



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

FY2003-2005 Performance Plan

May 2004

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DoD CBRNDP Performance Plan – Contents

Section	Page
1.0 INTRODUCTION.....	1
1.1 Overview of the DoD CBRNDP Performance Plan.....	2
1.2 Vision, Mission, Goals, and Values of the CBRNDP	3
1.3 Joint CBRN Defense Functional Concepts and Operational Goals	4
1.4 Performance Plan Methodology	5
1.5 Summary of Key Performance Metrics.....	9
2.0 OVERVIEW: ADVANCED DEVELOPMENT AND PROCUREMENT PERFORMANCE GOALS AND MEASURES.....	14
2.1 OPERATIONAL GOAL 1: <i>SENSE</i>	14
2.2 OPERATIONAL GOAL 2: <i>SHAPE</i>	21
2.3 OPERATIONAL GOAL 3: <i>SHIELD</i>	23
2.4 OPERATIONAL GOAL 4: <i>SUSTAIN</i>	33
3.0 SCIENCE AND TECHNOLOGY BASE PERFORMANCE GOALS AND MEASURES.....	38
3.0 OVERVIEW	38
3.1 CB DEFENSE S&T PLANNING	38
3.2 DOD CB DEFENSE SCIENCE AND TECHNOLOGY BASE PROGRAM.....	39
3.3 DEFENSE TECHNOLOGY OBJECTIVES.....	40
3.4 <i>BASIC RESEARCH</i> (PROGRAM ELEMENT 0601384BP)	46
3.5 <i>APPLIED RESEARCH</i> (PROGRAM ELEMENT 0602384BP)	56
3.6 <i>ADVANCED TECHNOLOGY DEVELOPMENT</i> (PROGRAM ELEMENT 0603384BP).....	85
4.0 CBRN DEFENSE HOMELAND SECURITY AND FORCE PROTECTION.....	103
4.1 WMD Civil Support Team (WMD-CST) Advanced Technology Development..	103
4.2 WMD-CSTs and Installation Protection	104
5.0 DOD CBRNDP DEFENSE MANAGEMENT PRACTICES	107
5.0 OVERVIEW	107
5.1 CB DEFENSE MANAGEMENT PRACTICES – GOALS AND MEASURES ..	107
5.2 CHEMICAL/BIOLOGICAL DEFENSE (RDT&E Management Support)	108

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1.0 INTRODUCTION

The Department of Defense (DoD) Chemical, Biological, Radiological, and Nuclear Defense Program (CBRNDP) performance plan provides an assessment of the most recently completed fiscal year (FY03) and outlines performance targets for the next two year (FY04–FY05) for the program. This performance plan demonstrates compliance with the Government Performance and Results Act (GPRA), which requires agencies to submit an annual performance plan to Congress. This plan establishes a *process* by which the CBRNDP can measure the effectiveness of the various projects under the CBRNDP and assessing their contributions to the operational goals and the mission of the program. This process provides a tool for identifying programmatic strengths and weaknesses aid in the effective oversight and management of the program by providing a tool to assist in making investment decisions.

In the past, DoD's management priorities have been defined by near-term operational threats. In the Report of the *2001 Quadrennial Defense Review*, DoD outlined a new approach that tailored the balanced scorecard concept to provide a management framework to help defense managers balance investment priorities against risk over time.¹ DoD has tailored the Balanced Score Concept and outlined four broad areas of risk management that support the Department's vision, mission, and goals. (See **figure 1.**) DoD pursues an investment strategy that seeks to reduce overall program risk by balancing risk in each of the following areas.

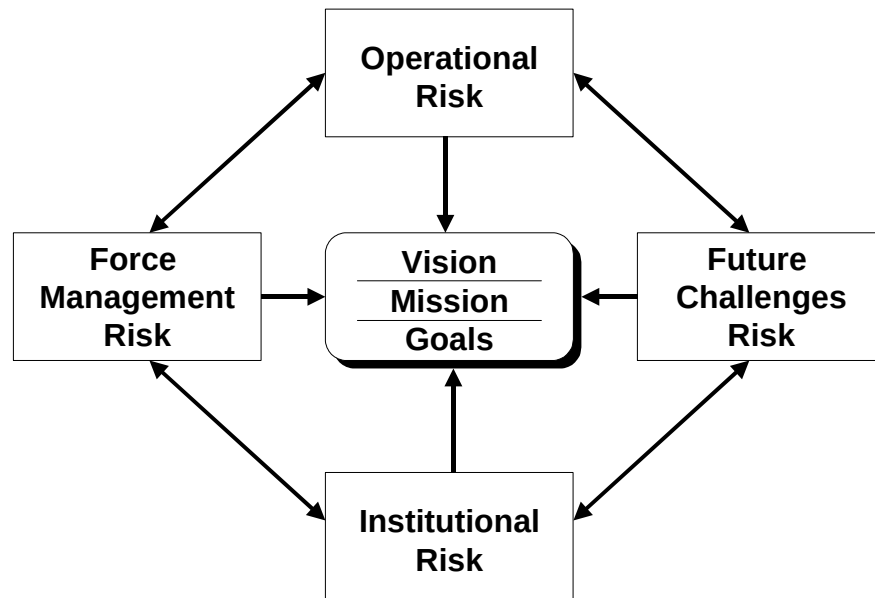


Figure 1. Managed Risk Strategy

- *Force management risk* results from issues affecting the ability to recruit, retain, train, and equip sufficient numbers of quality personnel and sustain the readiness of the force while accomplishing its many operational tasks.
- *Operational risk* stems from factors shaping the ability to achieve military objectives in a near-term conflict or other contingency.

¹ The balanced scorecard concept was introduced by Professor Robert S. Kaplan and Dr. David P. Norton in the *Harvard Business Review* in 1992.

- *Future challenges risk* derives from issues affecting the ability to invest in new capabilities and develop new operational concepts needed to dissuade or defeat mid- to long-term military challenges.
- *Institutional risk* results from factors affecting the ability to develop management practices, processes, metrics, and controls that use resources efficiently and promote the effective operation of the Defense establishment.

1.1 OVERVIEW OF THE DOD CBRNDP PERFORMANCE PLAN

The DoD CBRNDP has adapted the Balanced Score Concept of the Department to provide a managed risk strategy for the program. Since its establishment in 1994 following Congressional passage of the FY94 National Defense Authorization Act (50 USC 1522), the CBRNDP has integrated research, development, and acquisition (RDA) funds into defense-wide accounts that are overseen by a single office within the Office of the Secretary of Defense.

The DoD CBRNDP has prepared this performance plan to align itself more closely with the tenets of the Government Performance and Results Act (GPRA). Specifically, the plan:

- Establishes explicit and outcome-oriented goals linked to warfighters' ability to survive, fight, and win in a CB environment;
- Identifies quantitative and/or qualitative performance measures that can be used to assess progress towards goal achievement;
- Describes how performance data is validated;
- Describes how RDT&E activities of participating DoD and non-DoD organizations are coordinated to achieve program goals; and
- Identifies human capital, financial, and resource challenges or external factors that limit the ability of the program to achieve its goals.

The major portions of this performance plan link performance goals with performance measurements in terms of those systems and programs, which support the warfighter requirements and goals.

Section 1 provides the vision, mission, goals and performance measures for the CBRNDP. This section also provides a summary of key performance measures.

Section 2 analyzes performance goals and measurements that support the advanced development and acquisition phases of CB defense systems in support of *Corporate Goal 1*. (See Figure 4 below for summary of DoD CBRNDP Corporate Goals.) This section focuses on programs support core warfighter operational goals.

Section 3 analyzes the science and technology base of the program to include basic and applied research and advanced technology development, which support essential capabilities meeting warfighter requirements in support of *Corporate Goal 2*.

Section 4 analyzes performance goals and measurements that support the advanced development and acquisition phases of CB defense systems in support of *Corporate Goal 1*. In contrast to section 2, section 4 focuses on programs related to antiterrorism, force protection, installation protection, and homeland security support activities.

Section 5 analyzes management practices in support of *Corporate Goal 3: Oversee DoD CB defense modeling and simulation efforts* and *Corporate Goal 4: Improve DoD CB defense*

management practices – become a high performance organization. Performance goals, which support each corporate level goal of the CBRNDP, establish a measurable path to incremental achievement of specific goals. These 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 environments.

1.2 VISION, MISSION, AND VALUES OF THE CBRNDP

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

Figure 2. CBRN Defense Program Vision

This vision statement provides focus and direction to chemical and biological defense research, development, and acquisition efforts. While the principal focus of the CBRNDP vision is on threats to the warfighter, the vision recognizes the increasing role and importance 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 *Department of Defense Annual Report to the President and the Congress*, 2002 outlines the paradigm shift in force planning that resulted from changes outlined in the *Quadrennial Defense Review*, September 2001. Requirements are based on supporting the "4-2-1" Force Planning Construct.

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 of 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.

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

Figure 3. CBRN Defense Program Mission

In order to support the 4-2-1 force-sizing construct and to implement to program vision, **Figure 3** defines the mission for the CBRNDP. Over the next year, the Department will review this mission and the supporting operational goals to address its evolving role in combating terrorism and homeland security.

A key element in providing a means to establish progress in fulfilling the program mission is the definition of corporate goals for the CBRNDP, as shown in **figure 4**. Corporate goals provide the broad warfighter requirements for CB defense operations. These operational goals provide direction for the development, acquisition, and fielding of CB defense equipment. The CBRNDP thus develops, acquires, and fields equipment that meets warfighter requirements while reducing acquisition costs and time of development. Figure 4 defines the corporate operational goals (and provides a summary of the key materiel capabilities that support these goals.)

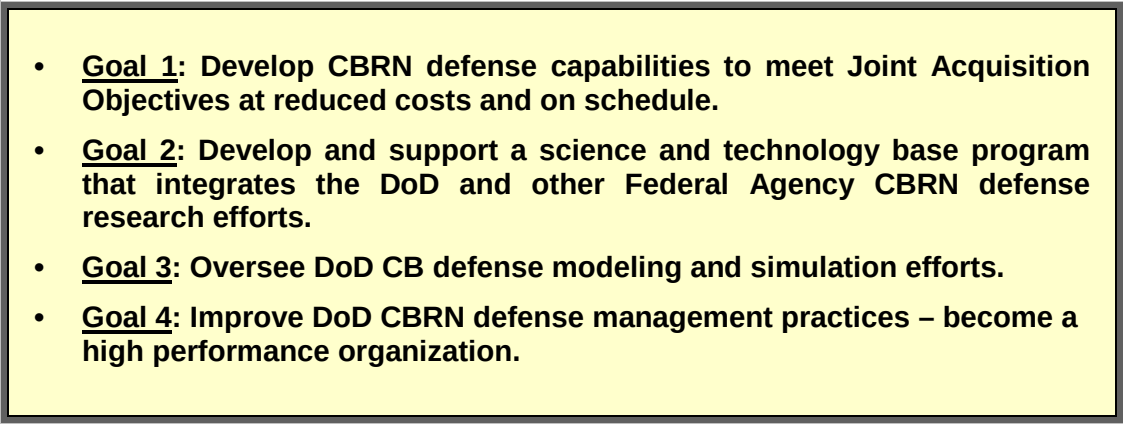
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- **Goal 1: Develop CBRN defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule.**
 - **Goal 2: Develop and support a science and technology base program that integrates the DoD and other Federal Agency CBRN defense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

Figure 4. CBRN Defense Program Corporate Goals

1.3 Joint CBRN Defense Functional Concepts and Operational Goals

In July 2003, the JRO-CBRN Defense completed a CBRN Defense Baseline Capabilities Assessment. Prior assessments focused on systems rather than on capabilities. In order to validate the process, the initial baseline assessment focused on the traditional warfighter mission, or passive defense capabilities. Future assessments will establish a baseline for all DoD CBRN defense missions, including force protection, consequence management, and homeland security, while updating the assessment of passive defense capabilities. In addition, the baseline capability assessment establishes an integrated joint functional concept that supersedes the concepts of Avoid, Protect, and Decontaminate that are outlined in Joint Publication 3-11, *Joint Operations in an NBC Environment*. **Figure 5** defines the Joint CBRN defense joint functional concepts—Sense, Shape, Shield, and Sustain. The joint functional concepts represent an integrated network of capabilities to support the warfighter. No single system, technology, or approach is sufficient to defend against the spectrum of CBRN agents, delivery systems, and adversaries, which may use these weapons to counter U.S. superiority in conventional forces.

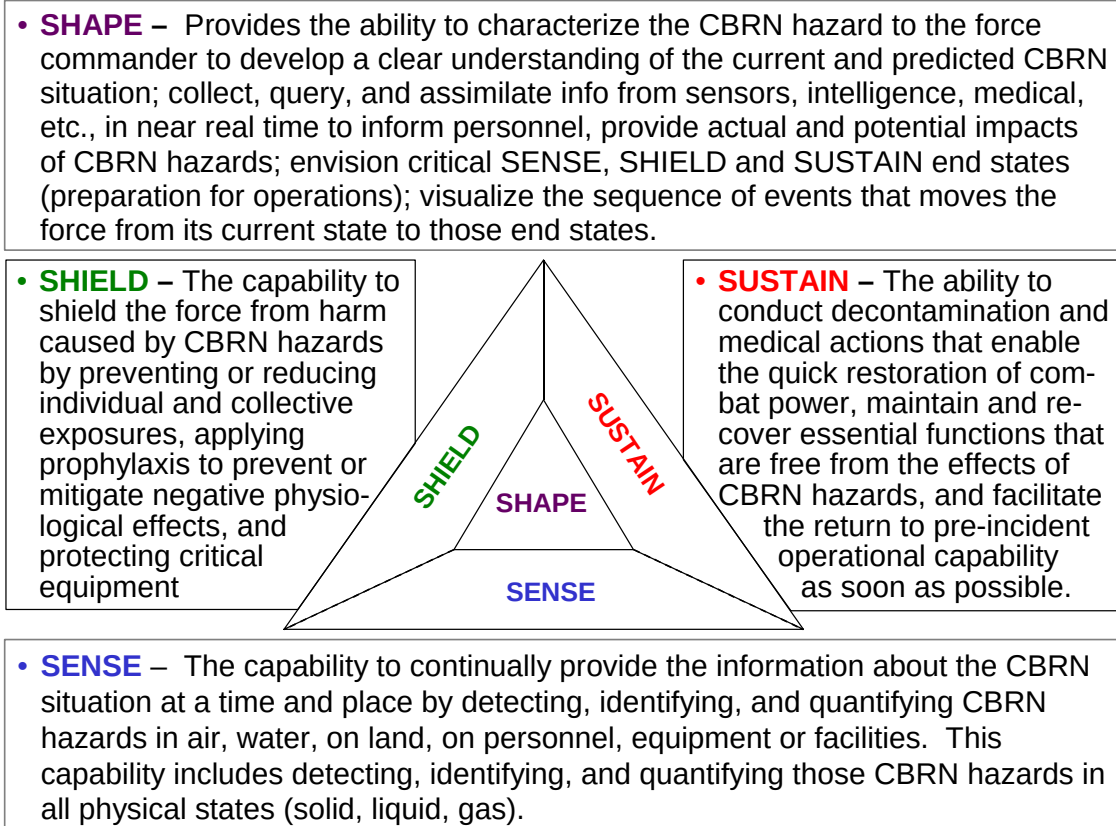


Figure 5. Joint CBRN Defense Joint Functional Concepts (*Sense, Shape, Shield, Sustain*)

Figure 6 identifies CBRN defense operational goals. Each operational goal is directly associated with one of the Joint Functional Concepts. In turn, specific projects and programs within advanced development and procurement are associated with one or more of the operational goals. Section 2 of this plan provides the assessment of these programs and the status of their progress in supporting operational goals.

Sense	Shape	Shield	Sustain
1. Point Detection (Chemical, Biological, and Radiological)	4. Integrated Early Warning	7. Respiratory and Ocular Protection	11. Individual Decontamination
2. Stand-off Detection	5. Battlespace Management	8. Percutaneous Protection	12. Equipment Decontamination
3. NBC Reconnaissance (Chemical, Biological, and Radiological)	6. Battlespace Analysis	9. Expeditionary Collective Protection	13. Fixed Site Decontamination
		10. Medical Prophylaxes	14. Medical Diagnostics
			15. Medical Therapeutics

Figure 6. CBRN Defense Operational Goals

1.4 PERFORMANCE PLAN METHODOLOGY

1.4.1 Data Identification and Analysis

The performance plan draws on information and consolidates data from several sources, including:

- DoD CBRNDP Modernization Plan,
- DoD CBRNDP Research, Development, and Acquisition (RDA) Plan,
- DoD CBRNDP Logistics Support Plan,
- The Joint Warfighting Science and Technology Plan,
- The Defense Technology Area Plan,
- The Chemical and Biological Defense (CBD) Technology Area Review and Assessment (TARA),
- JRO-CBRND Annual CBRN Defense Baseline Capabilities Assessment
- The DoD CBRNDP Annual Report to Congress,
- President's Budget Submissions for the DoD CBRN Defense Program.

In addition, the performance plan draws on current data contained in documents prepared in support of the PPBS, including Defense Planning Guidance, the CBRNDP Program Strategy Guidance, the Program Objectives Memorandum, the President's Budget and supporting detailed information in the RDT&E and Procurement Congressional Justification Books.

In order to measure the performance of individual programs within the overall CBRNDP, programs are assessed to determine how each actually performed in comparison to the stated program targets. The specific targets represent the program objectives for each year. **Figure 7** illustrates the sources of information that allow a comparison over time. As illustrated, the *targets* for each fiscal year (FY) are derived for that year's corresponding President's Budget Submission to Congress. The accomplishments are reported in the President's Budget Submission immediately following the completion of that fiscal year. Thus, the FY05 President's Budget Submission includes FY03 Accomplishments. FY04 and FY05 Targets are derived from their respective budget submissions.

This methodology provides a means of ensuring accurate data reporting. Where targets are met, this is stated as "targets met" rather than repeating the targets. Where program accomplishments may be at variance with program targets, the differences are explained. Variances do not necessarily mean poor performance. Variances may occur as a result of schedule changes in supporting programs, changes in funding, or unexpected test results.

When changes are made to a program after the budget is submitted, changes are explained following the completion of that fiscal year. This allows for a fair comparison by providing a detailed description of accomplishments and the variance from the targets. Targets are not changed to reflect accomplishments. Thus, for example, funds added to the FY03 budget above the President's Budget Request result in changes to the FY03 targets. However, since these changes occurred after the FY03 President's Budget was submitted, the additional resources and targets will be explained in the FY03 accomplishments.

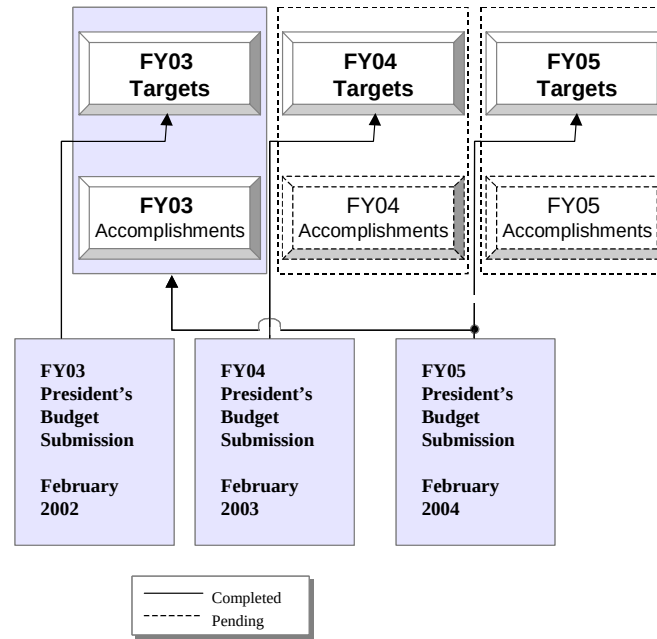


Figure 7. Performance Plan Methodology

1.4.2 Performance Analysis

Analysis of program data is only part of the assessment process. The next step in the assessment is a comparison of the results of the data analysis against performance goals, operational goals, corporate goals, and the overall CBRNDP mission. Following are several assumptions and criteria that guide the assessment of programs.

- Operational goals are driven by and derived from Joint Function Concepts, hence the mission, goals, and operational concepts drive program development.
- Operational goals are *supported by* programs, rather than being driven by programs.
- All funded programs should support an operational goal. (The only exception is for supporting technologies, which are necessary for the development or execution of a program.)
- A program may support more than one operational goal.
- Multiple programs supporting the same operational goal can be evaluated to determine complementarities, synergies, or redundancies.
- Not all operational goals may be supported by a program. This may be the result of the development of a new mission or operational goal, or from the lack of an available technology.
- Programs that do not support an operational goal may not be demonstrated to support the program mission and may reflect an inappropriate use of resources.

1.4.3 Advanced Development and Acquisition Performance Goals and Measures

For FY03, the cumulative procurement targets identified are interim planning figures that reflect the evolving strategy to the force planning structure described in the 2002 Defense Planning Guidance. The DoD CBRN Defense Program is in the process of identifying specific system requirements to support new Defense Planning Guidance. The force planning construct that had been based on the quantities required to support two nearly simultaneous Major Theater

Wars (MTWs) has been replaced. Defense Planning Guidance published subsequent to this review outlines a new force planning construct, known as the 1-4-2-1 force planning construct. (See Section 1.2.) Acquisition objectives listed in this plan represent planning targets in FY03 and do not represent requirements for the 1-4-2-1 force planning construct, which will be validated in 2004.

The following sections provide near-term performance goals, performance measures, and targets that support program corporate level goals. For the purpose of this strategy plan, FY2003 is the current assessment year, for which actual performance can be assessed; FY2004 and FY2005 are the future assessment years for which targets are established, and will be assessed in future annual performance plans. Future material solutions refer to those that will be addressed during years cited, some of which may be in the technology base.

1.4.3.1 Metric Description. Research, Development and Acquisition (RDA) programs within the DoD CBRNDP aim to ensure that U.S. forces are provided with the best equipment, which will ensure survivability and mission accomplishment on any future battlefield where chemical or biological agents are employed. The increased complexity of modern warfare demands that CB defense equipment be fielded in the most cost effective and expeditious manner possible. Additionally, the evolving threat environment requires a capabilities-based approach, which requires identifying capabilities that U.S. military forces will need to defend against adversaries since specific adversary's intentions may not be possible to determine. Specific materiel solutions are identified which support numerous Combatant Command requirements. Each materiel solution's progress is measured by monitoring specific performance goals and targets in the planning years. Each of these metrics supports the ultimate objective; that of fielding new and improved CB defense equipment to our warfighting forces.

1.4.3.2 Verification and Validation (V&V) of Metrics. V&V is accomplished through a number of processes. First and foremost, the Planning, Programming, Budgeting and Executing (PPBE) System is the key process employed by the DoD CBRNDP and is used to ensure that program performance goals and targets are implemented into its budget. Through the PPBS, the program apportions resources annually in support of the goals articulated in the planning process.

The Deputy Assistant to the Secretary of Defense of Chemical/Biological Defense, DATSD(CBD), issues detailed planning guidance annually in the DoD CBRNDP Program Strategy Guidance, which is used in formulating and preparing the Program Objective Memorandum (POM). This document serves as a strategic planning document, and provides a framework for assessment of the POM and how well it meets stated goals and targets. In conjunction with the publication of the POM, the JRO-CBRND develops an assessment of how well the goals are met. The OSD staff in turn assesses these goals, as the POM is reviewed and adjusted through a review process, culminating in the finalization of the President's Budget for the DoD CBRNDP. The PPBE process is an effective mechanism for the DATSD(CBD) to match operational CB defense goals and targets with the appropriate budgetary resources in a fiscally constrained environment.

In addition to the annual PPBE process, the DoD CBRNDP relies on an oversight process, which permits reviews of program status on a monthly basis through staff review of JSCBIS Information Sheets. System PMs and item managers prepare quarterly system summary sheets, which are reviewed by the OSD staff. Selected systems are then selected for review at quarterly In-Process-Reviews held for senior leadership of the DoD CBRNDP.

Another V&V mechanism used by the CBRNDP is the Annual Report to Congress. During preparation of the report, the CB defense community reports annual progress within the various facets of the program. Annual accomplishment and plans for the future, as well as issues and factors that limit the ability of the program to achieve its goals, are documented and summarized along with the President's Budget.

For the performance metrics related to the Joint Functional Concepts (see Section 1.5), these are developed through an annual assessment process conducted by the JRO-CBRN Defense. Approval and validation of the results of the assessment is provided by the Joint Requirements Oversight Council (JROC) annually.

1.5 SUMMARY OF KEY PERFORMANCE METRICS

1.5.1 Measuring Progress Towards Operational Goals (*Operational Risk*)

Following the JROC approved Baseline Capability Assessment of July 2003, **figures 7a-d** illustrates the assessment of core warfighting capabilities and provides a measure of how each operational goal is progressing as well as each overall joint functional concept. Each operational goal is measured on a relative scale of 0–10 with “10” representing fielding of objective capabilities. This assessment will be expanded in the future to include additional warfighting mission, specifically including consequence management, force protection, installation protection, and homeland security support activities. The baseline assessment provides a summary evaluation of what capability levels U.S. forces have today and what capabilities are anticipated in the future. These assessments assumed planned schedules will be achieved and threshold key performance parameters (KPPs) will be met for all systems.

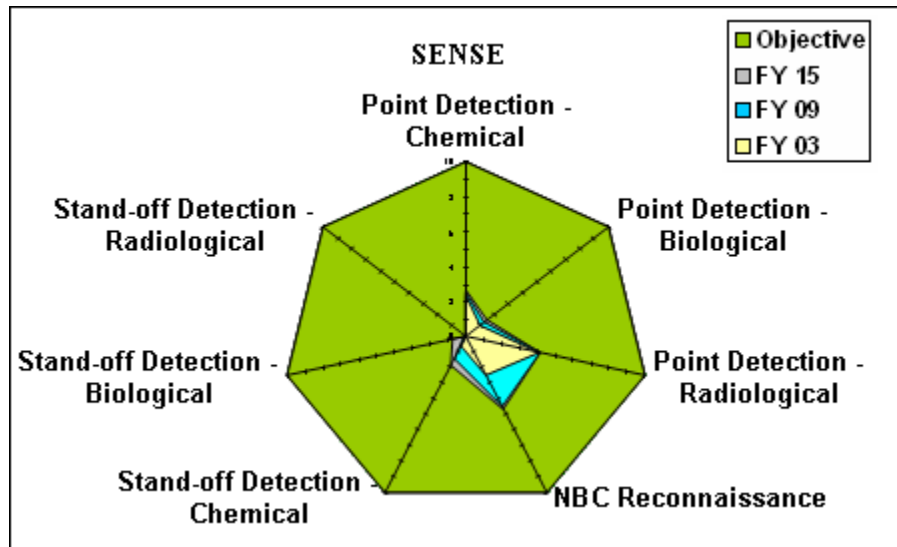


Figure 7a. CBRN Defense Summary Assessment of Core Capabilities – SENSE

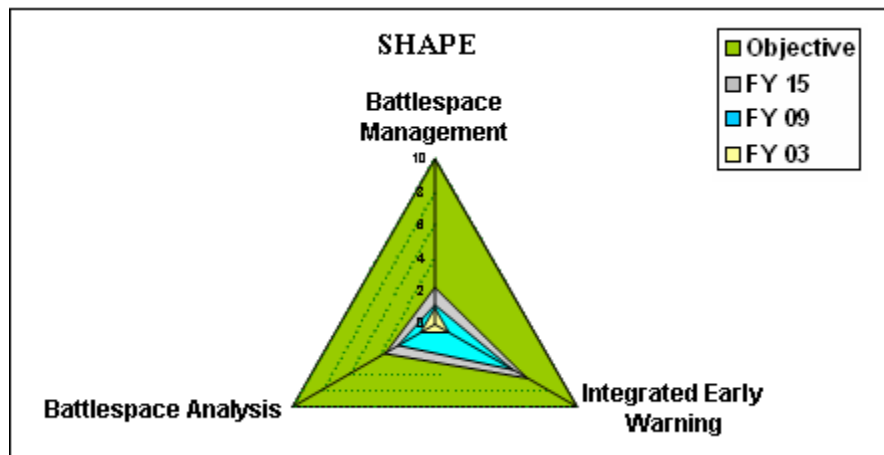


Figure 7b. CBRN Defense Summary Assessment of Core Capabilities – SHAPE

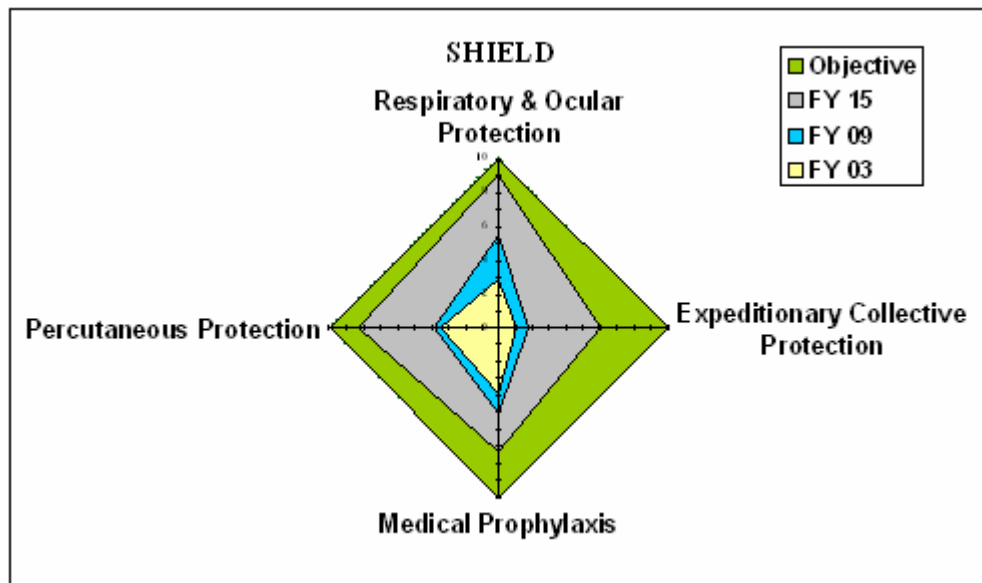


Figure 7c. CBRN Defense Summary Assessment of Core Capabilities – SHIELD

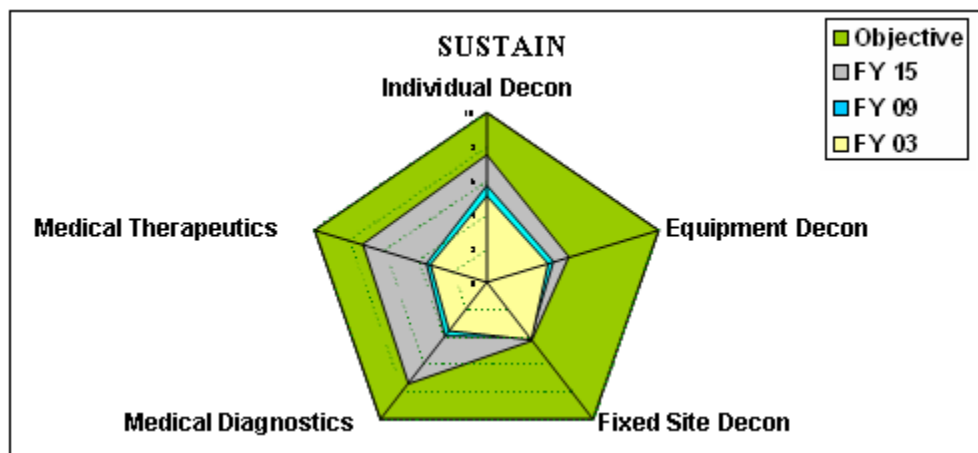


Figure 7d. CBRN Defense Summary Assessment of Core Capabilities – SUSTAIN

1.5.2 Developing and Deploying Transformational Capabilities (*Future Challenges Risk*)

This section provides a summary of key activities in (1) advanced development, and (2) the science and technology base. Oversight of the CBRNDP is tailored by creating an “index of systems” to measure performance of CBRNDP functional areas based on the criticality, complexity and cost of individual CBRNDP 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 as an indicator of the general programmatic health of the functional area. The standard exit criteria for a program selected as a Sentinel system will be successful Full Rate Production Decision Review by the Defense Acquisition Executive (DAE).

The initial Sentinel CBRNDP systems include:

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

Figure 8 illustrates the planned acquisition cycle time for the Sentinel systems. The target acquisition time has been established by DoD for Major Defense Acquisition Programs. This same target is used for comparison by the CBRNDP for its sentinel systems. As shown, two of the systems have not reached the Milestone B (program start) decision point.

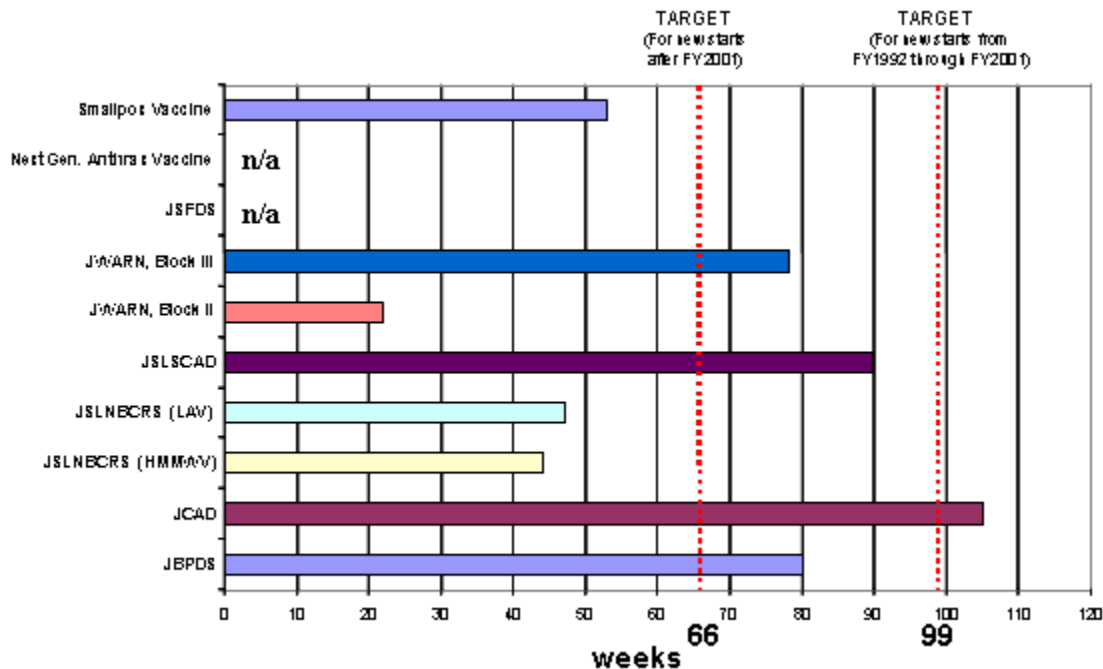


Figure 8. Acquisition Cycle Time for CBRNDP Sentinel Systems

For science and technology programs, **Figure 9** provides a summary of Defense Technology Objectives (DTOs), which represent key high priority projects within the science and technology base. A complete assessment of the science and technology programs is provided in Section 3.0 of this plan.

	FY2002		FY2003	FY2004
	Goal	Actual	Goal	Goal
Percent of DTOs Rated Green (on track)	80	58*	80	80
Total Number of DTOs	25 of 31	18 of 31*		

* Ten CBD DTOs were rated as yellow [Y] and three as red [R]

Figure 9. Status of DTOs as rated by the Chemical and Biological Defense Technology Area Review and Assessment

1.5.3 Logistics and Training Capabilities (*Force Management Risk*)

Critical chemical and biological defense capabilities for the warfighter are provided through the operations and maintenance (O&M) accounts of the Military Departments in addition to the RDA funds of the CBRNDP. *Logistics Risks Assessments* are provided in Chapter 3 of the DoD CBRNDP Annual Report to Congress and provides information on capabilities in stock and available to the warfighter at the end of FY03.

Data on personnel trained is provided in Chapter 3 of the DoD CBRNDP Annual Report to Congress. Examples of the metrics for training include the following:

- Summary of Army Medical Department (AMEDD) CBRN Training
- Total AMEDD Personnel Trained
- Air Force Medical Service (AFMS) Medical Management of Biological and Chemical Casualties—Training for Providers
- AFMS CBRNE Training for Deployable Personnel
- Navy Medical CBRN Defense Training Status

Additional information on exercises, training standards, and related chemical and biological defense training activities is also detailed.

1.5.4 Improving Management Practices (*Institutional Risk*)

Managing institutional risk results from factors affecting the ability to develop management practices, processes, metrics, and controls that use resources efficiently and promote the effective operations. Following are key management activities that are being pursued to manage institutional risk.

Streamlining the decision process — Chapter 1 of the Annual Report of the CBRNDP describes the management and oversight structure. The most significant changes in the management structure was the program reorganization that was approved on April 22, 2003. This reorganization streamlined the decision process by reducing the number of milestone decision authorities from nine to one. The Milestone Decision Authority (MDA) for the CBRNDP is the Under Secretary of Defense for Acquisition, Technology and Logistics, USD(AT&L). The USD(AT&L) has delegated MDA responsibilities (except for selected systems) to the Joint Program Executive Officer for Chemical and Biological Defense.

Program Balance — Annex H of the Annual Report of the CBRNDP provides information on RDA funding. DoD annually reviews the program budget to ensure that program activities are balanced among science & technology, advanced development, and procurement to ensure technology transitions as well as to ensure capabilities are being developed to address near, mid, and far term operational needs.

Improving Test & Evaluation Infrastructure — Annex J of the Annual Report of the CBRNDP provides information on the DoD test and evaluation (T&E) infrastructure. In addition to this baseline assessment, DoD will begin to implement a plan to maintain and improve the critical T&E infrastructure over the future years defense program.

ADVANCED DEVELOPMENT AND PROCUREMENT PERFORMANCE GOALS AND MEASURES

2.0 OVERVIEW

Advanced development and procurement within the CBRNDP is a critical means for ensuring that the U.S. military has the capability to operate effectively and decisively in the face of nuclear, biological, or chemical warfare threats at home or abroad. Advanced development and procurement specifically support **Corporate Goal 1: Develop CBRN defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule.** The six operational goals outlined in Section 1.3 above provide the link between the programs described below and the overall mission of the CBRNDP. The following information is provided for each operational goal in this section:

- A list of current and future materiel solutions,
- Procurement data, including:
 - (1) an assessment of procurement targets vs. actual accomplishments for FY02, and
 - (2) procurement targets for FY03 and FY04.
- RDT&E data, including:
 - (1) an assessment of RDT&E targets vs. actual accomplishments for FY02, and
 - (2) RDT&E targets for FY03 and FY04.
- An overall assessment for activities supporting each operational goal.

2.1 OPERATIONAL GOAL 1: SENSE

2.1.1 *Performance Goal 1.1 – Point Detection (Chemical, Biological, and Radiological)*

Current Materiel Solutions	Future Materiel Solutions
Chemical Point Detection	
M8A1 Chemical Agent Alarm (Legacy) M22 ACADA Improved (CA) Point Detection System (IPDS) M8 paper (Service O&M responsibility) M9 paper (Service O&M responsibility) M256A1 Detector Kit (Service O&M responsibility) Chemical Agent Monitor (CAM) (Legacy system) Improved CAM (ICAM) M272A1 Water Test Kit (Service O&M responsibility)	Joint Chemical Agent Detector (JCAD) Joint CB Agent Water Monitor (JCBAWM)
Biological Point Detection	
Portal Shield Biological Integrated Detection System (BIDS) DoD Biological Sampling Kit	Joint Biological Point Detection System (JBPDS)— Block I, and II
Radiological Point Detection	
- AN/UDR-13 Pocket Radiac - AN/PDR-75 Radiac - AN/PDR-77 Radiac - AN/VDR-2 Radiac - Multi-Function Radiac - ADM-300A	n/a

2.1.2 Materiel Solutions Performance Measurements – Point Detection (Chemical, Biological, and Radiological)

2.1.2.1 Current Procurement Targets – JCAD

Systems	FY03		FY04	FY04
	Target	Actual	Target	Target
Joint Chemical Agent Detector (JCAD)	773 [0 of 216,126 procured]	100 [0 of 216,126 procured]	80	106

2.1.2.2 Current R&D Targets – JCAD

FY 2003 Targets	Actual Performance
- Complete hardware and software development based upon results from contractor and government developmental testing. - Continue systems engineering and logistics planning. Begin engineering support for LRIP. - Continue system interface design of JCAD systems and user platforms. - Complete government developmental test and evaluation. - Begin IOT&E using procurement funded LRIP units (790 planned for FY03).	- Continued hardware and software development based upon results from Contractor Validation Testing (CVT) - Continued systems engineering and logistics planning - Continued technical data and logistics support - Continued designing JCAD system interface with user platforms - Completed CVT and preplanning for government Developmental Testing (DT). - Continued planning for Initial Operational Test and Evaluation (IOT&E).

2.1.2.3 Future R&D Targets – JCAD

FY 2004 Targets	FY 2005 Targets
- Complete hardware and software development. - Initiate government evaluation of commercial detectors. - Purchase commercial off-the-shelf (COTS) systems and support (up to 105 systems at \$26K each). - Continue systems engineering support.	- Continued hardware and software development based upon results from CVT. - Continued systems engineering and logistics planning.

2.1.2.4 Current Procurement Targets – JBPDS

Systems	FY03		FY04	FY05
	Target	Actual	Target	Target
Joint Biological Point Detection System	133 [133 of 2,793 procured]	71 [124 of 2,793 procured; Note: includes 54 purchased through DERF accounts.]	111	118

2.1.2.5 Current R&D Targets – JBPDS

FY 2003 Targets	Actual Performance
- Complete US Army IOT&E (Army at Dugway Proving Ground, UT) and final report. - Initiate USMC IOT&E (Eglin Air Force Base, FL). - Initiate US Air Force IOT&E (Eglin Air Force Base, FL).	- Completed Multi-Service Initial Operational Test and Evaluation (MOT&E) Phase I for US Army. Initiated MOT&E Phases II-IV for US Air Force (USAF), US Marines Corp (USMC) and US Navy (USN). - Completed Military Utility Assessment for Dry Filter Units. - Continue reliability, availability and maintainability (RAM) growth towards meeting objective requirements including Built in Test

FY 2003 Targets	Actual Performance
	- Supported improvements to the trigger/detection Line Replaceable Units (LRU) improvement study - Supported execution of the Navy Developmental Test (DT), US Army (USA) and US Air Force (USAF) environmental testing, biological performance testing, and survivability assessment - Supported planning of the DT, environmental testing, biological performance testing, and survivability assessment.

2.1.2.6 Future R&D Targets – JBPDS

FY 2004 Targets	FY 2005 Targets
- Complete advanced Biological Aerosol Warning System (BAWS) upgrade for Low Rate Initial Production (LRIP) systems to meet Joint Operational Requirements Document (JORD) objective requirements for detection. - Complete Multi-Service Operational Test and Evaluation (MOT&E) for the Army, Navy, and Air Force (Phases II-V). Provide final System Evaluation Report (SER).	- Initiate planning and execution of MOT&E Phase VI for the Army, Navy, and Air Force Continue configuration management including reliability, availability, and maintainability, and Integrated Logistics Support (ILS) improvements. - Initiate, select, and validate improved trigger/detector Line Replaceable Unit (LRU). - Initiate, select, and validate upgraded identifier LRU to meet objective requirement for number of agents and sensitivity.

2.1.3 Performance Goal 1.1 – Standoff Detection (Chemical, Biological, and Radiological)

Current Materiel Solutions	Future Materiel Solutions
Chemical Standoff Detection	
M21 Remote Sensing Chemical Agent Alarm (RSCAAL) (Legacy System) AN/KAS-1, Chemical Warfare Directional Detector (Legacy System)	Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD) ARTEMIS
Biological Standoff Detection	
	Joint Biological Standoff Detection System (JBSDS)
Radiological Standoff Detection	
None	none

2.1.4 Materiel Solutions Performance Measurements – Standoff Detection (Chemical, Biological, and Radiological)

2.1.4.1 Current Procurement Targets

2.1.4.2 Current Procurement Targets – JSLSCAD

Systems	FY03		FY04	FY05
	Target	Actual	Target	Target
JSLSCAD	0 [0 of 2,352 procured]	0 [0 of 2,352 procured]	31	5

2.1.4.3 Current Research & Development (R&D) Targets – JSLSCAD

FY 2003 Targets	Actual Performance
- Continue PQT and IOT&E. - Continue technical data package and acquisition documentation for Milestone (MS) C. All program documentation will be reviewed and updated to support MS C. This includes: Acquisition Strategy, Acquisition Baseline,	- Continued Production Qualification Test (PQT) for initial development JSLSCAD. - Continued technical data package and acquisition documentation for MS C. All program documentation was reviewed and

FY 2003 Targets	Actual Performance
Performance Specifications, and Environment Assessment. IPR package preparation and coordination is also included. Continue the review and preparation of technical manuals, logistics support, and training materials. All logistics documentation to include: Technical Manuals; Integrated System Support Plans; and Logistics Support Plans will be updated based on test results. In addition, Materiel Fielding Plans, fielding schedules, and platform integration guides will be prepared and approved.	updated to support LRIP MS C. Continued the review and preparation of technical manuals, logistics support, and training materials. All logistics documentation was updated based on test results.

2.1.4.4 Future R&D Targets – JSLSCAD

FY 2004 Targets	FY 2005 Targets
- Initiate support of the Stryker Nuclear Biological Reconnaissance Vehicle (NBCRV) Production Qualification Test and Limited User Test (LUT). - Initiate methodology development to support the comparison of commercially available remote sensing detectors. - Choose and purchase candidate remote sensing detectors for testing. - Initiate and conduct testing of remote detectors to support National Research Council (NRC) findings.	- Continue testing to support NRC findings. - Initiate evaluation of candidate commercial remote detection systems. - Integrate commercial systems into platforms. - Support remote sensing test facility design and use for testing of commercial detectors.

2.1.4.5 Current R&D Targets –Artemis

FY 2003 Targets	Actual Performance
- ARTEMIS - Continue to prepare source documentation for MS B and issue draft Request for Proposal (RFP). Maintain document library and information network for all data, research, and other program information. Perform financial management, scheduling, planning, and reporting. Continue SBA activities to reduce cost, schedule, and performance risks; increase the quality, military worth, and supportability of fielded systems; and reduce total ownership costs throughout the system life cycle. Continue to develop and update the JSTRAP and the supportability analysis. - Continue to develop system architecture, draft system specification, conduct risk analyses and develop risk mitigation plan through a Joint SE IPT. - Continue test strategy and test methodology development to include simulant to real agent correlation and agent fate. Continue TEMP development through a Joint T&E IPT. - Continue risk reduction efforts to further reduce overall program risk in support of the development of key components of an active emitter multi-wave LIDAR technology. Key components considered high risk are solid state lasers, non-consumable detectors, and advanced detection algorithms. Demonstrate and validate performance of these components. - Support the development of standoff detection test	- Continued to prepare source documentation for Milestone (MS) B. Maintained document library and information network for all data, research, and other program information. Continued Simulation Based Acquisition (SBA) activities to reduce cost, schedule, and performance risks; increased the quality, military worth, and supportability of fielded systems; and reduced total ownership costs throughout the system life cycle. - Continued to develop and update the Joint System Training Plan (JSTRAP) and the supportability analysis - Continued to develop system architecture, draft system specification, conduct risk analyses and develop risk mitigation plan through a Joint System Engineering (SE) Integrated Product Team (IPT). - Continued test strategy and test methodology development to include simulant to real agent correlation and agent fate. - Continued Test and Master Plan (TEMP) development through a Joint Test and Evaluation Integrated Process Team (T&E IPT) - Continued risk reduction efforts to further reduce overall program risk in support of the development of key components of an active emitter multi-wave LIDAR technology. Key components considered high risk are solid state lasers, non-consumable detectors, and advanced detection algorithms.

FY 2003 Targets	Actual Performance
infrastructure to provide the capability to adequately test the Artemis system. Develop an active standoff chamber fixture for testing the Artemis system against live chemical warfare agents. Develop precise referee systems to support evaluation of the Artemis system in an open air simulant test.	Demonstrated and validated performance of these components – Initiated support for the development of stand-off detection test infrastructure to provide the capability to adequately test the ARTEMIS system. Developed an active stand-off chamber fixture for testing the ARTEMIS system.

2.1.4.6 Future R&D Targets –Artemis

FY 2004 Targets	FY 2005 Targets
– Continue update of Milestone B program documentation. Perform financial management, scheduling, planning, and reporting. Continue SBA activities to reduce cost, schedule, and performance risks; increase the quality, military worth, and supportability of fielded systems; and reduce total ownership costs throughout the system life cycle. Continue to develop and update the JSTRAP and the supportability analysis – Continue update of system architecture, system specification and risk mitigation plan through a Joint SE IPT. – Continue test strategy and test methodology development to include simulant to real agent correlation, simulant and test range selection, aerosol and liquid spectra collection. Update TEMP through a Joint T&E IPT – Continue risk reduction efforts to further reduce overall program risk in support of the development of key components of an active emitter multi-wave LIDAR technology. Key components considered high risk are solid state lasers, non-consumable detectors, and advanced detection algorithms. Demonstrate and validate performance of these components – Continue support for the development of stand-off detection test infrastructure to provide the capability to adequately test the ARTEMIS system. Develop an active stand-off chamber fixture for testing the ARTEMIS system against chemical warfare simulants. Develop precise referee systems to support evaluation of the ARTEMIS system in an open air simulant test.	– Continue update of MS B program documentation, conduct MS B decision, issue draft and final Request for Proposal. Perform financial management, scheduling, planning, and reporting. Continue SBA activities to reduce cost, schedule, and performance risks; increase the quality, military worth, and supportability of fielded systems; and reduce total ownership costs throughout the system life cycle. Continue to develop and update the JSTRAP and the supportability analysis. – Finalize system architecture, system specification and risk mitigation plan through a Joint system engineering IPT. – Finalize systems evaluation plan, test strategy and test methodology development. Finalize TEMP through a Joint T&E IPT. – Complete component advanced development work.

2.1.4.7 Current R&D Targets – JBSDS

FY 2003 Targets	Actual Performance
- Initiate the transition of the early warning standoff systems developed in the TT-Bio program into the Systems Integration phase of the JBSDS program. This includes software development, modeling and simulation analysis, and preparation of program documentation. - Initiate and complete Developmental Testing (DT) of competing candidate systems.	– Initiated the transition of the early warning stand-off systems developed in the TT-Bio program into the Systems Integration phase of the JBSDS program. This included software development, modeling and simulation analysis, and preparation of program documentation – Initiated and completed Developmental Testing (DT) of competing candidate systems. – Initiated limited Operational Testing (OT) and assessment of JBSDS competing candidate systems.

2.1.4.8 Future R&D Targets – JBSDS

FY 2004 Targets	FY 2005 Targets
– Initiate planning for Initial Operational Test and Evaluation (IOT&E).	– Complete contract (including contractor support of Production Verification Test (PVT) and Initial

FY 2004 Targets	FY 2005 Targets
– JBSDS - Award development contract to one of two competing candidate systems to enhance performance, develop Integrated Logistic Support (ILS) and documentation (technical manuals, specifications, etc.), and support Low Rate Initial Production (LRIP). – JBSDS - Initiate development of next generation JBSDS system. This includes modeling and simulation analysis, market research analysis, and Cost As An Independent Variable (CAIV) analysis – Initiate background testing and analysis at multiple locations to refine detection/discrimination algorithm. – Initiate evaluation of CBMS II Chemical Biological Monitoring System.	– Operational Test and Evaluation (IOT&E). – Complete PVT – Complete IOT&E – Continue the development of Next Generation JBSDS. Award Advanced Development contract to develop the Next Generation JBSDS.

2.1.5 Performance Goal 1.3 – NBC Reconnaissance (Chemical, Biological, and Radiological)

Current Materiel Solutions	Future Materiel Solutions
M93A1 NBC Recon System (Block I) Biological Integrated Detection System	M93A1 NBC Recon System (Block II) Joint Light NBC Recon System (HMMWV/LAV)

2.1.6 Materiel Solutions Performance Measurements – NBC Reconnaissance (Chemical, Biological, and Radiological)

2.1.6.1 Current Procurement Targets – NBCRS (Block II)

Systems	FY03		FY04	FY05
	Target	Actual	Target	Target
M93A1 NBC Recon System (Block II)	0	0	17	0
Renamed NBCRV	0 of 95 procured	0 of 95 procured		

2.1.6.2 Current R&D Targets – NBC Reconnaissance Vehicle (NBCRV)

FY 2003 Targets	Actual Performance
– Complete NBCRS sensor suite engineering development and conduct Interim Progress Review to begin Low Rate Initial Production phase. – Complete Production Qualification Test (PQT) & Early User Test (EUT).	– NBCRV - Completed sensor suite engineering development, and provided sensor suite equipment to Project Manager Brigade Combat Teams (PMBCT) for the testing of four Stryker vehicles. – Initiated PQT and initiated and completed Limited EUT.

2.1.6.3 Future R&D Targets – NBCRV

FY 2004 Targets	FY 2005 Targets
– n/a (Product transition to procurement.)	– n/a

2.1.6.4 Current Procurement Targets – JSLNBCRS

Systems	FY03		FY04	FY05
	Target	Actual	Target	Target
JSLNBCRS (HMMWV & LAV Variants)	0	3	14	16
		HMMWV Variant	HMMWV Variant	LAV Variant

2.1.6.4 Current R&D Targets – Joint Lightweight NBC Reconnaissance System, HMMWV/LAV variants (JSLNBCRS)

FY 2003 Targets	Actual Performance
- Start DT I for LAV variant. - Continue development of TICs and TIMs software for CBMS Block II transition to JSLNBCRS procurement. - Conduct DT III for LRIP HMMWV variants. - Start IOT&E for LAVs and HMMWVs for full rate production/Milestone C.	– Completed HMMWV Developmental Test II Electromagnetic Interference (EMI), Electromagnetic compatibility (EMC), High Altitude Electromagnetic Pulse (HEMP), interoperability, and Limited User Test – Completed chemical software and algorithm development. Performed chemical agent tests for Chemical Biological Mass Spectrometer (CBMS) Block II transition to JSLNBCRS procurement – Completed program analysis and preparation for Milestone C Low Rate Initial Production (LRIP) review. Program analysis included review of test data, and future program layout – Continued development/design/integration of LAV variant under System Demonstration and Development (SDD) contract and to support additional work effort during the extended period of performance. – Initiated and completed the design, integration, and conduct of the Mobile Chemical Agent Detector (MCAD) excursion. – Continued the development of the integrated training package.

2.1.6.5 Future R&D Targets – JSLNBCRS

FY 2004 Targets	FY 2005 Targets
– Initiate DT I for LAV variant. – Initiate TICs and TIMs software upgrade for CBMS Block II transition to JSLNBCRS procurement. Initiate improvements to biological detection/identification capability. Initiate Non-Traditional Agent (NTA) and chemical vapor algorithm, and start testing – Continue development/design of LAV enhancements, install automatic fire suppression system, LAV Generation II upgrades and test support – Initiate multiservice Operational Test and Evaluation (MOT&E) planning/coordination.	– Continue TICs and TIMs software upgrades for CBMS Block II transition to JSLNBCRS procurement. Continue improvements to biological detection/identification capability. Complete NTA and chemical vapor testing. – Initiate multi-service Operational Test and Evaluation (MOT&E). – Initiate LAV Developmental Test (DT) of sensors and regression testing of Engineering Change Proposals. – Continue multi-service engineering support.

2.2 OPERATIONAL GOAL 2: SHAPE

Because the FY03 and FY04 budgets were developed prior to the baseline capability assessment, performance goals for battlespace management and battlespace analysis are not identified separately from integrated early warning.

2.2.1 Performance Goal 2.1 – Integrated Early Warning.

Current Materiel Solutions	Future Materiel Solutions
Joint Warning and Reporting Network (JWARN) Block I (Interim Standardization)	JWARN Block II JWARN Block III Joint Effects Model (JEM)

2.2.2 Materiel Solutions Performance Measurements – Integrated Early Warning

2.2.2.1 Current Procurement Targets – JWARN Block I

Systems	FY03		FY04	FY05
	Target	Actual	Target	Target
Joint Warning and Reporting Network (JWARN) Block I	0 [0 of 3,158 procured]	0 *(See note)	20	45

*** Note:** Block I fielding was completed. It was a software integration effort based on urgent need requirements identified by the U.S. Marine Corps and the U.S. Army. Block I standardized NBC warning and reporting throughout the services. During the Block I effort, the joint services procured Commercial-Off-The-Shelf (COTS) NBC warning and reporting software and three Government-Off-The-Shelf (GOTS) downwind hazard prediction models. COTS software was bundled with GOTS software and distributed to all services. The objective of Block I was first to meet an urgent need identified by the U.S. Army and the U.S. Marine Corps for automated NBC warning and reporting tools, and second to standardize NBC Warning and Reporting requirements across the Services.

2.2.2.2 Current R&D Targets – JWARN – Block II and III

FY 2003 Targets	Actual Performance
- Continue Block II integration of NBC legacy and future detector systems and conduct Development Testing (DT) and Operational Assessment (OA) for full system requirements. - Prepare documentation for Block II MS C.	- Developed JWARN C4I hosted mission application software and assessed system communication requirements. - Prepared and improved documentation and processes for JWARN Quality Assurance, Configuration Management, Program Management, and Integration.

2.2.2.3 Future R&D Targets – JWARN – Block II and III

FY 2004 Targets	FY 2005 Targets
- Conduct Program Management and Oversight of JWARN and JWARN Initial Capability (JIC) Development efforts. - JIC Component Development. - Plan for and initiate JWARN Developmental Test/Operational Assessment (DT/OA). - Provide integration support for JWARN with Joint Effects Model (JEM) and Joint Operational Effect Federation (JOEF). - Integrate JIC with C4I Systems. - Mission Application Software Integration Support - Operational Assessment Planning - Development of JWARN Communications Interface Device (JCID)	- Continue Block II integration of GCCS level C4ISR systems and interface development. - Conduct DT/OA. - Prepare documentation for Block III Milestone C. - Continue Block II Development. - Continue Block II DT/OA . - Continue Program Management and Oversight and prepare documentation for MS C and conduct MS C for Low Rate Initial Production (LRIP) decision.

2.2.2.4 Current R&D Targets – Joint Effects Model (JEM) Block I

FY 2003 Targets	Actual Performance
- Complete transition from tech base. Integrate counterforce, passive defense, and hazard/incident software models into a complete system. Develop logistics documentation, initiate Post Deployment Software Support planning, and establish online document library and information network for all data, research, and other program information. Update MS B program documentation and conduct MS B decision. Conduct source selection for development of a standardized hazard prediction model. Perform financial management, scheduling, planning, and reporting. - Develop TEMP and Verification, Validation, and Accreditation (VV&A) plan. Complete analysis of existing field test data associated with the hazard prediction models Vapor, Liquid and Solid Tracking (VLSTRACK), Hazard Prediction and Assessment Capability (HPAC), and Personal Computing Program for the Chemical Hazard Prediction (D2PC) and identify data gaps. Prepare for and conduct Early Operational Assessment (EOA). Initiate Independent Validation and Verification (IV&V) effort. Develop and refine warfighter use cases. Perform engineering analysis and evaluation of software design documentation. Establish and conduct Configuration Control Board (CCB). Continue technical data transition of HPAC, VLSTRACK, and D2PC models. - Award contract for the development of engineering builds (software only) in support of the Block I for transition to the SDD phase.	- All targets met.

2.2.2.5 Future R&D Targets – JEM Block I and II

FY 2004 Targets	FY 2005 Targets
- Complete development of logistics/training plans and materials. Complete Post Deployment Software Support (PDSS) plans. Support continued warfighter Integrated Process Team (IPT) involvement and conduct Milestone (MS) B - Award contract for formal software development. Finalize service command and control system integration plans. Complete formal software development. Perform contractor level software testing. Initiate integration activities with Service Global Command and Control System (GCCS) variants and other Command and Control (C2) systems. Verify system interoperability requirements - Develop detailed Developmental and Operational test plans. Perform Independent Validation & Verification (IV&V) activities during software development. Update the Test and Evaluation Master Plan (TEMP) and the Verification Validation and Accreditation (VV&A) plan to support MS C. Complete data gap analysis of CBRN/TIC/TIM field trials. Produce IV&V exhibits to support class accreditation. Initiate Government Developmental Testing.	- JEM Block I - Complete development of logistics/training plans and materials. Complete Post Deployment Software Support (PDSS) plans. Conduct MS C. Support continued Warfighter Integrated Process Team (IPT) involvement in program. Perform financial management, scheduling, planning, and reporting. - JEM Block I - Award contract for formal software development. Finalize service command and control system integration plans. Complete formal software development. Perform contractor level software testing. Perform integration activities with all service Global Command and Control System (GCCS) variants and other Command and Control (C2) system. Verify system interoperability requirements - JEM Block I - Conduct Developmental and Operational testing. Continue Independent Validation & Verification (IV&V). Update the Test and Evaluation Master Plan (TEMP) and the Verification Validation and Accreditation (VV&A) plan to support Milestone (MS) C. Produce T&E and VV&A reports.

2.3 OPERATIONAL GOAL 3: SHIELD

2.3.1 Performance Goal 3.1 – Respiratory and Ocular Protection.

Current Materiel Solutions	Future Materiel Solutions
M40/M40A1 Mask M42 Tank Mask (Legacy) MCU-2A/P Mask (Legacy)	Joint Service General Purpose Mask (JSGPM)
Aircrew Eye/Respiratory Protective Mask (AERP)- Legacy System CB Respiratory System M45 Aviation Protective Mask M48 Apache Mask (Legacy System)	Joint Service Aviation Mask (JSAM)
	JS Chemical Environment Survivability Mask (JCESM) (See JSGPM)
M41 Protective Assessment Test System (PATs)	JS Mask Leakage Tester (JSMLT) Miniaturized / Lightweight / Improved PATs

Note: The M41 PATs will be replaced by the JSMLT beginning in FY03.

2.3.2 Materiel Solutions Performance Measurements– Respiratory and Ocular Protection

2.3.2.1 Current Procurement Targets – Respiratory and Ocular Protection

Systems	FY03		FY04	FY05
	Target	Actual	Target	Target
JSGPM	0	0	0	70,000
Second Skin, Mask MCU-2/P	1,897,167 [1,897,167 of 1,897,167 procured]	1,051,000 [1,051,000 of 1,897,167 procured]	0	0
CB Respiratory System	300 [5,035 of 7,919 procured]	300 [4,743 of 7,919 procured]	0	0
M48 Protective Mask	0 [0 of 3,877 procured]	0 [0 of 3,877 procured]	0	0
M41 PATs	1000 [8,790 of 12,182]	1000 [8,790 of 12,182]	0	0
Joint Service Mask Leakage Tester	1,241 [1,241 of 1,439 procured]	1,030 [0 of 1,439 procured]	482	458

2.3.2.2 Current R&D Targets – JSGPM

FY 2003 Targets	Actual Performance
- Continue preparation of program/project documentation to achieve MS C. - Continue execution of logistics support plan. Develop manuals and finalization of supportability plans. - Continue System Demonstration including system support packages for PQT/IOT&E. - Continue documentation and planning for DT/OT. - Continue development of a JSGPM variant as a lightweight complement to the JSGPM against limited threats.	- Continued preparation of program/project documentation. Documentation includes Single Acquisition Management Plan (SAMP), the Manpower and Personnel Integration (MANPRINT) Plan, and Performance Specifications. - Continued Logistics Support Planning. This effort includes development of manuals and finalization of supportability plans. - Continued System Demonstration. System Demonstration efforts included system support packages for PQT/IOT&E. - Continued documentation and planning for Developmental and Operational Testing (DT/OT). Tested redesigned prototypes to assess shortcomings identified during System Integration Phase. - Continued development of the JSCESM as a lightweight complement to the JSGPM against limited threats.

2.3.2.3 Future R&D Targets – JSGPM

FY 2004 Targets	FY 2005 Targets
– Continue System Demonstration. System Demonstration includes system support packages for Production Qualification Testing and Initial Operational Testing and Evaluation. – Continue preparation of program/project documentation. Documentation includes the MANPRINT Plan, and Performance Specifications. – Continue Developmental and Operational Testing. Generate test incident reports and corrective action plans to address test results during mask design and prototype production. – Continue Logistics Support Planning. This effort includes development of manuals, and finalization of supportability plans. – Complete development of the JSCESM as a lightweight complement to the JSGPM against limited threats. – Initiate support for the development of the Improved Protective Mask (IPM).	– Complete System Demonstration. System Demonstration includes system support packages for Production Qualification Testing and Multiservice Operational Testing and Evaluation. – Complete preparation of program/project documentation. Documentation includes the Single Acquisition Management Plan and performance specifications. – Complete Development (Production Qualification Testing) and Operational (Limited User Test) Testing. Complete test and evaluation reports. Purchase 1000 test articles at \$150 each, for a total of \$150,000 for Multiservice Operational Test and Evaluation. – Complete developmental Logistics Support Planning. This effort includes completion of manuals, and finalization of supportability plans.

2.3.2.4 Current R&D Targets – Joint Service Aviation Mask (JSAM)

FY 2003 Targets	Actual Performance
- Finalize system design and complete development. Begin logistics activities and sustainment planning to include tech order preparation, provisioning, and fielding plan - Continue program management activities, to include updating programmatic and technical documentation. Continue test planning documents such as the Test Evaluation Master Plan in preparation for Developmental Testing (DT) and Operational Testing (OT). - Start and complete system validation, develop production processes and hard tooling to fabricate DT and OT units. - Initiate material buy and begin assembly of DT units.	– Received Milestone B approval, awarded the System Demonstration and Development (SDD) contract, continued program management activities, conducted start of work meeting, and the preliminary design review – Continued systems engineering, design and integration tasks. Began logistics activities and sustainment planning. Initialized program working groups. – Initiated developmental manufacturing process planning for material, parts and peculiar support equipment. Began preliminary tooling efforts with vendors and initiated a limited set of subcomponent level tests. – Initiated fabrication of models and prototype assemblies for various size mask system parts for functionality evaluation by the integration control groups.

2.3.2.5 Future R&D Targets – Joint Service Aviation Mask (JSAM)

FY 2004 Targets	FY 2005 Targets
– Continue system design, engineering and fabrication activities; develop production processes and plan for adequate tooling in preparation for fabrication of units. – Continue contractor and government developmental test and evaluation planning activities, to include integration with selected aircraft. – Continue program management, logistics and sustainment planning. Prepare program and technical documentation.	– Complete contractor developmental testing. Continue documentation and planning in preparation for testing. Initiate Government developmental test and evaluation. – Complete material purchase, fabrication, and assembly of 332 DT units at an average unit cost of \$6112. – Continue system design, engineering and fabrication activities; develop production processes and ensure tooling is adequate to fabricate units.

FY 2004 Targets	FY 2005 Targets
	– Continue contract and government program management, logistics and sustainment planning.

2.3.3 Performance Goal 3.2 – Percutaneous Protection.

Current Materiel Solutions	Future Materiel Solutions
Battledress Overgarment (Legacy System) Saratoga, JS Lightweight Integrated Suit Technology (JSLIST) Black Vinyl Overboots (Service O&M responsibility) 7, 14, 25-mil Gloves (Service O&M responsibility)	JSLIST Block I and II Glove Upgrades
Aircrew Uniform Integrated Battledress (AUIB) (Legacy system) Chemical Protective Undercoverall (Service O&M responsibility) CWU-66/77 Aircrew Ensemble (Legacy system)	Joint Protective Aviator Ensemble (JPACE)

2.3.4 Materiel Solutions Performance Measurements

2.3.4.1 Current Procurement Targets – Percutaneous Protection

Systems	FY03		FY045	FY05
	Target	Actual	Target	Target
JSLIST	334,205 [2,282,441 of 6,848,136 procured]	1,154,356 [3,102,592 of 6,848,136 procured]	271,183	342,400

2.3.4.2 Current R&D Targets – JSLIST Block I & II Glove Upgrade, MPS

FY 2003 Targets	Actual Performance
- Award multiple competitive contracts for system development and demonstration. - Conduct durability and chemical validation testing for air/ground missions. - Conduct project management and plan test readiness reviews. - Conduct air/ground Operational Test (OT) and complete MS C. - Conduct field durability trials for air/ground missions. - Conduct chemical validation test trials. - Conduct air/ground OT and complete Milestone C documentation.	– Block I Glove Upgrade - Completed air/ground Operational Test (OT) and completed Milestone (MS) C. – Block II Glove Upgrade - Awarded multiple competitive contracts for system development and demonstration. – Block II Glove Upgrade - Conducted durability and chemical validation testing for air/ground missions. – Block II Glove Upgrade - Conducted project management and planned test readiness reviews. – Multi-Purpose Sock (MPS) - Conducted field durability trials for air/ground missions. – MPS - Conducted chemical validation test trials. – MPS - Conducted air/ground OT and prepared MS C documentation.

2.3.4.3 Future R&D Targets – JSLIST Block II Glove Upgrade

FY 2004 Targets	FY 2005 Targets
– Block II Glove Upgrade - Complete IOT&E and initiate chemical validation testing. – Block II Glove Upgrade - Conduct preparations for MS C Low Rate Initial Production (LRIP). – MPS - Complete air/ground operational tests and complete MS C. – MULO - Form alternative footwear solutions project team, conduct market survey, form acquisition strategy, initiate durability and chemical testing	– Block II Glove Upgrade - Complete chemical agent validation testing and complete IOT&E. – Block II Glove Upgrade - Complete preparations for MS C Full Rate Production (FRP). – MULO - Complete alternative footwear solutions chemical and

FY 2004 Targets	FY 2005 Targets
	durability testing, complete IOT&E, and complete MS C.

2.3.4.4 Current R&D Targets – JPACE

FY 2003 Targets	Actual Performance
- Complete DT IIB testing. Conduct Critical Design Review (CDR). Fabricate 350 prototype ensembles of each candidate for combined DT/Operational Test (OT) (700 total at \$525 each). Initiate combined DT/OT system level testing and initial Operational Assessment (OA) to verify system level performance and assess operational suitability and durability. Testing includes aircraft integration testing (crashworthiness, early flight, and aircraft compatibility) on six aircraft and system level chemical simulant testing (Man In Simulant Test). - Continue developing and updating program, logistics, and technical documentation required to ensure that ensembles will be fully supported when fielded. Continue updating garment specifications and patterns.	- Completed DT IIB and DT IIA2 testing. Conducted CDR. Fabricated 578 prototype ensembles of one candidate for combined DT/OT (578 total at \$440 each). Initiated combined DT/OT system level testing and initial Operational Assessment (OA) to verify system level performance and assess operational suitability and durability. Testing included aircraft integration testing (windblast, ejection, water egress, early flight, and aircraft compatibility in support of obtaining flight clearance of Field Durability Developmental Test (FDDT).) - Continued development and update of program, logistics, and technical documentation required to ensure that ensembles will be fully supported when fielded. Updated garments specifications and patterns.

2.3.4.5 Future R&D Targets – JPACE

FY 2004 Targets	FY 2005 Targets
- Continue combined DT/OT with durability and other system level testing, including chemical Man in Simulant Test (MIST), aerosol test, and swatch test. Develop and test contaminated doffing procedures, and acquire final safe-to-fly decision from the services. - Prepare for Independent Operational Test & Evaluation (IOT&E). Conduct Milestone (MS) C decision for LRIP of ensembles. - Award contract option to manufacture LRIP ensembles. - Continue developing and updating program, logistics, and technical documentation required to ensure that ensembles will be fully supported when fielded. Update and finalize garment specifications and patterns based on DT/OT results.	- Complete IOT&E. Conduct MS C decision for LRIP of ensembles. Award contract options to manufacture LRIP ensembles. - Finalize garment specifications and patterns. Conduct System Verification Review (SVR). Conduct Full Rate Production decision. - Finalize program, logistics, and technical documentation required to ensure that ensembles are fully supported.

2.3.5 Performance Goal 3.3 – Expeditionary Collective Protection.

Current Materiel Solutions	Future Materiel Solutions
Various Gas-Particulate Filter Unit (GPFU) configurations (Legacy systems) Modular Collective Protection Equip. (Legacy systems) Selected Area CPS, Ship CPE, (Legacy systems) Ship CPS Backfit	Joint CP Equipment (JCPE) Shipboard Collective Protection Equipment (SCPE)

Current Materiel Solutions	Future Materiel Solutions
M20A1 SCPE (Legacy system) Portable CPS (Legacy system)	Joint Transportable Collective Protection Shelter (JTCOPS) Block I Joint CP Equipment
CB Protective Shelter (CBPS)	
CB Deployable Medical Shelter (CBDEPMEDS)/ Chemically Hardened Air Transportable Shelter (CHATH)	

2.3.6 Materiel Solutions Performance Measurements – Expeditionary Collective Protection

2.3.6.1 Current Procurement Targets Measurements – Expeditionary Collective Protection

Systems	FY03		FY04	FY05
	Target	Actual	Target	Target
Ship CPS Backfit (protective zones backfitted)	8 [17 of 51 procured]	7 [16 of 51 procured]	5	5
CBPS	37 [204 of 1,224 procured]	37 [204 of 1,224 procured]	22	0
CP DEPMEDS/CHATH	0	0	0	0

2.3.6.2 Current R&D Targets – Joint Collective Protection (CP) Equipment

FY 2003 Targets	Actual Performance
- Complete development of 2000 CFM particulate filters to reduce logistics costs. Complete live agent testing of improved 100/200 CFM gas filters. Complete development and testing of one improved recirculation filter unit to reduce logistics costs. Complete development and testing of noise reduction and abatement for CB shelter systems utilizing sound barriers. Complete testing of 30 in service 100/200 CFM gas filters to determine service life. Complete design and testing of the thermal efficiency of CB protected shelter systems - Perform development and testing to increase efficiency of CPS supply fan motors to operate at peak performance over the entire range of filter loading. Continue developmental prototypes of a suite of improved airlocks to reduce purge times and provide simultaneous entry/exits for all existing CB shelter systems. Complete study to determine the contamination control area requirements that meet NATO standards. Complete development of logistical support plan for prior JCPE items. Continue the system engineering of capability sets with improved components. - Complete development of a modified M28 liner for large capacity shelters. Continue design and testing of an improved liner material, construction, and enclosures.	- Completed development and testing of 2000 cubic feet per minute (CFM) particulate filters to reduce logistics costs. Completed live agent testing of improved 200 CFM gas filter. Completed development and testing of one improved recirculation filter unit to reduce logistics costs. Completed development and testing of sound barriers for noise reduction and abatement within Chemical and Biological (CB) shelter systems. Completed testing of 30 in-service 100/200 CFM gas filters to determine service life. Completed design and testing of the thermal efficiency of CB protected shelter systems. Completed development and testing of Fan Filter Assembly (FFA) 400-100 and M93 Modular Collective Protection Equipment (MCPE) candidate motor/blowers for CB shelter systems to improve efficiency, reliability, size, and weight. Completed study to determine the contamination control area requirements that meet NATO standards. Completed development of logistical support plan for prior JCPE items. Completed the system engineering of capability sets with improved components. Completed development and testing of an automatic power transfer switch for Collectively Protected Expeditionary Medical Support (CPMEMEDS). Completed design and testing of a Collective Protection (CP) modification kit for fielded heater systems. Completed design and testing to reduce the CB filter blower heat load. Completed study to investigate environmental control unit (ECU) and power applications to CP shelters. Completed performance testing of CB liners for long term storage in temperature extremes and alternate seam configurations. Completed development

FY 2003 Targets	Actual Performance
Complete development and testing of automatic power transfer switch for CPEMEDS. Complete design and test of CP modification kit for fielded heater systems. Complete design and testing to reduce the CB filter blower heat load. Complete study to investigate ECU and power applications to CP shelters. Continue testing of CB liners for long term storage in temperature extremes and alternate seam configurations. Complete development and testing a CB liner seam tester. Complete development and testing of a improved repair process for CB liners. Complete development and testing of a CP latrine for CPEMEDS.	and testing of a CB liner seam tester. Completed development and testing of an improved repair process for CB liners - Continued program management and IPT support. Continued integration and testing of a Tunnel Airlock Litter Patient (TALP) with a Modular General Purpose Tent System (MGPTS). Continued development of a suite of improved airlocks to reduce purge times and provide simultaneous entry/exits for all existing CB shelter systems. Continued development and testing of a modified M28 liner for large capacity shelters. Continued design and testing of improvements to liner material, construction, and enclosures. Continued development and testing of a CP latrine for CPEMEDS. Continued development and testing of a CP latrine for CPEMEDS. - Initiated development and testing to increase efficiency of collective protection system supply fan motors to operate at peak performance over the entire range of filter loading.

2.3.6.3 Future R&D Targets – Joint Collective Protection (CP) Equipment

FY 2004 Targets	FY 2005 Targets
- Complete development and testing of a CP latrine for CPEMEDS. Complete development and testing of a modified M28 liner for large capacity shelters. Complete development and testing to increase efficiency of collective protection system supply fan motors to operate at peak performance over the entire range of filter loading. Complete live agent testing of improved 100/200 CFM gas filters. Complete testing of developmental prototypes of a suite of improved airlocks to reduce purge times and provide simultaneous entry/exits for all existing CB shelter systems. Complete integration and testing of a Tunnel Airlock Litter Patient (TALP) with a Modular General Purpose Tent System (MGPTS). - Continue program management and IPT support. Continue design and testing of improvements to liner material, construction, and enclosures. - Initiate testing to determine effectiveness of CB shelters while subjected to extreme environmental conditions. Complete development and testing of an individual distribution breathing air hose. Complete development and testing of a filter moisture indicator. Initiate development and testing of a small shelter system (SSS) contamination control area (CCA) and airlock integration. Complete development of shipboard CP automation. Initiate development and testing of a collective protection blast operational analysis.	- Complete design and testing of improvements to liner material, construction, and enclosures. Complete testing of CB shelters subjected to extreme environmental conditions. Complete development and testing of a SSS CCA/airlock integration. Complete development and testing of a collective protection blast operational analysis. Complete development and testing of 100/200 CFM gas filters to provide protection against selected toxic industrial chemicals (TICs). - Continue program management and IPT support. - Initiate and complete 28 Volt Direct Current modified M93 gas particulate filter unit. Initiate filter capacity service life study for land-based facilities by testing samples of used filters to determine a more accurate filter change out schedule.

2.3.6.4 Current R&D Targets – Shipboard Collective Protection (SCPE)

FY 2003 Targets	Actual Performance
Complete shipboard testing of improved CPS fan rotors. Test data will be used to revise CPS fan rotor performance specification. Complete final year of verification testing to validate the four-year performance of improved prefilters and HEPA	Completed shipboard testing of improved CPS fan rotors. Test data will be used to revise CPS fan rotor performance specification. Completed final year of verification testing to validate the four year performance of improved prefilters and HEPA

FY 2003 Targets	Actual Performance
filters. Complete testing and evaluation of HEPA filter performance degradation after TIC/TIM exposure. - Complete development and testing of two electronic differential pressure gauges for remote reading to improve shipboard CPS maintenance	filters. Completed testing and evaluation of HEPA filter performance degradation after TICs/Toxic Industrial Materials (TIMs) exposure. - Completed development and testing of two electronic differential pressure gauges for remote reading to improve shipboard CPS maintenance

2.3.6.5 Future R&D Targets – Shipboard Collective Protection (SCPE)

FY 2004 Targets	FY 2005 Targets
- n/a (transition to procurement).	- n/a

2.3.6.6 Current R&D Targets – Joint Transportable Collective Protection Shelter Block I

FY 2003 Targets	Actual Performance
- Release a Request for Proposals, evaluate proposals and award a development contract. Begin the design phase of the program.	<i>Transition to JCPE</i>

2.3.6.7 Future R&D Targets – Joint Transportable Collective Protection Shelter Block I

FY 2004 Targets	FY 2005 Targets
- n/a (Preparing for transition to procurement.)	

2.3.6.8 Current R&D Targets – CBPS P3I

FY 2003 Targets	Actual Performance
- Fabricate two ESS prototypes at unit cost of \$250K, finalize design and complete Technical Data Package. - Conduct performance testing on one ESS prototype. - Finalize design concept for ESS and document in technical data package. Integrate ESS onto non-vehicle based platform. Manage CBPS P3I.	- Awarded contract to fabricate two SP-ESS prototypes at a unit cost of \$393K. - Conducted preliminary testing on two SP-ESS prototypes. - Finalized design concept for SP-ESS. - Purchased materials and integrated systems.

2.3.6.9 Future R&D Targets – CBPS P3I

FY 2004 Targets	FY 2005 Targets
- Program stopped pending completion of MAA and reassessment of the ORD.	

2.3.7 Performance Goal 3.4 – Medical Prophylaxes.

Current Materiel Solutions	Future Materiel Solutions
Medical Biological	
Licensed Anthrax vaccine Licensed Smallpox vaccine	Biological Defense Vaccines, <i>e.g.</i> , Multivalent Equine Encephalitis, Recombinant Botulinum AB, Plague, Staphylococcal Enterotoxin B (SEB), Ricin and Next Generation Anthrax vaccine
Medical Chemical	
Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP) (Service O&M responsibility)	Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP) Vesicant Prophylaxis Cyanide Pretreatment

2.3.8 Materiel Solutions Performance Measurements – Medical Prophylaxes

2.3.8.1 Current R&D Targets – Biological Defense Vaccines

FY 2003 Targets	Actual Performance
<u><i>Smallpox Vaccine</i></u> - Continue Smallpox and Vaccinia Immune Globulin (VIG) stability studies. - Complete 4th and 5th stages of a Phase I Clinical Trial (safety and immunogenicity). - Complete Process optimization and lot manufacture validation. - Produce three consistency lots, achieving first-year baseline stockpile quantities (4 million doses). - Submit IND annual reports and manufacturing amendments for Smallpox vaccine and VIG.	<u><i>Smallpox Vaccine</i></u> - Continued Smallpox and Vaccinia Immune Globulin (VIG) stability studies. Completed fourth and fifth stages of a Phase 1 clinical trial (safety and immunogenicity). - Submitted Investigational New Drug (IND) annual reports and manufacturing amendments to the FDA for Smallpox vaccine and VIG.
<u><i>Tularemia Vaccine</i></u> - Complete characterization studies and continue development of surrogate marker of efficacy. - Conduct immunogenicity and toxicity studies. - Complete cGMP pilot lot production and conduct final container stability testing of pilot lot.	<u><i>Tularemia Vaccine</i></u> - Completed cGMP pilot lot production and conducted final container stability testing of pilot lot. - Completed characterization studies and completed initial development of surrogate marker of efficacy assay. - Completed immunogenicity and toxicity studies.
<u><i>Recombinant Botulinum Vaccine</i></u> - Complete adjuvant formulation studies. - Complete bulk cGMP lot production of A/B. - Initiate bulk stability and final container stability testing of pilot lot. - Initiate planning and preparation for Phase I clinical trial. - Complete cGMP pilot lot manufacturing of serotypes A and B bivalent vaccine.	<u><i>Recombinant Botulinum Vaccine</i></u> - Completed manufacturing process development including initial adjuvant formulation studies (Block I). - Completed current Good Manufacturing Practices (cGMP) pilot lot manufacturing of serotype A and initiated final container stability testing (Block I). - Initiated non-clinical studies for bivalent (serotypes A&B) vaccine (Block I). - Initiated planning and preparation for Phase 1 clinical trial (Block I).
<u><i>Next Generation Anthrax Vaccine</i></u> - Continue process definition work for a candidate recombinant protective antigen NGAV. - Manufacture and characterize master cell and working cell banks. - Conduct assay development and validation. Initiated technology transfer and process definition for a candidate recombinant protective antigen NGAV. - Initiate cGMP pilot lot production. - Initiate product stability studies. - Conduct Clinical Phase I trial.	<u><i>Next Generation Anthrax Vaccine</i></u> - Continued product stability studies. - Completed manufacturing process development and cGMP pilot lot production. - Initiated Phase 1 clinical trial.
<u><i>Equine Encephalitis Vaccines</i></u> - Continue assay development and validation. - Continue stability and lot release testing on cGMP pilot lot of the VEE 1A/B component. - Conduct higher animal species neurovirulence testing and equine safety study of VEE 1A/B component.	<u><i>Equine Encephalitis Vaccines</i></u> - Continued assay development and qualification. - Continued stability and lot release testing on pilot lot for non-clinical studies. - Conducted non-human primate

FY 2003 Targets	Actual Performance
	neurovirulence testing and equine safety study of the VEE 1AB vaccine component. – Initiated cGMP manufacture of lot for clinical use.
<u>Plaque Vaccine</u> – Continue process development efforts to include: optimization, formulation, and stability studies, the manufacture of 5 demonstration runs and process transfer. Continue assay development and validation. – Begin animal immunogenicity studies and non-clinical testing. – Initiate bulk stability, container stability, and reconstitution stability testing on pilot lot.	<u>Plaque Vaccine</u> – Continued process development efforts to include: optimization, formulation, and stability studies the manufacture of 2 demonstration runs. – Continued assay development and validation. – Initiated animal immunogenicity studies and non-clinical testing.

2.3.8.2 Future R&D Targets – Biological Defense Vaccines

FY 2004 Targets	FY 2005 Targets
<u>Recombinant Botulinum Vaccine</u> – Continue non-clinical studies and final container stability testing (Block I). – Submit IND application (Block I). – Initiate Phase 1 clinical trial execution and monitoring (Block I). – Initiate process validation, to include qualification and validation of fermentation and purification processes and manufacture of serotypes A and B (Block I). – Assay development, small-scale process development and manufacture of cell banks for serotypes C, E, and F (Block II).	<u>Recombinant Botulinum Vaccine</u> – Continue process validation efforts for serotypes A and B (Block I). – Complete Phase 1 clinical trial and receive final report (Block I). – Complete non-clinical studies and continue stability testing (Block I).
<u>Equine Encephalitis Vaccines</u> – Complete assay development and qualification and complete lot release testing on the cGMP pilot lot. – Initiate Phase 1 clinical trial on the VEE vaccine. – Submit IND application for V3526 vaccine. – Complete cGMP lot for clinical use.	<u>Equine Encephalitis Vaccines</u> – NA
<u>Plaque Vaccine</u> – Continue stability testing and initiate animal testing. – Manufacture cGMP pilot lot and 3 qualification lots. – Complete toxicology and immunogenicity testing. – Prepare and submit IND application to FDA. – Conduct Phase I clinical trial and perform animal efficacy studies on the UK vaccine candidate in order to collect data for a down-select decision.	<u>Plaque Vaccine</u> – Continue stability testing. – Initiate Phase 1 clinical trial.
<u>Next Generation Anthrax Vaccine</u> – Continue Phase 1 clinical trial.	<u>Next Generation Anthrax Vaccine</u> – Complete Phase I clinical Trial.

2.3.8.3 Current R&D Targets – Improved Pyridostigmine Bromide and SERPACWA

FY 2003 Targets	Actual Performance
<u>Pyridostigmine Bromide</u> – Complete storage and stability testing and complete FDA required additional studies. – Finalize and submit NDA to FDA.	<u>Pyridostigmine Bromide</u> – Annual storage and stability testing completed. – Continued three studies to validate surrogate markers for human efficacy. (Human ex vivo muscle study, human ex vivo blood study and higher animal species ex vivo study).

FY 2003 Targets	Actual Performance
	- Completed FDA manufacture study to validate surrogate marker in small animal - Received FDA approval.
<u>SERPACWA</u> - Complete FDA manufacturing requirements.	<u>SERPACWA</u> – Completed FDA manufacturing requirements – Completed production line process validation. – Continued self-life monitoring, and FDA required Phase IV testing.

2.3.8.4 Future R&D Targets – Improved Pyridostigmine Bromide and SERPACWA

FY 2004 Targets	FY 2005 Targets
Pyridostigmine Bromide – Conduct Storage and Stability testing – Continue ex vivo human muscle and non-human primate studies to demonstrate efficacy vs. surrogate markers.	<u>Pyridostigmine Bromide</u> – Conduct storage and stability testing – Continue ex vivo human muscle and non-human primate studies to demonstrate efficacy vs. surrogate markers.
<u>SERPACWA</u> – Continue FDA manufacturing requirements, re-design packaging, production line process validation, shelf-life monitoring, and complete field trial.	<u>SERPACWA</u> – Complete FDA manufacturing requirements, redesign packaging, production line process validation, and shelf-life monitoring.

2.3.8.5 Current R&D Targets – Active Topical Skin Protectant and CW Agent Prophylaxis

FY 2003 Targets	Actual Performance
- Science and technology base (S&T) program. Pending transition from S&T	

2.3.8.6 Future R&D Targets – Active Topical Skin Protectant and CW Agent Prophylaxis

FY 2004 Targets	FY 2005 Targets
- Pending transition from S&T	

2.4.19 Performance Goal 4.10 Medical post treatments for CW agents.

Current Materiel Solutions	Future Materiel Solutions
Nerve Agent Antidote Kit (NAAK)* Convulsant Antidote Nerve Agent (CANA) * Sodium thiosulfate/nitrate* Multi-chamber Autoinjector*	Vesicant Agent Countermeasures Advanced Anticonvulsant Improved Nerve Agent Treatment System

*(Service O&M responsibility)

2.4 OPERATIONAL GOAL 4: SUSTAIN

2.4.1 Performance Goal 4.1 – Individual Decontamination.

Current Materiel Solutions	Future Materiel Solutions
M291 skin decon kit (Purchase is a Service O&M responsibility) M295 individual equipment decon kit (Purchase is a Service O&M responsibility)	M291 skin decon kit (Sorbent based) M295 individual equipment Decon kit (Sorbent based)

2.4.2 Materiel Solutions Performance Measurements – Individual Decontamination

2.4.2.1 Current R&D Targets – M291 and M295 Decon Kits

FY 2003 Targets	Actual Performance
- Apply for FDA approval of M291 skin decon kit	

2.4.2.2 Future R&D Targets – M291 and M295 Decon Kits (Sorbent based)

FY 2004 Targets	FY 2005 Targets
None	None

2.4.3 Performance Goal 4.2 – Equipment Decontamination.

Current Materiel Solutions	Future Materiel Solutions
M11 Decon App, Portable (Legacy system) M13 Decon App, Portable (Legacy system) (both with DS-2)	M100 Sorbent Decon System (SDS)
M17A2 Lightweight Decon System (Legacy System)	Modular Decon System (MDS)
	Joint Service Sensitive Equipment Decon System (JSSEDS) Block I, II, and III
M12 Power-Driven Decon Apparatus (Legacy system)	Joint Service Family of Decontamination System (JSFDS) - Blocks I, II, and III

2.4.4 Materiel Solutions Performance Measurements – Equipment Decontamination

2.4.4.1 Current Procurement Targets –M100 Sorbent Decon System

Systems	FY02		FY04	FY05
	Target	Actual	Target	Target
M100 Sorbent Decon System	130,000 [130,000 of 1,120,544]	166,500 [166,500 of 1,120,544]	24,240	0
Modular Decontamination System	0 [0 of 465]	0 [0 of 465]	0	0
Joint Service Family of Decontaminant Systems (JSFDS)	90,000	80,000	150,038	298

2.4.4.2 Current R&D Targets – Joint Service Family of Decontamination Systems (JSFDS)

FY 2003 Targets	Actual Performance
- Complete OT report for decontaminant to satisfy CENTCOM UNS. - Complete Developmental Test and Evaluation (DT&E) animal safety studies and preliminary animal efficacy studies for Block III skin decontaminants. - Conduct detail test planning and procure decontaminants for testing for Block I (approximately 8,000 gallons at average cost of \$18 per gallon).	- Completed Operational Test (OT) report for decontaminant to satisfy CENTCOM UNS. Conducted follow-on testing on CENTCOM UNS decontaminant to resolve issues identified during Development Testing (DT) and OT. - Completed foreign comparative testing of Reactive Skin Decontamination Lotion (RSDL) to support submission of to the Food and Drug Administration. - Completed downselection testing, evaluated test results and down-selected skin decontaminant for

FY 2003 Targets	Actual Performance
- Initiate OT&E for Block I to support a Milestone III. - Conduct DT I and initiate DT II test for Block I decontaminant and update program documentation. Conduct optimization/feasibility testing of various forms of applying Block I decontaminants to support Block II performance specifications development. - Initiate DT II for Block III Skin decontaminants to generate data to support Food and Drug Administration (FDA) approval	JSPDS contract award. - Awarded contract for JSPDS skin decontaminant and initiated development testing (DTIII) to address outstanding safety, wound compatibility and packaging issues. - Restructured program to reflect an evolutionary acquisition strategy that will expedite fielding of an increased capability to the warfighter Continued development of program documentation. - Performed test methodology and laboratory capability improvements to support testing of the JSM-PDS, JSTDS and JSSDS to include ability to perform larger scale decontamination operations with simulants. Developed and validated new live agent and simulant test methodologies to aide bridging the gap between development and operational testing. Revised the Test and Evaluation Master Plan (TEMP).

2.4.4.3 Future R&D Targets – Joint Service Family of Decontamination Systems (JSFDS)

FY 2004 Targets	FY 2005 Targets
- Continue development testing (DT III) to address outstanding safety, wound compatibility and packaging issues. - Initiate JSM-PDS and JSTDS, small-scale and large-scale, DT I downselection testing to include live agent system level testing. - Continue development of program documentation, such as the Request for Proposal, Logistics Support Plan and System Acquisition Management Plan. Manage contracting effort and downselection process. - Perform engineering and logistics trade off studies for the JSM-PDS and JSTDS. - Finalize Test and Evaluation Master Plan (TEMP), down-selection test methodology, System Acquisition Management Plan and Request for Proposal for JSPDS, JSM-PDS and JSTDS to support a Milestone (MS) B decision. - Procure test units for down-selection testing (70 systems at average cost of 60K) - Perform engineering and logistics studies to include an evaluation of alternative means of enhancing decontamination of aircraft to expedite an increase in capability in the near term, to identify potential simulants for use in testing or training and to establish baseline for evaluating improvements in logistics.	- Complete packaging testing and continue long-term safety and wound compatibility tests for JSPDS (DT III). - Complete DTI operational assessment (OA)/DT II and initiate DT III for JSM-PDS and JSTDS. - Continue development of program documentation, such as the Request of Proposal, Logistics Support Plan and System Acquisition Management Plan. Manage contracting effort and downselection process - Perform market survey and initiate development of program acquisition documentation for JSSDS. - Perform studies of technologies for improving personnel/skin decontamination capability including assessment of potential of wound decontamination. - Perform analysis of alternatives, including testing, for using decontamination simulants in lieu of decontaminants and agents for training. - Perform study to determine potential of selected systems to decontaminate toxic industrial chemicals and new threat agents.

2.4.4.4 Current R&D Targets – JSSEDS Block I

FY 2003 Targets	Actual Performance
- Conduct Block I program Interim Progress Review (IPR) to finalize Block I technology and system design.	- Completed Block I prototype testing and conducted program Interim Progress Review (IPR) to finalize Block I technology and system design.

FY 2003 Targets	Actual Performance
- Award contract to develop and fabricate Block I developmental test systems (eight items at \$300K each) which implement design improvements from the prior year prototypes. - Initiate pre-production Block I system test design.	- Awarded fluid optimization contracts to characterize solvent and filtration mechanism for removal or neutralization of chemical and biological agents. - Initiated market survey for commercial industrial base for solvent/disinfectant technologies. - Initiated identification of materials of construction for sensitive equipment. - Initiated Block II/III Milestone B documentation, which includes Test and Evaluation Master Plan, System Acquisition Master.

2.4.4.5 Current R&D Targets – JSSEDS Block I

FY 2004 Targets	FY 2005 Targets
- Complete optimization effort of primary solvent-based system. - Initiate development of pre-cleaning decontamination system to remove gross contamination from sensitive equipment. - Initiate System Development & Demonstration (SDD) Statement of Work. - Develop acquisition documentation support for Increment I of JSSED ORD. - Develop, coordinate and process Increment I Temp.	- Finalize planning for DT to include upgrade of test chambers. - Complete optimization effort of primary solvent base system. - Complete the system integration of pre-clean capability and initiate military utility testing. - Initiate development of acquisition logistics.

2.4.4.6 Current R&D Targets – JSSEDS Blocks II and III (JPID)

FY 2003 Targets	Actual Performance
- Prepare and submit Block II/III Milestone B documentation, which includes Test and Evaluation Master Plan, System Acquisition Master Plan, and Acquisition Program Baseline. - Prepare Request for Proposal for Block II/III combined development effort.	

2.4.4.7 Current R&D Targets – JSSEDS Blocks II and III (JPID)

FY 2004 Targets	FY 2005 Targets
- Continue documentation for Milestone (MS) B. - Initiate support for the Integrated Product Team. - Initiate identification of platform materials compatibility testing. - Initiate market survey for commercial base. - Update Analysis of Alternatives (AoA). - Initiate developmental test (DT) planning. - Initiate Industry Day for exploration of S&T and develop exchange with service/industry.	- Continue support to the Integrated Product Team. - Continue DT and plan for operational testing (OT). - Award contract for prototype test units for DT (build six systems @ \$50K each). - Develop the Technology Readiness Evaluation. - Complete documentation for MS B. - Initiate documents/package for MS C.

2.4.5 Performance Goal 4.3 – Fixed Site Decontamination.

Current approach is being re-evaluated. Fixed site decontamination RDA efforts are being addressed through separate projects, including the Joint Service Man-Portable Decon. System, Joint Service Transportable Decon System, Joint Service Stationary Decon System, and the Joint Service Personnel/Skin Decontamination System.

2.4.6 Materiel Solutions Performance Measurements– Fixed Site Decontamination

See note in Section 2.4.5 above.

2.4.7 Performance Goal 4.4 – Medical Diagnostics.

Current Materiel Solutions	Future Materiel Solutions
None (interim measure- manual medical diagnoses and Theater Army Medical Labs)	Joint Biological Agent Identification and Diagnostic System (JBAIDS)

2.4.8 Materiel Solutions Performance Measurements – Medical Diagnostics**2.4.8.1 Current R&D Targets – JBAIDS**

FY 2003 Targets	Actual Performance
- Select winning contractor from the remaining two candidate “fly-off” tested designs. - Purchase 25 development prototype JBAIDS and 128,000 test assay kits to support development and operational testing (OT) requirements. - Conduct development testing at contractor’s facility and government laboratories. Conduct JBAIDS hardware reliability and environmental testing. - Submit JBAIDS agent (anthrax and 2 targets) 510(k) package for FDA review and clearance. - Review contractor developed JBAIDS technical manuals, review training packages, complete system drawing requirements to support a physical configuration audit of the design.	- Completed source selection efforts; achieved Milestone (MS) B. - Awarded contract to develop a reusable, portable, modifiable biological agent identification and diagnostic system; purchased 25 test articles to be delivered in FY04. - Completed Test Evaluation Master Plan (TEMP) with Developmental and Operational Test and Evaluation (DOT&E) oversight and four military services' operational test agencies; planned developmental testing (DT) efforts; and planned BW test sample preparation efforts - Lengthy source selection process caused FY03 targets for conduct of DT, JBAIDS Anthrax assay 510(k) submission, physical configuration audit, and tech/training manual development to be shifted to FY 2004.

2.4.8.2 Current R&D Targets – JBAIDS

FY 2004 Targets	FY 2005 Targets
<u>JBAIDS BLK I</u> - Complete DT and Operational Assessment (OA) - Develop hardware and assays; conduct physical configuration audit of the design; deliver test articles; conduct hardware qualification testing; and continue hardware engineering change proposal process, hardware upgrading and BW assay development; review contractor developed technical manuals and training packages. - Submit JBAIDS 510(k) package for anthrax assay for FDA review and clearance. - Initiate Operational Testing (OT) planning efforts. - Critical Reagent Program (CRP): support to JBAIDS includes providing biological agent panels and nucleic acid reference standards	<u>JBAIDS BLOCK I</u> - Achieve MS C decision. - Complete BW assay development, conduct IOT&E, and continue FDA 510(k) submission and testing process for remaining assays. - Critical Reagent Program (CRP): continue support to JBAIDS to include providing biological agent panels and nucleic acid reference standards; immunoassay reagents; antibodies and antigen reference standards. In addition, develop a unified DoD culture collection to standardize test and evaluation for JBAIDS and throughout DoD.

2.4.9 Performance Goal 4.5 – Medical Therapeutics.

Current Materiel Solutions	Future Materiel Solutions
Medical Biological	
Antibiotics (Service O&M responsibility)	Broad spectrum antibiotics Antitoxins Anti-viral drugs

Current Materiel Solutions	Future Materiel Solutions
Medical Chemical	
Antidote Treatment – Nerve Agent Autoinjector (ATNAA)	Improved Nerve Agent Treatment System (INATS)

2.4.10 Materiel Solutions Performance Measurements – Medical Therapeutics

2.4.10.1 Current R&D Targets – Medical Chemical Therapeutics

FY 2003 Targets	Actual Performance
<u>Advanced Anticonvulsant</u> - Prepare and submit documentation for Investigational New Drug application. - Continue development of the manufacturing processes, material requirements, formulation, and packaging to be used in clinical studies. - Prepare documentation for a conduct MSII in-process review. - Complete evaluation of FDA approved seizure drugs for nerve agent induced seizures. - Initiate determination of optimum serum levels of midazolam in higher animal species model.	- Initiated optimum serum levels of midazolam and neuropathological analysis studies in non-human primate models. - Initiated documentation for Investigational New Drug (IND) application. - Completed evaluation of FDA approved seizure drugs. - Continued discussions with FDA regarding design of appropriate clinical studies. These discussions precluded preparation of IND package and pursuit of manufacturing processes. These efforts will be pursued in FY 04 and FY 05.
<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u> - Continued shelf-life extension stability studies required by the FDA.	<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u> - Continued shelf-life extension stability studies required by the FDA.

2.4.10.2 Future R&D Targets – Medical Chemical Therapeutics

FY 2004 Targets	FY 2005 Targets
<u>Advanced Anticonvulsant</u> - Continue optimum serum levels of midazolam and neuropathological analysis studies in non-human primate models. - Conduct pre-IND/regulatory strategy with the FDA. - Initiate rodent and non-human primates pre-clinical studies under Good Laboratory Practices (GLP) guidelines, and initiate acute toxicology study regarding intramuscular use of midazolam.	<u>Advanced Anticonvulsant</u> - Complete FDA IND/regulatory strategy. - Complete optimum serum levels of midazolam and neuropathological analysis studies in non-human primate models, rodent and non-human primates pre-clinical studies under GLP guidelines, and acute toxicology study regarding intramuscular use of midazolam. - Initiate and complete animal efficacy studies. - Initiate development of manufacturing processes. - Initiate clinical study of therapeutic dosage and maximum tolerable human dose study.
<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u> - Continued shelf-life extension stability studies required by the FDA.	<u>Antidote Treatment-Nerve Agent Autoinjector (ATNAA)</u> - Complete shelf-life extension stability studies required by the FDA.
<u>Improved Nerve Agent Treatment System (INATS)</u> - Initiate process development/current Good Manufacturing Practices (cGMP) pilot lots and initiate acute toxicology and stability studies.	<u>Improved Nerve Agent Treatment System (INATS)</u> - Complete non-human primate oxime studies and acute toxicology and stability studies. - Complete process development/cGMP pilot lot. - Prepare documentation for IND application. - Initiate human safety studies.

SCIENCE AND TECHNOLOGY BASE PERFORMANCE GOALS AND MEASURES

3.0 OVERVIEW

The science and technology base (S&T) of the Chemical and Biological Defense Program provides essential capabilities to develop technological advantage over any potential adversaries and prevent technological surprise. Within S&T there are three budget activities and three research areas, and project funding codes for each. (See **Table 1.**)²

Table 1. CBRNDP Science and Technology Base Project Funding Codes

Budget Activity (Program Element)	Research Area		
	Non-Medical S&T	Medical S&T	
	CB Defense	Chemical Defense	Biological Defense
BA1 - Basic Research (0601384BP)	CB1	TC1	TB1
BA2 - Applied Research (0602384BP)	CB2	TC2	TB2
BA3 - Advanced Technology Development (0603384BP)	CB3, CP3	TC3	TB3

The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of S&T efforts. The long term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (for example, how many breakthroughs in basic science were made last year.) However, using an approach similar to those used in the performance plans of other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation—there are a variety of qualitative and quantitative performance measures that may be used to demonstrate progress of S&T efforts towards outcomes, which fulfills the requirements of the GPRA.

The basic performance measure established for S&T efforts is the independent expert panel review. The CBRNDP has adopted this practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), has been conducted annually by the CBRNDP. The TARA panel provides a presentation of their findings and recommendations to the Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD.

3.1 CB DEFENSE S&T PLANNING

To ensure U.S. military preeminence in the long term, the Department must continue to focus investments on new generations of defense technologies. The Defense Science and Technology Strategy, with its supporting Basic Research Plan, Joint Warfighting Science and Technology Plan, and Defense Technology Area Plan, is the foundation of the science and technology (S&T) program. The Office of the Secretary of Defense, the Joint Staff, the military departments, and the defense agencies collaboratively develop the S&T program. Objectives of S&T planning are to:

- ensure projects support warfighter requirements,
- identify gaps in existing defense and commercial research,
- ensure collaborative planning and execution of the S&T program,

² Biological Warfare Defense programs funded under DARPA project BW-01 are not addressed in this performance plan except for those projects identified as Defense Technology Objectives.

- reduce undesired duplication of effort,
- provide the basis for independent expert panel reviews.

3.2 DOD CB DEFENSE SCIENCE AND TECHNOLOGY BASE PROGRAM

This section provides the objectives and metrics for the overall CB defense S&T program. An overall assessment is provided below. Actual and planned performance on specific projects is detailed in the following sections on S&T.

3.2.1 CB Defense Science and Technology Outcome Measure

CB Defense S&T is...	
...minimally effective when...	... successful when...
• All major commodity areas are rated GREEN and no sub-areas are rated RED by the TARA panel. • Research efforts contribute to increased knowledge regarding CB threats and science and technologies to defend against these threats. • Projects support goals and timelines stated in planning documents, specifically the <i>Joint Warfighting Science and Technology Plan</i> and the <i>Defense Technology Area Plan</i>.	• All commodity areas are rated GREEN by the TARA panel. • New capabilities are successfully demonstrated and transition to advanced development.

3.2.1.1 Metric Description. The metric for science and technology base projects is a qualitative assessment of the results of basic research, applied research, and advanced technology development compared to their intended purposes. This qualitative methodology for measuring the outcomes of the science and technology base is allowed by the GPRA (31 USC 1115(b)) as an alternative to the quantitative performance measures. The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of research efforts. The long term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (for example, how many breakthroughs in basic science were made last year.) This approach is similar to those used in the performance plans other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation. Qualitative performance measures are provided for each of the projects listed in table 1. Qualitative performance measures are assessed by an independent panel as well as by the accomplishment of specific project targets identified and detailed in each of the project areas below. The assessment includes an evaluation of the information provided to determine whether it is sufficient to allow for an accurate, independent determination of the program activity’s performance. An important element of the research efforts—especially for basic and applied research—is the evaluation and elimination of unsuccessful technologies. While not always identified as a specific target, the scientific method contributes to increased knowledge by eliminating efforts that will not contribute to project objectives.

3.2.1.2 Validation and Verification Methodology. The basic performance measure established for S&T efforts is the *independent expert panel review*.³ This is in keeping with White House guidance to ensure that independent assessments of research programs evaluate both the quality of programs and progress of research towards stated goals.⁴ The CBRNDP has

³ *Evaluating Federal Research Programs: Research and the Government Performance and Results Act*, Washington, D.C: National Academy Press, 1999.

⁴ See memorandum from The White House, Neal Lane and Jacob J. LE, “Follow-On Guidance for FY 2001 Interagency Research and Development Activities,” June 8, 2000.

adopted this practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), is conducted annually by the CBRNDP. The TARA panel provides a presentation of their findings and recommendations to Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD. **Table 2** provides a summary of the assessment of each of the commodity areas within the CBRNDP, and table 3 provides the assessment by the TARA Panel of each of the DTOs presented during the FY2003 review.

Table 2. 2003 TARA Assessment of CB Defense S&T Commodity Areas

CB Defense Science and Technology Commodity Area	TARA Rating
DETECTION	YELLOW
PROTECTION	GREEN
MEDICAL CHEMICAL DEFENSE	GREEN
MEDICAL BIOLOGICAL DEFENSE	YELLOW
DECONTAMINATION	GREEN
INFORMATION SYSTEMS TECHNOLOGY	GREEN

3.2.2 Assessment of CB Defense Science and Technology Outcome Measure

Overall, the DoD CBRNDP science and technology base has been effective. Most areas have been rated green by the TARA panel. In addition, there were several technologies that completed successful demonstrations over the past year, and as detailed in the following sections, there are several examples of technology transitions to advanced development.

3.3 DEFENSE TECHNOLOGY OBJECTIVES (DTOs)

The Department's commitment to transforming U.S. military forces requires robust and stable funding for the S&T program. S&T expenditures support basic research as well as focused investments guided by DTOs. DTOs provide a framework for S&T efforts by identifying:

- What specific technologies will be developed and/or demonstrated.
- What specific milestones are to be reached, using what approaches.
- Which customers will benefit.
- What specific benefits the customers will gain.
- What level of funding will be programmed and from what sources.
- What quantitative metrics will indicate progress.

Within the CBRNDP, DTOs fund approximately one-third of S&T efforts. DTOs are the building blocks of the defense S&T Program. They represent only high priority Service and Defense Agency programs, consistent with the Defense Planning Guidance and the Defense S&T Strategy. DTOs are one of the key S&T planning tools. They are used to assist in planning and programming S&T funds, they help in articulating key efforts and goals, and they provide a key performance measure for contribution of the S&T effort to warfighter needs. All updates, changes, and approvals of DTOs are made by the Defense Science and Technology Advisory Group (DSTAG), the senior S&T advisory body within the Department. Assessments of DTO performance are provided annually by the TARA.

The CBRNDP S&T efforts continue to demonstrate new capabilities for the warfighter. Progress of DTOs is shown in the following tables. Progress in other portions of S&T is shown in section 3.4. For FY2003, 58% of the DTOs were rated green, which was less than the target of

80%. Several factors contributed to these ratings, including: (1) pursuit of leading edge research, which included accepting technical risks on several projects, (2) aggressive scheduling of milestones by the DTO managers, and (3) more realistic assessment of costs, schedules, and technical performance by the TARA panel. The TARA Panel made specific recommendations on each of the DTOs that were not rated green, and they will review and assess these efforts in FY2004.

Table 3. Status of Defense Technology Objectives as Rated by the Chemical and Biological Defense Technology Area Review and Assessment

	FY2003		FY2004	FY2005
	Goal	Actual	Goal	Goal
Percent of DTOs Rated Green (on track)	80	58	80	80
Total Number of DTOs	25 of 31	18 of 31	18 of 31*	

* Thirteen CBD DTOs were rated as yellow [Y] and none as red [R].

Table 4. 2003 TARA Rating of Chemical and Biological Defense DTOs

DTO No.	DTO Title	TARA Rating
CB.08	Advanced Absorbents for Protection Applications	GREEN
CB.20	Automated Genetic Identification	GREEN
CB.24	Medical Countermeasures for Encephalitis Viruses	YELLOW
CB.27	Therapeutics Based on Common Mechanisms of Pathogenesis	GREEN
CB.30	Medical Countermeasures for Vesicant Agents II	YELLOW
CB.31	Medical Countermeasures for Brucellae	YELLOW
CB.32	Alternative Delivery Methods for Recombinant Protein Vaccines	GREEN
CB.34	Recombinant Plague Vaccine Candidate	YELLOW
CB.35	Standoff Biological Aerosol Detection	YELLOW
CB.36	Universal End-of-Service-Life Indicator for NBC Mask Filters	GREEN
CB.37	CB Agent Water Monitor	YELLOW
CB.38	Activity-Based Detection and Diagnostics	GREEN
CB.40	Immune Building Program	GREEN
CB.42	Environmental Fate of Agents	YELLOW
CB.43	Chemical and Biological Warfare Effects on Operations	GREEN
CB.44	Oxidative Formulation	GREEN
CB.45	Self-Detoxifying Materials for CB Protective Clothing	GREEN
CB.46	Recombinant Ricin Vaccine	GREEN
CB.47	Improved Immunodiagnostic Platform	GREEN
CB.48	Improved Oxime	GREEN
CB.49	Integrated CB Standoff Detector	YELLOW
CB.50	Lightweight Integrated CB Detection	YELLOW
CB.51	Low-Level CW Agent Exposure: Effects and Countermeasures	GREEN
CB.52	Detection of CB Contamination on Surfaces	YELLOW
CB.53	Wide-Area Aerial Reconnaissance for Chemical Agents	YELLOW
CB.54	Therapy for Smallpox and other Pathogenic Orthopoxviruses	GREEN
CB.55	Chemical and Biological Hazard Environment Prediction	YELLOW
BE.10	High-Resolution Meteorological Nowcasting for CB Hazard Prediction	GREEN
I.08	CB Warfare Agent Screening and Analysis	GREEN
I.09	Portable Isotopic Neutron Spectroscopy (PINS)	GREEN
L.07	Terrorist CB Countermeasures	YELLOW

3.3.1.1 Metric Description. Table 4 lists specific DTOs assessed during 2003. Detailed descriptions of these DTOs are found in The DoD CBRNDP Annual Report to Congress, Annexes A–E. Each DTO is reviewed annually by an independent peer review panel, called the Technology Area Review and Assessment (TARA) panel. The goal is to have at least 80% of the DTOs rated green. The total number of DTOs varies per year based on new DTO assignments and completion of DTO efforts. Total DTO funding varies per year and may represent between 25%–50% of total science and technology base funds. During the 2003 TARA, 13 CBD DTOs were rated as yellow and none as red. Table 5 provides a summary explanation DTOs or technology areas listed in Tables 2 and 3 that were not rated green.

Table 5. Summary of Explanations for Selected 2003 TARA CB Defense DTOs

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.24 Medical Countermeasures for Encephalitis Viruses	YELLOW	•Strengths: –Persistent in working towards a single vaccine candidate with the promise of transitioning V3526 to the JVAP. –Excellent outcome regarding safety and efficacy of vaccine candidate. –Protects in rodents and NHPs in the aerosol model. •Finding: –Projects have not progressed to the point that a full Technical Data Package (TDP) to FDA will be delivered within the milestones. There is a lack of success in transition planning in the area of vaccine research. Recommendation: If follow-on DTOs are proposed, the data requirements must be based on discussions with JPEO-CBD, JRO-CBRN, and FDA, and achievable milestones set.
CB.30 Medical Countermeasures for Vesicant Agents II	YELLOW	•Strengths: –Making progress with relatively common anti-inflammatories. –Good results for the mouse ear vesicant model (MEVM) with some candidates. –Initiated transition package (data). –Funds set aside for safety testing. –Responsive to 2002 TARA recommendations. •Finding: –Appears to be insufficient time remaining to complete a TDP milestone given the number of candidates remaining to be down-selected. Recommendation: If countermeasures for the vesicant threat are proposed as a follow-on DTO, the data set requirements must be based on discussions with JRO-CBRN, JPEO-CBD, and FDA, and achievable milestones set.
CB.31 Medical Countermeasures for Brucellae	YELLOW	•Strengths: –Good findings. –Re-scoped effort per 2002 TARA recommendations. •Finding: –Projects have not progressed to the point that a full Technical Data Package (TDP) to FDA will be delivered within the milestones. There is a lack of success in transition planning in the area of vaccine research. Recommendation: If follow-on DTOs are proposed, the data requirements must be based on discussions with JPEO-CBD, JRO-CBRN, and FDA, and achievable milestones set.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.34 Recombinant Plague Vaccine Candidate	YELLOW	•Strengths: –Good basis for choice of vaccine with lots of results to back-up the conclusions. –Prevents distribution from lungs, but still major problems with lesions in lungs. –Sharing resources with the UK on the development of surrogate marker assays. –Focusing on aerosolized form of inhalational plague based on advice from 2002 TARA. •Finding: –Projects have not progressed to the point that a full Technical Data Package (TDP) to FDA will be delivered within the milestones. There is a lack of success in transition planning in the area of vaccine research. Recommendation: If follow-on DTOs are proposed, the data requirements must be based on discussions with JPEO-CBD, JRO-CBRN, and FDA, and achievable milestones set.
CB.35 Standoff Biological Aerosol Detection	YELLOW	•Strengths: –Extensive down-select that encompasses both passive and active technologies over two spectral bands (MWIR and LWIR). –Numerous collaborations with DoD partners, academia, and DOE laboratories. •Finding: –Performance parameters for technologies to address standoff and integrated detection applications derive from a complex set of physical and biological characteristics, and operational scenarios. Simple technology down-selection processes (e.g., voting by experts) is insufficient in the absence of robust understanding of the trade space. Recommendation: Use modeling to define and optimize performance parameters within the applicable trade spaces, and adjust DTOs in the next fiscal year, as necessary, to accommodate the outcomes of the modeling analysis.
CB.37 CB Agent Water Monitor	YELLOW	•Strengths: –Ambitious, numerous, and challenging goals. –Results show progress. –Collaborating and leveraging related efforts through the tech base, Congressional plus-ups, and others. –Good that the effort is looking at expected hydrolysis products rather than just the agents. •Finding: –Schedule does not support adequate time to complete DTO with so many options still remaining. Recommendation: Program manager should adopt, immediately, a stringent selection approach in consultation with JRO-CBRN.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.49 Integrated CB Standoff Detector	YELLOW	•Strengths: –Good approach using real agents and simulants for algorithm evaluation. –Tunable option to provide more robustness, but it does add complexity. –Attention is being paid to the decontamination protocol of the windowless chamber between virus tests to ensure data is not compromised. •Finding: –Performance parameters for technologies to address standoff and integrated detection applications derive from a complex set of physical and biological characteristics, and operational scenarios. Simple technology down-selection processes (e.g., voting by experts) is insufficient in the absence of robust understanding of the trade space. Recommendation: Use modeling to define and optimize performance parameters within the applicable trade spaces, and adjust DTOs in the next fiscal year, as necessary, to accommodate the outcomes of the modeling analysis.
CB.50 Lightweight Integrated CB Detection	YELLOW	•Strengths: –Appropriate goal in combining chemical with biological point sensor. –Good mix of technologies being explored, with some promising candidates. –Commitment to user views when deciding on parameters, metrics, and addressing the tradespace. –Multi-lab collaborations with DoD, academia, DOE, and international partners. •Finding: –Performance parameters for technologies to address standoff and integrated detection applications derive from a complex set of physical and biological characteristics, and operational scenarios. Simple technology down-selection processes (e.g., voting by experts) is insufficient in the absence of robust understanding of the trade space. Recommendation: Use modeling to define and optimize performance parameters within the applicable trade spaces, and adjust DTOs in the next fiscal year, as necessary, to accommodate the outcomes of the modeling analysis.
CB.52 Detection of CB Contamination on Surfaces	YELLOW	•Strengths: –Down-selection process is logical, clearly presented, and well underway. –Sensitive to operational concerns. •Finding: –Performance parameters for technologies to address standoff and integrated detection applications derive from a complex set of physical and biological characteristics, and operational scenarios. Simple technology down-selection processes (e.g., voting by experts) is insufficient in the absence of robust understanding of the trade space. Recommendation: Use modeling to define and optimize performance parameters within the applicable trade spaces, and adjust DTOs in the next fiscal year, as necessary, to accommodate the outcomes of the modeling analysis.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.53 Wide-Area Aerial Reconnaissance for Chemical Agents	YELLOW	•Strengths: –Strong start on a new DTO effort which builds on the successes of DTO CB.19 (Chemical Imaging Sensor). –Fundamental concept is sound, potentially valuable, and meets a priority need. •Finding: –Performance parameters for technologies to address standoff and integrated detection applications derive from a complex set of physical and biological characteristics, and operational scenarios. Simple technology down-selection processes (e.g., voting by experts) is insufficient in the absence of robust understanding of the trade space. Recommendation: Use modeling to define and optimize performance parameters within the applicable trade spaces, and adjust DTOs in the next fiscal year, as necessary, to accommodate the outcomes of the modeling analysis.
CB.55 Chemical and Biological Hazard Environment Prediction	YELLOW	•Strengths: –Very important work that needs to be done. –Good overall goals that addresses both open and urban environments. –Joint operational requirement. •Finding: –Significant technical risk due to need for relevant datasets and validation approaches for varied urban environments.
L.07 Terrorist CB Countermeasures	YELLOW	•Strengths: –Small CAD will use one unit to sample for CBW and TIC vapors in the presence of interferents, on surfaces, in air, and using swabs. –Biological Agent Mass Spectroscopy (BAMS) will be time-gated to discriminate the background. •Finding: –Significant technical challenges for BAMS in the areas of pathogen libraries, adequate robust testing in realistic environments such that both schedule and budget are at risk. Recommendation: Coordinate with existing mass spectrometer-based biological material identification programs across DoD S&T programs. Empanel an independent Scientific Steering Group to advise on technical matters related to pathogen biology and testing protocols.

3.3.1.2 V&V Methodology. Each TARA team includes about ten members, including experts from outside the Department. The non-DoD members include experts in relevant fields from other U.S. government agencies, private industry, and academia. The TARA team assesses DTOs in terms of three factors—budget, schedule, and technical performance—and assign the programs a Red, Yellow, or Green rating based on how well they are progressing toward their goals. The assessment of technical performance includes a qualitative assessment of how risk is managed, especially for innovative or leading edge research that may involve high technical risk. This method of peer review is accepted and endorsed by the S&T stakeholders. Adjustments are made to program plans and budgets based on the ratings awarded. The following criteria are used in assigning ratings:

- Green – Progressing satisfactorily toward goals.
- Yellow – Generally progressing satisfactorily, but some aspects of the program are proceeding more slowly than expected.
- Red – Doubtful that any of the goals will be attained.

The DTO ratings are semi-quantitative metrics, reflecting the opinions of independent experts. The DTOs contain quantitative metrics, which provide a basis for determining progress of that effort towards a warfighter payoff.

3.4 BASIC RESEARCH (PROGRAM ELEMENT 0601384BP)

This program element (PE) funds the Joint Service core research program for CB defense (medical and non- medical). The basic research program aims to improve the operational performance of present and future DoD components by expanding knowledge in relevant fields for CB defense. Moreover, basic research supports a Joint Force concept of a lethal, integrated, supportable, highly mobile force with enhanced performance by the individual soldier, sailor, airman, or marine. Specifically, the program promotes theoretical and experimental research in the chemical, biological, medical, and related sciences. Research areas are determined and prioritized to meet Joint Service needs as stated in mission area analyses and Joint operations requirements, and to take advantage of scientific opportunities. Basic research is executed by academia, including Historically Black Colleges and Universities and Minority Institutions (HBCU/ MIs), and government research laboratories. Funds directed to these laboratories and research organizations capitalize on scientific talent, specialized and uniquely engineered facilities, and technological breakthroughs. The work in this program element is consistent with the Joint Service Nuclear, Biological, and Chemical (NBC) Defense Research, Development, and Acquisition (RDA) Plan. Basic research efforts lead to expeditious transition of the resulting knowledge and technology to the applied research (PE 0602384BP) and advanced technology development (PE 0603384BP) activities. This project also covers the conduct of basic research efforts in the areas of real- time sensing and diagnosis and immediate biological counter-measures. The projects in this PE include basic research efforts directed toward providing fundamental knowledge for the solution of defense- related problems and new- improved military capabilities, and therefore, are correctly placed in Budget Activity 1.

3.4.1 CB Defense Basic Research (Project CB1)

This project funds basic research in chemistry, physics, mathematics, life sciences, and fundamental information in support of new and improved detection technologies for biological agents and toxins; new and improved detection technologies for chemical threat agents; advanced concepts in individual and collective protection; new concepts in decontamination; and information on the chemistry and toxicology of threat agents and related materials.

3.4.1.1 CB1 Performance Goal (Outcome). The goal of the CB defense non-medical basic research program is to increase scientific understanding of the mechanisms and processes involved in the detection, protection against, and decontamination of chemical and biological warfare agents.

3.4.1.2 CB1 Outcome Measure

CB1 is minimally effective when	CB1 is successful when
- The results provide fundamental information in support of new and improved defensive systems, including information on – biosensors, – aerosol sciences, – chemistry and toxicology of bioactive compounds, – thin film technology development, – integrated detection of energetic and hazardous materials, – optical recognition technologies,	Information, technologies, or processes are transitioned to applied research or advanced technology development

CB1 is minimally effective when	CB1 is successful when
– biological point detection, – protection, – decontamination, – simulants, – information technology • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	

3.4.1.3 CB1 Actual and Planned Performance

FY2003 Targets	Actual Performance
<u>Biological Detection</u> - Continue investigations of novel technologies to rapidly and definitively detect and identify BW simulants and agents in environmental matrices. Initiate new effort based on light scattering approach.	<u>Biological Agent Identification Detection</u> - Initiated experimental apparatus to evaluate a novel optical signature called Polarization Opposition Effect (POE) for use as a bacterial spore particle (aerosol) discriminator. Initiated synthesis of candidate stochastic sensor elements based on biotinylated oligosaccharides; initiated screening testing. Completed validation of experimental apparatus. Demonstrated optical separation of similar bacterial species. Initiated investigations of micro-channel mixing via configurable heating and surfaces.
<u>Chemical Detection</u> - Continue efforts to detect CW agents using solid-state nano-arrays and analysis of degradation products.	<u>Chemical Stand-off Detection</u> - Initiated investigations of the applicability of new techniques to the analysis of hyperspectral Fourier transform infrared data. Initiated investigations of a novel two-photon fluorescence spectroscopy method and potential applicability to stand-off CB detection.
<u>New Detection Technologies</u> – Initiate research on methods of combining chemical and biological agent detection on surfaces into one device. Include a variety of spectroscopic techniques focusing on portions of the electromagnetic spectrum not previously utilized for CB agent detection	<u>Integrated CB Detection</u> - Initiated proof of principle investigations of novel materials for selective interactions with CW agent simulants in conjunction with optical (liquid crystal) amplification to enhance detection. Continued investigations of surface modified gold nanoclusters for detection of CW agents. <u>Detection of Chemical and Biological Pollutant Agents in Water</u> - Initiated development of advanced wide bandgap piezoelectric semiconductors and micro machined sensing structures. Initiated development of and immobilized phages/antibodies as specific sensing elements. Initiated evaluation of test bed sensors for real time detection.
<u>Decontamination</u> - Complete investigations of environmentally benign decontamination materials based on peroxy carbonates; transition to development program. Initiate new efforts to develop advanced decontamination materials to allow treatment of sensitive equipment, phase transfer materials, and solution chemistry.	<u>Solution Decontamination</u> - Initiated investigations of and developed methodology for determination of the chemical structure semi-solid materials with absorbed CB agents. Initiated studies of the decontamination mechanism of secondary catalytic oxidants generated by the addition of monovalent salts to a peracid-dioxirane. Initiated investigations of the efficacy of artificial nucleases for anti-bacterial and anti-viral activity. Initiated investigations of the utility of high-field Nuclear Magnetic Resonance (NMR) methodology in conjunction with tandem mass spectrometry to determine structures of biologically derived toxins. Continued investigations of chemical strategies designed for fast dissolution and deactivation/destruction of CW agents rapidly in organic nanoemulsions.

FY2003 Targets	Actual Performance
	<u>Sensitive Equipment Decontamination</u> - Initiated investigation of efficacy of vaporous dimethyl dioxirane for decontamination of BW agents. <u>Nanoemulsions for Decontamination</u> - Developed and validated the efficacy of nanoemulsions for the purpose of decontaminating biological threat agents. The nano-emulsion can be formulated into a cream, liquid, or spray.
<u>Information Technology</u> - Continue efforts to directly couple information into warning system by neural coupling.	
<u>Protection</u> - Continue investigations of self-assemblies for protective materials. Initiate effort to investigate agent interactions with microporous surfaces at the molecular level using Magic-Angle Spinning Nuclear Magnetic Resonance (MAS-NMR) spectrometry, Xray Photoelectron Spectroscopy (XPS), and thermal desorption methods.	<u>Respiratory Protection</u> Initiated theoretical and empirical studies related to the physical and chemical interactions of vapors with surfaces. Individual Protection (Clothing) - Initiated use of patterned electrospray of nanofibers to enhance particulate protection. Continued investigations of surface-modified membranes and measurement of differential permeation rates for chemical vapors and water vapor. <u>Chemical Warfare Protection Research Project</u> Purchased a state-of-the-art mass spectrometer. The sensitive instrument was used to accurately identify minute quantities of biomarkers from exposures to nerve agents, as well as biomarkers of other organophosphates that inhibit nerve signal transmission. Until recently, the only biomarkers indicating exposure to nerve agents are enzymes known as cholinesterases. However, recent research indicates certain proteins also react with nerve agents. Research on the proteins and their respective mechanisms could lead to an improved prophylaxis for nerve agents
<u>Supporting Science</u> - Continue investigations of the behavior of CW agents and simulants under ambient environmental conditions. Make available preliminary volatility and environmental adsorption data to Applied Research efforts for the Agent Fate program.	<u>Chemical Threat Agents</u> Investigated simulant volatility in humidified air.
	<u>Agroterrorist Attack Response</u> - Studied simulated response to a virus introduced into livestock

3.4.1.4 CB1 Future Targets

FY 2004 Targets	FY 2005 Targets
<u>Biological Agent Identification Detection</u> Complete proof of principle experimentation; complete theoretical correlations to experimental data for POE. Continue synthesis of candidate stochastic sensor elements; continue screening testing. Demonstrate proof of principle for separation of BW agent surrogates. Complete initial investigations of the relationships between physical-chemical properties and optical separation of biological agent simulants. Continue investigations of micro-channel mixing via configurable heating and surfaces by comparison of data and model prediction. Initiate investigations of antimicrobial peptides for applicability as bio-detection elements; initiate testing program. Initiate effort to characterize polymorphic regions of B. mallei genome using ribotyping, repetitive sequence polymerase chain reaction, and	<u>Biological Agent Identification Detection</u> Complete testing of candidate ion channel stochastic sensor elements. Complete investigations of micro-channel mixing via configurable heating and surfaces. Complete development of test articles and procedures. Continue testing of antimicrobial peptides. Continue effort to characterize polymorphic regions of B. mallei genome using ribotyping, repetitive sequence polymerase chain reaction, and randomly amplified polymorphic DNAs.

FY 2004 Targets	FY 2005 Targets
Randomly Amplified Polymorphic DNAs.	
<u><i>Chemical Stand-off Detection</i></u> Complete investigations of the applicability of new techniques to the analysis and processing hyperspectral Fourier Transform Infrared data. Complete investigations of novel two-photon fluorescence spectroscopy method and potential applicability to stand-off CB detection. Transition to BA2 as appropriate	
<u><i>Integrated CB Detection</i></u> Complete proof of principle investigations of novel materials for selective interactions with CW agent simulants in conjunction with optical amplification to enhance detection. Complete investigations of surface modified gold nanoclusters for detection of CW agents. Initiate investigations of modified nanofilaments for detection of CB warfare agents.	<u><i>Integrated CB Detection</i></u> Complete investigation of modified nanoelectrodes for the detection of CB agents. Initiate novel approaches for improved CB detection as appropriate
	<u><i>Information Systems Technology</i></u> Initiate basic research effort(s) in support of information systems technology.
<u><i>Individual Protection (Clothing)</i></u> Evaluate effectiveness of nanofiber-coated fabrics for protection against particulate materials. Complete investigations of surface modified membranes. <u><i>Respiratory Protection</i></u> Complete theoretical and empirical investigations of the mechanisms of interactions of vapors with active surfaces. <u><i>Shelter Protection</i></u> Initiate investigations of the interrelationships between the chemical, physical, and transport properties of novel butyl rubber membranes prepared by electrospinning.	<u><i>Respiratory Protection</i></u> Initiate research into understanding physical adsorption processes for toxic industrial chemicals and CW agents on novel adsorbent materials. <u><i>Shelter Protection</i></u> Continue investigations of the interrelationships between the chemical, physical, and transport properties of novel butyl rubber membranes prepared by electrospinning.
<u><i>Solution Decontamination</i></u> Complete feasibility studies for determination of semi-solid materials chemical composition with absorbed CB agents. Complete studies of the decontamination mechanism of secondary catalytic oxidants generated by the addition of monovalent salts to a peracid-dioxirane. Complete investigations of the efficacy of artificial nucleases for anti-bacterial and anti-viral activity. Complete investigations of the utility of high-field NMR methodology in conjunction with tandem mass spectrometry to determine structures of biologically derived toxins. Complete investigations of chemical strategies designed for dissolution and deactivation/destruction of CW agents rapidly in organic nanoemulsions. <u><i>Sensitive Equipment Decontamination</i></u> Complete investigation of efficacy of vaporous dimethyl dioxirane for decontamination of BW agents.	<u><i>Decontamination</i></u> Initiate novel research efforts with potential for advanced agent decontamination capability.
<u><i>Chemical Threat Agents</i></u> Investigate CW agents volatility in humidified air.	<u><i>Chemical Threat Agents</i></u> Continue investigations of thickened CW agent volatility in humidified air.

3.4.1.5 Assessment of CB Defense Basic Research. Basic research efforts in FY2003 for project CB1 are effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several

new research projects were initiated in FY2003. (Also, Congressionally directed programs were successfully executed during FY2003.) Some research efforts successfully transitioned to applied research. Examples of basic research accomplishments include, (1) providing information on the ambient volatility of neat and thickened chemical warfare agents as a function of relative humidity and ambient temperature, and (2) demonstrate a novel strategy for an integrated CB detector (using cavitands and liquid crystals) that simultaneously achieve high specificity, sensitivity, rapid response for integrated CB point detectors.

3.4.2 Medical Biological Defense Basic Research (Project TB1)

This project funds basic research on the development of vaccines and therapeutic drugs to provide effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. This project also funds basic research employing biotechnology to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include current science and technology program areas in medical biological defense diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines) and directed research efforts.

3.4.2.1 TB1 Performance Goal (Outcome). The goal of medical biological defense basic research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of diseases caused by biological warfare (BW) agents, and the preventive, therapeutic, and diagnostic sciences underlying the technologies to counter these threats.

3.4.2.2 TB1 Outcome Measure

TB1 is minimally effective when	TB1 is successful when
- The results provide fundamental information in support of new and improved defensive systems, including information on – Bacterial Therapeutics, – Bacterial Vaccines, – Toxin Therapeutics, – Toxin Vaccines, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, – Laboratory-based and Analytical Threat Assessment Research. - The results of research are published in peer-reviewed journals or presented at scientific conferences - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.2.3 TB1 Actual and Planned Performance

FY2003 Targets	Actual Performance
<u>Diagnostic Technologies</u> - Conduct basic research on new diagnostic approaches to the early recognition of infection; develop reagents and associated assays to aid in identifying new host and agent-specific biological markers that can be used for early recognition of infection. Continue research to develop, evaluate, and explore new technological approaches for diagnosis of potential biological warfare threat agents and for concentrating and processing clinical samples to support rapid identification and diagnostics.	<u>Diagnostic Technologies</u> - Conducted basic research on new diagnostic approaches to the early recognition of infection; developed reagents and associated assays to aid in identifying new host and agent-specific biological markers that can be used for early recognition of infection. Continued research to develop, evaluate, and explore new technological approaches for diagnosis of potential biological warfare threat agents and for concentrating and processing clinical samples to support rapid identification and diagnostics.

FY2003 Targets	Actual Performance
<u>Therapeutics, Anthrax studies</u> - Continue extramural research efforts toward the development and testing of new approaches for the treatment of inhalational anthrax. Focus will continue on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on an enzyme target, NADs, which is critical for the germination and vegetative life cycle of B. anthracis.	<u>Therapeutics, Anthrax Studies</u> - Continued extramural research efforts toward the development and testing of new approaches for the treatment of inhalational anthrax. Focus continued on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on the enzyme target nicotinamide adenine dinucleotide (NAD), which is critical for the germination and vegetative life cycle of Bacillus anthracis, the etiologic agent for anthrax.
<u>Therapeutics, Bacterial</u> - Correlate metabolic measurements as a rapid and sensitive means to detect antibiotic activity with conventional susceptibility determinations and appropriate animal models of infection. Establish collaborative research and development agreements with pharmaceutical companies to test new and investigational antibiotics. Initiate evaluation of selected therapeutic compounds against Brucella.	<u>Therapeutics, Bacterial</u> - Correlated metabolic measurements as a rapid and sensitive means to detect antibiotic activity with conventional susceptibility determinations and appropriate animal models of infection. Established collaborative research and development agreements with pharmaceutical companies to test new and investigational antibiotics. Initiated evaluation of selected therapeutic compounds against Brucella.
	<u>Medical BW Defense, Engineered Pathogen Identification and Countermeasures Program</u> - Identified the impact of biowarfare pathogens on the human body using computer models and direct protein analysis. Developed counteracting drugs based on a comprehensive understanding of how the potential drug candidates impact the human body, outside of their desired effect against the pathogen.
<u>Therapeutics, Toxin</u> - Identify novel human and chimeric monoclonal antibodies by phage display methodology to aid in determining potential as botulinum neurotoxin therapeutics. Perform custom synthesis of lead compounds identified by high-throughput screening assays for botulinum neurotoxin and SE toxins. Co-crystallize toxin and lead therapeutics and collect x-ray diffraction datasets. Support development of combinatorial libraries and diversity sets for potential toxin therapeutics.	<u>Therapeutics, Toxin</u> - Identified novel human and chimeric monoclonal antibodies by phage display methodology to aid in determining potential as botulinum neurotoxin therapeutics. Performed custom synthesis of lead compounds identified by high-throughput screening assays for botulinum neurotoxin and staphylococcal enterotoxins (SE). Co-crystallized toxin and lead therapeutics and collected x-ray diffraction datasets. Supported development of combinatorial libraries and diversity sets for potential toxin therapeutics. <u>Therapeutics, Toxin, Bioprocessing Facility</u> Developed a detailed design for the construction of a current Good Manufacturing Practice (cGMP) compliant facility capable of producing human monoclonal antibodies (MAbs) to botulinum neurotoxins (BoNT) for use in phase I clinical trials.
<u>Therapeutics, Viral</u> - Initiate development of intervention strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Continue research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target.	<u>Therapeutics, Viral</u> - Initiated development of intervention strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Further characterized the innate immune response in mice, which indicated that a subset of cytokines can protect mice from lethal Ebola virus challenge. Continued research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target. Developed an assay for high-throughput

FY2003 Targets	Actual Performance
	interaction between Ebola virus proteins (VP40 and TSG101). Completed sequencing of Marburg and Ebola virus strains and isolates..
<u><i>Vaccines, Bacterial</i></u> - Develop mutations in various biological agents for in vivo expressed genes to examine role in virulence. Characterize the mechanism(s) of vaccine resistance in selected strains of various biological agents. Determine mechanisms and correlates of protection with efficacious <i>B. mallei</i> vaccines. Evaluate differences in the course of brucella infection in different mouse strains. Test multiagent vaccine constructs for immunogenicity in animal models. identify strains of various agents that may be resistant to existing vaccines and/or those under advanced development.	<u><i>Vaccines, Bacterial</i></u> - Developed mutations in various biological agents for in vivo expressed genes to examine role in virulence. Characterized the mechanism(s) of vaccine resistance in selected strains of various biological agents. Determined mechanisms and correlates of protection with efficacious <i>Burkholderia mallei</i> vaccines. Evaluated differences in the course of <i>Brucella</i> infection in different mouse strains. Tested multiagent vaccine constructs for immunogenicity in animal models.
<u><i>Vaccines, Toxin</i></u> - Compare the efficacy of constructs with neutralizing epitopes in other domains of botulinum neurotoxin serotypes with the current heavy chain (Hc) subunit toxin vaccine candidates.	<u><i>Vaccines, Toxin</i></u> Compared the efficacy of constructs with neutralizing epitopes in other domains of botulinum neurotoxin serotypes with the current heavy chain (Hc) subunit toxin vaccine candidates.
<u><i>Vaccines, Viral</i></u> - Complete investigating poxvirus immunity to determine the feasibility of replacing VIG with monoclonal antibodies and constructing a new vaccine to replace the vaccinia virus vaccine. Investigate the role of cytotoxic T cells in the Ebola virus-mouse model.	<u><i>Vaccines, Viral</i></u> Completed investigating poxvirus immunity to determine the feasibility of replacing vaccinia immune globulin (VIG) with monoclonal antibodies and for constructing a new vaccine to replace the vaccinia virus vaccine for smallpox. Investigated the role of cytotoxic T cells in the Ebola virus-mouse model.

3.4.2.4 TB1 Future Targets

FY 2004 Targets	FY 2005 Targets
<u><i>Diagnostic Technologies</i></u> Continue basic research on new diagnostic approaches to the early recognition of infection focusing on technologies compatible with future comprehensive integrated diagnostic systems. Continue to develop reagents and assays for appropriate biological markers for early recognition of infection and identify new host and agent-specific biological markers. Continue research directed toward new technological approaches for diagnosis of biological threat agents and new sample processing technologies.	<u><i>Diagnostic Technologies</i></u> Continue research on diagnostic approaches for early recognition of infections compatible with future comprehensive integrated diagnostic systems; continue to develop and identify new host and agent-specific biological markers that can be used for early recognition of infection. Continue research directed toward new technological approaches for diagnosis of biological threat agents and toward concentrating and processing clinical samples to support rapid diagnostics.
<u><i>Therapeutics, Bacterial</i></u> Evaluate novel lead antimicrobial compounds in small animal models for anthrax and plague.	<u><i>Therapeutics, Bacterial</i></u> Perform expanded in vivo studies on novel antimicrobial compounds against validated biological warfare threat agents.
<u><i>Therapeutics, Toxin</i></u> Continue custom synthesis of structural analogs of lead compounds identified by high-throughput screening assays for botulinum and SE toxins. Refine x-ray data for toxin-inhibitor co-crystal structures of most promising botulinum neurotoxin and SE inhibitors. Perform computational chemistry studies to refine lead compound co-crystal structures.	<u><i>Therapeutics, Toxin</i></u> Evaluate experimental neuronal drug delivery systems for lead botulinum neurotoxin treatment modalities in vitro and ex vivo. Explore theoretical feasibility of a single therapeutic to target multiple botulinum neurotoxin serotypes.
<u><i>Therapeutics, Viral</i></u> Continue research for development of intervention	<u><i>Therapeutics, Viral</i></u> Continue research for development of intervention

FY 2004 Targets	FY 2005 Targets
strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Complete research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target. Generate baculovirus-expressed Ebola virus proteins for use in research studies. Identify sequences within Ebola virus genes that are highly susceptible to short interfering RNA-mediated degradation.	strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Test antiviral compounds in rodent models. Utilize in vitro assays based on filovirus polymerase to screen potential antiviral drugs. Screen functional knockout libraries with virus-like particles and live virus to identify pathogenicity determining factors. Engineer heterologous viruses to express Ebola virus-specific short interfering RNAs and assess their ability to inhibit Ebola virus replication in tissue culture.
<u><i>Vaccines, Bacterial</i></u> Continue studies on the molecular mechanisms of pathogenesis of selected BW threat agents. Identify additional virulence determinants of Brucella species. Initiate a study to identify and characterize novel virulence proteins of F. tularensis.	<u><i>Vaccines, Bacterial</i></u> Continue to characterize novel virulence genes and gene products of selected bacterial threat agents to support discovery of new medical countermeasures.
<u><i>Vaccines, Toxin</i></u> Conduct computational chemistry studies to develop next generation botulinum neurotoxin and recombinant ricin toxin A-chain (rRTA) vaccines. Evaluate theoretical feasibility of multivalent vaccines by protein engineering. Evaluate the role of glycosylation or other structural modifications in reducing efficacy of botulinum neurotoxin vaccines.	<u><i>Vaccines, Toxin</i></u> Clone and express chimeric constructs to evaluate practical feasibility of multivalent toxin vaccines by protein engineering.
<u><i>Vaccines, Viral</i></u> Complete investigating the role of cytotoxic T cells in the Ebola virus-mouse model. Examine the use of virus-like particles (VLP) as antigen for vaccines for filoviruses. Initiate research to investigate the role of cytotoxic T cells in the filovirus model in non-human primates.	<u><i>Vaccines, Viral</i></u> Continue investigating the role of cytotoxic T cells in the higher animal model of filovirus infection. Continue development of animal models of aerosol infection with filoviruses. Continue evaluation of the use of virus-like particles (VLP) as antigens for vaccines for filoviruses.
<u><i>Vaccines, Plant Vaccine Development</i></u> Develop plant-based subunit vaccines as countermeasures against biological warfare agents.	
<u><i>Vaccines, Plant Derived Vaccine Against Anthrax and Smallpox</i></u> Develop plant-based subunit vaccines against anthrax and smallpox as countermeasures against agents of biological warfare. Express both proposed vaccines in edible plants using a constitutive expression system based on transgenic plants. Express in spinach functionally important epitopes of the anthrax recombinant Protective Antigen (rPA) and the B5R protein of the smallpox virus, using a transient expression system based on plant virus vectors. Evaluate immunogenicity of plant-based vaccines in animal models.	

3.4.2.5 Assessment of Medical Biological Defense Basic Research. Basic research efforts in FY2003 for project TB1 are at least minimally effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2003.

3.4.3 Medical Chemical Defense Basic Research (Project TC1)

This project emphasizes understanding of the basic action mechanisms of nerve, blister (vesicating), blood, and respiratory agents. Basic studies are performed to delineate mechanisms and sites of action of identified and emerging chemical threats to generate required information for initial design and synthesis of medical countermeasures. In addition, these studies are further designed to maintain and extend a science base. Categories for this project include science and technology program areas (Nerve Agent Defense, Vesicant Agent Defense and Chemical Warfare Agent (CWA) Defense) and directed research efforts (Low Level CWA Exposure and Non-Traditional Agents).

3.4.3.1 TC1 Performance Goal (Outcome). The goal of medical chemical defense basic research is to increase scientific understanding of the mechanisms, processes, and effects of chemical warfare (CW) agents and the science involved in the detection, protection against, and decontamination of CW agents.

3.4.3.2 TC1 Outcome Measure

TC1 is minimally effective when	TC1 is successful when
- The results provide fundamental information in support of new and improved defensive systems, including information on – Toxicology of exposures to low levels of CW agents, – Pretreatments for chemical agent exposures, – Therapeutics for chemical agent exposures, – Non-traditional agents. - The results of research are published in peer-reviewed journals or presented at scientific conferences - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.3.3 TC1 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<i>Pretreatments</i> - Target mechanism of vesicant injury and explore intervention of pro-inflammatory mediators and calcium modulators. Investigate efficacy of sulfur donors as anti-cyanide pretreatments. Develop animal model to test cyanide pretreatment compounds. Express and purify a recombinant human CaE for crystallization. Evaluate circulatory stability of recombinant bioscavengers.	<i>Nerve Agent Defense, Biological Scavengers</i> Expressed and purified a recombinant human carboxylesterase for crystallization. Evaluated circulatory stability of recombinant bioscavengers. <i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i> Targeted mechanism of vesicant injury and explored intervention of pro-inflammatory mediators and calcium modulators. Conducted proteomic analysis of sulfur mustard toxicity. <i>CWA Defense, Cyanide Medical Countermeasures</i> Investigated efficacy of sulfur donors as anti-cyanide pretreatments. Developed animal model to test cyanide pretreatment compounds.
<i>Therapeutics</i> - Incorporate biomarker panels into screening modules. Evaluate combination therapies for neuroprotection efficacy. Evaluate antidotes representing new strategies to improve medical countermeasures against conventional and emerging agents.	<i>CWA Defense, Inhalation Therapeutics</i> Assessed respiratory dynamics and lung biochemical function in male and female guinea pigs following exposure to CWAs. <i>Nerve Agent Defense, Nerve Agent Anticonvulsants</i> Evaluated antidotes representing new strategies to address medical countermeasure requirements against conventional and emerging agents. <i>Nerve Agent Defense, Neuroprotection</i> Evaluated combination therapies for neuroprotection efficacy. Developed neurobehavioral assessment necessary to evaluate

FY2003 Targets	Actual Performance
	efficacy of neuroprotective therapies.
<u><i>Diagnostics</i></u> - Conduct electrophysiological analysis of CWAs in cultured cells. Analyze central nervous system (CNS) and peripheral protein production following soman exposure. Develop new assays for HD adducts in plasma and for diagnosing cyanide exposure.	<u><i>CWA Defense, Medical Diagnostics</i></u> Incorporated biomarker panels into screening modules. Conducted electrophysiological analysis of CWAs in cultured cells. Analyzed central nervous system (CNS) and peripheral protein production following soman exposure. Developed new assays for HD adducts in plasma and for diagnosing cyanide exposure.
<u><i>Low Level Chemical Warfare Agent Exposure</i></u> - Continue studies on neurotoxic effects of low dose CWA exposure. Continue investigation of alterations in muscle physiology due to repetitive low dose CWA exposure. Characterize ultrastructural morphology, immunochemistry and gene expression following low level chemical exposure. Study the effects of low level chemical exposure on extracellular neurotransmitter levels. Evaluate organophosphate anhydrolase enzyme for potential use as a biomarker to confirm low level chemical exposure.	<u><i>CWA Defense, Low Level CWA Exposure</i></u> Investigated alterations in muscle physiology due to repetitive low dose CWA exposure. Characterized ultrastructural morphology, immunochemistry, and gene expression following low level chemical exposure. Studied the effects of low level chemical exposure on extracellular neurotransmitter levels. Evaluated organophosphate anhydrolase enzyme for potential use as a biomarker to confirm low level chemical exposure.

3.4.3.4 TC1 Future Targets

FY 2004 Targets	FY 2005 Targets
<u><i>Nerve Agent Defense, Neuroprotection</i></u> Evaluate drug treatment strategies and combinations of therapies for nerve agent-induced seizures.	<u><i>Nerve Agent Defense, Neuroprotection</i></u> Continue to evaluate drug treatment strategies and combinations of therapies for nerve agent-induced seizures.
<u><i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i></u> Identify mechanism of action of vesicant pretreatment compounds. Determine effects of sulfur mustard (HD) on cell structure using multiphoton laser scanning microscopy. Analyze in vitro effects of HD on cellular energy metabolism. Study in vitro biochemical changes induced by HD.	<u><i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i></u> Explore purification and delivery strategies of vesicant pretreatments. Continue to analyze in vitro effects of HD on cellular energy metabolism. Continue to study in vitro biochemical changes induced by HD.
<u><i>Chemical Warfare Agent Defense, Inhalation Therapeutics</i></u> Investigate enzymatic targets of HD. Conduct a dose-response assessment of early acute lung injury in rodents administered intravascular HD. Determine the biochemical effects in male and female guinea pigs following exposure to chemical warfare agents.	<u><i>Chemical Warfare Agent Defense, Inhalation Therapeutics</i></u> Identify intervention targets to acute lung injury caused by CWAs. Continue dose-response assessment of any acute lung injury in rodents administered intravascular CWAs. Conduct histopathology studies in male and female guinea pigs following exposure to CWAs.
<u><i>Chemical Warfare Agent Defense, Medical Diagnostics</i></u> Identify molecular intracellular proteomic changes following HD exposure.	<u><i>Chemical Warfare Agent Defense, Medical Diagnostics</i></u> Pursue development of a nanodevice for diagnosing CWA exposure using synthetic modeling and molecular imprinting.
<u><i>Chemical Warfare Agent Defense, Low Level Chemical Warfare Agent Exposure</i></u> Identify biomarker(s) to indicate low level chemical exposure. Continue studies of neurotoxic effects of low dose chemical agent exposure. Examine potential for immunological deficits following nerve agent exposures. Identify potential medical countermeasures for low level	<u><i>Chemical Warfare Agent Defense, Low Level Chemical Warfare Agent Exposure</i></u> Examine multiple biomarkers as confirmatory for low level chemical exposure. Continue studies of possible immunological deficit following low level chemical nerve agent exposure. Examine physiological

FY 2004 Targets	FY 2005 Targets
chemical warfare nerve agent and HD exposure <u><i>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</i></u> Investigate changes to pulmonary airway resistance and permeability of Pulmonary microvessels induced by exposure to various concentrations of platelet activating factor (PAF). Identify changes in the global gene expression profile of cultured human epidermal keratinocytes (HEK) in response to NTA exposure using DNA microarrays and genomics techniques to aid in considering strategies leading to medical countermeasures.	parameters that may alter sensitivity to low level CWAs. Continue to identify potential medical countermeasures for low level CWA exposures. <u><i>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</i></u> Compare the direct effects of PAF on smooth muscle, hematic constituents, and lung to determine role in toxicity. Continue to identify changes in the global gene expression profile of cultured HEK exposed to NTAs using DNA microarrays and genomic techniques to aid in considering strategies leading to medical countermeasures.

3.4.3.5 Assessment of Chemical Biological Defense Basic Research. Basic research efforts in FY2003 for project TC1 are effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2003.

3.5 APPLIED RESEARCH (PROGRAM ELEMENT 0602384BP)

The use of chemical and biological weapon systems in future conflicts is an increasing threat. Funding under this PE sustains a robust program, which reduces the danger of a CB attack and enables U. S. forces to survive and continue operations in a CB environment. The medical program focuses on development of vaccines, pretreatment, and therapeutic drugs, and on casualty diagnosis, patient decontamination, and medical management. In the non- medical area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection systems. This program also provides for conduct of applied research in the areas of real- time sensing and immediate biological countermeasures. This PE also provides concept and technology demonstrations of new system concepts that will shape the development for environmental monitoring, medical surveillance, and data mining/ fusion/ analysis subsystems. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. Efforts under this PE transition to and provide risk reduction for Advanced Technology Development (PE: 0603384BP), Advanced Component Development and Prototypes (PE: 0603884BP) and System Development and Demonstration (PE: 0604384BP). This project includes non- system specific development directed toward specific military needs and therefore is correctly placed in Budget Activity 2.

3.5.1 Chemical and Biological Defense Applied Research (Project CB2)

This project addresses the urgent need to provide all services with defensive materiel to protect individuals and groups from threat CB agents in the areas of detection, identification and warning, contamination avoidance via reconnaissance, individual and collective protection, and decontamination. The project provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and NBC survivability. Of special interest are two Defense Technology Objectives described as follows: (1) The fate of CW agents following deposition onto natural and man- made materials found in operation environments including battlefields and air bases and (2) toxicological effects resulting from low- level exposure to CW agents, e.g., less than 0.1 EC₅₀, as well as the relationships between concentration and total exposure as measured by the product of concentration and time. This

project focuses on horizontal integration of CB defensive technologies across the Joint Services. The DTOs provide a means to shape the development of selected technologies within this project.

3.5.1.1 CB2 Performance Goal (Outcome). The goal of the CB defense non-medical applied research program is to increase scientific understanding of the mechanisms and processes involved in chemical and biological warfare (CBW) agents and potential applications of this information for the development of advanced technologies for the detection, protection against, and decontamination of CBW agents.

3.5.1.2 CB2 Outcome Measure

CB2 is minimally effective when	CB2 is successful when
- The results provide fundamental information in support of new and improved defensive systems, including information on – biosensors for point detection and early warning, – critical reagents for biological agent detection & identification, – aerosol sciences, – threat agents, – agent dispersion and fate modeling, – advanced materials for individual protection, – advanced methods and materials for decontamination, – chemistry and toxicology of bioactive compounds, – man portable thin film technology, – integrated detection of energetic and hazardous materials, – optical recognition technologies, – new detection technologies. - The results of research are published in peer-reviewed journals or presented at scientific conferences - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	- Information, technologies, or processes are transitioned to applied research or advanced technology development - All DTOs are rated GREEN by the TARA Panel.

3.5.1.3 Metric Description. The metric for CB2 is described in Section 3.2.1.1. Applied research also includes several specific DTOs, which are described in Chapter 2 and Annexes A–D of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.5.1.4 CB2 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<u>Advanced Adsorbents for Protection Applications (DTO-CB08)</u> - Identify at least one adsorbent bed composition that provides the level of protection required by the JSGPM and JCPE programs for all CW agents and the highest priority TICs. Develop at least one adsorbent bed composition providing for effective P/TSA system performance (meeting JCPE requirements) for all chemical warfare agents and all high priority TICs.	<u>Advanced Adsorbents for Protection Applications (DTO CB08)</u> Completed database and model of adsorption equilibrium and rate processes for four agent classes. Identified adsorbent bed compositions that provide the level of protection required by the JSGPM, JCPE, and JTCOPS programs for all CW agents and the highest priority toxic industrial chemicals (TICs). For single pass applications several adsorbent compositions were transitioned to Joint Program Manager for Individual Protection for use in the JSGPM and for regenerative applications several proposed bed compositions were identified for full spectrum protection capability (light to heavy TIC/CWA).
<u>Biological Sample Preparation System (BSPS) for Biological Identification (DTO-CB20)</u> - Continue develop of new taggant chemistry for multi-agent, multiplexing PCR assays. Complete redesign and initiate modifications to the breadboard.	<u>Biological Sample Preparation System (BSPS) for Biological Identification (DTO CB20)</u> Continued development of new taggant chemistry for multi-agent, multiplexing PCR assays. Conducted a feasibility analysis of what is required to make multiplex and multi-agent assays cost effective. Conducted an analysis of alternatives (AoA) based on feasibility

FY2003 Targets	Actual Performance
	study to design an optimized platform using multi-agent, multiplexing PCR assays. Analysis of alternatives determined that this approach was not cost effective to field. This effort was terminated at the end of FY03.
<u>Standoff Biological Aerosol Detection (DTO-CB35)</u> - Initiate construction of breadboard biological standoff detection system based on the results of the downselect, user input, and prior year testing.	<u>Stand-off Biological Aerosol Detection (DTO CB35)</u> Initiated construction and characterization of breadboards to demonstrate the capability to detect and discriminate between biological and 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.
<u>End-of-Service-Life Indicators for NBC Mask Filters (DTO-CB36)</u> - Complete baseline evaluations of candidate technologies. Downselect best candidate technologies. Fabricate and evaluate ESLI/filter concept models. Optimize baseline design and determine optimum ESLI location.	<u>End-of-Service-Life Indicators (ESLI) for NBC Mask Filters (DTO CB36)</u> Completed baseline evaluations of candidate technologies. Performed analysis of battlefield interferents. Conducted a value-added analysis to assess benefits of the ESLI to the warfighter. Downselected to top three candidate technologies. Fabricated and evaluated ESLI/filter concept models. Optimized baseline design and determine optimum ESLI location.
<u>Detection of Agent in Water</u> - Complete technology assessment transition to Advanced Technology Development.	<u>Chemical/Biological Agent Water Monitor (DTO CB37)</u> Completed downselection of technology for the detection of chemical agents in potable water. Continued technology development of detection of biological agents in potable water to include sample processing and preparation. Initiated the process for a Milestone A decision, transitioned effort to Advanced Technology Development.
<u>Environmental Fate of Agents (DTO-CB42)</u> - Complete literature survey effort which will review and rate documents from a very large survey done by Battelle for DTRA. Surface evaporation data will be extracted from this and added to the data base. Laboratory studies will focus on processes affecting VX deposited onto concrete, both on and within the substrate, so that detailed modeling can be done to accurately predict the associated contact and inhalation hazards. The same agent-substrate baseline tests will be done at multiple locations to result in the first correlation of agent fate behavior between wind tunnels and outdoor facilities. The rate of absorption of thickened chemical agents on concrete and subsequent desorption will be measured to provide crucial data needed for better CONOPS for fixed sites.	<u>Predictive Modeling - Agent Fate (DTO CB42)</u> Fielded Phase I Chemical Hazard Estimation Methodology and Risk Assessment Tool. (CHEMRAT). Constructed two tools for simulating and assessing the evaporation of toxic liquids from contaminated surfaces. Developed a surface evaporation assessment tool to evaluate methodologies and compare with actual agent test results. Completed a VLSTRACK sensitivity analysis. Completed a surface evaporation database, which includes 26,115 field trials and data for coated surfaces and other military materials. <u>Methodology Development - Agent Fate (DTO CB42)</u> Determined VX fate (reaction kinetics) on/within concrete by nuclear magnetic resonance (NMR) methods. Developed methodology for varying humidity and temperature by NMR with simulants. Optimized and validated the head space solid phase micro extraction (HS-SPME) method for analyzing chemical warfare agents on surfaces. Completed HS-SPME measurements of VX on concrete, asphalt, and soil at multiple temperatures. <u>Lab-Scale Wind Tunnel Studies - Agent Fate (DTO CB42)</u> Focused technical efforts on building and validating lab wind tunnels for agent surface evaporation testing. Three levels/scales of laboratory apparatus have been characterized and proven out for agent fate testing. Measured surface evaporation of HD on glass in field and lab scale testing. Characterized properties affecting surface evaporation, i.e., spread factors, porosity, etc. <u>Large-Scale Wind Tunnel Studies - Agent Fate (DTO CB42)</u> Developed Agent Wind Tunnel Test Matrix for three agents (GD, HD, and VX) plus thickened variants, four substrates (asphalt, concrete, grass, sand), and three levels of temperature, relative humidity, wind speed, and droplet size. Defined statistically optimized test schedule of 62 experiments for each agent/surface

FY2003 Targets	Actual Performance
	combination. Validated mid scale lab wind tunnel for agent surface evaporation testing in Czech Republic and correlated with work in U.S. <u>Environmental Fate of Agents</u> Conducted Phase 2 of the literature survey and analysis effort. A matrix of planned number of tests versus agent and substrate for laboratory, wind tunnel, and open-air scales was completed. Techniques for formulation and dispersal of thickened agent was established and documented. The surface evaporation database was completed to include data found by the literature search. Laboratory studies, wind tunnel tests, and field trials for live agents was performed and documented. Data addressed rates of evaporation, ad/absorption, desorption, decay, and droplet spread; chemical adsorption effects on equilibrium; and contact transfer as a function of time. A baseline improved surface evaporation inhalation and contact hazard module was developed. CHEMRAT used the baseline model and new threat scenarios.
<u>Chemical and Biological Warfare Effects on Operations (DTO-CB43)</u> - Complete and demonstrate initial operational capability of APOD module. Conduct independent Validation and Verification (V&V) of fighter base module. Initiate development and testing of Sea Port of Debarkation (SPOD) module.	<u>Chemical and Biological Warfare Effects on Operations (DTO CB43)</u> Completed initial operational capability of Aerial Port of Debarkation (APOD) module. Conducted independent validation and verification (V&V) of fighter base module. Initiated development and testing of Sea Port of Debarkation (SPOD) module.
<u>Oxidative Decontamination Formulation (DTO-CB44)</u> - Conduct contact hazard and off-gas testing on coupons and continue material compatibility testing for the peroxycarbonate approach. Optimize formulations using the peracid approach and conduct live agent testing with candidate formulations. Integrate other oxidative approaches into the DTO.	<u>Decontamination, Oxidative Decontamination Formulation (DTO CB44)</u> Conducted contact hazard and off gas testing on coupons and initiated material compatibility testing for the peroxycarbonate decontamination solution. Optimized formulations using the peracid approach and conducted live agent testing. Integrated other oxidative approaches into the DTO. Developed concepts for delivery of multi-component liquid and solid decontaminants.
<u>Self-Detoxifying Materials for Clothing Applications (DTO-CB45)</u> - Continue to assess new reactive compounds and treatments for improved detoxification in membranes. Develop concepts for nanoreactors and surface-migrating phases for improved agent breakdown within membranes and coatings. Select relevant reactive nanoparticles and polymeric materials for subsequent processing and testing studies. Characterize the reaction kinetics and loading capacity of N-halamines treated materials with CWA simulants.	<u>Self-Detoxifying Materials for Clothing Applications (DTO CB45)</u> Continued to assess new reactive compounds and treatments for improved detoxification in membranes. Developed concepts for nanoreactors and surface-migrating phases for improved agent breakdown within membranes and coatings. Selected relevant reactive nanoparticles and polymeric materials for subsequent processing and testing studies. Characterized the reaction kinetics and loading capacity of N-halamines treated materials with CWA simulants.
<u>CB Standoff Detection, Integrated CB Detection</u> - Initiate construction of wide agent spectrum detection system based on downselect.	<u>Integrated CB Stand-off Detector (DTO CB49)</u> Conducted initial downselection of potential technologies based on market survey and user input. Downselection process involved user community as well as internal and external technical experts and included performance, logistics, platform, operational concerns, maturity, and cost factors. Downselection process determined that efforts within DTO CB35 were needed as a basis to further development of integration concepts at an acceptable risk. DTO

FY2003 Targets	Actual Performance
	CB49 was merged into DTO CB35 in FY04.
<u>CB Point Detection, Integrated CB</u> - Initiate exploration of new concepts for small, combined chemical and biological identifiers. Initiate feasibility studies of "low consumable or reagentless" concepts. Develop and test the redesigned Py-GC-IMS hardware and software for improved chemical and biological discrimination. Continue evaluation and development of novel concepts, methodologies, and techniques for biological discrimination, advanced aerosol handling, and triggering capabilities for chemical aerosols.	<u>Lightweight Integrated CB Detection (DTO CB 50)</u> Developed and partially populated database on technological parameters for downselection criteria. Initiated an AoA to downselect best technologies to meet the requirements of the Joint Modular CB Detector. Focused on physical methodologies like optical spectroscopy and pyrolysis gas chromatography ion mobility spectroscopy to address the requirements. <u>Point Detection, Integrated CB</u> Initiated exploration of new concepts for small, combined chemical and biological sensors. Continued evaluation and development of millimeter wave spectroscopy and data fusion techniques to combine chemical and biological detection requirements.
	<u>Detection of CB Contamination on Surfaces (DTO CB52)</u> Performed preliminary downselection of technologies to include factors such as performance, logistics, platform, operational concerns, maturity, and cost. Initiated construction of breadboards 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.
<u>CB Standoff Detection, Chemical Standoff</u> - Initiate construction of hyperspectral sensor in preparation for airborne sensor demonstration.	<u>Wide Area Aerial Reconnaissance for Chemical Agents (DTO CB53)</u> Performed airborne phenomenology tests to adopt existing hyperspectral imaging sensors (100-Hz, 2x8 TurboFT and 0.3-Hz, 128x128 Adaptive Infrared Imaging System (AIRIS)) as next generation chemical stand-off sensors. Completed engineering designs for a 30-Hz, 64-pixel TurboFT, and a 3-Hz, 128x128 AIRIS.
<u>IST, CB Environment</u> - Improve next-generation model (MESO) to include wet biological modifications, improve accuracy over rough terrain, and further improvements to boundary layer atmospheric physics. Evaluate performance of computational fluid dynamics model (CBW-CFX) on ships and fixed land structures and identify areas for improvement. Demonstrate performance of coupled weather/CBW dispersion model. Evaluate performance of hazard evolution codes updated by agent environmental effects data.	<u>CB Environment (DTO CB55)</u> Improved next-generation model (MESO) to include wet biological modifications, improved accuracy over rough terrain, and further improvements to boundary layer atmospheric physics. Evaluated performance of computational fluid dynamics model (CBW-CFX) on ships and fixed land structures and identify areas for improvement. Demonstrated performance of coupled weather/CBW dispersion model. Evaluated performance of hazard evolution codes updated by agent environmental effects data.
<u>CB Standoff Detection, Biological Standoff</u> - Initiate program for the collection of spectral data of biological aerosols. Collect quantitative scattering and absorption spectra on biological simulant aerosols.	
<u>CB Point Detection, Biological Identification</u> - Complete development of Force Discrimination Assay (FDA). Continue development and testing automation of chip-based phylogenetic analysis of biological materials. Complete feasibility study to determine technological issues associated	<u>Point Detection, Biological Identification</u> Continued development of Force Discrimination Assay (FDA). Continued development and testing on automated chip-based phylogenetic analysis of biological materials. Continued development and testing of quantum dot technology for application to enhance antibody ticket technology for improved stability and sensitivity. Conducted evaluation and continued development of

FY2003 Targets	Actual Performance
with microwave spectroscopy of biological materials under ambient conditions. Continue development of non-Taqman chemistry for PCR. Laboratory demonstrate quantum dot technology for application to enhance antibody ticket technology for improved stability and sensitivity.	database for protein markers from biological agents for mass spectroscopy based systems. Evaluated the potential of aptamers as substitutes for antibodies in current platforms.
	<u><i>Polymer Based Chemical and Biological Sensors</i></u> Developed a technique for processing carbon based MEMS for use in biosensors. The carbon based MEMS are in the form of a micro-bridge array fabricated using standard integrated circuit methods to detect the presence of a biological agent through the use of low frequency resonance (i.e. vibration) of a freestanding bridge structure.
	<u><i>Bioinformatics</i></u> Extended the CYTOSCAPE software architecture and relational databases to allow the easy manipulation of data from disparate sources in order to incorporate the higher-order information from proteomic and metabolomic data to give a holistic view of any organism.
	<u><i>Bio-Compact Disk Application Development</i></u> Demonstrated the feasibility of rapid, real time molecular detection and identification of a panel of biological warfare agents (BWA) on a modified compact disc system. The system will be automated, have a low unit cost, and require little training or expertise to employ.
	<u><i>Chem-Bio Defense Initiatives Fund</i></u> Identified proteomic biomarkers for the expansion of national database; enhanced a stand-off sensor to detect agents on surfaces; enhanced a field portable nucleic acid based biodetector; evaluated novel concepts for a lightweight, miniature chemical stand-off detector; evaluated concepts for a hand held biological agent detector; assessed novel materials for biological decontamination capabilities.
	<u><i>National Consortium for Countermeasures to Biological and Chemical Threats</i></u> Assessed an aptamer based high throughput sensor for rapid screening and detection of biological agents; evaluated an integrated system to detect bioterrorist events and natural epidemics; assessed the capabilities of synthetic, aptamer based antiviral vaccines; investigated novel countermeasures to selected viral diseases including encephalitis.
	<u><i>Anthrax Bio Defense Technologies</i></u> Initiated development and commercialization of an inexpensive and robust hand-held sensor that can be used by military field personnel with minimal training to detect low levels of bio warfare (BW) agents. The technology is based on antibodies supported on Love Shear horizontal acoustic wave devices. Preliminary data has shown that this technology has the potential to provide biological identification at an enhanced sensitivity of 10 to 100 times over current systems, within a few minutes, in a hand-held unit.
<u><i>Collective Protection, Filtration</i></u> - Complete proof-of-principle testing and evaluation of 50 CFM pressure-temperature swing	<u><i>Collective Protection, Filtration</i></u> Completing database and model of adsorption equilibrium and rate processes for high priority TICs. Optimized candidate adsorbents

FY2003 Targets	Actual Performance
adsorption filter to validate model. Initiate 200 CFM pressure-temperature swing adsorption filter to assess scalable model and applicability for advanced system integration. Optimize candidate adsorbents for use in regenerative filtration (PSA/TSA) applications that are effective against a wide spectrum of TIC and Chemical Warfare Agents (CWA). Complete evaluation of electrostatic filter particulate and aerosol capture enhancement and degradation effects of TICs on HEPA filters and ways to mitigate. Finish trade study assessing feasibility and application of open and closed circuit air supply and rebreather technologies. Complete chemical and physical Residual Life Indicators sensor testing.	for use in regenerative filtration applications that are effective against a wide spectrum of TIC and Chemical Warfare Agents (CWA). Completed development of initial pressure, temperature, and electrical swing adsorption (P/T/E/SA) regeneration models and fabrication of test stands. Completing proof of principle testing and evaluation of 50 CFM pressure temperature swing adsorption filter to validate model. Completing evaluation of electrostatic and biocidal filter enhancement for aerosol and particulate capture and deactivation. Evaluated degradation effects of TICs on HEPA filters and proposed mitigation concepts. Completed initial literature review for developing hybrid air purification systems incorporating technologies providing broad protection. Finished trade study assessing feasibility and application of open and closed circuit air supply and rebreather technologies. Completed chemical and physical residual life indicators (RLI) sensor testing and developed RLI prototype concept.
<u>Collective Protection, Shelters</u> - Continue development and evaluation of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals). Testing of new CB skin material including constructed shelter systems. Continued development and testing of chemistries for self-decontaminating shelter materials. Complete initial assessment and modeling of shelter materials failure mechanisms to conventional weapons blast pressure effects and transition to JCPE.	<u>Collective Protection, Shelters</u> Continued development and evaluation of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals). Two new hermetic seals for shelters were fabricated and tested. Four new CB shell materials were developed to include constructed shelter systems. Completed initial computational fluid dynamic modeling of one airlock system. Continuing development and testing of chemistries for self decontaminating shelter materials. Completed initial assessment and modeling of shelter materials failure mechanisms to conventional weapons blast pressure effects and proposed transition to JCPE.
<u>Individual Protection, Clothing</u> - Complete testing of fielded and developmental protective garment materials to evaluate their effectiveness against TICs, and provide recommendations to the user community. Develop and produce a first generation membrane that has optimized permselectivity through ion implantation. Complete transport and physical characterization of selected candidates, and initiate detailed analysis of structure-property relationships. Optimize materials and material treatment solutions for overgarments to improve protection against NTA aerosols. Initiate a study to assess the effects of atmospheric temperature and wind on agent penetration of Individual Protection Equipment (IPE). Validate recent research that indicates that intermittent cooling to various body regions can provide as much cooling benefit (in terms of core temperature reduction) as cooling continuously, but at a fraction of the MCS capacity.	<u>Individual Protection, Clothing</u> Completed testing of fielded and developmental protective garment materials to evaluate their effectiveness against TICs, and to provide recommendations to the user community. Characterized the surface phenomena occurring in ion implanted polymers and determined the transport properties of moisture and chemicals of those polymers. Completed transport and physical characterization of selected candidate permselective membranes, and initiated detailed analysis of structure property relationships. Optimized materials and material treatment solutions for overgarments to improve protection against NTA aerosols. Identified sampling techniques and assessed clothing air velocities as an initial step in evaluating the effects of atmospheric temperature and wind on agent penetration of IPE. Validated recent research which indicates that intermittent cooling to various body regions can provide as much cooling benefit (in terms of core temperature reduction) as cooling continuously, but at a fraction of the MCS capacity. Inadequate funding to continue development of this area during FY04. Funding to resume in FY05.
<u>Individual Protection, Masks</u> - Begin development of advanced mask concepts focusing on lightweight system integration, a wider range of protection, and improved	<u>Individual Protection, Masks</u> Initiated development of advanced mask concepts focusing on lightweight system integration, a wider range of protection, and reduced thermal load. Assembled advanced mask concept

FY2003 Targets	Actual Performance
thermal attenuation. Assemble advanced mask concept system for preliminary human factor studies. Initiate optimization of candidate sorbent media structures by the testing of media properties and the modification of that media to improve performance. Optimize candidate lens materials through the evaluation of chemical and physical properties and the modification of that material to enhance performance. Develop and evaluate new and improved mask technologies to improve protection, flow dynamics, heat and moisture transfer, and fogging. Identify appropriate aerosol generation and detection equipment, develop and validate test procedures, and conduct protection factor study using mask headform tester and controlled leaks.	prototypes for preliminary human factor studies. Initiated optimization of candidate sorbent media structures by the testing of media properties and the modification of that media to improve performance. Optimized candidate lens materials through the evaluation of chemical and physical properties and the modification of that material to enhance performance. Developed and evaluated new and improved mask technologies to improve protection through novel sealing and pressurization options. Identified appropriate aerosol generation and detection equipment, developed and validated test procedures.
<u>Decontamination, Sensitive Equipment</u> - Initiated feasibility studies for decontamination technology solutions for JSSED Block II and III using plasma technology and spot cleaning methodology using reactive solid/solvent suspensions.	<u>Decontamination, Sensitive Equipment</u> Completed feasibility studies for interior decontamination technology solutions for JSSED using plasma technology approaches. Developed a man portable approach for the cleaning of small sensitive surfaces based upon reactive sorbents in solvent suspensions.
<u>Decontamination, Solution Chemistry</u> - Optimize formulations for chemical and biological decontamination systems. Initiate material compatibility and efficacy testing on an expanded test bed for promising approaches. Optimize an innovative catalytic buffering system to provide pH control in solution decon formulations. Complete final kinetics and panels testing for the combined enzyme decontamination system.	<u>Decontamination, Solution Chemistry</u> Completed evaluation of multi-enzyme decontamination system for G, V and H class agents.
<u>Decontamination, Solid Phase Chemistry</u> - Develop and demonstrate novel solid and sorbent decontamination applications using nanoscale metal oxides, solvents, and reactive additives.	<u>Decontamination, Solid Phase Chemistry</u> Completed evaluation of novel solid and sorbent decontamination applications using nanoscale metal oxides, zeolites and solid phase reduction/oxidation couples.
<u>SS&T, Aerosol Technology</u> - Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological and chemical detection technology, and operating at the Joint Service low temperature requirement (-28 degrees F). Fabricate and test the first breadboards of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range and for wind speeds up to 60 mph. Fabricate and test the first breadboards of a new generation of aerosol concentrators and collectors using mini-machining technology to reduce the size, power consumption, and weight of aerosol components in order to meet the	<u>Aerosol Technology</u> Fabricated and tested novel high efficiency aerosol inlet brassboard. Designed and fabricated first breadboards of novel aerosol collectors and concentrators for low temperature, low power, and full particle size range operation. Initiated computational fluid dynamics (CFD) studies to assess and improve performance of various aerosol collector and concentrator devices of military interest. Characterized performance of a variety of novel design and developmental aerosol collectors in aerosol chambers and wind tunnels. Developed novel aerosol generation device for high air speed testing. Initiated construction of enhanced lidar aerosol test cell. Fabricated and tested automated ink jet aerosol generator.

FY2003 Targets	Actual Performance
stringent requirements for advanced detection systems. Continue to provide controlled biosimulant aerosol challenges and begin providing chemical agent simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for Joint Field Trials.	
<u>SS&T, Threat Agents</u> - Complete the assessment of long-term needs in threat agent data and needs for improved simulants in CB defense materiel development, and participate in a collaborative inter-agency laboratory program to fill the data gaps and improve simulants. Continue to synthesize, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Initiate characterization of fundamental properties of <i>Y. pestis</i>. Develop a secure database environment for bioinformatics. Continue assessment of bacteria persistence. Complete research on new simulants for novel chemical threat agents. Continue research on simulant BG spores and improvement of simulant <i>Erwinia herbicola</i>. Initiate research for a new viral simulant. Continue development of an agent/simulant knowledge base technical information system with emphasis on collection of biological agent and simulant data and quality assessment of chemical and biological agent and simulant data.	<u>Threat Agents and Simulants</u> Interfaced with intelligence community to determine synthesis targets. Continued to fill data gaps relative to physical properties of conventional and novel chemical threat agents. Continued to develop quantum chemical methods to discover novel synthesis routes for chemicals of interest. Interfaced with intelligence community to focus investigations of biological agents and stimulants of concern. Novel preparations of spores from stimulants, non-pathogenic and pathogenic anthrax were implemented. Size of multiple bacillus species was measured. Determined the fluorescence spectrum of seven different bacillus spores. Initiated TEM analysis of <i>Yersinia</i> species. Evaluated sporocidal activity of three military decontaminants on non-pathogenic and pathogenic anthrax on two surfaces of military interest. Initiated integration of data produced in this project with ASK Biological Database. Measured size distributions of several <i>Bacillus</i> species. Developed design for modifying Eh outer membrane protein using molecular genetic techniques. Demonstrated that antigens giving rise to bands in Western blot analysis are also present in cell wall preps from <i>E. coli</i>. Identified two cross-reaching proteins (<i>E. coli</i> and Eh) by N-terminal sequencing as outer membrane proteins. Identified additional CB stimulant and agent data requirements and data. ASK v2.1 reviewed for accuracy and software updated. ASK v2.0 User's Manual and help files were completed. Continued outreach program to maintain awareness of activities at other sites. Continued efforts to identify biosimulant needs of the RDT&E user community. Identified monoclonal antibodies for six antigenic targets against a 12-mer peptide library expressed in <i>E. coli</i>.
<u>Low Level Chemical Agent Operations Toxicology Studies</u> - Complete non-rodent GB inhalation studies to characterize Ct relationships for low level, longer duration exposures. Complete methodology development for VX inhalation exposures and initiate VX studies in rats. Continue dose-metric methodology efforts to understand internal dosage following exposures. Develop methods applicable to physiological modeling for understanding the impact of route of exposure on toxicological effects from low level concentration and extended duration exposures to nerve agents.	<u>Low Level Operational Toxicology Studies</u> Completed inhalation data sets to define longer time, lower level operational effects for sarin (GB) in swine and a second generation agent (GF) in rats. Developed a valid marker (dosimetric) for nerve agent exposure suitable for predicting agent effects across species to refine operational human health risk assessment.
<u>IST, CB Planning, Training, Analysis</u> - Demonstrate HLA or DIS application of hazard models. Conduct statistical analysis of results of agent toxicity load variation in several hazard prediction models for fixed	<u>Planning, Training and Analysis</u> Demonstrated HLA application of hazard models. Conducted statistical analysis of results of agent toxicity load variation in several hazard prediction models for fixed site application.

FY2003 Targets	Actual Performance
site application.	
<u>IST, Simulation Based Acquisition</u> - Initiate testing of prototyping models against highest priority CBD objects. Develop and demonstrate a breadboard virtual prototype system (VPS).	<u>Simulation Based Acquisition</u> Initiated testing of prototyping models against highest priority CBD objects. Developed and demonstrated a breadboard virtual prototype system.
<u>IST, CB Battle Management</u> - Complete battle management Front End analysis. Expand studies to address data fusion approaches for multiple sensors. Assess value added at system-level (multiple networked CB sensors and non-CB sensors) through modeling and demonstration. Initiate examination of methods to improve real-time, network-aided decision making, and visualization of network responses.	<u>Battle Management</u> Expanded studies to address data fusion approaches for multiple sensors. Assessed value added at system-level (multiple networked CB sensors and non-CB sensors) through modeling and demonstration. Initiated examination of methods to improve real-time, network-aided decision making, and visualization of network responses.
	<u>Countermeasures to Biological and Chemical Threats</u> Continued studies of combinative toxicity of biological toxin mixtures. Continued study into mechanisms of cell death. Successfully performed initial tests of selenium based antibiotic and anti-viral compounds. Continued with successful development of non-woven materials for use in decontamination suits. Continued modeling of biological dispersion in buildings and cities. Continued studies of natural mechanisms of ricin breakdown. Continued development of an ultraviolet visible based miniature diode detector for chemical and biological agents.
	<u>Air Purification Collective and Individual Protection</u> Developed and evaluated filter material formulations for efficacy against biological threat agents.
	<u>Air Contaminant Monitoring System</u> Employed novel networking technologies to link environmental air quality monitoring sensors to determine feasibility to detect, track and respond to an intentional chemical warfare agent release in an urban and suburban setting.

3.5.1.5 CB2 Future Targets

FY 2004 Targets	FY 2005 Targets
<u>Advanced Adsorbents for Protection Applications (DTO CB08)</u> Complete validation of single-pass and regenerative filtration adsorption models. Complete performance verification of adsorbents for use in NBC filtration systems with emphasis on regenerative materials. Selected adsorbent beds will undergo performance verification testing to fully assess the performance constraints expected in the host filter system. These evaluations will consider adsorbent bed performance under a wide range of agent challenge concentration scenarios and environmental conditions. Selection of the best adsorbent bed composition for regenerative filtration application will be made. If temperature swing adsorption and pressure swing adsorption are both considered viable regenerative filter technologies, at least two different adsorbent bed compositions will be selected.	<u>Stand-off Biological Aerosol Detection (DTO CB35)</u> Evaluate breadboards via field testing and demonstrate the capability to detect and discriminate biological vs non-biological agents at concentration of 1,000 ACPLA at a range of 1 km. Initiate feasibility studies to integrate chemical and biological capabilities with the objective of maintaining demonstrated capabilities. <u>End-of-Service-Life Indicators for NBC Mask Filters (DTO CB36)</u> Assess the effects of common battlespace interferents on ESLI performance. Optimize ESLI design and complete demonstration testing on ESLI filter prototype(s). Investigate new indicators (or optimize existing indicators as required) to detect sorbent depleting battlefield contaminants., or optimize existing indicators as required, to detect sorbent depleting battlefield contaminants.

FY 2004 Targets	FY 2005 Targets
<u><i>Stand-off Biological Aerosol Detection (DTO CB35)</i></u> Complete construction and characterization of breadboards to demonstrate the capability to detect and discriminate biological and non-biological agents at a concentration of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km. <u><i>End-of-Service-Life Indicators for NBC Mask Filters (DTO CB36)</i></u> Fabricate and conduct demonstration testing of ESLI filter concept models to verify ESLI is a reliable indicator of gas life depletion for key target agents (i.e., GB, HD, CK, AC and CG). Assessments will include determining the effects of common environmental factors (heat and humidity) that may impact ESLI performance and evaluating the effects of long term storage. <u><i>Predictive Modeling - Agent Fate (DTO CB42)</i></u> Develop evaporation and liquid contact models and integrate into the Joint Effects Model (JEM). Expand surface evaporation database to include all agent/simulant data from large area surfaces and continually add data generated from the Agent Fate program. Expand the features and accuracy of CHEMRAT by including current data from the Agent Fate program to support Operation Iraqi Freedom and future military operations. Calibrate VLSTRACK by adjusting parameters relevant to secondary evaporation to provide better vapor hazard and liquid persistence estimates. Enhance SRFSIM and SURFIT assessment tools by including secondary evaporation methodology from the Hazard Prediction Assessment Capability model (HPAC). Perform sensitivity analysis of HPAC 4.0.3 secondary evaporation methodology. <u><i>Methodology Development - Agent Fate (DTO CB42)</i></u> Determine degradation products of agents on surfaces of interest such as concrete. Using HS-SPME, measure and correlate VX, GD, and HD on Czech concrete vs. NIST standard concrete. Using HS-SPME, measure VX, GD, and HD on asphalt, soil and metal/glass at three humidity levels and compare single vs. multiple droplets surface contamination. Initiate HS-SPME measurements of NTAs. Initiate soil methodology development and determine sorption and fate of GD on dry sand and its response to simulated rainfall. Determine the fate of RVX, NTA, and HD on concrete by NMR and add GD if schedule allows. <u><i>Lab-Scale Wind Tunnel Studies - Agent Fate (DTO CB42)</i></u> Measure surface evaporation of HD and GD on asphalt in lab wind tunnels. Measure surface evaporation of HD	<u><i>Methodology Development - Agent Fate (DTO CB42)</i></u> Determine degradation products of agents on surfaces of interest such as concrete. Examine the fate of VX, GD and NTA on asphalt by NMR. Examine the fate of V analogs, NTAs and thickened agents on surfaces under different temperature and humidity conditions by HS-SPME. Determine sorption and fate of VX on sand and clay soil. Determine sorption and fate of GD and VX on assembled test soil. <u><i>Predictive Modeling - Agent Fate (DTO CB42)</i></u> Evaluate Agent Fate secondary evaporation model versus the VLSTRACK module and evaluate each with agent field trials to determine accuracy of downwind vapor predictions. Tune model/module and integrate into JEM. Transition effort to JEM Program Office. Continue to work the scaling of agent vapor concentrations from laboratory to outdoor test conditions. Continue CHEMRAT update with new agent fate test data. Continue to update secondary evaporation model with new agent fate test data and incorporate into JEM. <u><i>Lab-Scale Tunnel Studies - Agent Fate (DTO CB42)</i></u> Initiate surface residual agent testing to determine contact hazard. Complete surface evaporation tests of VX and NTAs on asphalt. Measure surface evaporation of thickened HD, GD and VX on asphalt and concrete. <u><i>Large-Scale Wind Tunnel Studies - Agent Fate (DTO CB42)</i></u> Develop methodology to correlate lab scale to large scale and outdoor test results. Design and conduct validation tests of surface evaporation model for agents on concrete. <u><i>Chemical and Biological Warfare Effects on Operations (DTO CB43)</i></u> Test and finalize toward JOEF Block II transition. Develop Marine Expeditionary Force HQ, depot, and railhead modules. Perform internal V&V. Prepare for external V&V by PM. <u><i>Decontamination - Oxidative Formulation (DTO CB44)</i></u> Complete chamber testing over operational temperature range, finish material compatibility testing, and formulate new oxidative approaches into a dry powder and/or concentrated liquid. <u><i>Self-Detoxifying Materials for Chemical/Biological Protective Clothing (DTO CB45)</i></u> Demonstrate reactivity stability to realistic time, temperature, and use conditions. Optimize materials and

FY 2004 Targets	FY 2005 Targets
and VX on concrete in lab wind tunnels. Initiate investigations of VX and NTAs on asphalt. <u>Large-Scale Wind Tunnel Studies - Agent Fate (DTO CB42)</u> Initiate surface evaporation of thickened GD, VX, and HD on concrete and asphalt. Complete fabrication and certification of large scale wind tunnel in the UK. Field Testing Methodology will be reviewed to prepare for resumption of outdoor testing in FY05. Continue wind tunnel testing of HD, GD, and VX on asphalt, sand, and vegetation. <u>Decontamination - Oxidative Formulation (DTO CB44)</u> Initiate chamber testing over operational temperature range, finish material compatibility testing and formulate peroxy carbonate and peracid candidates into a dry powder and/or concentrated liquid. Finalize formulation of newly added oxidative approaches and conduct material compatibility and agent testing. <u>Self-Detoxifying Materials for Chemical/Biological Protective Clothing (DTO CB45)</u> Demonstrate ability to produce materials employing self detoxification chemistries for G-agents, VX, and HD by 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/cm²/day. Demonstrate effectiveness of scaled up N-halamine treated materials against significant biological. Demonstrate nanoparticle reactivities in excess of 2 mg agent/cm²/day in both fiber and coating form. Downselect most reactive, cost effective nanoparticle compositions and optimize those materials for reactivity rates and range of materials they detoxify <u>Lightweight Integrated CB Detection (DTO CB50)</u> Complete the population of the technical parameter database. Transition the analysis of alternatives to advance development for downselection for best technology to meet the requirements of the Joint Modular CB Detector. <u>Low Level Operational Toxicology Studies (DTO CB51)</u> Complete initial inhalation studies for the nerve agents GF and VX. Deliver a refined operational human health risk assessment for those agents suitable for integration into Operational Risk Management processes used by commanders in military settings. Evaluate the utility of diverse non-human data for extrapolation to human conditions based on a common dosimetric. <u>Detection of CB Contamination on Surfaces (DTO</u>	processing conditions for reactive fibers/membranes. Improve durability and overall cost effectiveness of scaled up electrospun self detoxifying membranes, N-halamine treated textiles, and materials containing reactive nanoparticles. Downselect reactive particles and processing approach for fibers/membranes. Select materials from DTO and related projects (DARPA SBIR, congressional program) for the development of prototype garments. Measure chemical/aerosol breakthrough of candidate fabrics. Measure durability and effectiveness of candidate fabrics from all sources. Conduct toxicology and live agent testing of manufactured fabrics. Optimize/downselect fabric design from agent and durability testing. <u>Detection of CB Contamination on Surfaces (DTO CB52)</u> Reinitiate breadboard construction and characterization due to FY04 funding adjustments. Initiate feasibility studies to determine the ability to detect biological agents on surfaces. <u>Wide-Area Aerial Reconnaissance for Chemical Agents (DTO CB53)</u> Complete the development a 3-Hz, 128x128 tunable hyperspectral imager (AIRIS). Characterize the sensor performance of the AIRIS for technology downselection in FY06. Complete off-line algorithms and signal processing techniques. <u>Chemical and Biological Hazard Environment Prediction (DTO CB55)</u> Enhance the complex terrain and flow around structures modeling capability to address variable surface characterization and solar effects on agent evaporation. Perform code optimization and validation of the complex terrain and flow around structures tools. <u>Advanced Air Purification System Model (DTO CB61)</u> Develop model for hybrid air purification systems that incorporate mature unit processes for the purpose of providing broader protection than current single pass filter technology. Develop a matrix model for hybrid air purification systems that can address wide application requirements by providing the optimal mix of technologies. <u>Point Detection, Integrated CB</u> Complete exploration of novel, small, chemical and biological sensors. Initiate exploration and concept development for new concepts for small, combined chemical and biological identifiers. Conduct feasibility studies and perform a cost benefit analysis on "low consumable or reagentless" concepts. Complete first

FY 2004 Targets	FY 2005 Targets
<u>CB52)</u> Collect data on three surfaces for four surety agents using laser enhanced Raman spectroscopy to detect the presence of the chemical agents. Effort reduced due to FY04 funding adjustments. <u>Wide-Area Aerial Reconnaissance for Chemical Agents (DTO CB53)</u> Complete the development a 30-Hz frame rate, 64-pixel Fourier transform infrared (FTIR) hyperspectral imager (TurboFT). Continue the development of AIRIS. Characterize the sensor performance on the TurboFT for downselection of technology in FY06. Initiated development of off-line algorithms and signal processing techniques. <u>Chemical and Biological Hazard Environment Prediction (DTO CB55)</u> 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. Investigate availability of high altitude disbursement model in support of JEM Block II <u>Point Detection, Biological Identification</u> Complete development and demonstration of Force Discrimination Assay (FDA). Complete development and testing automation of chip-based phylogenetic analysis of biological materials. Identify engineering/manufacturing issues for the transition of quantum dot technology to the Critical Reagent Program for application to enhance antibody ticket technology for improved stability and sensitivity. Continue development of database for protein markers from biological agents for mass spectroscopy based systems. <u>Point Detection, Integrated CB</u> Continue exploration of novel concepts in small, combined chemical and biological sensors. Continue development of millimeter wave spectroscopy. <u>Laser Induced Surface Analysis (LISA) Prototype</u> Construct and demonstrate a laser enhanced Raman system that can detect the presence of chemical agent on surfaces at a contamination level of 0.5 g/m2 and suitable for integration into a recon vehicle to demonstrate on the move capability. 850 <u>Collective Protection, Shelters</u> Continue development and testing of advanced CB shelter materials and prototype shelter system components (shell, liner, support, airlocks, seams and seals). Identify and test optimal chemistries for self decontaminating shelter materials and applications.	generation breadboard based on millimeter wave spectroscopy. <u>Point Detection, Biological Identification</u> Initiate development of micro-array concepts to meet high throughput and reduce logistical burden on biological identification requirements. Complete mass spectroscopy database development and transition to advanced technology development to populate database to extend biological material information. <u>Individual Protection, Clothing</u> Optimize ion implantation conditions for maximum permselectivity and demonstrate optimized membranes. Complete analysis of membrane structure property relationships, optimize the most promising membranes, evaluate the properties of modified membranes, and produce and evaluate fabric systems which include the optimized membranes. Investigate selectively permeable membranes and new reactive membranes for addressing NTA aerosols, and conduct agent testing of optimized NTA protective systems. Develop swatch test technology for assessing role of wind speed, temperature in challenge penetration of individual protection equipment. Initiate development of advanced ensemble closure technologies to reduce/prevent aerosol penetration. Identify thermal management technologies for protective ensemble applications. <u>Collective Protection, Shelters</u> Continue development and testing of advanced CB shelter materials and prototype shelter systems (shell, liner, support, airlocks, seams, seals and self decontaminating materials). Perform testing of shelter components incorporating self decontaminating materials. <u>Collective Protection, Filtration</u> Characterize and optimize performance of advance aerosol/particulate removal processes providing enhanced protection. Develop regenerative filtration advanced technology demonstrator. <u>Individual Protection, Masks</u> Develop advanced mask system prototypes using enhanced technologies to the maximum extent possible. Continue optimization of candidate sorbent media structures by testing of the properties of the media and modification of that media to improve performance. Continue optimization of candidate lens materials through the evaluation of chemical and physical properties and the modification of that material to enhance performance. Develop at least three technology concepts by integrating best option technologies and conduct both laboratory and human factors evaluations.

FY 2004 Targets	FY 2005 Targets
Conduct airflow modeling of airlock and contamination control area configurations to optimize designs to reduce dwell time, increase entry/exit rate, and facilitate dual entry and exit of personnel, patients and supplies. <u>Individual Protection, Masks</u> Refine advanced mask system concepts using actual technologies to the maximum extent possible. Optimize candidate mask sealing options and assess antifogging and moisture control technologies. Prepare human use bio-aerosol protection factor assessment protocol, establish and validate test procedures, and conduct human PF study with monodisperse inert aerosols. <u>Collective Protection, Filtration</u> Characterize constraints of mature candidate adsorbent compositions against a wide range of TIC and CWA including aging, chemical reaction regeneration cycles, relative humidity, temperature, and material compatibility. Optimize regenerative process (including, temperature, pressure, ECS, cycle time) using verified candidate adsorbent materials. This task will mature the technology for future consideration as an advanced technology demonstrator. Complete literature review and database of unit processes for developing hybrid air purification systems. Downselect anti-microbial aerosol/particulate filter media, complete initial testing and develop enhanced prototype. <u>Decontamination, Sensitive Equipment</u> Complete evaluation of man portable approaches for the cleaning of small sensitive surfaces for use in the interior of vehicles and aircraft. <u>Decontamination, Solid Phase Chemistry</u> Initiate evaluation of oxidatively enhanced nanoparticles as reactive sorbents for both chemical and biological agent decontamination. <u>Aerosol Technology</u> Experimentally and by CFD analysis, initiate investigations of inlets to facilitate aerosol collection in high air speed conditions. Continue experimental and CFD studies of microHEPA, electrostatic collector, mini-slit and other low power aerosol collection devices. Fabricate and test breadboard aerosol collector capable of low temperature operation. Characterize and evaluate emerging collectors and collection technology. Develop new aerosol generation and analysis techniques including methodology development to generate suitable chemical simulant aerosol challenges. Complete enhanced lidar aerosol test cell to support stand-off detection tests. Continue development of new	Establish and validate bio-aerosol protection factor assessment test procedures, and conduct human PF study with polydisperse inert aerosols. <u>Decontamination, Solid Phase Chemistry</u> Assess new materials being investigated under basic research programs for potential use and transition as reactive and sacrificial coatings. Evaluate oxidatively enhanced reactive nanoparticles and initiate testing of novel nanocrystalline zeolites. <u>Decontamination, Sensitive Equipment</u> Assess immature technologies as identified in market surveys and the analysis of alternatives for potential JSSE product improvements. <u>Threat Agents and Simulants</u> Continue and expand efforts to determine and validate new synthesis targets. Continue to fill data gaps relative to classical and novel threat agents, toxic industrial chemicals, and CWA simulants. Investigate physical properties and decontamination properties of <i>B. mallei</i> and baculovirus. Complete effort to identify and validate non-pathogenic antigen mimics. <u>Threat Agents</u> Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continue to characterize fundamental properties of <i>Y. pestis</i> and initiate work on <i>B. mallei</i>. Complete characterization of fundamental properties of a viral family and continue characterization of a second viral family selected by biodefense priorities. Complete improvement of <i>Erwinia herbicola</i> antigenicity, and continue exploration of novel "peptide-based" bio simulants and research on a new viral simulant. Continue upgrading the data in the agent/simulant knowledge base technical information system and initiate the collection and quality assessment of toxicology data. <u>Aerosol Technology</u> Continue investigations of approaches to advanced inlets for aerosol collection in high air speed conditions. Continue experimental and CFD studies of microHEPA, electrostatic collector, impeller, mini-slit, and other low power aerosol collection devices. Continue characterization of emerging collectors and collection technology. Upgrade existing chambers and wind tunnels. Continue evaluations of new and prototype chemical detectors using chemical simulant aerosols. Initiate CFD modeling for the windbreak approach of sampling omnidirectionally from high speed flows.

FY 2004 Targets	FY 2005 Targets
methodology for quantifying biological aerosols captured in collector/concentrator characterization experiments. <u>Threat Agents and Simulants</u> Continue efforts to determine and validate new synthesis targets. Discontinue quantum chemistry research due to funding reductions. Continue to fill data gaps relative to classical and novel threat agents, toxic industrial chemicals, and CWA simulants. Complete investigations of physical and decontamination properties of B. anthracis. Investigate physical properties and decontamination properties of E. herbicola and baculovirus. Continue update of classified ASK databases and provide to CBIAC when completed. Continue effort to identify and validate non-pathogenic antigen mimics. Complete methodology development for assessing inhalation toxicity of non-traditional agents. <u>Threat Agents</u> Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continue to characterize fundamental properties of Y. pestis. Continue characterization of fundamental properties of a viral family and initiate characterization on a second viral family selected by biodefense priorities. Complete validation studies on simulant BG spores and continue improvement of Erwinia herbicola antigenicity, exploration of novel "peptide-based" bio simulants, and research on a new viral simulant. Continue development of an agent simulant knowledge base technical information system with emphasis on completion of environmental database and initiate the collection and quality assessment of classified and incapacitating agent data. Load bioinformatics database with fundamental non-medical properties. <u>Biological Agent Fate</u> Initiate an accelerated all-source compilation and analysis of existing literature data that addresses the persistence (viability) of biological warfare agents released into the operational environment. Conduct a state of current research expert workshop in conjunction with NATO/allied investigators to document research efforts in the fate of biological agents. Deliver a documented assessment of identified data gaps and produce a targeted Defense Technology Objective (DTO) research program. <u>Battle Management</u> Initiate efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses under the auspices of Joint	<u>Biological Agent Fate</u> Initiate a targeted Defense Technology Objective (DTO) research program that corrects deficiencies in the understanding of the persistence (viability) of biological warfare agents intentionally released into operational environments. Multiple media, such as food and water deliveries, as well as concerns for interior surfaces as identified by the DoD Joint Requirements Office will be included in this effort. <u>Low Level Operational Toxicology Studies</u> Complete cross-validation studies, based on a validated dosimetric, for exposure route comparison that refine operational human health risk assessments for exposure to the nerve agents. Extend the useful range of prediction out in time for inhalation exposures to GF expected in various military response settings. Initiate VX studies that extend time-effect predictive capability. <u>Simulation Based Acquisition</u> Complete tool design and begin prototype construction and testing. Use iterative user-focused design techniques to enhance tool usability and acceptance. <u>Battle Management</u> Continue efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses within the current and planned C4ISR architecture.

FY 2004 Targets	FY 2005 Targets
Warning and Reporting Network (JWARN) program requirements in concert with the C4ISR architecture. <u>Planning, Training and Analysis</u> Test and finalize APOD and SPOD representation. Define Contamination Avoidance for Seaports of Debarkation (CASPOD) data requirements. Populate SPOD representation. Support Joint Operational Effects Federation (JOEF) Block I demonstration. Perform independent validation and verification on core model. <u>Simulation Based Acquisition</u> Develop support tools for future acquisition decisions that would emerge from a study of CBRNDP requirements. Identify user base from within the CBRNDP. Begin prototype tool design efforts. <u>Automated Lipid Phase Detection of Toxic Compounds</u> Automated lipid phase detection of toxic compounds program is being baselined. <u>Bioinformatics</u> Continue creating tailored approaches to extract and rapidly analyze biological data to enhance the study of chemical and biological threat agent effects. <u>Bioinformatics Network</u> Create linkages which interactively approach the extraction of rapid analysis of biological data. <u>Bioinformatics Equipment</u> Explore technologies for bioinformatics equipment. <u>Early Warning and Detection Program</u> Explore technologies for early warning and detection. <u>LSH-SAW Biosensor</u> Investigate acoustic wave technology for biosensors. <u>Detection of Chemical, Biological and Pollutant Agents in Water</u> Continue technology development to detect CB and pollutant agents in potable water sources. <u>Air Containment Monitoring System</u> Continue development of systems for contained air monitoring for chemical agents. <u>Atmospheric Plasma for Bio Defense Decon</u> Investigate technologies for atmospheric plasma for biological defense decontamination. <u>Rapid Decontamination System for Nerve Agents</u> Explore technologies for rapid decontamination system for nerve agents.	

FY 2004 Targets	FY 2005 Targets
<u>Remote Optical Sensing Program</u> Explore technologies for remote optical sensing. <u>Consortium for Countermeasures for Biological Threats</u> Develop multiple technologies and implementations to counter the threat of attack using biological threat agents against civilian and military populations. <u>Center for Information Assurance Security</u> Investigate technologies for information assurance security. <u>GMU Center for Bio Defense</u> George Mason University Center for biological defense program being baselined. <u>Long Range Biometric Target ID System</u> Explore technologies for a long range biometric target identification system.	

3.5.1.6 Assessment of Chemical and Biological Defense Applied Research. Applied research efforts in FY2003 for project CB2 are at least minimally effective. Many areas of CB defense applied research were successful. The assessment is based on two factors: (1) several DTOs in this area was rated yellow by the TARA and one was rated red. All efforts have developed plans to address concerns identified and will be re-assessed in FY2003. (2) Several technologies successfully transitioned to advanced development. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2003. Additionally, execution began on several new Congressionally added projects, including the CB Defense Initiatives Fund.

3.5.2 Medical Biological Defense Applied Research (Project TB2)

This project funds applied research on the development of vaccines, therapeutic drugs, and diagnostic capabilities to provide an effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. Innovative biotechnological approaches and advances will be incorporated to obtain medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include Defense Technology Objectives (DTO); science and technology programs in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines); and directed research efforts, including the Chemical and Biological Defense Initiative (CBDI) fund.

3.5.2.1 TB2 Performance Goal (Outcome). The goal of CB defense medical biological defense applied research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of BW agents in order to develop preventive and therapeutic protection and diagnostic technologies for BW agents.

3.5.2.2 TB2 Outcome Measure

TB2 is minimally effective when	TB2 is successful when
- The results provide fundamental information in support of new and improved defensive systems, including information on - Bacterial Therapeutics, - Toxin Vaccines, - Bacterial Vaccines, - Toxin Therapeutics, - Viral Therapeutics, - Viral Vaccines, - Diagnostic Technologies, and - Protocols to Enhance Biological Defense. - The results of research are published in peer-reviewed journals or presented at scientific conferences - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	- Information, technologies, or processes are transitioned to applied research or advanced technology development - All DTOs are rated GREEN by the TARA Panel.

3.5.2.3 Metric Description. The metric for TB2 is described in Section 3.2.1.1. Applied research also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.5.2.4 TB2 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<u>Medical Countermeasures for Brucella (DTO)</u> - Determine whether over-expression of vaccine antigens in candidate live vaccines increases protective efficacy. Continue to develop and validate in vitro systems in mice and higher animal species to reliably quantify the intensity of potentially protective immune responses and determine the immune system components that eliminate infection complications following use of live attenuated candidate vaccines.	<u>Vaccines, Bacterial, Medical Countermeasures for Brucella (DTO CB31)</u> Determined whether over-expression of vaccine antigens in candidate live vaccines increases protective efficacy. Continued to develop and validate in vitro systems in mice and non-human primates to reliably quantify the intensity of potentially protective immune responses in animals vaccinated with live and subunit vaccines.
<u>Medical Countermeasures for Encephalitis Viruses (DTO)</u> - Complete studies on production of the live, attenuated VEE vaccine virus constructs, their genetic stability, and transmission potential of candidate VEE virus vaccines in competent vector mosquitoes.	<u>Vaccines, Viral, Medical Countermeasures for Encephalitis Viruses (DTO CB24)</u> Completed studies on production of the live attenuated Venezuelan equine encephalitis (VEE) virus vaccine constructs, their genetic stability, and their transmission potential as live attenuated viruses in competent vector mosquitoes.
<u>Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO)</u> - Downselect formulations for intranasal, inhalational, and/or transdermal delivery of recombinant protein vaccines. Propose commercial or proprietary device for delivery of vaccines.	<u>Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32)</u> Downselected formulations for intranasal, inhalational, and/or transdermal delivery of recombinant protein vaccines. Proposed commercial or proprietary devices for delivery of vaccines. <u>Vaccines, Needle-less Delivery Methods for Recombinant Protein Vaccines</u> Assessed novel, minimally invasive delivery technologies for the administration of protein subunit biodefense vaccine candidates, including rPA and recombinant staphylococcal enterotoxin B (rSEB) vaccines, and either rSEA vaccine or recombinant F1-V fusion protein plague vaccine.

FY2003 Targets	Actual Performance
<u>Diagnostic Technologies</u> - Apply new diagnostic approaches to the early recognition of infection, adapting the technologies to current and future comprehensive integrated diagnostic systems. Apply new technological approaches for diagnosis of potential biological warfare threat agents in laboratory studies using relevant clinical samples. Apply new technological approaches for concentrating and processing clinical samples to support rapid biological agent identification. Apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.	<u>Diagnostic Technologies</u> Applied new diagnostic approaches to the early recognition of infection, adapting the technologies to current and future comprehensive integrated diagnostic systems. Applied new technological approaches for diagnosis of potential biological warfare threat agents in laboratory and field studies using relevant clinical samples. Applied new technological approaches for concentrating and processing clinical samples to support rapid biological agent identification. Applied research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.
<u>Therapeutics, Bacterial</u> - Evaluate novel antibiotics and other therapeutics in established in vitro assays and animal models. Establish a database of therapeutic profiles for various species of bacterial threat agents.	<u>Therapeutics, Bacterial</u> Evaluated novel antibiotics and other therapeutics in established in vitro assays and animal models. Established a database of therapeutic profiles for various species of bacterial threat agents.
<u>Therapeutics, Toxin</u> - Continue high-throughput assessment of candidate therapeutic inhibitors for botulinum neurotoxin. Complete testing and development of cell-free assay for assessment of candidate therapeutic inhibitors of staphylococcal enterotoxin (SE). Select lead candidate inhibitors based upon results in cell-free and cell-based assays and prepare toxin-inhibitor crystals for x-ray diffraction analysis. Evaluate the outcome of structural stabilization and optimization studies on lead inhibitors of botulinum and SE.	<u>Therapeutics, Toxin</u> Continued high-throughput assessment of candidate therapeutic inhibitors for botulinum neurotoxin. Completed testing and development of cell-free assay for assessment of candidate therapeutic inhibitors of staphylococcal enterotoxin (SE). Selected lead candidate inhibitors based upon results in cell-free and cell-based assays and prepared toxin-inhibitor crystals for x-ray diffraction analysis. Evaluated the outcome of structural stabilization and optimization studies on lead inhibitors of botulinum and SE.
<u>Therapeutics, Viral</u> - Continue assessing the potential for immunotherapy against Ebola virus in higher animal species models. Identify pharmacological compounds provided by industry that disrupt filovirus growth in cell culture. Assess therapeutic action of compounds in mouse and higher animal models of filovirus infection. Continue research for development of a variola animal model at CDC.	<u>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> Determined the optimum dose of cidofovir in the appropriate non-human primate model using both the lethal pulmonary and lesional infection models with monkeypox. Characterized disease pathogenesis in both animal models. Performed studies to establish the therapeutic window in the variola model developed with the CDC. <u>Therapeutics, Viral</u> Continued assessing the potential for immunotherapy against Ebola virus in non-human primate models. Initiated characterization of sixteen monoclonal antibodies to identify other protective epitopes on Ebola virus glycoprotein (GP). Identified pharmacological compounds provided by industry that disrupt filovirus growth in cell culture. Assessed therapeutic action of compounds in mouse and higher animal models of filovirus infection. Continued research for development of a variola animal model at the Centers for Disease Control and Prevention (CDC).
<u>Medical Countermeasures</u> - Accelerate research to define criteria for successful therapeutics against toxins and viruses to	<u>Therapeutics, Medical Countermeasures</u> Accelerated research to define criteria for successful therapeutics against toxins and viruses to obtain diverse compounds such as

FY2003 Targets	Actual Performance
obtain diverse compounds such as inhibitors, channel-blockers, natural product extracts, and peptides that show promise as potential therapeutics against botulinum neurotoxins, staphylococcal enterotoxin, ricin toxin, and viruses. Continue characterizing and refining the variola higher animal model for smallpox for use in determining the effectiveness of post-exposure therapies.	inhibitors, channel-blockers, natural product extracts, and peptides that show promise as potential therapeutics against botulinum neurotoxins, staphylococcal enterotoxin, ricin toxin, and viruses. Continued characterizing and refining the smallpox higher animal model for use in determining the effectiveness of post-exposure therapies.
<u>Vaccines, Bacterial</u> - Develop mutants in various agents for in vivo expressed genes to examine role in virulence. Characterize the mechanism(s) of vaccine resistance in selected strains of various agents. Determine mechanisms and correlates of protection with efficacious glanders vaccines. In support of rPA vaccine candidate entry into component advanced development, complete evaluation of immunogenicity and efficacy of rPA isoform species in the rabbit model; continue to develop reagent standards for use in an in vitro potency assay; and complete collection of immune serum for evaluation in a higher animal species passive transfer study. In support of recombinant plague vaccine development, complete development of anti-V antigen competitive enzyme-linked immunosorbent assay (ELISA) and cytotoxicity inhibition assays; complete determination of the range of protection of the vaccine candidate against other virulent strains of <i>Y. pestis</i> in animals; and complete studies in mice on alternate vaccine administration routes, dose, formulation and mucosal adjuvants.	<u>Vaccines, Bacterial</u> Developed mutants in various agents for in vivo expressed genes to examine role in virulence. Characterized the mechanism(s) of vaccine resistance in selected strains of various agents. Determined mechanisms and correlates of protection with efficacious glanders vaccines. Completed evaluation of immunogenicity and efficacy of recombinant protective antigen (rPA) isoform species in the rabbit model; continued to develop reagent standards for use in an in vitro potency assay; and completed collection of immune serum for evaluation in non-human primates passive transfer study, all in support of rPA vaccine candidate entry into technology development. Completed development of anti-V antigen competitive enzyme-linked immunosorbent assay (ELISA) and cytotoxicity inhibition assays; completed determination of the range of protection of the vaccine candidate against other virulent strains of <i>Y. pestis</i> in animals; and completed studies in mice on alternate vaccine administration routes, dose, formulation and mucosal adjuvants, all in support of recombinant plague F1-V vaccine candidate entry into technology development.
<u>Vaccines, Toxin</u> - Complete efficacy studies on recombinant ricin toxin A-chain (rRTA) vaccine candidates and downselect to two lead candidates. Scale up process development for rRTA vaccine candidates; conduct analytical test qualification for identity and stability studies of rRTA candidates; and develop potency assay for rRTA vaccine candidates.	<u>Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46)</u> Completed efficacy studies in rodents on recombinant ricin toxin A-chain (rRTA) vaccine candidates and downselected to lead candidate and alternate. Performed scale up process development for lead rRTA vaccine candidate; conducted analytical test qualification for identity and stability studies of lead rRTA candidate; and developed a potency assay for rRTA vaccine candidates. Developed non-human primate model for testing lead vaccine candidate
<u>Vaccines, Viral</u> - Assess mechanism of immunity that protects against disease from Ebola virus in lower animal models. Develop assays to measure markers to validate the efficacy of vaccine candidates in established model systems for Ebola virus. Develop higher animal species models for EEE virus.	<u>Vaccines, Viral</u> Assessed mechanism of immunity that protects against disease from filoviruses (Marburg and Ebola viruses) in vivo. Developed assays to measure markers to validate the efficacy of vaccine candidates in established model systems for filoviruses. Developed non-human primate models for western equine encephalitis virus (WEE).
<u>Genetically Engineered Threat Medical Countermeasures</u> - Accelerate research efforts directed toward compiling and	<u>Therapeutics, Genetically Engineered Threat Medical Countermeasures</u> Accelerated research efforts directed toward compiling and

FY2003 Targets	Actual Performance
prioritizing function-related structural elements that constitute known toxins and virulence factors of biological threat agents. Continue developing integrated databases of protein domains or three-dimensional structural elements identified as virulence factors in biological threat organisms.	prioritizing function-based structural elements that constitute known toxins and virulence factors of biological threat agents. Continued developing integrated databases of protein domains or three-dimensional structural elements identified as virulence factors in biological threat organisms.
<u>Vaccines</u> - Evaluate additional vaccine candidates for delivery using the multiagent delivery platform. Develop virus constructs and obtain commercially produced humanized mouse monoclonal antibodies to evaluate protective immune responses. Investigate the potential of live vaccine candidates for bacterial threat agents.	<u>Vaccines</u> Evaluated additional vaccine candidates for delivery using the multiagent delivery platform. Developed virus constructs and obtained commercially produced humanized mouse monoclonal antibodies to evaluate protective immune responses. Investigated the potential of live vaccine candidate for bacterial threat agents.
	<u>Therapeutics, Monoclonal Antibody Based Technology</u> Continued research toward development of a proprietary heteropolymer (HP) system as a potential therapeutic for acute anthrax intoxication. Conducted in vivo assessment of the HP system in a transgenic mouse strain expressing the human CR-1 receptor on red blood cells. Performed in vivo assessments comparing the therapeutic capability of monoclonal antibody 14B7, which has high affinity for anthrax toxin, alone and within the HP system. <u>Therapeutics (CBDI), Bacterial, The National Center for Biodefense</u> Developed prophylaxes and treatments to test the effectiveness of a combination of lethal toxin inhibitors/blockers and antibiotics in reducing the mortality rate of anthrax infection. Tested the effectiveness of protease inhibitors in treating late-stage anthrax infection. Determined the role of Toll Like Receptors (TLRs) as targets for specific and broad-spectrum protection by developing and testing TLR antibodies and soluble receptors. <u>Therapeutics (CBDI), Bacterial, Heteropolymer Technologies for Anthrax Immunity</u> Developed an immunotherapeutic for the post-exposure treatment of inhalational anthrax in conjunction with antibiotics. This immunotherapeutic is a bispecific immunoconjugate heteropolymer (HP) biopharmaceutical agent targeting the protective antigen (PA) component of anthrax toxin. The two antibodies, anti-PA and anti-CR1, will be humanized. <u>Therapeutics (CBDI), Bacterial, Oral Anthrax Antibiotic</u> Used combinatorial chemistry and rational drug design to synthesize additional antibacterial agents. Screened these agents for pharmacological activity. Optimized inhibitors to provide acceptable in vivo biological activity and other characteristics critical for drug development. Optimized lead compound synthesis for commercial production. Completed in vivo safety pharmacology and toxicology studies required for first-time-in-man and proof-of-principle biowarfare organisms. <u>Therapeutics (CBDI), Bacterial, Rapid Antibody-Based Countermeasures</u> Analyzed convalescent sera samples from survivors of the Fall 2001 anthrax attacks in the USA, supplied by U.S. Army Medical Research Institute of Infectious Diseases

FY2003 Targets	Actual Performance
	(USAMRIID), using a proteomics platform to identify key antigens that are recognized by the human immune system during an anthrax infection. Performed proteomics analysis for a fully virulent <i>Yersinia pestis</i> strain, the etiologic agent for plague, grown in animals to identify secreted or membrane proteins that can serve as targets for the development of vaccines or diagnostic and therapeutic antibodies. Optimized an existing diagnostic/therapeutic antibody using proprietary technologies.
	<u>Vaccines, Organic Vaccine Production</u> Evaluate and determine the usefulness of methods/technologies to develop vaccines through alternative unconventional means.

3.5.2.5 TB2 Future Targets

FY 2004 Targets	FY 2005 Targets
<u>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> Continue preclinical virology studies (including animal efficacy studies) required for a supplemental New Drug Application for cidofovir and provide technical data and support to the drug license holder. Compare the variola animal model to the monkeypox animal model and human monkeypox to qualify models to be proposed under the FDA animal efficacy rule. Initiate development of an oral prodrug of cidofovir.	<u>Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> Complete preclinical virology studies (including animal efficacy studies) required for a supplemental New Drug Application for intravenous (IV) cidofovir. Continue evaluation of oral prodrug of cidofovir to determine its feasibility as a replacement for intravenous (IV) cidofovir.
<u>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</u> Develop laboratory-based test and evaluation standards for comparing similar diagnostic/detection assays and reagents. Elevate assays, previously handed off to advanced development, to consistent test and evaluation standards and prepare technical data packages for these assays/reagents.	<u>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</u> Continue to elevate previously transitioned assays to test and evaluation standards established during FY04.
<u>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58)</u> Initiate applied research to define correlates of immunity that protect against disease from alphaviruses (EEE and WEE viruses). Develop DNA and replicon-based vaccine constructs/platforms as western and eastern equine encephalitis (WEE/EEE) vaccine candidates.	<u>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Equine Encephalitis Vaccine (DTO CB58)</u> Continue to analyze mutants with various engineered attenuating mutations to determine their suitability for use as vaccine platforms. Initiate studies to establish an eastern equine encephalitis (EEE) virus non-human primate efficacy model.
<u>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</u> Investigate recombinant human antibodies as passive immunotherapeutics. Synthesize structural analogs of active-site inhibitors identified by high-throughput screening. Identify candidate botulinum neurotoxin (BoNT) receptor antagonists as therapeutic candidates. Establish a central database and compound repository.	<u>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</u> Test combinations of human monoclonal antibodies against multiple BoNT serotypes in cell-based systems. Expand proof-of-concept for BoNT target rescue and replacement in cholinergic neurons.
<u>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</u> Initiate development of animal models of aerosol infection with	<u>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</u> Incorporate iterative improvements in vaccine candidates as determined from characterization

FY 2004 Targets	FY 2005 Targets
filoviruses. Initiate applied research to define correlates of immunity that protect against disease from filoviruses. Develop animal models for Ebola-Sudan virus. Conduct preliminary characterization of leading vaccine candidates. <u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u> Develop assays methodologies and drug formulations or prodrugs for analysis. Evaluate monoclonal antibodies to viral specific proteins for their ability to neutralize virus. Identify critical host-cell proteins integral to viral replication, viral budding, or viral entry. Generate Ebola virus VP40 and GP mutant constructs as well as a tetra cysteine-fusion of VP40 in mammalian and bacterial expression vectors. <u><i>Therapeutics, Bacterial</i></u> Perform additional in vivo studies on efficacy of selected antimicrobial compounds against various bacterial threat agents in small animal models. Initiate studies of selected Food and Drug Administration (FDA)-licensed antibiotics to support consideration for changing label indications against biological warfare (BW) threat agents. <u><i>Therapeutics, Toxin</i></u> Initiate testing of lead inhibitors of SE using in vivo model systems for assessment of therapeutic efficacy. Standardize in vivo model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy. <u><i>Therapeutics, Viral</i></u> Develop fluorescent-based methods for high-throughput screening for antiviral efficacy and cellular toxicity. Continue research to identify pharmacological compounds provided by industry that may intervene in filovirus-induced shock. Continue the assessment of the therapeutic action of compounds in mouse models of filovirus infection. Complete research for development of a variola animal model at CDC. <u><i>Therapeutics, Heteropolymer Monoclonal Antibody-Based Technology</i></u> Produce and purify milligram quantities of H25 antibody for a 4-liter scale spinner production. Determine functional and biophysical properties of the purified antibody. Confirm the utility and acceptability of the antibody produced from the cell lines for further product development. Develop analytical transfer methods and assays for monoclonal antibodies (MAbs) and heteropolymers (HPs) and conduct animal studies. <u><i>Therapeutics, Bacterial, Heteropolymer Technologies for Anthrax Immunity</i></u> Evaluate protective efficacy in rabbits exposed to lethal doses of aerosolized anthrax using the proprietary anthrax antibody, ETI-204. Assess the level of bacteremia in treated versus untreated animals.	studies and concurrent testing. <u><i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i></u> Generate mutant Marburg virus proteins and evaluate their ability to interact with other Marburg virus proteins. Develop information on characteristics distinguishing protective and nonprotective monoclonal antibodies. <u><i>Therapeutics, Bacterial</i></u> Perform therapeutic efficacy studies in non-human primate models. Continue studies on selected FDA-licensed antimicrobial compounds to support consideration for changing label indications for use against BW threat agents. <u><i>Therapeutics, Toxin</i></u> Develop surrogate endpoints of human clinical efficacy for SE therapeutics. <u><i>Therapeutics, Viral</i></u> Assess therapeutic action of pharmacological compounds provided by industry in mouse and non-human primate models of filovirus infection. <u><i>Diagnostic Technologies</i></u> Continue applying new diagnostic approaches to the early recognition of infections. Technologies will be adapted to current and future comprehensive integrated diagnostic systems. Continue applying new technological approaches for diagnosis of potential biological warfare threat agents in laboratory and field studies using clinical samples. Apply new technological approaches for processing clinical samples and apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples. <u><i>Vaccines, Bacterial</i></u> Continue to perform laboratory research (demonstrate surrogate efficacy, design and validate in vitro correlates of protection, and stability studies) to support development of lead vaccine candidates against plague (F1-V fusion antigen vaccine) and anthrax (rPA vaccine). <u><i>Vaccines, Toxin</i></u> Continue studies on the ability of intact catalytic and translocation domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Continue studies to increase immunogenicity of existing recombinant BoNT

FY 2004 Targets	FY 2005 Targets
<u><i>Therapeutics, Bacterial, Rapid Antibody-Based Biological Countermeasures</i></u> Develop diagnostic and therapeutic antibodies against anthrax and identify new targets associated with anthrax and plague pathology. Identify additional targets associated with anthrax and plague virulence and screen for novel antibodies to detect and protect against related bioweapons. Discover novel, validated protein targets. Develop diagnostic antibodies optimized for affinity and selectivity to biowarfare agents. Create a collection of human therapeutic antibodies for passive immunity protection against bioweapons and more effective treatment against pathogens and toxins. <u><i>Diagnostic Technologies</i></u> Continue to apply new diagnostic approaches directed toward early recognition of infection, selecting technologies that can be adapted to current and future comprehensive integrated diagnostic systems. Continue laboratory and field studies using relevant clinical samples to apply new technological approaches for diagnosis of potential biological warfare threat agents. Continue to apply new technological approaches for concentrating and processing clinical samples to support rapid agent identification and to apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples. <u><i>Vaccines, Bacterial</i></u> Complete the evaluation of potential subunit and live-attenuated glanders vaccine candidates in small animal models and prepare a technical data package summarizing the glanders vaccine research program. Perform preliminary studies toward development of an acellular brucella vaccine candidate. Continue to perform in vitro and in vivo studies to support advanced development of the rPA vaccine candidate. <u><i>Vaccines, Toxin</i></u> Initiate studies on the ability of intact catalytic and translocation domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Initiate studies to increase immunogenicity of recombinant BoNT heavy chain (Hc) subunit vaccine candidates by varying adjuvant and/or method of delivery. Continue developing in-process and release assays for recombinant BoNT Hc vaccine candidates. Qualify in vivo and in vitro concept model systems for assessment of recombinant ricin vaccine candidate efficacy and surrogate endpoints of human clinical efficacy. <u><i>Vaccines, Viral</i></u> Investigate the use of the oligonucleotide CpG as an adjuvant with live attenuated alphavirus vaccine candidates to determine their effect on immunity conferred by the vaccines. <u><i>Vaccines, Needle-less Delivery Methods for Vaccines</i></u> Examine the potential for intradermal (ID) delivery to provide antigen dose-sparing benefits, faster seroconversion, and	vaccine candidates via adjuvants and/or delivery methods. Complete developing in-process and release assays for recombinant BoNT vaccine candidates. Continue recombinant ricin vaccine candidate stability testing. Develop surrogate endpoints of clinical efficacy in non-human primates for the candidate ricin vaccine. Test novel adjuvants with lead ricin vaccine candidate in vivo. <u><i>Vaccines, Viral</i></u> Continue research studies investigating the effect on immunogenicity by the use of the oligonucleotide CpG as an adjuvant with live attenuated alphavirus vaccine candidates.

FY 2004 Targets	FY 2005 Targets
reduction or elimination of alum. Examine the safety and immunogenicity of the ID delivery of the anthrax rPA with or without alum adjuvant. Compare intramuscular (IM) injection with standard needles. Pursue further development of formulation technologies for rPA and rSEB providing improved shelf-life stability. Develop and test rapidly reconstituting rPA powders and systems for ID delivery in mouse challenge studies. Identify rapidly reconstituting formulations and delivery systems for the rSEB vaccine candidate. <u><i>Vaccines, Viral, Multivalent Ebola, Marburg Filovirus Program</i></u> Develop a multivalent vaccine platform capable of inducing potent humoral and cellular immune responses against two strains of Ebola viruses (bivalent) and three strains of Marburg viruses (trivalent) for biodefense. <u><i>Vaccines, Bacterial, Oral Anthrax and Plague Vaccine</i></u> Develop an oral combination vaccine against anthrax and plague using proprietary technology for attenuated live bacterial vaccines. Support preclinical animal testing of vaccine constructs developed for the oral combination vaccine against anthrax and plague. <u><i>Vaccines, Bacterial, Novel Pharmaceuticals for Anthrax</i></u> Develop the Helinz-treated vaccine platform, with application in both cancer and infectious disease, including those agents that pose threats to bioterrorism. <u><i>Medical Biological Warfare Defense, Global Pathogen Portal</i></u> Collect and collate genetic information about pathogens from the CDC and the National Institute of Allergy and Infectious Diseases "A", "B", and "C" lists of pathogens and their close relatives using a global pathogen portal bioinformatic software architecture. <u><i>Medical Biological Warfare Defense, Vaccines and Therapeutics to Counter Biothreats</i></u> Conduct applied research to develop vaccines and therapeutics to counter BW threat agents. <u><i>Medical Biological Warfare Defense, Advanced Emergency Medical Response</i></u> Conduct applied research toward development of advanced emergency medical response capabilities.	

3.5.2.6 Assessment of Medical Biological Defense Applied Research. Applied research efforts in FY2003 for project TB2 were at least minimally effective. Many areas of medical biological defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. A few DTOs were rated yellow and there was a need identified to characterize more of the effort as DTOs. Extensive research continues to be conducted in several research areas supporting several major

operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2003, including the execution the CB Defense Initiative Fund.

3.5.3 Medical Chemical Defense Applied Research (Project TC2)

This project funds medical chemical defense applied research and emphasizes the prevention of chemical casualties through application of pharmaceuticals for prevention and treatment of the toxic effects of nerve, blister, respiratory, and blood agents. This project supports applied research of prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic drug compounds that have the potential to counteract the lethal, physical, and behavioral toxicities of chemical agents. It also supports development of medical chemical defense materiel that ensures adequate patient care, field resuscitation, and patient management procedures. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Nerve Agent Defense, Vesicant Agent Defense and Chemical Warfare Agent (CWA) Defense), and directed research efforts (Low Level CWA Exposure, Non- Traditional Agents (NTAs), and Mustard Gas Antidote).

3.5.3.1 TC2 Performance Goal (Outcome). The goal of medical chemical defense applied research is to increase scientific understanding of the mechanisms of action and effects of CW agents in order to demonstrate and develop technologies for preventive and therapeutic protection and diagnostics.

3.5.3.2 TC2 Outcome Measure

TC2 is minimally effective when	TC2 is successful when
- The results provide fundamental information in support of new and improved defensive systems, including information on – diagnostics, – low-level toxicology, – pre-treatments, – therapeutics, – novel threats, – optical recognition technologies, – new detection technologies. - The results of research are published in peer-reviewed journals or presented at scientific conferences - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	- Information, technologies, or processes are transitioned to applied research or advanced technology development - All DTOs are rated GREEN by the TARA Panel.

3.5.3.3 Metric Description. The metric for TC2 is described in Section 3.2.1.1. Applied research also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.5.3.4 TC2 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<i>Medical Countermeasures for Vesicant Agents II (DTO)</i> - Identify therapeutic window for administering compounds to mitigate the effects of HD exposure. Evaluate combination therapies for HD exposure in animal models.	<i>Vesicant Agent Defense, Medical Countermeasures for Vesicant Agents II (DTO CB30)</i> Identified therapeutic window for administering compounds to mitigate the effects of HD exposure. Evaluated combination therapies for HD exposure in animal models.
<i>Diagnostics</i> - Pursue development of an ocular device	<i>Chemical Warfare Agent Defense, Medical Diagnostics</i>

FY2003 Targets	Actual Performance
for self-examination of pupillary response to nerve agent exposure. Continue development of analytical methods to measure biological matrices (e.g., blood, urine, tissue) following CWA exposure. Develop confirmatory forensic diagnostic capabilities and rapid screening technology for field applications.	Continued development of analytical methods to measure biological matrices (e.g., blood, urine, tissue) following CWA exposure. Developed confirmatory diagnostic capabilities and rapid screening technology for field applications. Pursued development of an ocular device for self-examination of pupillary response to nerve agent exposure.
<u>Pretreatments</u> - Develop physiological pharmacokinetic models of CWAs. Evaluate the safety and circulatory stability of recombinant bioscavengers. Determine specific carbohydrate structures of human serum butyrylcholinesterase for reference material for Good Laboratory Practices (GLP) and current Good Manufacturing Practices (cGMP) production. Generate serum carboxylesterase-deficient mice for use in testing efficacy of nerve agent bioscavengers. Evaluate several classes of compounds that behave by different mechanisms of action, to include methemoglobin formers and sulfur donors, to pursue development of a cyanide pretreatment.	<u>Nerve Agent Defense, Biological Scavenger</u> Developed physiological pharmacokinetic models of CWAs. Evaluated the safety and circulatory stability of recombinant bioscavengers. Determined specific carbohydrate structures of human serum butyrylcholinesterase as reference material for Good Laboratory Practices (GLP) and current Good Manufacturing Practices (cGMP) production. Generated serum carboxylesterase-deficient mice for use in testing efficacy of nerve agent bioscavengers.
<u>Therapeutics</u> - Evaluate new FDA-approved drugs for treatment of HD-induced ocular injury. Optimize formulation for an ocular rinse that treats HD-induced ocular injury. Evaluate treatments for HD-induced pulmonary injury. Develop experimental protocol to evaluate drugs, drug combinations and drug treatment protocols with potential to control nerve agent-induced seizures. Evaluate ability of midazolam and anticholinergics to terminate nerve agent-induced seizures in a higher animal species model. Evaluate antagonists of apoptosis and the blockade of HD-induced toxicity. Examine modulation of intracellular calcium to protect against soman-induced seizure related brain damage. Develop and test neuroprotectant drugs to protect against status epilepticus following nerve agent exposure. Assess alternate higher animal species as models for nerve agent toxicity and medical countermeasures.	<u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Developed experimental protocol to evaluate drugs, drug combinations and drug treatment protocols with potential to control nerve agent-induced seizures. Evaluated ability of midazolam and anticholinergics to terminate nerve agent-induced seizures in a non-human primate model. <u>Nerve Agent Defense, Neuroprotection</u> Developed and tested neuroprotectant drugs to protect against status epilepticus following nerve agent exposure. Assessed alternate non-human primates as models for nerve agent toxicity and medical countermeasures. <u>Vesicant Agent Defense, Cutaneous Therapeutics</u> Evaluated new FDA-approved drugs for treatment of HD-induced ocular injury. Optimized formulation for an ocular rinse that treats HD-induced ocular injury. <u>Vesicant Agent Defense, Mustard Gas Antidote</u> Explored the use of free and liposome-encapsulated antioxidants as a medical countermeasure to HD exposure. <u>Vesicant Agent Defense, Vesicant Medical Countermeasures</u> Evaluated antagonists of apoptosis and the blockade of sulfur mustard (HD)-induced toxicity. <u>Chemical Warfare Agent Defense, Cyanide Medical Countermeasures</u> Evaluated several classes of compounds that behave by different mechanisms of action, to include methemoglobin formers and sulfur donors, to pursue development of cyanide pretreatment. <u>Chemical Warfare Agent Defense, Inhalation Therapeutics</u> Evaluated treatments for HD-induced pulmonary injury. <u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u>

FY2003 Targets	Actual Performance
	Evaluated the toxicity of percutaneously applied organophosphorus compounds and the effectiveness of skin decontamination methods.
<u>Low Level Chemical Warfare Agent Exposure</u> - Identify prophylactic and therapeutic compounds to treat low level chemical exposure using in vitro cellular model. Utilize a behavioral assessment model in guinea pigs to study the effects of low level chemical warfare agent exposure.	<u>Chemical Warfare Agent Defense, Low Level CWA Exposure: Effects and Countermeasures (DTO CB51)</u> Assessed short-term behavioral, physiological, and neuropathological effects of sarin (GB) nerve agent in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness.
<u>Non-Traditional Agents (NTAs)</u> - Evaluate cardiac toxicity following NTA toxicity in cardiac muscle cells and animal models. Synthesize and screen oxime reactivation compounds for nerve agents. Consider anti-organophosphate antibodies as an FGA treatment strategy. Evaluate bioscavenger pretreatment as medical countermeasure against NTAs in guinea pigs.	<u>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</u> Evaluated cardiac toxicity following NTA exposure in cardiac muscle cells and animal models. Evaluated bioscavenger pretreatment as medical countermeasure against NTAs in guinea pigs. <u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Initiated chemical assay development to detect candidate oxime(s) for use against traditional nerve agents and NTAs in biological fluids, stability studies, and studies to identify and characterize a surrogate marker for efficacy, drawing from an array of promising compounds already identified.

3.5.3.5 TC2 Future Targets

FY 2004 Targets	FY 2005Targets
<u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Continue assay development, stability studies, and studies to identify and characterize a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and NTAs.	<u>Nerve Agent Defense, Improved Oxime (DTO CB48)</u> Complete assay development and stability studies. Complete the identification and characterization of a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and NTAs.
<u>Chemical Warfare Agent Defense, Low Level CWA Exposure: Effects and Countermeasures (DTO CB51)</u> Assess short-term behavioral, physiological, and neuropathological effects of VX nerve agent in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness. Initiate studies on the effects of current prophylactic and therapeutic treatments on the maximum tolerated dose for repeated CWA exposures and on other indices of chemical agent toxicity.	<u>Chemical Warfare Agent Defense, Low Level CWA Exposure: Effects and Countermeasures (DTO CB51)</u> Assess VX nerve agent and HD-induced changes in respiratory function produced by low-dose exposures of varying duration. Complete assessments of the short-term effects of VX nerve agent 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. Complete assessments of the effects of current CWA treatments on toxicity at low doses of exposure.
<u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u> Determine the effects of NTAs on energy metabolism of cardiac cells and the effectiveness of decontamination on percutaneous NTAs. Conduct electrophysiological evaluation of cardiovascular, respiratory, muscular and cortical dysfunction.	<u>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</u> Evaluate the effectiveness of anticonvulsants against seizures produced by NTAs, in vivo persistence of NTAs, and current medical countermeasures against NTAs. Conduct evaluation of respiratory dynamics and lung biochemistry.
<u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u> Determine efficacy of midazolam and anticholinergic drug combinations against seizures and lethality caused by nerve agents. Determine minimal amount of atropine	<u>Nerve Agent Defense, Nerve Agent Anticonvulsants</u>

FY 2004 Targets	FY 2005 Targets
needed to sustain survival in non-human primates exposed to nerve agent. <u><i>Nerve Agent Defense, Biological Scavenger</i></u> Determine pharmacokinetics of CWAs and the impact of pretreatment in guinea pigs. Determine x-ray crystallographic structure of catalytic scavengers. Continue pretreatment intervention studies of vectors to deliver bioscavenger genes. Characterize animal models to test efficacy of nerve agent bioscavengers. Test physiologic pharmacokinetic model of CWAs. <u><i>Nerve Agent Defense, Neuroprotection</i></u> Test Food and Drug Administration (FDA)-approved drugs shown to be neuroprotective in both anatomic and behavioral studies. <u><i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i></u> Conduct screening of candidate antivesicant compounds. Develop in vitro and in vivo models to support efficacy studies of new antivesicant countermeasures. <u><i>Vesicant Agent Defense, Cutaneous Therapeutics</i></u> Identify candidate treatment strategies and collate findings in concert with medical experts and relevant research teams. Define in vitro/in vivo models, establish pathophysiological endpoints, and define cellular and tissue consequences of exposure. <u><i>Vesicant Agent Defense, Mustard Gas Antidote</i></u> Enhance the effectiveness of Signal Transduction Inhibition Methodology Antioxidant Liposomes (STIMAL), also known as the Redox Regulating Liposome (RRL), by further product development. Elucidate the pathophysiology of mustard agents in previously developed in vitro and in vivo models. Explore additional modalities such as pharmacogenomically-based drugs and complement blockade. Complete initial efficacy studies of STIMAL against HD. Conduct detailed studies on the inhalation of mustards (bis-2-CEES) to determine if oxidative stress is a significant part of the pathophysiology. <u><i>Chemical Warfare Agent Defense, Cyanide Medical Countermeasures</i></u> Evaluate cyanide toxicity using an inhalation model. Investigate efficacy of sulfur donors and methemoglobin formers as cyanide pretreatment. <u><i>Chemical Warfare Agent Defense, Inhalation Therapeutics</i></u> Screen clinically available drugs for potential efficacy against HD using the mouse model.	Define in vitro and in vivo models for study of improved nerve agent countermeasures. <u><i>Nerve Agent Defense, Biological Scavenger</i></u> Complete development of transgenic animal models that can produce sufficient amounts of recombinant enzyme scavengers for clinical trials. Complete feasibility testing of vector/gene combinations to validate the concept of gene therapy for bioscavengers. Continue pretreatment intervention studies of vectors to deliver bioscavenger genes. <u><i>Nerve Agent Defense, Neuroprotection</i></u> Continue testing FDA-approved drugs shown to be neuroprotective in both anatomic and behavioral studies. <u><i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i></u> Define pharmacological categories for points of intervention in vesicant injury process. Screen potential antivesicant compounds. <u><i>Vesicant Agent Defense, Cutaneous Therapeutics</i></u> Characterize pathophysiological endpoints and continue elucidation of pathophysiological schema. Develop in vitro biological tissue assays. Identify additional potential intervention strategies. <u><i>Chemical Warfare Agent Defense, Cyanide Medical Countermeasures</i></u> Screen anti-cyanide compounds for efficacy. <u><i>Chemical Warfare Agent Defense, Inhalation Therapeutics</i></u> Test efficacious drugs in a modified inhalation therapy system. <u><i>Chemical Warfare Agent Defense, Medical Diagnostics</i></u> Continue development of diagnostic applications for miniaturized mass spectrometer. <u><i>Chemical Warfare Agent Defense, Skin and Wound Decontamination</i></u> Continue development of analytical and animal screening procedures for the evaluation of decontaminants and use them to screen for efficacy. Evaluate formulations designed to remove HD from reservoirs in the skin.

FY 2004 Targets	FY 2005 Targets
<u>Chemical Warfare Agent Defense, Medical Diagnostics</u> Initiate development of diagnostic applications for miniaturized mass spectrometer. Develop diagnostics that can be used to diagnose exposure via respiratory route. Refine analytical methods to measure scopolamine levels in blood and tissue. Investigate applicability of ocular device for self-examination of pupillary response. <u>Chemical Warfare Agent Defense, Skin and Wound Decontamination</u> Pursue development of screening procedures for the evaluation of decontaminants using analytical techniques and animal models. Determine the extent that HD forms a reservoir in skin using pig and hairless guinea pig skin models.	

3.5.3.6 Assessment of Medical Chemical Defense Applied Research. Applied research efforts in FY2003 for project TC2 are at least minimally effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2003.

3.6 ADVANCED TECHNOLOGY DEVELOPMENT (PROGRAM ELEMENT 0603384BP)

This program element demonstrates technologies that enhance the ability of U. S. forces to defend against, and survive CB warfare. This PE funds advanced technology development for Joint Service and Service- specific requirements in both medical and non- medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as counter-measures for CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the non- medical area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD CBW defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Work conducted under this PE transitions to and provides risk reduction for Advanced Component Development and Prototypes (PE 0603884BP) and System Development and Demonstration (PE 0604384BP) activities. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real- time sensing, accelerated BW operational awareness, and the restoration of operations following a BW/ CW attack. This program is dedicated to conducting proof- of- principle field demonstrations, and tests of system- specific technologies to meet specific military needs.

3.6.1 Chemical and Biological Defense Advanced Technology Development (Project CB3)

This program element demonstrates technologies that enhance the ability of U.S. forces to defend against, and survive chemical and biological (CB) warfare. This program element (PE) funds advanced technology development for Joint Service and Service-specific requirements in both medical and non-medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as countermeasures for CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the non-medical area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD Chemical/Biological Warfare (CBW) defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Also research efforts are planned to evaluate technologies for Weapons of Mass Destruction Civil Support Teams (WMD-CSTs). Work conducted under this PE transitions to and provides risk reduction for System Integration/Demonstration (PE 0603884BP/PE 0604384BP) activities. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated BW operational awareness, and the restoration of operations following a BW/CW attack. This program is dedicated to conducting proof-of-principle field demonstrations, and tests of system-specific technologies to meet specific military needs.

3.6.1 Chemical and Biological Defense Advanced Technology Development (Project CB3)

This project demonstrates technology advancements for Joint Service application in the areas of chemical and biological agent detection and identification, decontamination, and individual/collective protection, which will speed maturing of advanced technologies to reduce risk in system-oriented Advanced Component Development and Prototypes efforts. This project funds the Joint Service Family of Decontamination Systems (JSFDS) Program, the Joint Service Sensitive Equipment Decontamination (JSSED) Program, the Joint Chemical/ Biological Agent Water Monitor (JCBAWM), the Joint Biological Standoff Detection System (JBSDS), the Joint Service Wide Area Detector (JSWAD), and Joint Operational Effects Federation (JOEF).

3.6.1.1 CB3 Performance Goal (Outcome). The goal of the CB defense non-medical advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the detection, protection against, and decontamination of CBW agents.

3.6.1.2 CB3 Outcome Measure

CB3 is minimally effective when	CB3 is successful when
- The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: - Advanced materials for individual protection, - Detection of chemical and biological contamination, - Decontamination of sensitive equipment,	- Information, technologies, or processes are transitioned to applied research or advanced technology development - All DTOs rated GREEN by the TARA panel

CB3 is minimally effective when	CB3 is successful when
– Early warning chemical and biological detection capabilities • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	

3.6.1.3 Metric Description. The metric for CB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes A–D of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.6.1.4 CB3 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<u>Detection of Agent in Water</u> - Complete design and initiate build of brassboard system for demonstration. <u>Chemical and Biological Warfare Effects on Operations (DTO-CB43)</u> - Complete and transition Joint Effects Model to the Joint Warning and Reporting Network (JWARN). Complete and transition Simulation, Training and Analysis for Fixed Sites (STAFFS) to Joint Warfare Simulation (JWARS) and to JOEF Block I. <u>Decontamination, Sensitive Equipment</u> - Complete the validation, verification, and accreditation process for the JSSSED Block II/III AoA. Complete development and management plan for items identified by the AoA and complete TRL 4/5 requirements. Develop MS-B transition documentation. <u>Decontamination, Future Threat Agent Studies</u> - Conduct contact hazard evaluations using NATO protocols. Conduct off-gas hazard evaluations using NATO/TTCP protocols. <u>IST, Joint Operational Effects Federation (JOEF)</u> - Complete Analysis of Alternatives (AoA) and market survey. Complete the Test and Evaluation Master Plan (TEMP). Complete the acquisition strategy and supporting acquisition documentation. Complete Interoperability Assessment and System Threat Assessment. Prepare final documentation for transition to development. <u>Field Trials</u> - Conduct Technology Readiness Evaluations (TRE) of point and standoff CB detection systems. <u>Tech Transition</u> - Develop improved sample processing interface for UV MALDI-TOF mass spectrometer and incorporate into DARPA BioTOF device. Complete evaluation of upconverting phosphors for bio identification. Complete evaluation of anthrax-specific antibodies	<u>Lightweight Integrated CB Detection</u> - Continued evaluation and development of DOE's micro chem lab to meet Joint Modular CB detector requirements. <u>Point Detection, Detector Modifications</u> - Completed and demonstrated standard operating procedures for enhanced wet chemistry test kits and aerosol collectors/samplers as a "quick fix" for new chemical targets. Complete laboratory modification of point detection systems to enhance performance against new chemical targets and transitioned data package to the Automated Chemical Agent Detector Alarm acquisition program. <u>Evaluation of Fielded Decontaminants Against NTAs</u> - Completed stirred reactor studies on standard and emerging decontaminants against three NTAs. Conducted post decontamination contact hazard assessments for two NTAs. Conducted assessment studies on XE-555 resin and A-200 sorbent powder, used respectively in the M291 and M295 immediate decontamination kits, for two NTAs. <u>Decontamination, Sensitive Equipment</u> - Completed the JSSSED interior decontamination analysis of alternatives (AoA), which has been staffed to and accepted by the Program Manager. Conducted field demonstration trials on thermal decontamination approaches in actual cargo aircraft. Conducted chamber trials using vapor phase hydrogen peroxide system for decontamination of interiors. <u>Chemical and Biological Warfare Effects on Operations (DTO CB43)</u> - Prepared for transition of the fighterbase and casualty modules to Joint Operational Effects Federation (JOEF) program to support Block I Demonstration. Completed the first phase of independent verification of software. Baselined RESTOP ACTD results as model validation. Delivered airbase representation module and generic airbase module to the Defense Threat Reduction Agency. <u>Chemical and Biological Hazard Environment Prediction (DTO CB55)</u> - Transitioned Vapor Liquid Solid Tracking (VLSTRACK) Version 3.1 capabilities to the JEM Block I and JOEF programs. Continued development of

FY2003 Targets	Actual Performance
previously identified. Evaluate and refine catalytic oxidation filtration device. Initiate development of pathogen agents database with UV/IR MALDI and construct automated sample processing interface. Complete evaluation of Sandia foam for military decon. Refine gas microchem lab and initiate development of improved sample processing interface for fluidic microchem lab. Complete development of sample handling interface for HANAA. Extend MAGICChip capability to address additional pathogen agents. Initiate assessment of additional technologies in detection, decontamination, and filtration from other government agencies. <u>Evaluation of Technologies for Non Traditional Agents (NTA)</u> - Continue assessment of point detector modifications, development of spectral data-base, and evaluation of fielded decontamination systems against NTA.	advanced predictive capabilities (MESO). Enhanced the ability to analyze transport and flows over complex terrain and around structures such as ships (enhancements included addressing biological agent slurry transport, dusty agent behavior, and complex agent sources and sinks). <i>Fielded Decontamination Assessment, Non-Traditional Agent (NTA)</i> - Completed assessment of fielded decon system for NTAs. <i>Technical Readiness Evaluation</i> - Conducted Technical Readiness Evaluations (TRE) of point and stand-off CB detection systems. Conducted contact hazard evaluations using NATO protocols. Conducted off-gas hazard evaluations using NATO/TTCP protocols. <i>Technical Transition</i> - Developed an improved sample processing interface for UV Matrix Assisted Laser Desorption Ionization (MALDI) -Time Of Flight (TOF) mass spectrometer and incorporate into DARPA BioTOF device. Completed evaluation of upconverting phosphors for bio identification. Completed evaluation of anthrax-specific antibodies. Evaluated and refined catalytic oxidation filtration device. Initiated development of pathogen agents database with UV/IR MALDI and construct automated sample processing interface. Completed evaluation of Sandia foam for military decon. Completed development of sample handling interface for HANAA. Extended MAGICChip capability to address additional pathogen agents. Initiated assessment of additional technologies in detection, decontamination, and filtration from other government agencies. <i>Miniature Chemical and Biological Detectors</i> - Developed a prototype with a miniaturized reader and self-contained disposable credit card sized cartridges containing a detection array, all necessary reagents and buffers, and the microfluidics to conduct specific assays. The technology is based on individually addressable polymer microspheres. <i>Rapid Response Countermeasures to Biological and Chemical Threats</i> - Continued studies to enhance public health and safety in the event of an animal or human based bioterrorism event; developed and demonstrated a wide area, real time human health monitoring and reporting database; continued to develop very rapid methods to detect biological threat agents on surfaces, in food and in water; continued studies into factors affecting biological toxicity of selected agents; initiated design study for antibody libraries; initiated photocatalytic air disinfection methods study; continued to investigate taggants using non standard DNA; began development of a small, high performance cooler for first responders. <i>CBRN Threat Test Using Public/Private Assets (Sensor Net)</i> - Designed an Information Technology Infrastructure for Comprehensive Incident Management. This will provide a common data pathway for homeland security sensors such

FY2003 Targets	Actual Performance
	as CBRNE, meteorology, and visual sensors. <i>Bioterrorism/Agroterrorism Prediction and Risk Assessment</i> - Initiated a predictive model to study of effects of a virus introduced to US native species (i.e., cattle). <i>Advanced Chemical Detector</i> - Explored and validated an advanced chemical threat agent detector. <i>High Intensity Pulsed Radiation Facility for Chem-Bio Defense</i> - Developed studies to understand the effects of radiation on biological materials as a method to neutralize the pathogenic effects without disrupting the cellular characteristics of the biological materials. <i>Stand-off Sensor Assessment, Non-Traditional Agents (NTA)</i> - Established infrastructure to develop spectral signature. Developed spectral signature database. Assessed optical techniques to the detection of NTAs. <i>Bioterrorism Defense and Advanced Sensors</i> - Explored and validated the utility of advanced sensor technologies in combating bioterrorism.

3.6.1.5 CB3 Future Targets

FY 2004 Targets	FY 2005 Targets
<i>Stand-off, Sensor Assessment Non-Traditional Agents (NTA)</i> - Continue development of spectral database. Initiate enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs. <i>Chemical/Biological Agent Water Monitor (DTO CB37)</i> - Detection of Agent in Water - Initiate limited utility assessment to demonstrate technology. Develop assessment criteria and initiate a prototype design and build for the assessment. <i>Lightweight Integrated CB Detection (DTO CB50)</i> - Complete evaluation and continued development of DOE's micro chem lab to include bio threats. Initiate the evaluation of the pyrolysis-GC-IMS system and a trade off study to downselect the appropriate system concept to meet the Joint Modular CB Detection requirements. <i>Individual Protection, Clothing Non Traditional Agent (NTA)</i> - Identify appropriate simulant chemicals for NTA aerosols when testing protective clothing layers and systems. Determine the effects of water phase in protective clothing layers on protection against NTA simulants. <i>Decontamination, Oxidative Formulation (DTO CB44)</i> - Demonstrate products with existing applicator systems. Modify or develop alternative applicators. Conduct basic integration of products into a "simulated environment". Extend test bed to include multiple	<i>Support Additional TREs</i> - Conduct technology readiness assessments on technologies transitioning from the applied research program to include consequence management technologies. Examples are decontamination solution formulations, stand-off chemical detection, chem-bio agent water monitor, chemical point detectors with TIC/TIM/NTA capabilities, and biological agent identifiers and triggers. <i>Hot Lightweight Chemical Detector (LCD)</i> - Characterize and assess the performance of a breadboard (heated inlet version of the UK fielded LCD) against NTAs and traditional agents. The breadboard assessment will be the basis for the design and build of a prototype. The performance of the prototype will be assessed for transition suitability to the acquisition program Joint Chemical Agent Detector (JCAD). <i>Lightweight Integrated CB Detection (DTO CB50)</i> - Downselect technologies to the best two or three approaches. Prepare design concepts based on these approaches. <i>Stand-off Biological Aerosol Detection (DTO CB35)</i> - Establish a series of field test to evaluate and demonstrate the capability to detect and discriminate biological vs non- biological agents. <i>Chemical/Biological Agent Water Monitor (DTO CB37)</i> - Detection of Agent in Water - Complete prototype build and assessment methodology.

FY 2004 Targets	FY 2005 Targets
agents and NTAs. Conduct robust chamber studies using full-scale conceptual system testing with live agents. <i>Chemical and Biological Warfare Effects on Operations (DTO CB43)</i> - Preparation for transition of the fighterbase and casualty modules to Joint Operational Effects Federation (JOEF) program to support Block I Demonstration. Complete the first phase of independent verification of software. Baseline RESTOP ACTD results as model validation. Deliver airbase representation module and generic airbase module to the Defense Threat Reduction Agency. <i>Planning, Training, and Analysis</i> - Transition of STAFFS model to JOEF. Integration support putting NBC CREST and impact models into JOEF. <i>Chemical and Biological Hazard Environment Prediction (DTO CB55)</i> - 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. <i>Simulation Based Acquisition</i> - Initiate investigation of prototype software development requirements to meet performance specifications for a Virtual Prototyping System (VPS) that would support acquisition of CB defense end items to protect a variety of installations/facility types. If resources allow, and an affirmative decision is made, prototyping efforts would begin in this fiscal year. <i>Point Detection, Biological Identification</i> - Initiate development of an automated system to populate a biomarkers database system based on Mass Spec analysis. <i>Chemical and Biological Detectors</i> - Develop technologies for chemical and biological detectors. <i>Countermeasures to Biological and Chemical Threats Response</i> - Explore and evaluate technologies for countermeasures to biological and chemical threats response. <i>Handheld Biological Agent Detection System</i> - Evaluate technologies for handheld biological agent detection system. <i>Innovative Materials for MEMS Fabrication</i> - Explore technologies for innovative materials for MEMS fabrication. <i>Immunochemical Bio/Chem Agent Detector</i> - Develop and validate immunochemical biological and chemical agent detector technologies. <i>Bio-MEMS</i> - Develop and validate bio-MEMS	<i>Point Detection, Biological Identification</i> - Complete prototype build and assessment methodology. <i>LISA Prototype</i> - Assess the performance of the first generation detection algorithm under operational environments. Develop the second generation detection algorithm based on the assessed shortfalls of the first generation algorithm. Support additional work to transition technology into Chemical Unmanned Ground Reconnaissance (CUGR) ACTD. <i>Individual Protection, Clothing Non-Traditional Agent (NTA)</i> - Continue to identify appropriate simulant chemicals for NTAs aerosols when testing protective clothing layers and systems. Determine the effects of water phase in protective clothing layers on protection against NTA simulants. <i>Decontamination, Oxidative Formulation (DTO CB44)</i> - Conduct safety, health and environmental studies. Complete live agent and applicator breadboard testing. Complete TRL 5/6 requirements. <i>Chemical and Biological Hazard Environment Prediction (DTO CB55)</i> - 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. <i>Chemical and Biological Warfare Effects on Operations (DTO CB43)</i> - Test and finalize toward JOEF transition Block 2. Develop Marine Expeditionary Force HQ, depot, and railhead modules. Perform internal V&V. <i>Simulation Based Acquisition</i> - Complete prototype VPS and conduct a technology demonstration. Conduct analyses and studies to support a Milestone A determination for VPS. <i>Technical Transition</i> - Conduct competitive assessment of all mature mass spectrometric biodetection approaches. Complete assessment of selected technologies in detection, decontamination, and protection from other government agency programs identified for evaluation in previous FY. <i>Technical Readiness Evaluation</i> - Conduct Technology Readiness Evaluations (TRE) of point and stand-off CB detection systems. Conduct stirred reactor, contact hazard and off gas testing on emerging decontaminants not tested previously. <i>Stand-off, Sensor Assessment Non-Traditional Agent (NTA)</i> - Complete spectral database of NTAs. Complete enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs. The assessment will be used to develop a cost-benefit

FY 2004 Targets	FY 2005 Targets
technologies. <i>Vaporized Hydrogen Peroxide Tech for Decontamination</i> - Develop and validate vaporized hydrogen peroxide technologies for decontamination. <i>Technical Readiness Evaluation (TRE)</i> - Conduct TREs of point and stand-off CB detection systems. Conduct stirred reactor, contact hazard, and off gas testing on emerging decontaminants not tested previously. <i>Technical Transition</i> - Complete development of integrated UV MALDI-TOF and IR MALDI-TOF mass spectrometers. Complete catalytic oxidation filtration device. Complete evaluation of MAGICChip. Continue assessment of technologies in detection, decontamination, and filtration from other government agency programs. <i>Rapid Response Database Center</i> - Develop and validate rapid response database. <i>Reactive Air Purification</i> - Explore reactive air purification technologies. <i>High Intensity Pulsed Radiation Facility for CB Agent Defeat</i> - Explore technologies for a high intensity pulsed radiation facility for CB agent defeat. <i>Sensor Net/CBRN Threat using Public and Private Assets</i> - Develop and validate technologies for sensor net/CBRN threat using public and private assets. <i>Rapid Response Sensor Networking</i> - Evaluate technologies for rapid response sensor networking. <i>Chem-Bio Defense Initiative</i> - Develop multiple technologies and methodologies for the rapid detection of, and protection from biological agents utilizing both point and stand-off platforms. <i>SBIR</i> - Small Business Innovative Research	analysis on the value and potential to upgrade either fielded or developmental systems to detect and identify NTAs.

3.6.1.6 Assessment of Chemical and Biological Defense Advanced Technology

Development. Advanced Technology Development efforts in FY2003 for project CB3 were effective. Many areas of CB defense advanced technology development were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. Extensive development continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2003.

3.6.3 Counterproliferation Support Advanced Technology Development (Project CP3)

The mission of the Counterproliferation Program (CP) is to address shortfalls in the DoD deployed capability to defend against and counter the proliferation of WMD. By focusing on near term results, the CP accelerates delivery of new tools, equipment, and procedures to combat

forces. Under the passive defense pillar, CP enhances the efforts of the Chemical and Biological Defense Program. This project funds a variety of programs to defend our forces against WMD, such as the Biological Detection (BIODET), Biological Non-Systems (BIO Non Sys) efforts, Critical Reagents Program (CRP), Restoration of Operations (RESTOPS) and a Planning and Development for Advanced Concept Technology Demonstrations.

3.6.3.1 CP3 Performance Goal (Outcome). The goal of the counterproliferation support advanced technology development program is to demonstrate advanced capabilities and concepts involved in the detection, protection against, and decontamination of CBW agents.

3.6.3.2 CP3 Outcome Measure

CP3 is minimally effective when	CP3 is successful when
- The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: - Biological detection systems. - Critical reagents for biological detection and identification. - The results of research are published in peer-reviewed journals or presented at scientific conferences. - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed.	- Information, technologies, or processes are transitioned to applied research or advanced technology development. - All DTOs are rated GREEN by the TARA.

3.6.3.3 Metric Description. The metric for CP3 is described in Section 3.2.1.1. Advanced technology development also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the Restoration of Operations (RestOps) ACTD and the Contamination Avoidance as Sea Ports of Debarkation (CASPOD) ACTD.

3.6.3.4 CP3 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<u>CASPOD</u> - Perform technical testing of technologies for the CASPOD ACTD. <u>CASPOD</u> - Develop and test techniques, tactics, and procedures for the use of the CASPOD ACTD technologies. Acquire test equipment, provide test participants and evaluators, develop environmental compliance documentation for tests and preliminary demonstration.	<i>ACTD-PD</i> - Evaluated FY04 and FY05 ACTD candidates. Supported the evaluation of the Large Frame Aircraft Decontamination Demonstration for RestOps ACTD. Supported the completion of transition planning for RestOps ACTD. <i>RestOps</i> - Conducted RestOps ACTD lessons learned study and completed report on RestOps ACTD. Initiated transition planning for technology acquisition from the RestOps ACTD. <i>CASPOD</i> - Performed technical testing of technologies for the CASPOD ACTD. <i>CASPOD</i> - Developed test techniques, tactics, and procedures (TTP) for the use of the CASPOD ACTD technologies. Acquired test equipment, provided test participants and evaluators. Developed environmental compliance documentation for tests and preliminary demonstration.

FY2003 Targets	Actual Performance
	<i>RestOps</i> - Performed Large Frame Aircraft Decontamination Demonstration (LFADD) project. <i>RESTOPS</i> - Completed evaluation of technologies in final demonstration. Transition continues in FY04 to CP4 for residual support projects.

3.6.3.5 CP3 Future Targets

FY 2004 Targets	FY 2005 Targets
<i>ACTD-PD</i> - Perform technology demonstrations and maturity evaluation on Contaminated Surface Detector (CSD) in preparation for the CUGR ACTD in FY05. <i>ACTD-PD</i> - Develop CONOPS and procedures for Biological Warfare fusion cell for the Biological Warfare Countermeasures Initiative (BWCI) Counter Bio project in preparation for United States Pacific Command (PACOM) FY05 demonstration.	<i>ACTD-PD</i> - Initiate technology maturity evaluations for selection of technologies for future ACTD candidates. <i>ACTD-PD</i> - Initiate planning for ACTD candidates, explore potential CONOPS with ACTD candidates technologies.

3.6.3.6 Assessment of Counterproliferation Support Advanced Technology Development.

Advanced Technology Development efforts in FY2003 for project CP3 were at least minimally effective. The RestOps ACTD was completed and developed lessons learned and concepts of operations for fixed sites, however, minimal new technological capabilities were fielded as a result.

3.6.4 Medical Biological Defense Advanced Technology Development (Project TB3)

This project funds preclinical development of safe and effective prophylaxes and therapies (vaccines and drugs) for pre- and post- exposures to biological threat agents. This project also supports the advanced technology development of diagnostic devices to rapidly diagnose exposure to biological agents in clinical samples. A broad range of technologies involved in the targeting and delivery of prophylactic and therapeutic medical countermeasures and diagnostic systems is evaluated so that the most effective countermeasures are identified for transition to Advanced Development. Transitioning candidate vaccines, therapeutics, and diagnostic technologies to Advanced Development requires the development of scientific/ regulatory technical data packages to support the Food and Drug Administration (FDA) Investigational New Drug (IND) process and DoD acquisition regulations. Categories for this project include Defense Technology Objectives (DTOs); science and technology program areas in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines), directed research efforts (Bioadhesion Research, Medical Chemical/ Biological Counterterrorism Support, Medical Countermeasures, Advanced Diagnostics, and Vaccines); and efforts to transition promising medical biological defense technologies from DARPA.

3.6.4.1 TB3 Performance Goal (Outcome). The goal of the medical biological defense advanced technology development program is to increase scientific understanding and

demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for BW agents.

3.6.4.2 TB3 Outcome Measure

TB3 is minimally effective when	TB3 is successful when
- The results provide fundamental information and demonstrates advanced capabilities in support of new and improved defensive systems, including: – Bacterial Therapeutics, – Toxin Vaccines, – Bacterial Vaccines, – Toxin Therapeutics, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, and – Protocols to Enhance Biological Defense. - The results of research are published in peer-reviewed journals or presented at scientific conferences - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	- Information, technologies, or processes are transitioned to applied research or advanced technology development - All DTOs are rated GREEN by the TARA

3.6.4.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annex E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.6.4.4 TB3 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<u>Medical Countermeasures for Brucella (DTO)</u> - Demonstrate effectiveness of candidate vaccine in higher animal species challenge model for protective efficacy against a single pathogenic brucella species. Prepare a technical data package supporting transition of the optimum brucella vaccine candidate out of technology base. <u>Medical Countermeasures for Encephalitis Viruses (DTO)</u> - Identify final formulation of a trivalent VEE vaccine. Perform formulation and vaccine interference studies for VEE multivalent vaccine (for protection against VEE IA/B, VEE IE, VEE 3A). Perform potency and stability studies on VEE vaccine components. Support development of technical data package that addresses FDA requirements for an Investigational New Drug application and that supports transitioning the multivalent VEE vaccine candidate out of technology base. <u>Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO)</u> - Perform initial efficacy studies for single recombinant protein delivered by alternate route(s). Propose monovalent vaccine formulations for intranasal, inhalational, and/or transdermal delivery systems. Propose in vitro	<u>Therapeutics, Bacterial</u> - Conducted comparative assessment for safety and efficacy of immunomodulators and other types of broad-spectrum compounds against multiple bacterial threat agents. <u>Therapeutics, Toxin</u> - Prepared sufficient amounts of lead inhibitors of botulinum toxin and staphylococcal enterotoxin B (SEB) intoxication for testing ex vivo or in vivo. Evaluated feasibility of drugs approved by FDA for septic shock as adjunct SE therapeutics using in vitro assays. <u>Therapeutics, Viral</u> - Evaluated the combined approach of antiviral drug therapy and immunotherapy in treatment of disease from filoviruses and further characterized three new antiviral targets against Ebola. Continued evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox viruses. <u>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</u> - Began assessment and development of a clinical study site where sufficient monkeypox exists naturally in order to characterize the clinical course and pathogenesis of monkeypox.

FY2003 Targets	Actual Performance
correlate of immunity for surrogate endpoint of clinical efficacy. <u>Recombinant Plague Vaccine Candidate (DTO)</u> - Continue expanded studies in higher animal species for immunogenicity and efficacy and down-select the best higher animal species model. Continue studies to optimize vaccine production and formulation to support entry of the vaccine candidate into component advanced development. Complete a revised technical data package based on completed studies, to facilitate transition of the vaccine candidate out of technology base. <u>Diagnostic Technologies</u> - Continue comparing alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continue to develop, evaluate, and transition diagnostic assays to the PEO CBD in support of JBAIDS block I acquisition program. Identify immunodiagnostic technology options offering performance and design characteristics sufficient to address JBAIDS requirements. Demonstrate technical capability for detection of at least three biological agents (toxins) within two hours. <u>Therapeutics, Bacterial</u> - Conduct comparative assessment for safety and efficacy of immunomodulators and other types of broad-spectrum compounds against multiple bacterial threat agents. <u>Therapeutics, Toxin</u> - Prepare sufficient amounts of lead inhibitors of botulinum toxin and SEB intoxication for testing ex vivo or in vivo. Evaluate feasibility of drugs approved by FDA for septic shock as adjunct SE therapeutics using in vitro assays. <u>Therapeutics, Viral</u> - Evaluate the combined approach of antiviral drug therapy and immunotherapy in treatment of disease from filoviruses. Continue evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox viruses. <u>Vaccines, Bacterial</u> - Initiate a comparison of the safe and most efficacious vaccine candidates against select agent exposures. Analyze study data to determine best glanders vaccine candidate(s). Incorporate data for brucella and plague vaccine candidates into technical data packages for these vaccine candidates. Continue assay support and	<i>Diagnostic Technologies</i> - Continued comparing alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Compared overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continued to develop, evaluate, and transition diagnostic assays out of the technology base in support of the Joint Biological Agent Identification and Diagnostic System (JBAIDS) acquisition program. <i>Diagnostic Technologies, Improved Immunodiagnostic Platform (DTO CB47)</i> - Identified immunodiagnostic technology options offering performance and design characteristics capable of addressing operational requirements of the JBAIDS acquisition program. Demonstrated technical capability for detection of at least three biological agents (including toxins) in three biological matrices within two hours with the immunodiagnostic technology options. Conducted comparative laboratory evaluation trial of the immunodiagnostic technology options and identified top performing immunodiagnostic platform based on results of the laboratory evaluation trial. <i>Vaccines, Bacterial, Medical Countermeasures for Brucella (DTO CB31)</i> - Demonstrated effectiveness of candidate vaccine in non-human primate challenge model for protective efficacy against a single pathogenic Brucella species. Collected information for preparation of a technical data package supporting transition of the live, attenuated Brucella vaccine candidate out of technology base. <i>Vaccines, Viral, Medical Countermeasures for Encephalitis Viruses (DTO CB24)</i> - Demonstrated that the lead Venezuelan equine encephalitis (VEE) vaccine candidate, V3526, induced protection against the three VEE virus subtypes of concern (IA/B, IE, and IIIA), which would significantly reduce the complexity of a multivalent VEE vaccine. Completed analyses of the stability, safety, and efficacy (potency) of V3526 in mouse and non-human primate models. Determined the surrogate protection marker to be serum-neutralizing antibody in the non-human primate model. Completed the technical data package for the V3526 vaccine candidate and handed it off to the advanced developer. <i>Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32)</i> - Performed initial efficacy studies for single recombinant protein delivered by alternate route(s). Proposed monovalent vaccine formulations for intranasal, inhalational, and/or transdermal delivery systems. Proposed in vitro correlate of immunity for surrogate endpoint of clinical efficacy. <i>Vaccines, Bacterial, Recombinant Plague Vaccine Candidate (DTO CB34)</i> - Continued expanded studies in

FY2003 Targets	Actual Performance
studies on adjuvants and formulations in support of rPA vaccine candidate entry into component advanced development; continue to evaluate the efficacy of rPA immunity against B. anthracis strains of diverse geographic origins; and continue long-term rPA efficacy studies in rabbits and higher animal species. <u>Vaccines, Toxin</u> - Complete process development for botulinum toxin serotypes D and G in the Pichia yeast system. Support advanced development of recombinant SEB vaccine candidate by transitioning laboratory assays and data out of the technology base. <u>Vaccines, Viral</u> - Test promising vaccine strategies in higher animal species for the ability to protect against filoviruses (Marburg and Ebola viruses). Complete research studies for the development of vaccine candidates for WEE virus. <u>Defense Advanced Research Projects Agency (DARPA) Program Transition</u> - Continue expansion and definition of medical biological defense technologies transitioned from the DARPA. Complete lead optimization of a small molecule antibiotic, complete in vitro and in vivo safety and efficacy studies, and continue Investigational New Drug (IND) enabling studies. Develop two additional B-cell lines and extend the B-cell based diagnostic sensor technology to include toxin agents. Evaluate superantigen toxin antagonists in vitro assays. Use plant expression vectors to create transgenic whole-plant systems expressing plague vaccine antigens. Produce monoclonal antibodies directed against Ebola virus in transgenic plants (plantibodies). Optimize two classes of bacterial RNA-binding compounds with broad-spectrum antimicrobial activity. Apply DNA shuffling technology to identify novel antigens that show protection in mice against at least two encephalitic alphaviruses.	non-human primates for immunogenicity and efficacy and downselected the best non-human primate model. Continued studies to optimize vaccine production and formulation to support entry of the vaccine candidate into component advanced development. Completed a revised technical data package based on completed studies, to facilitate transition of the vaccine candidate out of technology base. <u>Vaccines, Bacterial</u> - Initiated a comparison of the safe and most efficacious vaccine candidates against select agent exposures. Analyzed study data to determine best glanders vaccine candidate(s). Incorporated data for Brucella and plague vaccine candidates into technical data packages. Continued assay support and studies on adjuvants and formulations in support of rPA and recombinant plague F1-V vaccine candidates progress through component advanced development; continued to evaluate the efficacy of rPA immunity against B. anthracis strains of diverse geographic origins; and continued long-term rPA efficacy studies in rabbits and non-human primates. <u>Vaccines, Toxin</u> - Completed the scale up process development of botulinum toxin serotype C vaccine candidate. Conducted process development work for botulinum toxin serotypes D and G vaccine candidates in the Pichia yeast expression system. <u>Vaccines, Viral</u> - Tested promising vaccine strategies in non-human primates for the ability to protect against filoviruses (Marburg and Ebola viruses). Continued research studies for the development of vaccine candidates for eastern and western equine encephalitis virus (EEE and WEE). <u>Vaccines, Vaccine Stabilization</u> - Developed chemical and physical methods to detect molecular changes in various candidate biodefense vaccine platforms and constructs that are responsible for loss of antigenicity at elevated temperatures. Confirmed that these changes confer the loss of vaccine activity under storage and shipping conditions. Developed accelerated stability high-throughput assays based upon these molecular changes found to be responsible for the vaccine's loss of antigenicity. Conducted screening of vaccine excipients for stabilization of proteins and viral particles. <u>Defense Advanced Research Projects Agency (DARPA) Program Transition</u> - Continued expansion and definition of medical biological defense technologies transitioned from the DARPA. Completed lead optimization of a small molecule antibiotic, completed in vitro and in vivo safety and efficacy studies, and continued IND enabling studies. Developed two additional B-cell lines and extended the B-cell based diagnostic sensor technology to include toxin agents. Evaluated superantigen toxin antagonists in vitro assays. Used plant expression vectors to create transgenic whole-plant systems expressing plague vaccine antigens. Produced monoclonal antibodies directed against Ebola virus

FY2003 Targets	Actual Performance
	in transgenic plants (plantibodies). Optimized two classes of bacterial RNA-binding compounds with broad-spectrum antimicrobial activity. Applied DNA shuffling technology to identify novel antigens that show protection in mice against at least two encephalitic alphaviruses. Identified and evaluated biomarkers for protection by a synthetic lipid A analog (aminoalkyl glucosaminide 4-phosphate) in mouse and non-human primate models. Developed small molecular structures that inhibit botulinum neurotoxin A (BoNT A) at nanomolar concentrations. Completed mechanism of action and lead optimization studies of a new class of antibiotics that target DNA-methylation in anthrax. <i>Medical Biological Warfare Defense, Bioadhesion Research to Combat Biological Warfare</i> - Generated recombinant anthrax antigens, native protective antigen, lethal factor, and capsular antigens and developed conjugated vaccine formulations. Constructed covalent conjugates and nanoparticles displaying various combinations of anthrax antigens and determined immunogenicity in animals. Conjugated various combinations of anthrax toxins and capsular materials and determined the optimal conjugate for generating protective immune responses.

3.6.4.5 TB3 Future Targets

FY 2004 Targets	FY 2005 Targets
<i>Therapeutics, Bacterial</i> - Continue the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in small animal models. <i>Therapeutics, Toxin</i> - Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for SE intoxication. Test FDA-approved drugs for septic shock as adjunct SE therapeutics in vivo. <i>Therapeutics, Viral</i> - Complete the evaluation of one antiviral drug formulation for orthopox viruses. Continue evaluating second drug formulation or prodrugs for orthopox viruses. <i>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</i> - Complete the assessment of the clinical study site to determine feasibility for use in a field trial of cidofovir to treat human monkeypox. Complete an initial dose seeking study using an oral form of cidofovir in the monkeypox primate model. <i>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</i> - Initiate ex vivo evaluation of lead compounds in model systems for therapeutic efficacy. Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for botulinum neurotoxin (BoNT) intoxication.	<i>Therapeutics, Bacterial</i> - Advance the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Enhance aerobiology capabilities and animal model development to facilitate bacterial therapeutics research. <i>Therapeutics, Toxin</i> - Conduct proof-of-concept studies in animal models with lead compounds shown to have potential as inhibitors of SEs. Enhance aerobiology capabilities and animal model development to facilitate toxin therapeutics research. <i>Therapeutics, Viral</i> - Finish characterization of genes identified in random homozygous knock-out screening and their evaluation as drug targets. Finish screening for inhibitors of ribonucleic acid (RNA) polymerase. Evaluate novel targets obtained from proteomic studies. Continue evaluating new drug formulations or prodrugs for orthopox viruses. Enhance aerobiology capabilities and animal model development to facilitate viral therapeutics research. <i>Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54)</i> - Complete technical data package supporting FDA approval of a labeled indication for pre- and post-exposure treatment for smallpox with intravenous (IV) cidofovir by the drug license holder.

FY 2004 Targets	FY 2005 Targets
<i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i> - Determine the basis for the pathogenesis of filovirus-induced shock or toxemia in animal models and identify potential mediators. <i>Diagnostic Technologies</i> - Continue to compare alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Continue to compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continue to develop, evaluate, and transition diagnostic assays out of the technology base in support of the JBAIDS acquisition program. <i>Diagnostic Technologies, Improved Immunodiagnosics Platform (DTO CB47)</i> - Complete interlaboratory evaluation of top performing immunodiagnostic technology option. Perform a multi-center evaluation trial of the top performing immunodiagnostic platform and prepare a technical data package detailing results of the multi-center trial. Recommend immunodiagnostic technologies for incorporation into JBAIDS acquisition program. <i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i> - Develop a technical data package format for delivering assays and reagents, in concert with the advanced developer. <i>Vaccines, Bacterial</i> - Continue to perform animal studies which support transition of potential Brucella vaccine candidates to advanced development. Perform studies to address the mechanism of protective cellular immunity induced by selected vaccine candidates. Continue studies supporting rPA and recombinant plague F1-V vaccine candidates clinical trials and progress toward licensure. Complete developmental work on the mouse potency assay in support of rPA vaccine candidate advanced development. <i>Vaccines, Toxin</i> - Produce and characterize inactivated BoNT light chain vaccine candidates and large-scale truncations of BoNT holotoxins. Clone and express existing BoNT vaccine candidates using selected plant-based expression systems. Initiate studies exploring multivalent vaccine technologies for protection against multiple botulinum neurotoxin serotypes. <i>Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32)</i> - Propose formulation/device/route for delivery of combinations of multiple recombinant proteins. Perform definitive efficacy	<i>Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59)</i> - Continue to evaluate high affinity recombinant human antibodies against BoNT in vivo. Develop surrogate endpoints of human clinical efficacy for BoNT therapeutics. Evaluate neuronal drug delivery systems for leading BoNT treatment modalities in vitro and ex vivo. <i>Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63)</i> - Identify and test leading antiviral technology candidates in appropriate animal model systems. <i>Diagnostic Technologies</i> - Continue to compare alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Initiate a detailed analysis of alternatives for an advanced integrated diagnostic system capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies using a combination of appropriate technologies. Continue to develop, evaluate, and transition diagnostic assays out of the technology base in support of the JBAIDS acquisition program. Analyze clinical samples obtained from human vaccinees receiving biodefense vaccines to evaluate host responses to the immunizations. <i>Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56)</i> - Deliver four nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer. Deliver four antigen detection assays and/or supporting reagents to the advanced developer. <i>Diagnostics Technologies, IT Medical Surveillance</i> - Demonstrate how to integrate medical surveillance information and potential CB threat agent information obtained through medical surveillance, with non-medical detection information; and work toward defining a draft Concept of Operations (CONOPS) for the application of these technologies. <i>Vaccines, Bacterial</i> - Continue to perform animal studies which support development of selected vaccine candidates against bacterial threat agents. Continue technology base studies in support of the development and eventual FDA licensure of the rPA and recombinant plague F1-V vaccine candidates. Enhance aerobiology capabilities and animal model development to facilitate research toward the development of bacterial vaccines. <i>Vaccines, Toxin</i> - Initiate evaluation of inactivated

FY 2004 Targets	FY 2005 Targets
studies on monovalent vaccine in second animal model. Evaluate in vitro correlate of immunity. <i>Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46)</i> - Complete toxicity assays, activity assays, and rodent efficacy <i>Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46)</i> - Complete toxicity assays, activity assays, and rodent efficacy studies for lead recombinant ricin toxin A-chain (rRTA) vaccine candidates. Conduct laboratory stability studies of the lead rRTA candidate. Evaluate lead candidate with in vitro models for vascular leak syndrome. Conduct efficacy studies in non-human primates with the lead rRTA vaccine candidate. <i>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58)</i> - Initiate the evaluation of candidate vaccine platforms/constructs against a minimum of one of the alphaviruses of concern (WEE or EEE) in the mouse efficacy model. Continue research for the development of live attenuated mutant viruses as vaccine candidates for EEE virus infection. Establish aerosol WEE animal efficacy models for evaluating vaccine candidates. <i>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</i> - Develop and improve animal models for evaluating vaccine candidates for protection against Ebola and Marburg viruses. <i>Defense Advanced Research Projects Agency (DARPA) Program Transition</i> - Continue expansion and definition of medical biological defense technologies transitioned from the DARPA. Complete chemical manufacturing and control studies and file an IND application for a small-molecule antibiotic effective against anthrax. Develop additional B-cell lines and evaluate the B-cell based diagnostic sensor technology on clinical samples. Develop a blood assay for the superantigen toxin antagonists. Optimize plant lines and obtain milligram-quantities of plague vaccine antigens from multiple plant species for in DNA shuffling in non-human primates for protection against three encephalitic alphaviruses. <i>Medical Biological Warfare Defense, Bioadhesion Research to Combat Biological Warfare</i> - Continue to generate recombinant anthrax antigens, native protective antigen, lethal factor, and capsular antigens and continue to develop conjugated vaccine formulations. Continue to construct covalent conjugates and nanoparticles displaying various combinations of anthrax antigens and determine immunogenicity in animals. Continue to conjugate various combinations of anthrax toxins and capsular materials and determine the optimal conjugate for generating protective immune responses.	BoNT light chain vaccine candidates as well as large-scale truncations of BoNT holotoxins in animal models. Continue studies on multivalent vaccine candidates to protect against multiple BoNT serotypes, including cloning and expression of genes for novel multivalent vaccine candidates. Enhance aerobiology capabilities and animal model development to facilitate research toward the development of toxin vaccines. <i>Vaccines, Viral</i> - Enhance aerobiology capabilities and animal model development to facilitate research toward the development of viral vaccines. <i>Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32)</i> - Demonstrate proof-of-concept for lead alternate vaccine delivery system(s). Complete preclinical research studies and prepare recommendations to support transition of commercial technology for alternate vaccine delivery out of the technology base. <i>Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46)</i> - Complete a comprehensive review of results with lead candidate, including potency, efficacy, adjuvant studies, toxicity, and pathology results in rodents. Complete efficacy studies and evaluate pathology in non-human primates with the lead vaccine candidate. <i>Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58)</i> - Continue evaluating the short-term efficacy of various vaccine platforms and constructs in available animal models. Determine the compatibility of selected vaccine platforms/constructs with Venezuelan equine encephalitis (VEE) vaccine candidate V3526. <i>Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60)</i> - Test leading vaccine candidates in worst-case scenarios (viral challenge dose, route, pre-existing vector immunity, and variation in viral challenge strain). <i>Defense Advanced Research Projects Agency (DARPA) Program Transition</i> - Conclude characterization and process development of candidate vaccines, therapeutics, and diagnostic technologies to determine if any are sufficiently mature to transition to development. Develop five additional B-cell lines and complete development and performance testing of a 16-channel B-cell based diagnostic sensor. Establish formulation for an orally bioavailable superantigen toxin antagonist.

3.6.4.6 Assessment of Medical Biological Defense Advanced Technology Development.

Advanced technology development efforts in FY2002 for project TB3 are effective. Many areas of medical biological defense applied research were successful. The TARA panel rated two DTOs in this area as yellow, primarily due to aggressive schedule risk. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002.

3.6.5 Medical Chemical Defense Advanced Technology Development (Project TC3)

This project supports the investigation of new medical countermeasures to include antidotes, pretreatment drugs, and topical skin protectants to protect U. S. forces against known and emerging CW threat agents. Capabilities are maintained for reformulation, formulation, and scale- up of candidate compounds using current good laboratory practices. Analytical stability studies, safety and efficacy screening, and preclinical toxicology studies are performed prior to full-scale development of promising pretreatment or treatment compounds. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Pretreatments, Therapeutics, and Diagnostics), and directed research efforts (Low Level Chemical Agent Exposure and Fourth Generation Agents).

3.6.5.1 TC3 Performance Goal (Outcome). The goal of the medical chemical defense advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for CW agents.

3.6.5.2 TC3 Outcome Measure

TC3 is minimally effective when	TC3 is successful when
- The results provide fundamental information and demonstrate advanced capabilities in support of new and improved defensive systems, including information on - chemical agent therapeutics, - chemical agent prophylaxes, - chemical agent diagnostics, - novel threat agents, - low level operational toxicology. - The results of research are published in peer-reviewed journals or presented at scientific conferences - Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	- Information, technologies, or processes are transitioned to applied research or advanced technology development - All DTOs are rated GREEN by the TARA.

3.6.5.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annex E of the 2004 *DoD CBRN Defense Program Annual Report to Congress*.

3.6.5.4 TC3 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<i>Medical Countermeasures for Vesicant Agents II (DTO)</i> - Complete preclinical safety and efficacy studies of selected vesicant therapy candidate compounds. Complete pharmacokinetic studies of	<i>Nerve Agent Defense, Nerve Agent Anticonvulsants</i> - Selected optimal anticholinergic drug for inclusion with midazolam anticonvulsant and established optimal treatment protocol in non-human primates.

FY2003 Targets	Actual Performance
vesicant countermeasure candidates. Perform additional studies necessary to completely characterize candidate therapy. Transition vesicant therapeutic candidates out of the technology base. <u>Diagnostics</u> - Evaluate hand-held cholinesterase monitor for clinical use. Validate immobilized cholinesterases and nerve agent hydrolyzing enzymes as diagnostics for nerve agent exposure. <u>Pretreatments</u> - Complete physiological pharmacokinetic model studies of expected human efficacy with various catalytic scavengers. Verify adequacy of transgenic animal model to produce recombinant catalytic enzyme scavenger. <u>Therapeutics</u> - Select optimal anticholinergic drug for inclusion with midazolam anticonvulsant and establish optimal treatment protocol in higher animal species. Complete preclinical studies of selected vesicant therapy candidate compounds. Evaluate commercially licensed wound healing medical therapeutics for HD-induced injuries. Evaluate therapeutic agents for pulmonary edema produced by whole-body exposure to CWAs in animal models. <u>Non-Traditional Agents (NTAs)</u> - Compare all nerve agents for induction of neurochemical changes. Evaluate efficacy of anticonvulsants against NTAs. Identify mechanism of oxime reactivation of NTA-inhibited acetylcholinesterase.	<i>Nerve Agent Defense, Biological Scavenger</i> - Completed physiological pharmacokinetic model studies of expected human efficacy with various bioscavengers. Verified adequacy of transgenic animal model to produce recombinant enzyme scavenger. <i>Nerve Agent Defense, Improved Oxime (DTO CB48)</i> - Conducted efficacy studies of candidate oxime(s) against traditional nerve agents and non-traditional agents (NTAs) in guinea pigs. Initiated down selection process. Synthesized appropriate quantities of each oxime for required studies. <i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i> - Completed preclinical studies of selected vesicant therapy candidate compounds. <i>Vesicant Agent Defense, Cutaneous Therapeutics</i> - Evaluated commercially licensed wound healing medical therapeutics for sulfur mustard (HD)-induced injuries. <i>Vesicant Agent Defense, Medical Countermeasures for Vesicant Agents II (DTO CB30)</i> - Completed preclinical safety and efficacy studies of selected vesicant countermeasure candidate compounds. Completed PK studies of vesicant countermeasure candidates. Performed additional studies necessary to completely characterize candidate therapy. Initiated preparation of a technical data package to support FDA requirements for an IND application. <i>Chemical Warfare Agent Defense, Inhalation Therapeutics</i> - Evaluated therapeutic agents for pulmonary edema produced by whole-body exposure to CWAs in animal models. <i>Chemical Warfare Agent Defense, Medical Diagnostics</i> - Evaluated hand-held cholinesterase monitor for clinical use. <i>Chemical Warfare Agent Defense, Skin and Wound Decontamination</i> - Pursued development of polyurethane immobilized cholinesterases and chemical agent hydrolyzing enzymes as skin and wound decontaminants for organophosphate CWAs. Developed protocols supporting the sponge decontamination concept and the detoxification of medically sensitive skin project. Evaluated formulations for efficacy. <i>Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs)</i> - Compared all nerve agents for induction of neurochemical changes. Evaluated efficacy of anticonvulsants against NTAs. Evaluated current nerve agent medical decontamination procedures against percutaneous NTAs.

3.6.5.5 TC3 Future Targets

FY 2004 Targets	FY 2005 Targets
<i>Nerve Agent Defense, Nerve Agent Anticonvulsants</i> - Determine efficacy of midazolam anticonvulsant and anticholinergic drug combinations against seizures and lethality produced by all current threat agents in the	<i>Nerve Agent Defense, Nerve Agent Anticonvulsants</i> - Assess application of emerging therapy for organophosphate insecticide poisoning to nerve agent exposure. Continue testing of midazolam and

FY 2004 Targets	FY 2005 Targets
guinea pig model. <i>Nerve Agent Defense, Biological Scavenger</i> - Initiate evaluation of human protein recombinant scavenger. Utilize transgenic animal model to produce adequate amounts of recombinant enzyme scavenger for preclinical testing. <i>Nerve Agent Defense, Neuroprotection</i> - Assess potential neuroprotectant treatments for nerve agent-induced brain pathology in guinea pig model. <i>Nerve Agent Defense, Improved Oxime (DTO CB48)</i> - Initiate efficacy and pharmacokinetic (PK) studies of candidate oxime(s) for use against traditional nerve agents and NTAs in non-human primates and safety/toxicity studies in two species. Continue the down selection process. <i>Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57)</i> - Evaluate the efficacy of candidate bioscavengers for protection against non-traditional nerve agents in multiple animal models. <i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i> - Pursue development of protective agent against HD-induced skin lesions. <i>Vesicant Agent Defense, Cutaneous Therapeutics</i> - Begin efficacy tests of promising treatment strategies. <i>Chemical Warfare Agent Defense, Medical Diagnostics</i> - Develop and test a non-invasive prototype instrument that measures blood gases via finger, ear, or toe. <i>Chemical Warfare Agent Defense, Skin and Wound Decontamination</i> - Continue development of skin and wound decontaminants for organophosphate CWAs. Continue to expand decontamination and detoxification efforts by developing HD decontaminants. <i>Chemical Warfare Agent Defense, Low Level CWA Exposure</i> - Evaluate the efficacy of the FDA-approved oxime treatment, pralidoxime chloride (2-PAM), against biochemical and behavioral effects induced by repeated low level exposure to chemical warfare nerve agents in guinea pigs.	anticholinergic drug combinations against seizures and lethality produced by all current threat agents. Initiate PK evaluations of selected anticonvulsants. <i>Nerve Agent Defense, Biological Scavenger</i> - Complete evaluation of human protein recombinant scavenger as a nerve agent countermeasure. Initiate preparation of technical data package for transition out of the technology base. <i>Nerve Agent Defense, Neuroprotection</i> - Initiate PK evaluations of selected neuroprotectants. <i>Nerve Agent Defense, Improved Oxime (DTO CB48)</i> - Complete efficacy, safety/toxicity and PK studies of candidate oxime(s) for use against traditional nerve agents and NTAs. Down select the leading candidate oxime(s). Prepare a technical data package that supports FDA requirements for an IND application and for transition of the best improved, broad-spectrum candidate oxime(s) out of the technology base. <i>Vesicant Agent Defense, Vesicant Medical Countermeasures</i> - Initiate PK evaluations of selected antivesicants. <i>Vesicant Agent Defense, Cutaneous Therapeutics</i> - Continue screening of promising treatment strategies, and prioritize successful strategies for further in-depth study. <i>Chemical Warfare Agent Defense, Medical Diagnostics</i> - Continue testing devices that measure blood gases via finger, ear, or toe. <i>Chemical Warfare Agent Defense, Skin and Wound Decontamination</i> - Continue development of concepts for nerve agent and HD skin and wound decontamination. <i>Chemical Warfare Agent Defense, Low Level CWA Exposure</i> - Evaluate the effects of selected pretreatment and/or therapeutic medical countermeasures, to include the FDA-approved Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP), on the detrimental actions of low dose chemical warfare nerve agent exposure in guinea pigs.

3.6.5.6 Assessment of Medical Chemical Defense Advanced Technology Development.

Advanced technology development efforts in FY2003 for project TC3 are effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2003.

4.0 CBRN DEFENSE HOMELAND SECURITY AND FORCE PROTECTION

Programs to provide CBRN defense in support of homeland security and force protection of integrated into several program elements of the DoD CBRN Defense Program. Specific efforts include programs and systems to equip the National Guard WMD Civil Support Teams, Joint Service Installation Pilot Program, and the Installation Protection Program. Descriptions of these capabilities are also provided in Annex F of the DoD CBRN Defense Program Annual Report to Congress.

4.1 WMD Civil Support Team Advanced Technology Development (Project CM3)

This project funds Pre- Systems Acquisition in support of Consequence Management teams around the Nation. National Guard Weapons of Mass Destruction Civil Support Teams (WMD CST) are being established in every state. These teams were created based upon the Defense Reform Initiative Directive #25 (DRID #25), Integrating National Guard and Reserve Component Support for Response to Attacks Using Weapons of Mass Destruction (WMD). The role of the Civil Support Teams (CSTs) were further codified in the National Security Strategy of October 1998, which builds upon the National Guard's ties to the communities throughout the nation, and its long- standing tradition of responding to national emergencies. The strategy allows the National Guard to provide forces and resources that the emergency manager requires to manage the potentially catastrophic effects of a WMD situation. The National Guard, as the lead organization for military support to local and state authorities, leverages its geographic dispersion across the nation to reduce response times, and allow for the majority of the country to be protected. As a result of Presidential and Secretary of Defense directives, the Department of Defense established the Weapons of Mass Destruction Civil Support Teams (WMD CST) to rapidly respond in support of a local incident commander to assess a suspected WMD incident scene, advise them of appropriate courses of action that will protect local populations from loss of life, injury, and significant property damage, and facilitate the development of their requests for assistance (RFAs) based on CST knowledge of available local, state and federal resources that can assist in the mitigation of a WMD emergency. This program funds the purchase and testing of commercial-off-the-shelf (COTS) components on the existing Table of Distribution and Allowances (TDA) of WMD CST, and evaluates new commercial products being considered for the WMD CST TDA for performance and ability to meet requirements.

4.1.1 CM3 Performance Goal (Outcome).

The goal of the WMD-CST advanced technology development program is to demonstrate advanced capabilities and concepts involved in the detection, protection against, and decontamination of CBW agents.

4.1.2 Metric Description.

The metric for CM3 is focused on providing improved capabilities to the WMD Civil Support Teams. Success accomplishment of research will result in transitioning of projects to the Civil Support Teams and support of DoD's homeland security mission.

4.1.3 CM3 Actual and Planned Performance:

FY2003 Targets	Actual Performance
Initiate purchase of COTS components on the Table of Distribution & Allowances (TDA) of the WMD CSTs.	WMD CST - Initiated evaluation of commercially produced level A and B suit ensembles being used by the National

FY2003 Targets	Actual Performance
Initiate evaluation of new commercial products being considered for TDA to determine performance and ability to meet WMD CST requirements.	Guard Bureau (NGB) WMD-CST and the United States Army Reserve (USAR) Reconnaissance and Decontamination Platoons.
Planning and support for test program for commercial equipment.	WMD CST - Initiated a joint evaluation with the Navy and Air Force to assess capabilities to meet the NGB WMD-CST Analytical Laboratory System (ALS) Block I requirements.

4.1.4 CM3 Future Targets

FY 2004 Targets	FY 2005 Targets
WMD CST - Continue to evaluate Chemical / Biological detection / identification technologies for insertion into WMD CST Tables of Distribution and Allowances (TDA).	WMD CST - Continue evaluation and testing of new commercial products being considered in response to WMD CST requirements.
WMD CST - Develop modifications to commercial systems and technologies in response to specific WMD CST operational requirements.	WMD CST - Develop modifications to commercial systems and technologies in response to specific WMD CST operational requirements.
	WMD CST - Implement modified requirements and transition processes and continue to participate in analysis of alternatives and for follow-on technology insertion options.

4.1.5 Assessment of WMD-CST Advanced Technology Development.

This effort is at least minimally effective. This effort completed its first year of activity in FY03 and was able to support the development and fielding of analytic equipment for WMD-CSTs. There were no DTOs in this area. As the homeland defense and homeland security missions evolve, technology development will be relied on to enhance new capabilities.

4.2 WMD-CSTs and Installation Protection (Projects CM4, CM5, CM6, and AT6)

This project funds studies in support of Weapons of Mass Destruction Civil Support (WMD CS) operations. This funding provides resources to successfully execute the Consequence Management RDA program. Weapons of Mass Destruction Civil Support Teams (WMD-CSTs) and U.S. Army Reserve Reconnaissance and Decontamination assets would receive the systems developed and procured under this program. The Force Protection - CB Installation Protection Program (CBIPP) consists of a highly effective and integrated CBRN installation protection and response capability. This capability includes detection, identification, warning, information management, individual and collective protection, restoration, and medical surveillance, protection and response. The communications network will leverage existing capabilities and be integrated into the base operational command and control infrastructure. The program will develop and procure the CBRN systems, Emergency Responder Equipment Sets, New Equipment Training (NET), Contractor Logistics Support, spares, and associated initial consumable items required to field an integrated installation protection capability at 200 DoD installations (185 CONUS and 15 OCONUS).

The growing threat of the use of CB agents in acts of terrorism places DoD installations and personnel at a higher risk. With that in mind, this budget item provides DoD with the means to address the threat of CB terrorism to DoD installations and personnel. It attempts to address the requirements identified in Presidential Decision Directive (PDD) 39 and PDD 62. Funding provides for the development of combating CB terrorism planning, training, and exercise

technologies; and the sustainment of those technologies in the outyears, as appropriate. Sponsors of projects funded under this budget item would include DTRA, Joint Staff J-34, Assistant Secretary of Defense Special Operation Low-Intensity Conflict (ASD (SO/LIC)), United States Army Edgewood Chemical and Biological Command (ECBC), United States Army Chemical School, Fort Leonard Wood (USACMLS), the Technical Support Working Group, and other organizations involved with combating CB terrorism.

4.2.1 Actual and Planned Performance:

FY2003 Targets	Actual Performance
<u>WMD-CST</u> Conduct chemical and biological research studies. Initiate developmental upgrade of Analytical Laboratory Systems (ALS). Provide government engineering and planning support. Initiated support planning and oversight efforts to coordinate equipment and operational issues for WMD-CSTs.	<u>WMD-CST</u> Conducted chemical and biological research studies. Initiated developmental upgrade of ALS. Provided government engineering and planning support. Initiated support planning and oversight efforts to coordinate equipment and operational issues for WMD-CSTs.
Perform program management support for Joint Service Installation Protection Program (JSIPP).	Performed program management support for Joint Service Installation Protection Program (JSIPP).

4.2.2 Future Targets

FY 2004 Targets	FY 2005 Targets
<u>WMD-CST</u> Initiate Phase II HAPSITE component testing. Initiate component level testing of commercial Level A and B ensembles. Continue development of Unified Command Suite (UCS) and ALS upgrades. Provide government engineering and planning support. Integrate test methodology development for CSTs into CBDP Test and Evaluation process. Coordinate with JPEO CBD PM Guardian for equipment, threat and operational issues. Participate in Requirements Capabilities Assessment Working Group (RCAWG) and support conduct of assessments and validation. Continue Advanced Concept Technology Demonstration (ACTD) to support system capability transition to CSTs. Develop transition plan for CBDP capabilities to PM WMD Civil Support Systems (CSS) and JPM Guardian consistent with CST requirements process.	<u>WMD-CST</u> Initiate Developmental Test for UCS and ALS. Initiate Initial Operational Test and Evaluation (IOT&E) of the UCS/ALS. Continue development of UCS and ALS upgrades. Provide government engineering and planning support. Continue participation in RCAWG. Provide technical and operational support for plans. Conduct demonstration and validation exercises for CSTs. Continue development and validation of test methodologies for transition of equipment to CSTs.
<u>Force Protection:</u> Initiate test and evaluation of emerging governmental and commercial CBRN detection, identification warning, individual and collective protection,	<u>Force Protection:</u> Complete test and evaluation of emerging governmental and commercial CBRN detection, identification warning, individual and collective protection,

FY 2004 Targets	FY 2005 Targets
decontamination, medical surveillance and protection technologies. Initiate independent installation evaluation assessments. Initiate software development of a CBRN knowledge base to support decision tools needed to determine installation critical CBRN requirements. Initiate an improved and lower cost biological aerosol warning system to support Dry Filter Units. System will provide improved warning of a potential biological release, supporting more rapid analysis. Initiate development and improvement of NBC warning system to support unique installation warning and reporting requirements. Engineering and technical support.	decontamination, medical surveillance and protection technologies. Complete independent installation evaluation assessments. Complete software development of a CBRN knowledge base to support decision tools needed to determine installation critical CBRN requirements. Develop an improved, lower cost biological aerosol warning system to support Dry Filter Units. This system will provide improved warning of a potential biological release, supporting more rapid analysis. Develop an improved NBC warning system to support unique, installation warning and reporting requirements. Develop improved biological identification technologies (electro-chemiluminescence) to support laboratory operations. Improvements will support the development of a multiplex immunoassay capability thereby reducing processing time and costs. Initiate and complete development of improved TIC detection and identification. Focus on improved automation to reduce costs. Engineering and technical support.
Develop after action reports for participating installations. Refine fixed site facility biological detection concept of operations (CONOPS) to reduce life cycle costs.	Perform analytical support for the JSIPP and perform analysis of standardized test requirements for first responder and civilian protection equipment.

Homeland Security and Force Protection Modernization Strategy

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

DOD CBRNDP DEFENSE MANAGEMENT PRACTICES

5.0 OVERVIEW OF CBRNDP MANAGEMENT PRACTICES

In Chapter 1 of the Annual Report to Congress on the DoD CBRNDP, the management and oversight structure of the DoD CBBP is described. In this year's report, the reorganization of the management and oversight structure is outlined as the structure is being implemented pursuant to the Implementation Plan for the Management of the DoD Chemical and Biological Defense Program approved April 22, 2003. As the CBRNDP has matured over the past decade, this reorganization brings management efficiencies that will facilitate program management.

This section of the report focuses on management practices in support of **Corporate Goal 3: Oversee DoD CB defense modeling and simulation efforts** and **Corporate Goal 4: Improve DoD CBRN defense management practices – become a high performance organization.**

In support of Corporate Goal 3, this section outlines the management and oversight activities associated with the oversight of DoD NBC defense modeling and simulation efforts. Technical and operational accomplishments are described in other parts of the Annual Report.⁵

Activities in support of CBRNDP management activities are detailed in Budget Activity 6 (RDT&E Management Support) of the President's Budget Submission. Specific management projects (and project reference) are as follows:

- Joint Doctrine and Training Support (DT6)
- Dugway Proving Ground (DW6)
- RDT&E Management Support (MS6)
- Joint Point Test (O49)
- Small Business Innovative Research (SBIR)

5.1 CB DEFENSE MANAGEMENT PRACTICES – GOALS AND MEASURES

5.1.1 CB Defense Management and Oversight Outcome Measures

CB Defense Management and Oversight is...	
...minimally effective when...	... successful when...
• All DoD research, development, and acquisition (RDA) efforts have documented plans that are reviewed and contribute to operational goals. • DoD RDA efforts are coordinated among the Services and Defense Agencies. • All RDA programs are issued to the field with accompanying doctrine and training to ensure their effective application.	• Technologies are leveraged by other agencies to support homeland security and related missions. • Commercial or other available technologies are leverage to accelerate the development or fielding schedule of priority programs.

5.1.1.1 Metric Description. The metric for management and oversight is a qualitative assessment. This qualitative methodology for measuring the outcomes is allowed by the GPRA (31 USC 1115(b)) as an alternative to the quantitative performance measures. Successful oversight allows for the application of performance-based measures to ensure to appropriate balance among the complex and interrelated family of chemical and biological defense systems. The balance must be continually review to ensure the appropriate mix of capabilities for contamina-

⁵ See Chapter 2 and Annex B of Volume 1 and programs associated with Operational Goal 2 in Section 2 of Volume 2 for research, development, and acquisition accomplishments. See Chapter 4 of Volume 1 for accomplishments associated with operations, training, and readiness.

tion avoidance, protection, and restoration, and among competing missions of passive defense, force protection, and consequence management, and also among the balance of near-term needs (procurement) versus long-term technological advancements (science and technology base.) An important element of the management and oversight success is what is not accomplished. That is, it is the role of management at times to make investment decisions and select among competing technologies, sometimes eliminating technologies that may have met the operational requirements though not as effectively as selected program, and sometime this means the elimination of funding for unsuccessful programs. Another key management metric is the successful coordination of research, development, and acquisition efforts among the many federal agencies pursuing similar efforts though for different missions (e.g. homeland security.)

5.1.1.2 Validation and Verification Methodology. A key oversight tool for management and oversight is the quarterly program oversight and evaluations of selected CB defense programs to ensure investments are on schedule, on budget, and meeting technical requirements (and taking corrective actions when they are not.)

5.1.2 Assessment of CB Defense Management and Oversight Outcome Measure

Overall, the DoD CBRNDP management and oversight has been effective, though many areas within the overall structure have required improvement to provide a more efficient approach. These changes are detailed in **Chapter 1** of Volume 1 of this report. Continued reports on the management and oversight process will be provided as the new structure is implemented during 2004.

5.2 CHEMICAL/BIOLOGICAL DEFENSE (RDT&E Management Support) (PROGRAM ELEMENT 0605384BP)

This program element provides research, development, testing and evaluation management support to the DoD CBRNDP. This effort funds joint doctrine and training support; funds sustainment of technical test capability at Dugway Proving Ground (DPG); and funds financial and program management support. Additionally, this program element funds the Joint Point Test program (O49), which provides a response to Combatant Commanders and Services regarding joint tests and research assessments. Joint Training and Doctrine Support (DT6) funds development of Joint Doctrine and Tactics, Techniques, and Procedures for developing CB defense systems. The training and doctrine efforts also fund CB modeling and simulation to support the warfighter.

Dugway Proving Ground (DW6), a Major Range and Test Facility Base, funding provides for CB defense testing of DoD materiel, equipment, and systems from concept through production; to include a fully instrumented outdoor range capability for testing with simulants that can be precisely correlated to the laboratory testing with live agents. It finances indirect test operating costs not billable to test customers, including indirect civilian and contractor labor; repair and maintenance of test instrumentation, equipment, and facilities; and replacement of test equipment.

The management support program (MS6) provides management support for the DoD CBRNDP to allow program overview and integration of overall medical and non-medical programs by the Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ATSD(NCB)), through the Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense (DATSD(CBD)); execution management by the Defense Threat

Reduction Agency (DTRA); integration of Joint requirements, management of training and doctrine by the Joint Requirements Office (JRO); Joint RDA planning, input to the Annual Report to Congress and Program Objective Memorandum (POM) development by the Program Analysis and Integration Office (PA&IO); review of joint plans and the consolidated CBRN Defense POM Strategy by Army in its Executive Agent role.

The management support program also funds the Joint Test Infrastructure Working Group (JTIWG) program to provide a mechanism to address test infrastructure and technologies needed to support Developmental Testing (DT) and Operational Testing (OT) of Department of Defense (DoD) CB defense systems and components throughout the systems' acquisition life cycle, as required in the RDA Plan. The JTIWG program funds a series of methodology, instrumentation, and associated validation programs to provide test infrastructure and technologies for testing RDA systems needed to support all services.

The Joint Concept Development and Experimentation Program (O49) funds provide planning, conducting, evaluating, and reporting on joint tests (for other than developmental hardware) and accomplishment of operational research assessments in response to requirements received from the Services and the Combatant Commanders for already fielded equipment and systems.

This Budget Activity also funds the Small Business Innovative Research (SBIR) program. The overall objective of the CBD SBIR program is to improve the transition or transfer of innovative CBD technologies between DoD components and the private sector for mutual benefit. The CBD program includes those technology efforts that maximize a strong defensive posture in a CB environment using passive and active means as deterrents. These technologies include CB detection; information assessment (identification, modeling, and intelligence); contamination avoidance; and protection of both individual soldiers and equipment.

5.2.3 CB DEFENSE (RDT&E Management Support) (Project DT6 – Joint Doctrine and Training Support)

The activities of this project directly support the Joint Service CB defense program; in particular, the development of Joint CBRN defense capability requirements and the improvement of CBRN defense related doctrine, education, training, and awareness at the Joint and Service levels. This effort funds (1) development, coordination, and integration of Joint CBRN defense capability requirements; (2) development/revision of medical and non-medical CBRN defense Multi-Service Tactics, Techniques, and Procedures (MTTP), Joint Doctrine and Tactics, Techniques, and Procedures (JTTP); (3) the United States Army Chemical School Joint Senior Leader Course (USACMLS JSLC); (4) assistance in correcting training and doctrine deficiencies covered in DODIG and GAO reports; (5) support of current and planned CBRN defense studies, analysis, training, exercises, and wargames; determine overlaps, duplication, and shortfalls; and build and execute programs to correct shortfalls in all aspects of CBRN defense also all DoD mission areas.

DT6 Actual and Planned Performance

FY2003 Targets	Actual Performance
Continue to support the development of medical, non-medical and special operations Multi-Service core NBC doctrine: (1) FM 3-11.5 NBC Decontamination; (2) FM 3-11.6 Field Behavior of NBC Agents; (3) FM 4-0.285 Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries. Continue to support the integration of CB defense considerations during the revision and development of selected joint doctrinal materials. Continue support to the integration and enhancement of NBC/WMD materials in joint and service professional education. Continue support to the CINCs with NBC/WMD exercise assistance and training. Draft/review Joint Operational Requirements Documents (ORDs): (1) Joint Service General Purpose Mask Milestone (MS) C; (2) Joint CB Agent Water Monitor MS B; (3) Joint Service Mask Leakage Tester MS C; (4) Joint Biological Tactical Detection System MS B; (5) Joint Warning and Reporting Network Block II; (6) Artemis MS B; (7) Joint Effects Model/Joint Ground Effects Model MS B; (8) Joint Operational Effects Federation MS B; (9) Cyanide Pretreatment System (Draft); (10) Joint Biological Agent Identification and Diagnostic System MS B; (11) Smallpox MS BI. Complete assessment of Tularemia stockpile requirements. Initiate Medical NBC Defense Doctrine and Training Assessment.	Continued to support the revision and development of CBRN defense medical and non-medical MTTPs. Continued to support the integration of CBRN defense considerations during the revision and development of selected joint doctrine and JTTPs
Continue requirements generation analysis: (1) Initiate Decontamination Mission Area Analysis; (2) Battle Management Mission Area Analysis; (3) Initiate Protection Mission Needs Analysis; (4) Medical Operational Impact Assessment; and (5) Initiate integrated Chemical/ Biological Standoff Detection Analysis of Alternatives (if required).	Continued to provide assistance in the development and enhancement of CBRN defense curriculum and wargaming at intermediate and senior level Joint and Service Colleges and Senior Service Non-Commissioned Officer Academies. Continued assistance and support for providing CBRN defense related improvements to the four phases of the Joint Training System at Combatant Commands. Continued to provide assistance in the implementation of required solutions for appropriate representation of CBRN defense in Combatant Command's modeling and simulation tools. Continued to provide CBRN defense related training support to Combatant Command staffs, services and the United States Coast Guard (USCG).
Continue to support additional joint participation in the Joint Senior Leaders' Course (JSLC).	<i>Target met.</i>
Continue support of Services M&S requirements. Finalize effects and behaviors tools for the standardization of the battlespace common operational picture. Define the requirements for simulation based virtual CBD environment for training, mission planning/ rehearsal, force development, and acquisition programs. Validate modeling and simulation requirements and tools for C4I systems.	Continued analyses to define capability gaps, capability needs and approaches to provide those capabilities within CBRN defense across all DoD mission areas. Continued analyses to support the development of joint architectures, joint operational concepts, and supporting technical annexes. Continued development, coordination and integration of joint capability requirements.

DT6 Future Targets

FY 2004 Targets	FY 2005 Targets
Continue to support the development of medical, non-medical and special operations Multi-Service core NBC doctrine: (1) NBC Aspects of Consequence Management; (2) NBC Defense of Theater Fixed Sites, Ports, and Airfields. Continue to support the integration of CB defense considerations during the revision and development of selected joint doctrinal materials. Continue support to the integration and enhancement of NBC/WMD materials in joint and service professional education. Continue support to the Combatant Commanders with NBC/WMD exercise assistance and training. Coordinate drafting/review of Joint ORDs.	Continue to support the revision and development of CBRN defense medical and non-medical MTTPs: (1) Potential Military Chemical/Biological Agents and Compounds; (2) CBRN Defense of Theater Fixed Sites, Ports, and Airfields; (3) Treatment of Nuclear and Radiation Casualties. Continue to support the integration of CBRN defense considerations during the revision and development of selected joint doctrine and JTTPs.
Continue analyses to support the definition phase of the requirements generation process, joint operational concepts, architecture development, and supporting technical annexes: (1) Toxic Industrial Materials prevalence in Areas of Responsibility on Operations and Tactics for Major Theaters of War and Military Operations other than War; (2) Operational factors affecting protective prophylaxis and pretreatment; (3) Standoff range optimization to support surveillance, reconnaissance, survey, and monitoring capabilities.	Continue to provide assistance in the development and enhancement of CBRN defense curriculum and wargaming at intermediate and senior level Joint and Service Colleges and Senior Service Non-Commissioned Officer Academies. Continue assistance and support for providing CBRN defense related improvements to the four phases of the Joint Training System at Combatant Commands. Continue to provide assistance in the implementation of required solutions for appropriate representation of CBRN defense in Combatant Command's modeling and simulation tools. Continue to provide CBRN defense related training support to Combatant Command staffs, services and the USCG.
Continue to support additional joint participation in the Joint Senior Leaders' Course (JSLC).	Continue to support additional joint participation in the JSLC.
Continue support of Services Battle Management requirements. Continue to define the requirements for simulation based virtual CBD environment to training, mission planning/rehearsal, force development, and acquisition programs. Validate modeling and simulation requirements and tools for C4I systems.	Continue analyses to define capability gaps, capability needs and approaches to provide those capabilities within CBRN defense across all DoD mission areas. Continue execution of the Joint Enabling Concept for CBRN Defense experimentation strategy. Continue analyses to support the development of joint architectures, joint operational concepts, and supporting technical annexes. Continue development, coordination and integration of joint capability requirements.

5.2.4 CB DEFENSE (RDT&E Management Support) (Project DW6 – Dugway Proving Ground)

Project provides the technical capability for testing DoD CB defense materiel, equipment, and systems from concept through production. It finances a portion of the required institutional test operating costs. Institutional test operating costs include institutional civilian and contractor labor; repair and maintenance of test instrumentation, equipment, and facilities; and replacement of test equipment.

DPG, a Major Range and Test Facility Base (MRTFB), is the reliance center for all DoD CB defense testing and provides the United States' only combined range, chamber, toxic chemical lab, and bio-safety level three test facility. Total institutional test operating costs are to be provided by the service component IAW DoDD 3200.11.

DPG uses state-of-the-art chemical and life sciences test facilities and test chambers to perform CB defense testing of protective gear, decontamination systems, detectors, and equipment while totally containing chemical agents and biological pathogens. DPG also provides a fully instrumented outdoor range capability for testing with stimulants that can be correlated to the laboratory testing with live agents.

The current level of institutional test operations funding requires that institutional costs continue to be passed to the program managers and acquisition programs. Passing institutional shortfall costs to the test customers will continue to result in increased test costs to an even greater degree than already exists. Increased test costs put critical developmental testing of CBD systems at risk of being deferred or eliminated, creating an overall increased risk for the decision-makers. Failure to fully fund the institutional portion of the developmental test mission results in insufficient developmental testing for system reliability, performance, and safety issues and failures in operational testing. Preservation of critical Test and Evaluation (T&E) workforce and expertise is also at risk.

The current level of modernization/revitalization funding at DPG increases the risk that some essential test facilities will not be available when needed to meet CB program test schedules. Readiness and condition of test ranges and laboratory equipment will be inadequate to meet the demand of testing state-of-the-art CBD program systems and supporting technologies. Test customers will be required to redirect program funds to upgrade DPG's test facilities. This redirection of program funds puts critical T&E of CBD systems at risk of being deferred or eliminated creating an overall increased risk to the CBDP. The need to refurbish or modernize a given test fixture or series of instrumentation in a given year results in test schedule slippage to subsequent years, thus impacting acquisition program milestones.

Projects programmed for testing at DPG include: Joint Service Lightweight Stand-off Chemical Agent Detector (JSLSCAD); Joint Service Lightweight Nuclear Biological Chemical Reconnaissance System (JSLNBCRS); Joint Service Lightweight Integrated Suit Technology (JSLIST); JSLIST Block II Glove Upgrade; Joint Biological Point Detection System (JBPDs); Joint Chemical Agent Detector (JCAD); Joint Service Sensitive Equipment Decontamination (JSSED); Technical Readiness Evaluation for Biological Stand-off Detection Systems; Joint Service General Purpose Mask (JSGPM); Artemis Chemical Stand-off Detector; Joint Protective Aircrew Ensemble (JPACE); and Joint Biological Stand-off Detection System (JBSDS).

DW6 Actual and Planned Performance

FY2003 Targets	Actual Performance
Provides for civilian labor and other supporting costs that cannot be directly identified to a specific test customer. These civilian personnel perform administration and staff support for DPG's CB test mission to include budget, surety operations, range control, COR duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing chemical and biological defense technologies and equipment.	Funded 40 percent of the civilian labor costs for United States Army Program Budget Guidance (PBG) authorizations. The balance is reimbursed from test customer funds. These civilian personnel support DPG's CB test mission included budget, surety operations, range control, Contracting Officer Representative (COR) duties, and environmental oversight. This account provided the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.

FY2003 Targets	Actual Performance
Provides for labor and supporting costs of contractor personnel performing administration and management of DPG's CB test mission contracts. This is the indirect portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by indirect funds; the balance is recouped from customers.	Funded three percent of targeted 20 percent of contract labor costs. The balance is reimbursed from test customer funds. This is the institutional portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by institutional funds; the balance is recouped from customers.
Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's TRIAD Test Complex (Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility).	Provided for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.
Provides for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. This includes evolving capability needs driven by change in threat and system requirements and equipment purchases to upgrade/replace aging equipment.	Provided for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. Efforts included: portable BL-3 laboratory; chemical agent protective materials swatch test fixture upgrades; field bio-defense instrumentation modernization; and purchases to upgrade/replace aging equipment and instrumentation.

DW6 Future Targets

FY 2004 Targets	FY 2005 Targets
Provides for civilian labor and other supporting costs that are not directly identifiable to a specific test customer. These civilian personnel perform administration and staff support for DPG's CB test mission to include budget, surety operations, range control, Contract Officer Representative (COR) duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.	Funding supports 40 percent of the civilian labor costs for Army PBG authorizations. The balance is reimbursed from test customer funds. These civilian personnel support DPG's CB test mission to include budget, surety operations, range control, COR duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.
Provides for labor and supporting costs of contractor personnel performing administration and management of DPG's CB test mission contracts. This is the indirect portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by indirect funds; the balance is recouped from customers.	Funding supports two percent of the targeted 20 percent of contract labor costs. The balance is reimbursed from test customer funds. This is the institutional portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by institutional funds; the balance is recouped from customers.
Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.	Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.
Provides for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. This includes purchases to upgrade/replace aging equipment.	Provides for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. Efforts include: chemical protective mask test fixture upgrades; chamber agent monitoring methodology developments; Polymerase Chain Reaction analysis improvements; and purchases to upgrade/replace aging equipment and instrumentation.

5.2.5 CB DEFENSE (RDT&E Management Support) (Project MS6 – RDT&E Management Support)

This project provides management support for the DoD CBDP. It includes program oversight and integration of overall medical and non-medical programs by the ATSD(NCB) defense programs through the DATSD(CBD), and the Director, DTRA. Funds execution management is provided by DTRA.

The project also funds development, coordination and integration of joint CBRN defense capability requirements, including assistance and support to the Combatant Commanders and Services to improve CBRN defense related doctrine, education, training, and awareness by the Joint Requirements Office (JRO) Joint CBRN defense Research, Development, and Acquisition (RDA) planning, input to the CBD Annual Report to Congress, and program guidance development by the Program Analysis and Integration Office (PA&IO).

The project includes programming support for the Joint Service CB Information System (JSCBIS) which serves as a budgetary and informational database for the DoD CBDP. Funding is provided for the CB Archive Information Management System (CBAIMS) a means to collect, assemble, catalog and archive CBD information from multiple service locations into a central repository and library.

Funding is also provided for the Test and Evaluation (T&E) Executive IPT, which serves as a mechanism to identify, develop, and manage test infrastructure and technology programs to support Developmental Testing (DT) and Operational Testing (OT) of DoD CBD systems, as outlined in the RDA Plan. The T&E Executive will fund a series of methodology, instrumentation, and associated validation efforts to provide test infrastructure and technologies for testing RDA systems needed to support all services.

Test infrastructure and technology programs have been prioritized in accordance with the RDA Plan and the annual NBC Joint Priority List (JPL). Programs will be structured to phase highest priority efforts in time to support RDA Plan required tests and schedules to the fullest extent possible.

Test Operating Procedures (TOPs) will be developed to standardize and document new test procedures and/or to update existing test procedures. All test infrastructure and technology programs will be centrally managed and coordinated with the Joint Service community to ensure that all Services' test and acquisition program needs are met..

MS6 Actual and Planned Performance

FY2003 Targets	Actual Performance
<i>CBAIMS</i> - Archive Chemical and Biological information from multiple service locations.	<i>CBAIMS</i> - Archived Chemical and Biological information from multiple service locations.
<i>JNBCDB MGT</i> - Provide oversight and analysis for the PPBS process.	<i>Army Executive MGT</i> - Provided oversight and analysis for the PPBES process.

FY2003 Targets	Actual Performance
<i>JSIG MGT</i> - Plan, coordinate and oversee the development and review of the: Joint CBRN operational requirements generation; DoD CBRNDP POM Strategy; Joint CBRN Modernization Plan; Integrated medical and non-medical CBRN Joint Priority List; CBRN Joint Future Operational Capabilities, and the CB Defense Annual Report to Congress.	<i>JRO MGT</i> - Represented the Services and Combatant Commanders in the development, coordination, and integration of CBRN defense operational capabilities across all DoD mission areas. Planned, coordinated and executed the development and review of the: Joint Enabling Concept for CBRN Defense; Joint CBRN defense capability requirements; DoD CBRNDP program guidance; Joint CBRN Defense Modernization Plan; Integrated medical and non-medical CBRN Defense JPL; CBRN Defense Joint Future Operational Capabilities, and the CBD Annual Report to Congress.
<i>JSMG MGT</i> - Develop assessments to support RDA Planning. Provide analytic programmatic support for development of POM Strategy, the BES, and the PB submissions. Respond to specialized evaluation studies throughout the PPBS process. Provide JSCBIS database management.	<i>JSMG MGT</i> - Developed assessments to support RDA Planning. Provided analytic programmatic support for development of program guidance, the Budget Estimate Submission, and the President's Budget (PB) submission. Responded to specialized evaluation studies throughout the Planning, Programming, Budgeting and Execution process. Provided management of JSCBIS.
<i>OSD MGT</i> - Perform program reviews/assessments, provide programmatic PPBS oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support.	<i>OSD MGT</i> - Performed program reviews/assessments, provided programmatic Planning, Programming, Budgeting and Execution (PPBE) oversight/analysis, provided congressional issue analysis and support. Supported financial management services provided by the DTRA such as funding distribution and execution reporting. Provided JSCBIS database support.

MS6 Future Targets

FY 2004 Targets	FY 2005 Targets
<i>CBAIMS</i> - Archive Chemical and Biological information from multiple service locations.	<i>CBAIMS</i> - Archive Chemical and Biological information from multiple service locations.
<i>JRO MGT</i> - Represent the Services and Combatant Commanders in the development, coordination, and integration of CBRN defense operational capabilities across all DoD mission areas. Plan, coordinate and execute the development and review of: Joint CBRN defense capability requirements; DoD CBRNDP program guidance; Joint CBRN Defense Modernization Plan; Integrated medical and non-medical CBRN Defense JPL; CBRN Defense Joint Future Operational Capabilities, and the CBD Annual Report to Congress.	<i>JRO MGT</i> - Represent the Services and Combatant Commanders in the development, coordination, and integration of CBRN defense operational capabilities across all DoD mission areas. Plan, coordinate and execute the development and review of: Joint CBRN defense capability requirements; DoD CBRNDP program guidance; Joint CBRN Defense Modernization Plan; Integrated medical and non-medical CBRN Defense JPL; CBRN Defense Joint Future Operational Capabilities, and the CBD Annual Report to Congress.
<i>PA&IO MGT</i> - Develop assessments to support RDA Planning. Provide analytic programmatic support for development of program guidance, the Program, Budget and Execution Reviews, and the President's Budget (PB) submissions. Respond to specialized evaluation studies throughout the Planning, Programming, Budgeting and Execution (PPBE) process. Provide JSCBIS database management.	<i>PA&IO MGT</i> - Develop assessments to support RDA Planning. Provide analytic programmatic support for development of program guidance, the Program, Budget and Execution Reviews, and the PB submissions. Respond to specialized evaluation studies throughout the PPBE process. Provide JSCBIS database management.

FY 2004 Targets	FY 2005 Targets
<i>JTIWG</i> - Initiate and conduct test methodology development, test system instrumentation integration, and test technology validation for refereeing agent simulant challenges for field testing (developmental and operational). Initiate planning, modeling, and development of an Interim Chemical Agent Active Standoff Detection Test Fixture.	<i>JTIWG</i> - Continue methodology development, test system instrumentation integration, and test technology validation for refereeing agent simulant challenges for field testing (developmental and operational). Refine methodology for data fusion and visualization. Procure additional ground truth instrumentation and initiate mobile capability.
<i>OSD MGT</i> - Perform program reviews/assessments, provide programmatic PPBS oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support.	<i>OSD MGT</i> - Perform program reviews/assessments, provide programmatic PPBE oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support.

5.2.6 CB DEFENSE (RDT&E Management Support) (Project O49 – JOINT CONCEPT DEVELOPMENT AND EXPERIMENTATION PROGRAM)

The objectives of the Joint Concept Development and Experimentation (JCDE) program are to plan, conduct, evaluate, and report on joint tests and experiments (for other than developmental hardware) and accomplish operational research assessments in response to requirements received from the Combatant Commanders and the Services. This program will provide ongoing input to the Combatant Commanders and Services for development of doctrine, policy, training procedures, and feedback into the RDT&E cycle.

O49 Actual and Planned Performance

FY2003 Targets	Actual Performance
Conduct field trials evaluating performance and procedures in a chemical environment. Field trials to be conducted are in support of operations: (1) determination of chemical droplet size, and (2) processing cargo and troops through an exchange zone.	Conducted field trials to evaluate performance and procedures in a chemical environment. Conducted field trials in support of operations: (1) determination of chemical droplet size, and (2) processing cargo and troops through an exchange zone (Phases I, II, and III)..
Conduct laboratory tests evaluating performance and procedures in a chemical environment. Conduct laboratory tests to address the effects of rotor wash on aircrew ensemble.	Conducted assessments to evaluate performance and procedures in a chemical environment. Conducted assessments of the effectiveness of interior building areas for use as chemical rest and relief areas.
Conduct assessments evaluating performance and procedures in a chemical environment. Conduct assessments of the effectiveness of interior building areas for use as chemical rest and relief areas.	Conducted CB Joint Technical Information Center Research. Conducted the following as necessary: Initial Evaluation, Literature Search, or a letter response with the results of the evaluation. Conducted further assessment to determine appropriate test methodology such as modeling, field test, laboratory test, and/or chamber test.
Conduct CB Joint Technical Information Center Research. Conduct the following as necessary: Initial Evaluation, Literature Search, or a letter response with the results of the evaluation. Conduct as necessary. Further assessment to determine if modeling, a field test, a laboratory test, and/or a chamber test is merited.	Completed test planning. Test support organizations are currently working on solar lighting methods and conditioning chamber.
Continue to conduct Technical Data Source Book Update. Continue incremental update of data and information generated from on going Project O49 activity.	Continued to conduct Technical Data Source Book update. Continued incremental update of data and information generated from on going Project O49 activity.

O49 Future Targets

FY 2004 Targets	FY 2005 Targets
Conduct assessments, laboratory and field tests evaluating performance and procedures in a chemical and biological environment in support of information requirements submitted by Combatant Commanders and Service representatives.	Conduct assessments, laboratory and field tests to evaluate performance and procedures in a chemical and biological environment in support of information requirements submitted by Combatant Commanders and Service representatives.
Conduct field tests evaluating performance and procedures in a chemical environment, to wit, the effectiveness of the C- 17 cargo aircraft in- flight checklist procedure for eliminating smoke and fumes.	Continue to conduct Technical Data Source Book updates by reviewing the literature and updating volumes of the source books with newly published material.
Conduct field tests to determine the level of incursion and condensation of chemical warfare agent vapors into tunnels and other underground structures.	Conduct a Joint Warfighter Experiment that addresses Concept of Operations (CONOPS) issues relating to Battlefield Space Awareness.
Conduct laboratory and field tests evaluating use of cargo covers made from various materials for equipment protection in a chemical or biological environment.	
Continue to conduct Technical Data Source Book updates by reviewing the literature and updating volumes of the source books with newly published material.	

5.2.7 CB DEFENSE (RDT&E Management Support) (Small Business Innovative Research (SBIR))

The CBD SBIR program is used to elicit innovative solutions from the small business community that address chemical and biological defense technology gaps confronting DoD and to include technologies that will also have high commercialization potential in the private sector. SBIR topics are developed in each of the following capability areas to address both chemical and biological threats: detection; protection (individual and collective); decontamination; modeling & simulation; and support science (6.1 R&D). Additionally, specific program areas include chemical and biological defense medical technologies that address pre-treatments, therapeutics; diagnostics; and emerging threats.

The Defense Threat Reduction Agency (DTRA), Chemical and Biological Defense Directorate, provides technical and programmatic oversight to SBIR topic generation in addition to proposal evaluation and selection. The Army Research Office-Washington (ARO-W) administers the day-to-day administrative activities of the CBD SBIR program and is responsible for the operation of the CBD SBIR Program Management Office.

The SBIR program was established by Congress in 1982, to permit small businesses (<500 employees) to develop and to speed the conversion of their research and development into new commercial products. SBIR allows smaller companies the opportunity to test high-risk theories and develop innovative technologies. The CBD SBIR program began soliciting proposals in 1998. Public Law 106-554, Small Business Reauthorization Act of 2000, extends the SBIR program through September 30, 2008.

All companies start at Phase I of a two-phase program. Phase I permits the firm to establish the feasibility and technical merit of a proposed innovation. A Phase II contract focuses on development of a pre-production prototype based on the proof-of-concept demonstrated during Phase I. Phase III establishes the commercialization and manufacturing of the completed technology development.

SBIR proposals are competitively evaluated based on their scientific and technical merit, and on the basis of their originality. Federal scientists or engineers that are subject matter experts for a particular topic area provide the review. Evaluation and assessment criteria include the technical merit of the proposal, qualifications of the principal investigator and key staff, potential commercial applications (dual-use technology), and, in the case of the CBD SBIR program, the benefits provided to the warfighter. Limited improvements do not get awarded SBIR funds; only products with a leap in capability providing next-generation capabilities are acknowledged.

5.2.7.1 SBIR Performance Goal (Outcome). The goal of the CB defense SBIR program is to transfer innovative CBD technologies between DoD components and the private sector for mutual benefit in all areas of CBD research.

5.2.7.2 SBIR Outcome Measure

SBIR is minimally effective when	SBIR is successful when
Contracts are awarded that demonstrate proof-of-principle or increase scientific understanding of CB defense technology research needs.	- SBIR efforts support the demonstration of technology objectives. - SBIR efforts support the transition of research efforts from the science and technology base to advanced development.

5.2.7.3 SBIR Performance. Since SBIR efforts represent a contracting process rather than a goal in itself, the targets for future years are determined based on the progress of research in ongoing and planned research areas. SBIR topics are updated every six months and reflect a broad range of CBD research activities. Following are CBD SBIR data for FY03 and FY04.

CBD SBIR FY03 Statistics:

In FY03, 20 CBD SBIR topics were published on 1 October 2002, as solicitation for Phase I proposals. A record number of proposals – 347 – were submitted in response to those topics, with 25 Phase I contracts being executed having a total value of \$1.9M. Ten new Phase II contracts were also awarded in addition to funding eleven ongoing (pre-FY03) Phase II development efforts. These CBD SBIR R&D efforts span both biological and chemical defense requirements and address technology gaps in all medical and non-medical CBD capability areas.

CBD SBIR FY04 Statistics:

Phase I SBIR topics were evaluated for relevancy to technical need and mission requirements prior to public release. From 271 proposals submitted in response to twenty published topics, an estimated 25 Phase I awards with a total value of \$1.75M will be issued during 3QFY04. Approximately 13 (estimated) successfully completed Phase I contracts will transition to Phase II, in addition to continued funding for ten ongoing (in-progress) Phase II contracts. Phase II contracts will account for approximately \$8.95M FY04 CBD SBIR funds. Prototypes delivered at the conclusion of the Phase II period-of-performance will be assessed for their ability to meet CBD program requirements and allow for transition of new technologies to the warfighter.

5.2.7.4 Assessment of SBIR. CBD SBIR efforts have been successful in FY03 and are projected to be in FY04, based on the large number of proposals received, contracts awarded, SBIR efforts transitioned to SBIR Phase II, and technologies leveraged to advanced key CB defense science and technology programs.