CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
	Total Program Element (PE) Cost	58241	75266	249842	106003	100922	87288	92228	Continuing	Continuing
CB3	CHEMICAL BIOLOGICAL DEFENSE (ADV TECH DEV)	15935	21553	27248	33964	33721	26599	31800	Continuing	Continuing
CM3	WMD - CIVIL SUPPORT TEAM (ADV TECH DEV)	0	0	2500	2500	2500	2500	2500	Continuing	Continuing
CP3	COUNTERPROLIFERATION SUPPORT (ADV TECH DEV)	9944	12492	11738	5327	5368	4697	4242	Continuing	Continuing
HS3	HOMELAND SECURITY (ADV TECH DEV)	0	0	162000	0	0	0	0	0	162000
TB3	MEDICAL BIOLOGICAL DEFENSE (ADV TECH DEV)	22394	29919	34200	50789	45560	40585	40675	Continuing	Continuing
TC3	MEDICAL CHEMICAL DEFENSE (ADV TECH DEV)	9968	11302	12156	13423	13773	12907	13011	Continuing	Continuing

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

A. Mission Description and Budget Item Justification: This program element demonstrates technologies that enhance the ability of U.S. forces to defend against, and survive chemical and biological (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 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. A Biological Defense Homeland Security Support Program is planned. The support program, as envisioned by the Office of Homeland Security, is to provide an integrated Homeland Security capability to detect, mitigate, and respond to biological-related incidents. Also research efforts are planned for evaluating technologies for Weapons of Mass Destruction Civil Support Teams (WMD CSTs). Work conducted under this PE transitions to and provides risk reduction for Demonstration/Validation (PE 0603884BP) and Engineering/Manufacturing Development (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.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

B. Program Change Summary:		FY 2001	FY 2002	FY 2003
Previous President's Budget (FY 2002 PB)		59905	69249	84250
Appropriated Value		0	75749	0
Adjustments to Appropriated Value		0	0	0
a. Congressional General Reductions		-407	-483	0
b. SBIR/STTR		-1014	0	0
c. Omnibus or Other Above Threshold Reductions		0	0	0
d. Below Threshold Reprogramming		1900	0	0
e. Rescissions		-132	0	0
Adjustments to Budget Years Since FY 2002 PB		0	0	165592
Current Budget Submission (FY 2003 PB)		58241	75266	249842

Change Summary Explanation:

Funding: FY03 - Increase to the technology base to fund a Homeland Security Support effort identified in the new Project HS3 (+$162,000K); increase to support advanced development for WMD Civil Support Teams in the new project CM3 (+$2,500K); increase to the technology base to accelerate the investigation and development of CBD technologies (+$1,500K); inflation adjustment to reflect current assumptions (-$408K).

Schedule:

Technical:

C. Other Program Funding Summary: See section B in the R2A's

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)	DATE February 2002
BUDGET ACTIVITY **RDT&E DEFENSE-WIDE/** **BA3 - Advanced Technology Development**	PE NUMBER AND TITLE **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

D. Execution: (Organizations receiving 10% or more of execution year funding)

Labs/Centers:

TB3 - U.S. Army Medical Research Institute of Infectious Diseases, Ft. Detrick, MD; CB3 - U.S. Army Soldier Biological and Chemical Command, APG-EA, MD; CB3 - U.S. Marine Corps, Quantico, VA.

Universities: None

FFRDCs: None

Contractors: None

Other: None

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CB3**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
CB3	CHEMICAL BIOLOGICAL DEFENSE (ADV TECH DEV)	15935	21553	27248	33964	33721	26599	31800	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project CB3 CHEMICAL BIOLOGICAL DEFENSE (ADV TECH DEV): 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 demonstration and validation efforts. This project funds the Joint Service Warning and Identification LIDAR (Light Detection And Ranging) Detector (JSWILD) Program, (JSWILD is transitioning to ARTEMIS in CP4, in FY01 and CA4, in FY02 and beyond.) 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). Additionally, this program funds the Small Unit Biological Detector (SUBD), Consequence Management Interoperability Service (CMIS), and the Chemical Biological Individual Sampler (CBIS). Also funded are research efforts in chemical biological detection technologies, advanced materiel research for filter materials, chemical and biological warfare effects on operations, and identification technologies to support the Joint Biological Point Detection System (JBPDS) Block II program.

A major effort is funded to conduct technologies transition from DOE and DARPA research to the CB defense programs.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CB3**

FY 2001 Accomplishments:

- 2142 Joint Service Warning and Identification LIDAR (Light Detection and Ranging) Detector (JSWILD) - Demonstrated brassboard system and transitioned technology to ARTEMIS (Active Standoff CW Detection System).
- 2386 Joint Service Sensitive Equipment Decontamination (JSSED) - Conducted development of sensitive equipment/items decontamination technologies (Block I). Identified candidate technologies for interior decontamination (Block II/III).
- 2191 Detection Technologies - Evaluated and supported accelerated efforts on technologies with significant potential for demonstration in various Advanced Concept Technology Demonstrations (ACTD) and upcoming mature development programs. Effort involved testing hyperspectral imaging systems and a representative RADAR system to provide cueing and early warning capabilities.
- 2702 Chemical Biological Advanced Materials Research - Demonstrated the value of advanced material used in protection concepts for filtration, clothing, and tentage.
- 742 Small Unit Biological Detection (SUBD) - Advanced the current component technologies to a final configuration and paid for contract closeout and archiving of data.
- 3842 Consequence Management Interoperability Service (CMIS) - Initiated development of a "common operating view" that enables DoD to view tactical information in advance of arriving at the scene of a Weapons of Mass Destruction (WMD) incident. Tailored Commercial Off-The-Shelf (COTS) software that is adapted to the "lowest common denominator." Evaluated Geospatial Information System (GIS) data and applications for WMD incidents.
- 1930 Chemical Biological Individual Sampler (CBIS) - Conducted testing and validation of COTS passive chemical samplers as well as developed the standard analytical method for these samplers. Conducted demonstrations that address critical operations issues.

Total 15935

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CB3**

FY 2002 Planned Program:

- 2000 Joint Chemical Biological Agent Water Monitor (JCBAWM) (DTO-CB37) - Initiate planning for technology transition to mature development. Initiate design of brassboard system for demonstration. Incorporate surety testing of component technologies as a parameter in design of brassboard.
- 1000 Chemical and Biological Warfare Effects on Operations (DTO-43) - Develop a general purpose model of the operations of large fixed-site facilities (air bases, Aerial Ports of Debarkation (APODs) and, Seaports of Debarkation (SPODs)), with the capability to represent chemical and biological warfare (CBW) attacks and their operational impacts.
- 1700 Miniaturized C/B Detectors (MEMS Technology) - Initiate a program for fieldable sensors using MEMS technology.
- 1300 Center for Bio Defense Statewide Medical Response System.
- 500 Detection Technologies - Complete assessment of hyperspectral imaging technologies and establish transition points for the highest potential payoff capabilities.
- 300 Joint Service Sensitive Equipment Decontamination (JSSED) - Complete analysis of alternatives.
- 300 Fourth Generation Agent (FGA) Decontamination - Initiate investigation of efficacy of fielded and developmental decon solutions against FGAs.
- 2088 Joint Effects Model (JEM) - Initiate analysis of alternatives and preparation of documentation to support transition to mature development. Initiate combination of candidate models to single model, and demonstrate.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CB3**

FY 2002 Planned Program (Cont):

- 10507 Technology Transition - Conduct acceptance testing of anthrax antibody mixtures under development for improved affinity. Implement improved sample treatment procedures for ultraviolet-infrared matrix-assisted laser desorption (MALDI) Time of Flight (TOF) mass spectrometer and prepare for field evaluation. Develop assays and initiate live agent testing of DARPA Micro Array of Gel-Immobilized Compounds (MAGIChip) nucleic acid identification technology for Bacillus species. Initiate automation of DARPA-developed MALDI mass spectrometry (MS). Initiate comparative evaluation for sensitivity and discrimination capability of UV-MALDI and V-IR MALDI MS candidates from DARPA and electrospray ionization (ESI) MS. Identify sample processing challenges for improvement. Evaluate suitability and identify engineering issues for militarization of DOE's microlab technology, Handheld Advanced Nucleic Acid Analyzer (HANAA), and decontamination foam system. Develop and test thermocatalytic air purifier technology for collective protection shelters, focus is on a DARPA technology in thin-foil high efficiency heat exchanger and system design. Expand the biological Joint Field Trial concept to a multi-tiered set of evaluation protocols to facilitate the characterization of candidate technology at varying levels of maturity.
- 1493 Joint Operational Effects Federation (JOEF) - Conduct Analysis of Alternatives (AoA) and market survey. Establish Joint System Architecture IPT and Joint T&E IPT. Coordinate and create the Test and Evaluation Master Plan (TEMP). Develop the acquisition strategy and supporting acquisition documentation. Demonstrate the maturity of the JOEF Blk I federate. Conduct Interoperability Assessment and a System Threat Assessment.
- 365 SBIR - Small Business Innovative Research efforts.

Total 21553

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CB3**

FY 2003 Planned Program:

- 4550 Joint Chemical Biological Agent Water Monitor (JCBAWM) (DTO-CB37) - Complete planning for technology transition to mature development. Complete design and initiate build of brassboard system for demonstration.
- 1493 Chemical and Biological Warfare Effects on Operations (DTO-43) - Complete and transition Joint Environmental Model to the Joint Warning and Reporting Network (JWARN). Complete and transition Simulation, Training and Analysis for Fixed Sites (STAFFS) to Joint Warfare System (JWARS) and to JOEF Block 1.
- 3569 Biological Identification - Develop next generation broad-spectrum discrimination and automated ID technologies toward demonstration and transition to JBPDS Block II.
- 2136 JSSED - Conduct targeted analysis of alternatives for Block II/III. Initiate documentation of technology findings to support transition to development.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002
BUDGET ACTIVITY **RDT&E DEFENSE-WIDE/** **BA3 - Advanced Technology Development**	PE NUMBER AND TITLE **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**
	PROJECT **CB3**

FY 2003 Planned Program (Cont):

- 14000 Technology Transition - Continue development of sample treatment procedures for MALDI-TOF mass spectrometer and demonstrate in a field evaluation. Continue development of assays and live agent testing of DARPA Micro Array of Gel-Immobilized Compounds (MAGIChip) nucleic acid identification technology for Bacillus species. Continue automation of DARPA-developed ultraviolet-infrared matrix-assisted laser desorption (MALDI) mass spectrometry (MS). Continue comparative evaluation and improve sensitivity and discrimination capability of UV-MALDI and UV-IR MALDI MS candidates from DARPA and electrospray ionization (ESI) MS. Initiate the militarization of DOE's microlab technology, Handheld Advanced Nucleic Acid Analyzer (HANAA), and decontamination foam system. Continue development and testing of thermocatalytic air purifier technology for collective protection shelters, focus is on a DARPA technology in thin-foil high efficiency heat-exchanger and system design. Continue development and initiate implementation of expanded multi-tiered set of evaluation protocols to address all stages of chemical/biological defense materiel development from system concept development to mature technology/NDI/COTS systems to facilitate fair evaluation of technology candidates from all sources.
- 1500 Advanced Filtration - Demonstrate fiber-immobilized carbon particles from DARPA project in mask filter designs (Joint Service General Purpose Mask (JSGPM), the Joint Service Aviator Mask (JSAM)), collective protection designs (JTCOPS (Joint Transportable Collective Protection Shelter) and production filters (Joint Collective Protection Equipment)).

Total 27248

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

PROJECT: **CB3**

B. Other Program Funding Summary:

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	To Compl	Total Cost
BJ4 BIOLOGICAL DEFENSE (DEMVAL)	5765	1560	3661	19163	19329	0	0	0	49478
CA4 CONTAMINATION AVOIDANCE (DEMVAL)	8866	16274	16963	1988	2997	0	0	0	47088
CO4 COLLECTIVE PROTECTION (DEMVAL)	1454	0	4390	0	0	0	0	0	5844
CP3 COUNTERPROLIFERATION SUPPORT (ADV TECH DEV)	9944	12492	11738	5327	5368	4697	4242	Cont	Cont
CP4 COUNTERPROLIFERATION SUPPORT (DEMVAL)	15709	15243	13423	20442	21137	24459	25516	Cont	Cont
DE4 DECONTAMINATION SYSTEMS (DEMVAL)	3368	6143	6972	12378	14220	3997	3992	Cont	Cont
IP4 INDIVIDUAL PROTECTION (DEMVAL)	16610	14317	0	0	0	0	0	0	30927

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DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CM3**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
CM3	WMD - CIVIL SUPPORT TEAM (ADV TECH DEV)	0	0	2500	2500	2500	2500	2500	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project CM3 WMD - CIVIL SUPPORT TEAM (ADV TECH DEV): 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 32 States. 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.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CM3**

This program funds the purchase and testing of Commercial-off-the-shelf (COTS) components on the existing Table of Distribution and Allowances (TDA) of Weapons of Mass Destruction Civil Support Teams (WMD CST), and evaluates new commercial products being considered for the WMD CST TDA for performance and ability to meet requirements.

FY 2001 Accomplishments: None

FY 2002 Planned Program: No planned program

FY 2003 Planned Program:

- 600 WMD CST - Initiate purchase of Commercial-off-the-shelf components on the Table of Distribution & Allowances (TDA) of the Weapons of Mass Destruction (WMD CSTs).
- 1250 WMD CST - Initiate evaluation of new commercial products being considered for TDA to determine performance and ability to meet WMD CST requirements.
- 650 WMD CST - Planning and support for test program for commercial equipment.

Total 2500

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

PROJECT: **CM3**

B. Other Program Funding Summary:

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	To Compl	Total Cost
CA4 CONTAMINATION AVOIDANCE (DEMVAL)	8866	16274	16963	1988	2997	0	0	0	47088
CM5 WMD - CIVIL SUPPORT TEAM (EMD)	0	0	1000	1000	14500	400	0	0	16900
CM6 WMD - CIVIL SUPPORT TEAM (MANAGEMENT SUPPORT)	0	0	1600	1600	1600	1600	1600	Cont	Cont
JA0004 WMD - CIVIL SUPPORT TEAM EQUIPMENT	2046	0	18959	8000	3047	44300	1600	Cont	Cont

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

PROJECT: **CP3**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
CP3	COUNTERPROLIFERATION SUPPORT (ADV TECH DEV)	9944	12492	11738	5327	5368	4697	4242	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project CP3 COUNTERPROLIFERATION SUPPORT (ADV TECH DEV): The mission of the Counterproliferation Program (CP) is to address shortfalls in the Department of Defense (DoD) deployed capability to defend against and counter the proliferation of Weapons of Mass Destruction (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) and Counterproliferation Support (Non-system) (CTP (NS)) efforts, Critical Reagents Program (CRP), Restoration of Operations (RESTOPS) and Planning and Development (PD) for Advanced Concept Technology Demonstrations.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CP3**

FY 2001 Accomplishments:

- 974 ACTD-PD - Performed technology maturity evaluations for selection of technologies for Integrated Chemical Biological ACTD. Initiated maturation of Standoff Detector for use as a surface chemical detector.
- 1757 BIODET - Produced nucleic acid primer libraries for testing and continued development of a biological detection capability using nucleic acids. Completed the transition to project CB3 for test, evaluation, and further assay development against live agents under tech transfer funds.
- 386 CRP - Completed current phase of development of reagents (antibodies and antigens) that are critical to the development, testing, and support of CP biological detection systems.
- 5708 CTP (NS) - Counterproliferation Non Systems (CTP (NS)) - Continued development and evaluation of generic detectors (Time of Flight (TOF) Mass Spectrometer and the (MS)/MS, Ultra Violet) with associated algorithms to provide increased warning time for tactical battlefield applications. Continued development, testing, and evaluation of automated sample preparation technology and protocols for Polymerase Chain Reaction (PCR) devices to improve identification specificity and sensitivity in future biological systems. Completed transition of TOF Mass Spectrometer to the CB3 program. Initiated synthetic environment tool for technology selection for RestOps scenarios. Initiated testing of warfare agents on RestOps scenario surfaces for use in modeling and simulation.
- 1119 RESTOPS - Completed assessment of universal novel chemical and biological decontaminants for use in the RestOps ACTD and fixed site decontamination programs.

Total 9944

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DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CP3**

FY 2002 Planned Program:

- 1885 ACTD-PD - Perform technology maturity evaluations, perform analysis of alternative technologies, and prepare acquisition strategy for Contamination Avoidance for Seaports of Debarkation (CASPOD) Advanced Concept Technology Demonstration.
- 2487 CTP (NS) - Initiate development and testing of improved UV detectors, UV micro-lasers, and algorithms. Initiate prototype development and testing of an optical based detector using high affinity nucleic acid aptamer chips. Initiate challenges to detector systems in development using Red Teams. Initiate development and testing of a new improved collector/concentrator and pre-separator devices for filtering and cleaning environment air samples.
- 3469 CTP (NS) - Continue development and evaluation of generic detectors (TOF MS/MS, UV) and associated algorithms to provide increased warning time for tactical battlefield applications. Continue development, testing, and evaluation of automated sample preparation technology and protocols for Polymerase Chain Reaction (PCR) devices to improve identification specificity and sensitivity in future biological systems.
- 3000 BIO Non Sys - Develop decontaminants, equipment, procedures, techniques, and tactics for decontamination of wide body aircraft.
- 1440 RESTOPS - Continue development of a synthetic environment tool for technology selection in RestOps scenarios. Continue testing of warfare agents on RestOps scenario surfaces for use in modeling and simulation. Continue development of maturing technologies for RestOps demonstrations.
- 211 SBIR - Small Business Innovative Research.

Total 12492

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**CP3**

FY 2003 Planned Program:

- 1892 ACTD-PD - Perform technology maturity evaluations for selection of technologies for future ACTD candidate.
- 2376 BIO Non Sys - Initiate short term projects resulting from collaborative efforts with non-DoD agencies to accelerate promising technologies that can fill technology gaps in the Chemical and Biological Defense programs.
- 3666 CTP (NS) - Continue development and demonstration of improved Hand Held Assay (HHA) device for fielded bio-detection systems, including legacy systems in an attempt to improve the three basic aspects of the HHA: reagents, format and solid phase. Initiate development of biological attribution technology to capture a suite of leading edge biotechnology techniques by which any sample of biological material could be analyzed to detect a specific signature that will lead to a determination of its origin.
- 3804 RESTOPS - Complete synthetic environment tool for technology selection in RestOps scenarios. Complete testing of warfare agents on RestOps scenario surfaces for use in modeling and simulation. Complete development of maturing technologies for RestOps demonstrations.

Total 11738

B. Other Program Funding Summary:	**FY 2001**	**FY 2002**	**FY 2003**	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**	**To Compl**	**Total Cost**
CP4 COUNTERPROLIFERATION SUPPORT (DEMVAL)	15709	15243	13423	20442	21137	24459	25516	Cont	Cont

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**HS3**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
HS3	HOMELAND SECURITY (ADV TECH DEV)	0	0	162000	0	0	0	0	0	162000

A. Mission Description and Budget Item Justification:

Project HS3 HOMELAND SECURITY (ADV TECH DEV): The intent of the Biological Defense Homeland Security Program, as envisioned by the Office of Homeland Security, is to provide an integrated Homeland Security capability to detect, mitigate, and respond to biological-related incidents. This capability will be achieved primarily through the integration of enhanced biological detection capabilities and the fusion of medical surveillance systems, wide-area environmental sensors, access control point monitors, and information management systems that will reduce the vulnerability of U.S. assets or will impact national interests. The prototype-fielded systems will be integrated and demonstrated as a pilot program in DoD bases and urban test beds. Test beds will include medical surveillance technology, biological and meteorological sensors, biological analytical instruments, and an integrated biological information network. Funding for this project also supports microbial forensic genomics, confirmatory analysis, and aerobiology testing for the Biological Counterterrorism Research Program.

FY 2001 Accomplishments: None

FY 2002 Planned Program: No planned program

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	HS3

FY 2003 Planned Program:

- 13000 Aerobiology Testing - Establish program capability for threat agent aerobiological research and model development, focusing on characterization of the properties of biological threat agents that are most significant for understanding the ramifications for medical and non-medical defensive measures.
- 3400 Signature Analysis - Integrate into a test bed system the ability to identify, catalog, and analyze observable data from sensors and medical surveillance activities using signature source term catalogs to identify potential threat events.
- 6900 Signature Analysis - Conduct detailed characterization through laboratory analysis of the background at two DoD bases and surrounding urban areas for the test beds.
- 8100 Medical Surveillance - Integrate into a test bed and demonstrate technologies providing point-of-care diagnostic capabilities in DoD installations and civilian hospitals and clinics.
- 2700 Medical Surveillance - Integrate technologies into a test bed to demonstrate patient syndromic reporting so that proliferation of diseases through military and civilian populations can be tracked.
- 2200 Medical Surveillance - Demonstrate technologies to integrate data from military and civilian hospital and pharmaceutical databases to provide indicators of bioterrorism threat events.
- 5900 Environmental Monitoring - Integrate into test beds existing networked point-detection technologies to demonstrate a capability to implement a layered architecture to protect wide areas and structures.
- 5700 Environmental Monitoring - Integrate into test beds existing networked stand-off detection technologies and real time detection, warning, and reporting through multi-mission sensor integration and with other data sources to demonstrate a capability to implement a layered architecture to protect wide areas and structures.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	HS3

FY 2003 Planned Program (Cont):

- 2200 Environmental Monitoring - Integrate into test beds mobile/transportable detection systems to demonstrate a capability for surveillance and monitoring of incident sites while preserving evidence for later forensic analysis.
- 9300 Access Control Point Monitoring - Integrate into test beds existing access control point monitoring technologies to demonstrate a capability to implement a layered architecture to protect choke points and special events.
- 1600 Access Control Point Monitoring - Integrate into test beds existing video surveillance technologies to demonstrate a capability to implement a layered architecture to protect choke points and special events.
- 6000 Access Control Point Monitoring - Integrate into test beds existing non-destructive stand-off technologies to demonstrate a capability to implement a layered architecture to protect choke points and special events.
- 4700 Data Mining, Fusion, and Analysis - Modeling and Analysis - Develop and integrate existing plume dispersion models into test bed data fusion and analysis subsystems to provide urban hazard prediction capability.
- 5000 Data Mining, Fusion, and Analysis - System Development - Develop, integrate and demonstrate data collection, storage, analysis, and decision support capabilities to support test bed applications.
- 2600 Data Mining, Fusion, and Analysis - Related Databases - Verify, validate and accredit relevant databases and data elements (pharmaceutical databases, veterinary databases) and integrate through the use of data mining algorithms to extract information to support biodefense objectives.
- 4000 Data Mining, Fusion, and Analysis - CT Information Network - Implement the DTRA Chemical Biological Information Network pilot program and integrate it into the DTRA national reach-back network.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	HS3

FY 2003 Planned Program (Cont):

- 6300 Data Mining, Fusion, and Analysis - Command, Control, and Communications - Integrate existing command, control, and communications systems and decision analysis tools to produce a test bed capability that ties together medical surveillance and environmental monitoring technologies to generate useful information for end users.
- 1000 Testing and Trials - Command Post Exercises - Conduct small scale exercise to evaluate initial concept of operations.
- 9900 Testing and Trials - Field Exercises - Conduct full field exercises for all test beds.
- 4000 Testing and Trials - Red Team Analysis - Develop and implement adversarial analysis to identify gaps in the test bed system-of-system architecture and subsystems.
- 8500 Requirements Analysis, System Integration and Program Support - Mission Infrastructure Protection - Identify information requirements of state, local, and national infrastructure managers to define functional requirements for decision support capabilities. Implement lessons learned from SMART building/2002 Olympics, NCR test bed, Hart Building decontamination, DARPA Immune Building, and other major projects into biodefense requirements process.
- 1000 Requirements Analysis, System Integration and Program Support - Baseline Self Assessment (BSA) - Implement expanded BSA for vulnerability identification and analysis for urban areas.
- 6000 Requirements Analysis, System Integration and Program Support - Test Bed Systems Engineering - Provide overarching systems engineering, design, and analysis of test bed systems to create a flexible architecture to accommodate evolving detection and surveillance capabilities.
- 15000 Requirements Analysis, System Integration and Program Support - Test Bed Integration - Develop and implement integrated test bed systems based on systems engineering design activities.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	HS3

FY 2003 Planned Program (Cont):

- 5000 Requirements Analysis, System Integration and Program Support - Independent Verification & Validation - Provide independent assessment of system level and subsystem level performance against identified functional requirements, including independent system, integration, and acceptance tests.
- 2000 Requirements Analysis, System Integration and Program Support - Long Range Planning - Analyze lessons learned from test bed activities and engineer future test bed systems by revising standards and updating system architectures for a biological defense homeland security support program.
- 10000 Microbial Forensic Genomics - Conduct developmental research on forensic genomics and threat agent identification. Conduct research to identify the necessary tools and biomarkers for accurate agent identification of new and emerging biological threats.
- 10000 Forensic Biological Analysis - Support the continued development and refinement of a certified forensic biological threat agent analytical capability. Devise technical approaches to support large fluctuations in sample throughput.

Total 162000

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

PROJECT: **HS3**

B. Other Program Funding Summary:

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	To Compl	Total Cost
HS4 HOMELAND SECURITY (DEMVAL)	0	0	55000	0	0	0	0	0	55000
HS6 HOMELAND SECURITY (MANAGEMENT SUPPORT)	0	0	6000	0	0	0	0	0	6000
HS9000 HOMELAND SECURITY PRODUCTION	0	0	30000	0	0	0	0	0	30000

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

PROJECT: **TB3**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
TB3	MEDICAL BIOLOGICAL DEFENSE (ADV TECH DEV)	22394	29919	34200	50789	45560	40585	40675	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TB3 MEDICAL BIOLOGICAL DEFENSE (ADV TECH DEV): 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 the Defense Advanced Research Projects Agency (DARPA).

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TB3

FY 2001 Accomplishments:

- 1000 Common Diagnostic Systems (DTO) - Conducted laboratory-based and field-based evaluations of portable nucleic acid analysis systems that enhance the diagnostic capabilities of field medical laboratories. Evaluated competing technical options for their operational compatibility with the field medical laboratory and a highly regulated medical center clinical laboratory.
- 1400 Medical Countermeasures for Brucella (DTO) - Determined the minimum immunogenic oral dose of the most promising live, attenuated vaccine candidate in higher animal species. Established fermentation conditions for growth of live, attenuated vaccine strain and prepared research master seed and research production seed stocks using processes defined to a level consistent with the intent of current Good Manufacturing Practices (cGMP).
- 600 Medical Countermeasures for Encephalitis Viruses (DTO) - Tested vaccine candidates for Venezuelan equine encephalitis (VEE) virus type 1E and VEE virus type 3A for efficacy in rodent animal models. Tested the VEE virus type 1E candidates for safety and efficacy in the higher animal species model and defined surrogate markers of protection for validation as acceptable markers of vaccine efficacy.
- 1500 Multiagent Vaccines for Biological Threat Agents (DTO) - Initiated testing of safety and efficacy in animals of products (individually and combined) intended for use in multiagent vaccines.
- 914 Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO) - Identified needle-less vaccine system components. Established protocols for studies in animals. Standardized animal models. Identified appropriate animal models for screening formulations.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TB3

FY 2001 Accomplishments (Cont):

- 650 Recombinant Plague Vaccine Candidate (DTO) - Completed a technical data package to support transition of the plague vaccine candidate out of technology base. Completed a study in a higher animal species demonstrating capability of the vaccine to provide 30% protection from virulent aerosol challenge.
- 750 Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate (DTO) - Performed comparative biochemical and biophysical characterization of rPA vaccine candidate and licensed anthrax vaccine adsorbed AVA). Performed comparative efficacy studies in animal models with rPA with licensed AVA. Conducted rPA- and AVA-immune passive transfer studies with homologous sera in mice and rabbits and completed a technical data package supporting phase 1 clinical trials and transition out of technology base.
- 1612 Diagnostic Technologies - Compared alternative medical diagnostic technologies and specimen-processing methods compatible with a comprehensive integrated medical diagnostic system for the rapid recognition of infections by validated biological threats (bacteria, viruses, and toxins) in laboratory-based and field-based studies.
- 802 Therapeutics, Bacterial - Tested selected immunomodulators in appropriate animal models for protection against plague and glanders.
- 555 Therapeutics, Toxin - Initiated stability testing of the recombinant ricin A-chain being used for enzymatic activity studies.
- 1233 Therapeutics, Viral - Determined dose and schedule for lead antiviral drug candidate for intravenous treatment of smallpox. Developed formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox and filoviruses.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ **BA3 - Advanced Technology Development**	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**TB3**

FY 2001 Accomplishments (Cont):

- 394 Vaccines, Bacterial - Explored laboratory formulations of candidate glanders and plague vaccines using various adjuvants to enhance immunogenicity.
- 250 Vaccines, Bacterial - Explored laboratory formulations of candidate next generation anthrax vaccine using various adjuvants to enhance immunogenicity.
- 4129 Vaccines, Toxin - Completed the process development (60 L scale-up) for vaccine botulinum toxin serotypes C1 and E in the Pichia yeast system and completed efficacy studies in animal models. Initiated formulation studies on a combinatorial recombinant pentavalent botulinum toxin vaccine. Developed reagents and assays to determine the quality and quantity of botulinum toxin, staphylococcal enterotoxin B (SEB), and ricin vaccines during process development. Prepared technical data package to support Investigational New Drug (IND) submission to the FDA for SEB vaccine candidate.
- 1416 Vaccines, Viral - Tested prime-boost vaccine candidates for Ebola virus in higher animal species models.
- 2000 Defense Advanced Research Projects Agency (DARPA) Program Transition - Evaluated promising medical biological defense technologies transitioning from the DARPA. These included novel molecular methods for selecting vaccine antigens, novel antibacterial agents, and plant-based expression of antibodies.
- 1500 Bioadhesion Research - Continued research evaluating the mechanisms that block the adhesion of pathogens, whether microbes or toxins, to host cells thereby preventing initiation of the disease/intoxication process. The research was aimed toward the development of medical countermeasures for two biological warfare (BW) threats (B. anthracis and Brucellae species) and an infectious disease (ID) agent (Norwalk virus).

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TB3

FY 2001 Accomplishments (Cont):

- 1689 Medical Chemical/Biological Counterterrorism Support - Continued research on the development of technologies to identify chemical and biological warfare agents (CBWA), laboratory procedures specific for the medical diagnosis or identification of CBWA exposure, information relevant to the collection of biological samples (blood, urine, or skin biopsy), and basic training in assay use and transition. Developed assays for use by the newly constituted National Guard Mobile Analytical Laboratory System (NGMALS).

Total 22394

FY 2002 Planned Program:

- 1000 Common Diagnostic Systems (DTO) - Complete an analysis of alternatives of portable nucleic analysis systems for detecting and identifying nucleic acids from a broad range of biological threat agents in clinical specimens. Prepare technical data package to support submission of a medical device application to the FDA prior to transitioning the candidate out of technology base.
- 1600 Medical Countermeasures for Brucella (DTO) - Prepare pilot lot of lead live, attenuated vaccine candidates using processes consistent with the intent of cGMP and use the pilot vaccine lot to perform pre-investigational new drug (IND) animal studies. Determine relative efficacy of lead candidates against B. melitensis in higher animal species challenge model.
- 800 Medical Countermeasures for Encephalitis Viruses (DTO) - Test vaccine candidates for VEE virus type 3A for efficacy in the higher animal species model and define surrogate markers of protection for validation as acceptable markers of vaccine efficacy. Redirect eastern equine encephalitis (EEE) and western equine encephalitis (WEE) virus vaccine development back to discovery and focus DTO on a multivalent VEE vaccine candidate.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**TB3**

FY 2002 Planned Program (Cont):

- 1700 Multiagent Vaccines for Biological Threat Agents (DTO) - Complete testing for safety and efficacy in animal models of candidate products (individually and combined) intended for use in a multiagent vaccine.
- 1205 Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO) - Define the quantitative relationships between toxin-specific antibodies or other indicators of immunity in mucosal surfaces and blood. Continue standardization of animal models.
- 940 Recombinant Plague Vaccine Candidate (DTO) - Perform studies to resolve which is the most appropriate higher animal species model for demonstrating capability of the recombinant plague vaccine candidate to provide protection from virulent aerosol and parental challenges. Continue expanded animal studies for immunogenicity and efficacy; continue to optimize formulation. Complete studies to establish a correlate of immunity.
- 1500 Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate (DTO) - Complete the biochemical and biophysical characterization of the rPA vaccine candidate. Evaluate efficacy of rPA in higher animal species and perform passive transfer studies with human AVA-immunized sera in mice, rabbits, and higher animal species.
- 1528 Diagnostic Technologies - Compare new diagnostic reagents, devices, and protocols in preclinical studies before transition to the regulatory compliant medical laboratory. Evaluate candidate diagnostic technologies in field-based studies and in a highly regulated medical center clinical laboratory prior to transitioning out of technology base.
- 718 Therapeutics, Bacterial - Evaluate, in animal models, selected immunomodulators in combination with efficacious antibiotics for protection against bacterial threat agents.
- 2573 Therapeutics, Toxin - Optimize formulation and pharmacodynamics of lead candidate licensed drugs that also inhibit staphylococcal enterotoxin B (SEB) induced intoxication.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TB3

FY 2002 Planned Program (Cont):

- 1436 Therapeutics, Viral - Continue evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox and filoviruses.
- 249 Vaccines, Bacterial - Continue to identify and validate correlates of protective immunity against anthrax, plague, glanders, and Brucella, in support of selected vaccine candidates.
- 653 Vaccines, Toxin - Complete formulation studies on a combinatorial recombinant pentavalent botulinum toxin vaccine. Perform formulation studies on a combinatorial SEB vaccine. Develop mutant recombinant ricin toxin A-chain (rRTA) antigens for potential use as vaccine candidates and initiate efficacy studies. Complete the development of reagents and assays to support process development of recombinant botulinum, ricin, and SEB vaccines. Initiate process development (60 L scale-up) for botulinum toxin serotypes D and G in the Pichia yeast system and complete efficacy studies. Execute process development for SE serotype A and complete efficacy studies. Define in vivo model systems for assessment of vaccine efficacy and surrogate endpoints of human efficacy for botulinum toxin and SEB intoxication. Plan transition of SEA and SEB vaccine candidates out of technology base.
- 1011 Vaccines, Viral - Determine optimal dose and schedule for vaccination against Marburg virus.
- 4000 Defense Advanced Research Projects Agency (DARPA) Program Transition - Expand DARPA transition efforts to include the development of novel molecular methods for selecting vaccine antigens, additional novel antibacterial agents, plant-based expression of antibodies, novel toxin antagonists, and novel diagnostic methods.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)	DATE February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TB3

FY 2002 Planned Program (Cont):

- 2000 Bioadhesion Program - Continue efforts to evaluate mechanisms that block the adhesion of pathogens, whether microbes or toxins, to host cells thereby preventing infection or intoxication. Define protective epitopes and novel delivery systems for use in vaccine formulations with a specific focus on early events in pathogenesis, especially bioadhesion. Use phage display peptide libraries to identify peptides mimetics for use in vaccine formulation. Construct vaccine candidates consisting of covalent conjugates and nanoparticles displaying those peptide mimetrics. Characterize immune responses in humans who have experienced inhalation and cutaneous anthrax exposure to identify the most immunogenic epitopes. Use microarray technology to characterize the genetic response profiles of vaccinated and /or challenged animals leading to effective immunity.
- 1250 Medical Countermeasures - Enhance advanced technology development of broad-spectrum therapeutic countermeasures for exposure to various classes of biological threats.
- 500 Advanced Diagnostics - Enhance advanced technology development efforts toward the development of advanced medical diagnostic capabilities for early presymptomatic detection of biological warfare agent (BWA) infection.
- 1250 Vaccines - Enhance advanced technology development and delivery of next-generation and generation-after-next vaccines and strategies, which will enhance the immune response to broad classes of biological threats.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**TB3**

FY 2002 Planned Program (Cont):

- 3500 Medical Chemical/Biological Counterterrorism Preparedness Support - Continue research on the development of technologies to identify chemical and biological warfare agents (CBWA), laboratory procedures for medical diagnosis of CBWA exposure, sample (blood, urine, or skin biopsy) collection information, bioassay use, and transition training. The research effort involves examining the infected host's transcriptional response to infection, recognizing specific genes that are expressed or repressed during the early stages of infection, providing "signature" markers that can be used to rapidly diagnose infectious diseases and bioterrorism agents, and developing DNA chips and assays for associated disease markers that focus on genes and their products, which provide the best discrimination of host responses to infectious bioterrorism agents.
- 506 SBIR - Small Business Innovative Research.

Total 29919

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**TB3**

FY 2003 Planned Program:

- 1700 Medical Countermeasures for Brucella (DTO) - Demonstrate effectiveness of candidate vaccine in higher animal species challenge model for protective efficacy against all three pathogenic species of Brucella. Determine relative efficacy of live vaccine candidates and subunit vaccines in higher animal species challenge model using Brucella melitensis (B. melitensis). Prepare a technical data package supporting an IND and transition the final vaccine candidate out of technology base.
- 800 Medical Countermeasures for Encephalitis Viruses (DTO) - 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. Prepare a technical data package that addresses FDA requirements for an Investigational New Drug application and that supports transitioning a multivalent VEE vaccine out of technology base.
- 1102 Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO) - Perform efficacy studies using downselected formulation/device in animal model. Propose in vitro correlate of immunity for surrogate endpoint of clinical efficacy.
- 1000 Recombinant Plague Vaccine Candidate (DTO) - Continue expanded studies in higher animal species for immunogenicity and efficacy, including the evaluation of long-term immunity, correlates of immunity, and range of protection against other virulent strains of Y. pestis. Complete a revised technical data package based on completed studies, to facilitate transition out of technology base.
- 4538 Diagnostic Technologies - Compare alternative diagnostic technologies for the rapid identification of biological threat agents 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 detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TB3

FY 2003 Planned Program (Cont):

- 1098 Therapeutics, Bacterial - Conduct advanced comparative assessment of immunomodulators and other types of broad-spectrum compounds for safety and efficacy against multiple biological threat agents.
- 4692 Therapeutics, Toxin - Prepare sufficient amounts of lead inhibitors of botulinum and SEB intoxication for testing in vivo.
- 2301 Therapeutics, Viral - 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 and filoviruses.
- 2111 Vaccines, Bacterial - Initiate a comparison of the safe and most efficacious vaccine candidates against selected 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.
- 669 Vaccines, Toxin - Complete process development (60 L scale-up) for botulinum toxin serotypes D and G in the Pichia yeast system. Complete efficacy studies on recombinant ricin toxin A-chain (rRTA) vaccine candidates and downselect best rRTA vaccine candidate.
- 2189 Vaccines, Viral - Determine and test the optimal vaccine strategy to protect against Ebola virus. Complete the development of vaccine candidates for WEE virus.

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DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**TB3**

FY 2003 Planned Program (Cont):

- 12000 Defense Advanced Research Projects Agency (DARPA) Program Transition - Continue expansion and definition of medical biological defense technologies transitioned from the DARPA. Characterize and perform process development on candidate vaccines and therapeutics deemed sufficiently mature for transitioning out of technology base.

Total 34200

B. Other Program Funding Summary:

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	To Compl	Total Cost
MB4 MEDICAL BIOLOGICAL DEFENSE (DEMVAL)	28465	34343	42617	46775	10271	14874	12361	Cont	Cont
MB5 MEDICAL BIOLOGICAL DEFENSE (EMD)	15772	48500	44718	20284	35904	36056	39815	Cont	Cont

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY: **RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development**

PE NUMBER AND TITLE: **0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**

PROJECT: **TC3**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
TC3	MEDICAL CHEMICAL DEFENSE (ADV TECH DEV)	9968	11302	12156	13423	13773	12907	13011	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TC3 MEDICAL CHEMICAL DEFENSE (ADV TECH DEV): 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).

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**TC3**

FY 2001 Accomplishments:

- 1300 Active Topical Skin Protectant (aTSP) (DTO) - Demonstrated the efficacy of protection against nerve and mustard agents of aTSP candidate formulations in two animal species. Evaluated effectiveness of combinations of selected reactive moieties.
- 700 Chemical Agent Prophylaxis II (DTO) - Examined scavengers derived from human proteins for immune response. Selected best nerve agent bioscavenger candidate(s) based on comparison of performance in decision tree network and other differentiating studies.
- 1000 Medical Countermeasures for Vesicant Agents II (DTO) - Evaluated efficacy of lead vesicant (mustard) countermeasure compounds using a decision tree network. Began vesicant therapy candidate safety and efficacy studies in two animal models.
- 55 Diagnostics - Evaluated modified advanced development equipment or technologies for far-forward screening and confirmation of exposure to mustard and nerve agents. Conducted surveys of existing commercial technologies and tested suitability of these items.
- 1759 Pretreatments - Tested promising new catalytic scavengers for efficacy and safety in two animal models. Determined 3D x-ray crystallographic structure of human carboxylesterase and paraoxonase-1.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: **February 2002**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	**0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)**	**TC3**

FY 2001 Accomplishments (Cont):

- 4154 Therapeutics - Evaluated the efficacy of lead vesicant countermeasure compounds identified in earlier screening efforts using a drug decision approach (decision tree network). Began vesicant candidate safety and efficacy studies in two animal models. Evaluated the optimal treatment strategy for mustard-induced ocular injury using steroid/antibiotic combinations. Evaluated commercially available off-the-shelf wound healing products to treat mustard-induced injuries. Determined lead anticholinergic drugs for use with midazolam as therapy for nerve agent exposure.
- 1000 Fourth Generation Agents (FGAs) - Conducted studies to determine best available countermeasures to FGAs based upon protection against lethality, pathology, physiological dysfunction, and behavioral incapacitation.

Total 9968

FY 2002 Planned Program:

- 1300 Active Topical Skin Protectant (aTSP) (DTO) - Complete aTSP formulation studies and demonstrate efficacy against estimated exposure levels of chemical warfare agents. Select candidate(s) for transition out of technology base.
- 1000 Chemical Agent Prophylaxis II (DTO) - Establish higher animal species models to evaluate lead scavengers for safety and efficacy. Convene Milestone In-Process Review (IPR) to approve transition of candidate scavengers to advanced development. Transition a chemical warfare agent prophylactic that will protect the warfighter for a period greater than eight hours against exposure to five times the Median Lethal Dosage (LD50) of nerve agent.

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TC3

FY 2002 Planned Program (Cont):

- 2000 Medical Countermeasures for Vesicant Agents II (DTO) - Identify combination therapy approaches that provide highest level of protection in animal models for safety and efficacy advanced screening. Conduct pharmacokinetic and formulation studies of vesicant countermeasure candidates. Initiate collection of preclinical data that will allow a preliminary safety assessment of toxicokinetics (TK) and Absorption, Distribution, Metabolism, and Excretion (ADME) of proposed treatments. Begin to design studies that conform to regulatory requirements.
- 361 Diagnostics - Investigate the toxicokinetics (TK) and absorption, distribution, metabolism, and excretion (ADME) of enzymatic metabolites following cyanide intoxication.
- 1677 Pretreatments - Complete development/validation of a process capable of producing sufficient amounts of enzyme scavenger material for clinical trials. Determine safety and efficacy of scavenger candidates in two animal species. Complete program studies and prepare a technical data package to address Food and Drug Administration (FDA) requirements for an Investigational New Drug (IND) application that supports transition out of technology base. Continue development of the transgenic animal model. Initiate investigation of the structure/activity relationships of treatment compounds used to prevent cyanide intoxication. Conduct pharmacology and toxicology studies on candidate compounds. Continue physiology based pharmacokinetics studies of the catalytic scavengers identified (carboxylesterase and paraoxonase-1).
- 3273 Therapeutics - Determine optimal combination of midazolam and anticholinergic drug and order of administration to obtain maximal anticonvulsant effect against seizures in a higher animal species model. Conduct studies designed to address FDA requirements to license ocular rinse that optimally treats mustard-induced injuries. Select combination therapy approaches that provide highest level of ocular protection and conduct safety and efficacy advanced screening in animal models. Study efficacy and safety of vesicant countermeasure candidates.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TC3

FY 2002 Planned Program (Cont):

- 1500 Fourth Generation Agents (FGAs) - Begin downselection process of best available countermeasure(s) against FGAs. Initiate formulation and bulk production feasibility efforts for countermeasures.
- 191 SBIR - Small Business Innovative Research.

Total 11302

FY 2003 Planned Program:

- 4000 Medical Countermeasures for Vesicant Agents II (DTO) - Complete preclinical safety and efficacy studies of selected vesicant therapy candidate compounds. Complete pharmacokinetic studies of vesicant countermeasure candidates. Perform additional studies necessary to completely characterize candidate therapy.
- 758 Diagnostics - Evaluate hand-held cholinesterase (ChE) monitor for hospital use. Validate immobilized cholinesterases and nerve agent hydrolyzing enzymes as diagnostics for nerve agent exposure.
- 2473 Pretreatments - Complete physiologically based pharmacokinetic model studies of expected human efficacy with various catalytic scavengers. Verify adequacy of transgenic animal model to produce recombinant catalytic enzyme scavenger.
- 2925 Therapeutics - Select optimal anticholinergic drug for inclusion with midazolam and establish optimal suggested treatment protocol in higher animal species. Complete preclinical studies of selected vesicant therapy candidate compounds. Evaluate commercially licensed wound healing medical therapeutics for mustard-induced injuries. Evaluate therapeutic agents for pulmonary edema produced by whole-body exposure to CWAs.

CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2A Exhibit)

DATE: February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development	0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ADVANCED DEVELOPMENT)	TC3

FY 2003 Planned Program (Cont):

- 2000 Fourth Generation Agents (FGAs) - Perform advanced assessment of medical countermeasures in guinea pigs by evaluation of physiological and histopathological parameters. Evaluate bioscavenger pretreatment as medical countermeasure against FGAs in guinea pigs. Conduct advanced assessment (pharmacokinetic and bioavailability) studies of lead medical countermeasures to FGAs in higher animal species for human efficacy estimation. Develop surrogate markers in guinea pigs for alternative medical countermeasures for FGA exposure. Develop downselection criteria for choice of the best of the candidates for improved medical countermeasures to FGA exposure.

Total 12156

B. Other Program Funding Summary:

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	To Compl	Total Cost
MC4 MEDICAL CHEMICAL DEFENSE (DEMVAL)	2078	1876	1764	1754	1705	2064	2107	Cont	Cont
MC5 MEDICAL CHEMICAL DEFENSE (EMD)	1050	1463	1973	1486	1448	1727	1763	Cont	Cont