
EEE – Eastern Equine Encephalomyelitis
EEG – electroencephalographic
ELISA – Enzyme-Linked Immunosorbent Assay

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
FGA – Fourth Generation Agents
FLEETEX – Fleet Exercise
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
GMP – Good Manufacturing Practice
GOCO – Government-Owned/Contractor-Operated
GP – glycoprotein
GPFU – Gas Particulate Filter Unit
GPRA – Government Performance and Results Act

-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
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
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
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
JAWG – Joint Assessment Working Group
JB1GU – JSLIST Block 1 Glove Upgrade
JB2GU – JSLIST Block 2 Glove Upgrade
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
 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
 JMNS – Joint Mission Need Statement
 JMRR – Joint Monthly Readiness Review
 JNBCDB – Joint NBC Defense Board
 JOA – Joint Operations Area
 JORD – Joint Operational Requirements Document
 JPACE – Joint Protective Aircrew Ensemble
 JPO-BD – Joint Program Office for Biological Defense
 JRCAB – Joint Readiness Clinical Advisory Board
 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
 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
 JSNBCRS – Joint Service NBC Reconnaissance System
 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 & T Plan

–L–

L – lewisite, a vesicant agent
 LAM – Louisiana Maneuvers
 LAV – Light Armored Vehicle
 LCBPG – Lightweight CB Protective Garment
 LD₅₀ – 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 and Simulation
M&S CA – Modeling and Simulation commodity Area
M&S R&D – Modeling and Simulation Research and 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
MASINT – Measures & 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
MCO – Marine Corps Order
MCPE – Modular Collective Protection System
MCU-2A/P – a chemical protective mask
MCWP – Marine Corps Warfighting Publication
MD – methyl dichlorarsine
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
MHC – Major Histocompatibility Complex
MICAD – Multipurpose Integrated Chemical Agent Detector
MIL STD – Military Standard
MIPR – Military Interdepartmental Purchase Request
MITS – Medical Identification and Treatment Systems
MLRS – Multiple Launch Rocket System
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
MULO – Multi-purpose Overboot
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)
NBCWP – NBC Defense Interservice Working Party
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
NGIC – National Ground Intelligence Center
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
NWDC – Naval Warfare Development Command

NWP – Naval Warfare Publication

–O–

O49 – Joint Contact Point and Test Project
 OAC – Officer Advance Course
 OBC – Officer Basic Course
 OCONUS – Outside the continental United States
 OG – Overgarment
 O&M – Operations & Maintenance
 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
 PAM – Preventative and Aerospace Medicine
 PATS – Protective Assessment Test System
 PB – President’s Budget
 PBAS – Program Budget Accounting System
 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 Objectives 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 and Evaluation
 RestOps – Restoration of Operations
 RFP – Request for Proposal
 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
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
STRAC – Standards in Training Commission
STS – Specialty Training Standard
SUBD – Small Unit Biological Detector
SWA – Southwest Asia

–T–

T&D – Transport and Diffusion

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
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
UCP – Upconverting Phosphors or Unified
Command Plan
UDP – Unit Deployment Program
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 and 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 and 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

VIC – Vector-In-Command

VIG – Vaccinia Immune Globulin

VLP – virus-like particles

VLSTRACK – Vapor, Liquid, and Solid Tracking
Model

VNTR – Variable Number Tandem Repeat

VPU – Vapor Protective Undergarment

VTC – Video Teleconference

VVA – verification, validation, and accreditation

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)

(INTENTIONALLY BLANK.)