# **CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)**

DATE

February 2006

BUDGET ACTIVITY

RDT&E DEFENSE-WIDE/

**BA3 - Advanced Technology Development (ATD)** 

PE NUMBER AND TITLE
0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

	COST (In Thousands)	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
	Total Program Element (PE) Cost	175182	234039	207114	259667	320350	342905	237652	Continuing	Continuing
СВ3	CHEMICAL BIOLOGICAL DEFENSE (ATD)	87033	110219	78236	72496	75429	67855	56786	Continuing	Continuing
СМ3	HOMELAND DEFENSE (ATD)	3256	0	0	0	0	0	0	0	3256
СР3	COUNTERPROLIFERATION SUPPORT (ATD)	4869	0	0	0	0	0	0	0	4869
TB3	MEDICAL BIOLOGICAL DEFENSE (ATD)	67899	88830	96736	143039	200722	229218	131723	Continuing	Continuing
TC3	MEDICAL CHEMICAL DEFENSE (ATD)	12125	23863	18893	31812	31656	32621	33785	Continuing	Continuing
TR3	MEDICAL RADIOLOGICAL DEFENSE (ATD)	0	0	2162	4441	4203	4523	6731	Continuing	Continuing
TT3	TECHBASE TECHNOLOGY TRANSITION	0	11127	11087	7879	8340	8688	8627	Continuing	Continuing

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A. Mission Description and Budget Item Justification: This program element (PE) 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 physical sciences 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 physical sciences 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 CB 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.

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**BA3 - Advanced Technology Development (ATD)** 

B. <u>Program Change Summary:</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Previous President's Budget (FY 2006 PB)	181972	164481	149428
Current Biennial Budget Estimate (FY 2007)	175182	234039	207114
Total Adjustments	-6790	69558	57686
a. Congressional General Reductions	-141	-3392	0
b. Congressional Increases	0	72975	0
c. Reprogrammings	-5158	0	0
d. SBIR/STTR Transfer	-1491	0	0
e. Other Adjustments	0	-25	57686

## **Change Summary Explanation:**

**Funding:** 

FY06 - Congressional increases to enhance projects within the science and technology base (+\$47,925K CB3; +\$25,050K TB3). Congressional general reductions and other adjustments (-\$1,332K CB3; -\$1,344K TB3; -\$500K TC3; -\$241K TT3). Reprioritization of programs within BA3 projects to support higher priority efforts (+\$2,839K CB3; +\$2,000K TB3; -\$4,839K TT3).

FY07 - Increase to enhance Medical Biological research efforts in support of the Transformational Medical Technology Initiative which focuses on broad-spectrum defenses against intracellular bacterial pathogens and hemorrhagic fevers (+\$59,400K TB3). Defense-wide directed offsets (-\$2,367K CB3; -\$1,143K TB3; -\$592K TC3; -\$68K TR3; -\$430K TT3). Inflation adjustment (+\$1,053K CB3; +\$1,348K TB3; +\$263K TC3; +\$30K TR3; +\$192K TT3).

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**BA3 - Advanced Technology Development (ATD)** 

**Schedule:** N/A

**Technical:** N/A

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PE NUMBER AND TITLE

PROJECT

0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

CB3

**BA3 - Advanced Technology Development (ATD)** 

	COST (In Thousands)	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	Cost to	Total Cost
		Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
(	CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD)	87033	110219	78236	72496	75429	67855	56786	Continuing	Continuing

## A. Mission Description and Budget Item Justification:

**Project CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD):** This project demonstrates technology advancements for joint service application in the areas of chemical and biological agent detection and identification, decontamination, modeling and simulation, and individual/collective protection which will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. This project funds science and technology to advance technology development.

## B. Accomplishments/Planned Program

	FY 2005	<u>FY 2006</u>	FY 2007
Congressional Interest Items	51471	47465	0

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**CB3** 

**BA3 - Advanced Technology Development (ATD)** 

## **FY 2005 Accomplishments:**

- 2579 Detecting Contaminants in Drinking Water Analyzed, tested and developed prototype CBRN and TIC/TIM sample
  concentration and detection technologies for use in-line with existing water purification units, and conducted research to
  determine water purification units performance in the removal of high threat CBRN agents and Toxic Industrial Chemicals
  (TICs).
- 992 Dual Use Detection Technology for Sick Building Syndrome Developed sensors for internal monitoring of buildings for the detection of hazardous materials in the event of terrorism and sick building syndrome.
- 3372 Handheld Biosensor and Continuous Monitor for Biodetection Developed optically based sensors for use as handheld systems for the detection of biological materials.
- 992 National Testbed for Rescue Robotics Developed test facilities for evaluating and assessing the performance of small robotics devices in surveillance and hazardous environments.
- 2579 Water Quality Sensors Developed a prototype hand-held, self-powered instrumentation system to analyze effluent water samples for presence of biological and chemical warfare agents or contaminants.
- 992 Adaptation Gaseous and Liquid Technology Decontamination Evaluated the suitability and use of proven gaseous and liquid decontamination technologies in human decontamination.
- Advanced Engineered Enzyme Decontamination System Developed enzyme decontamination systems for a broad range of chemical biological warfare agents. Screened and evaluated existing enzymes and bio-engineering enzyme to provide improved decontaminants.

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**BA3 - Advanced Technology Development (ATD)** 

### **FY 2005 Accomplishments (Cont):**

- 8430 Countermeasures to Chemical and Biological Defense/Rapid Response Developed new models and sensor systems for both medical and environmental application against chemical and biological hazardous materials.
- 2975 E-Smart Threat Agent Network Demonstrated a network of biological trigger systems to determine the value of data fusion to reduce false alarms and to increase the value of the information that each sensor can provide.
- 1984 Handheld Biological Agent Detection (HBAD) Developed optically based sensors for use as handheld systems to detect biological materials.
- 992 Hi-Int Pulsed Radiation for Chemical and Biological Agent Defeat Installed linear accelerator used to determine effective kill doses of radiation required to kill biological agent simulants or destroy chemical agent simulants.
- 2281 Immunochemical Biological/Chemical Threat Agent Detector Developed a multiplex, micro-array system based on both antibodies and nucleic acid type assays.
- 1686 Industry-Based Research to Miniaturize Chemical and Biological Detectors (Continuation only) Developed new production methods for solid state components used in the sensor systems.
- 4166 Laser Interrogation of Surface Agents (LISA) Inspector Developed a handheld Raman spectroscopy base system for the detection of contaminants on surfaces, primary focus is for detecting contamination on equipment or internal compartments.
- 1190 Polymer-Based Bio Mems Developed sensor elements based on polymer films to act as molecular recognition moieties and serve as a potential replacement for antibodies.

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**BA3 - Advanced Technology Development (ATD)** 

### **FY 2005 Accomplishments (Cont):**

- 992 Protection Against Toxic Industrial Chemical Continued development and validation of TIC list. Evaluated the protection provided by current protective materials against identified TIC threats.
- 1736 Rapid Response Bio-Chem Decontamination, Liquid and Dry (Decon Green) Optimized proven liquid and dry process decontamination technologies, packaging and delivery systems for rapid deployment in biological and chemical incidents.
- 992 Rapid Response Database Systems Center Developed a Research Demonstration Center and a Portable Training and Demonstration Center that will present first responders and their managers with real-time status reports of data collected from hospitals, schools, doctors, pharmacies and veterinary offices that could support a response to a bio-terrorist attack or other hazard.
- 992 Rapid Response Sensor Networking for Multiple Applications Refined the sensor and network design leading to a
  demonstration of the integrated network for detection and early warning.
- S554 Reactive Air Purification for Individual and Collective Protection (RAPICP) Completed the advanced media selection and the design of pre-industrialized test articles (full canisters) to be tested for performance and consistency. Initiated a controlled production run of two hundred (200) units in order to perform FY06 field evaluation and obtain feedback from military personnel. Continued the development of the 2'x2' advanced Triosyn COLPRO anti-microbial pre-filter as well as develop a new advanced, LPD integrated, stand alone HEPA-like/antimicrobial filter for COLPRO applications. Developed an advanced Triosynated membrane and improved pre-filter/filter design.

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### **FY 2005 Accomplishments (Cont):**

- 2777 Removal of NBC Agents in Drinking Water Analyze, test and developed prototype CBRN and Toxic Industrial Chemicals (TICs) removal technologies for use in-line with existing water purification units, and conduct research to determine water purification units performance in the removal of high threat CBRN agents and TICs.
- 447 Chemical Biological Defense Program Initiative Fund.
- Supported integration efforts to combat Weapons of Mass Destruction including capabilities-based assessments and synchronization of DoD efforts with other agencies.

#### **Total** 51471

### **FY 2006 Planned Program:**

- 991 Cooperative Unmanned Ground and Aerial Vehicle Incubator.
- 991 LISA-JCSD Solid-State Laser Technology.
- 991 Novel Sample Concentration Technologies for Contaminant Detection in Drinking Water.
- 991 Portable Rapid Bacterial Warfare Detection Unit.
- 991 Rapid Response Database Systems Continue development of a Research Demonstration Center and a Portable Training and
  Demonstration Center that will present first responders and their managers with real-time status reports of data collected
  from hospitals, schools, doctors, pharmacies and veterinary offices that could support a response to a bio-terrorist attack or
  other hazard.
- 1189 Chemical Biological Defense Program Initiative Fund Hackensack University Medical Center.

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**BA3 - Advanced Technology Development (ATD)** 

## FY 2006 Planned Program (Cont):

- 1486 Small Accelerators and Detection Systems.
- 1783 Personnel Decontamination Using Liquid Technology.
- 1981 Advanced Engineering Enzyme Decontamination Systems Develop enzyme decontamination systems for a broad range of chemical biological warfare agents. Screened and evaluated existing enzymes and bio-engineering enzyme to provide improved decontaminants.
- 1981 Notre Dame Center for Environmental Networked Embedded Sensor Technology (ND-CENEST).
- 2080 Self-Detoxifying Materials in CB Clothing.
- 2105 Industry-Based Research to Miniaturization Chemical and Biological Detectors Continue development of new production methods for solid state components used in the sensor systems.
- 2377 Immunological Biological/Chemical Agent Detector Develop a multiplex, micro-array system based on both antibodies and nucleic acid type.
- 2773 Removal of NBC Agents in Drinking Water Continue to analyze, test and develop prototype CBRN and Toxic Industrial Chemicals (TICs) removal technologies for use in-line with existing water purification units, and conduct research to determine water purification units performance in the removal of high threat CBRN agents and TICs.
- 2971 Hand-Held Biological Agent Detection (HBAD) System Develop an optically based sensors for the use as handheld systems
  for the detection of biological materials.

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**BA3 - Advanced Technology Development (ATD)** 

## FY 2006 Planned Program (Cont):

- 3367 Hand-Held Biosensor and Continuous Monitor for Biodetection Develop optically based sensors for the use as handheld systems for the detection of biological materials.
- 5545 Reactive Air Purification for Individual and Collective Protection.
- 5941 NIDS Hand-Held Biological Detectors.
- 6931 Chemical Biological Defense Program Initiative Fund.

**Total** 47465

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
Technology Readiness Assessment	4204	0	0

## **FY 2005 Accomplishments:**

• 4204 Technology Readiness Assessment - Initiated Technology Readiness Evaluation (TRE) of Collective Protection Equipment.

In FY06, efforts will be included in Project TT3 - Techbase Technology Transition.

**Total** 4204

	FY 2005	<u>FY 2006</u>	FY 2007
Technology Transition	0	4835	5052

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### **FY 2006 Planned Program:**

- 1680 Technology Transition Initiate competitive assessment of all mature technologies from areas outside of the Chemical Biological Defense Program for rapid technology insertion into the capability areas from MIT Lincoln Laboratory survey of the nano-technology industry.
- 3155 Transition of DARPA Semiconductor UV Optical Sources (SUVOS) technology to produce a low-cost biological aerosol detection system in collaboration between DHS and the CBDP. The technology target is to produce systems in the \$1000 range to allow wide spread deployment of the systems to provide an early warning capability. The technology is expected to transition to the Joint Biological Tactical Detection System and the DHS Low-Cost Biological Aerosol Detection System with an Advanced Technology Demonstration in early FY08.

**Total** 4835

## **FY 2007 Planned Program:**

• 5052 Technology Transition - Continue competitive assessment of all mature technologies from areas outside of the Chemical Biological Defense Program for rapid technology insertion into the capability areas of detection, decontamination, detection, and protection that support Joint Service Programs of Record.

**Total** 5052

	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Decontamination	1854	1970	4781

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### **FY 2005 Accomplishments:**

• Decontamination, Oxidative Formulation (DTO CB44) - Completed safety, health and environmental studies. Completed live agent chamber testing and determine which candidates meet efficacy requirements. Demonstrated limited operational utility of down-selected decontaminants and associated applicators using simulant field trials in relevant environments, and determined which candidates meet efficacy and operational requirements. Completed DTO and supported Joint Service Transportable Decontamination Systems (JSTDS), and Joint Portable Decontamination System (JPDS) requirements.

#### **Total** 1854

### **FY 2006 Planned Program:**

- 1245 Decontamination, Solutions Chemistry Develop and select peracetate solvent peroxide-based decontaminants with proper transport, storage, and efficacy and recommend transition to developmental program to support JPDS and Joint Service Transportable Decontamination System (JSTDS) (small and large scale); and initiate new research on transportation, storage, and use of hydrogen peroxide for decontamination to support JPDS and Joint Platform Interior Decontamination (JPID).
- 725 Decontamination, Solid Phase: Complete laboratory scale (large panel) testing of solid sorbent based on nanocrystalline metal oxides to support Joint Service Transportable Decontamination System (JSTDS) (small and large scale).

**Total** 1970

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### **FY 2007 Planned Program:**

- 2188 Decontamination, Solutions Chemistry Complete chamber testing on chlorine dioxide-based JPDS candidates and
  recommend transition to developmental program; and continue research on transportation, storage, and use of hydrogen
  peroxide for decontamination to support Joint Service Transportable Decontamination System (JSTDS) (small and large
  scale).
- 1405 Decontamination, Solid Phase Conduct enhanced testing to provide chamber scale studies to assess the impact of applicator process and procedures on solid sorbents based on nanocrystalline metal oxides to support Joint Service Transportable Decontamination System (JSTDS) (small and large scale).
- Decontamination, Alternative Process Continue research to develop a gaseous chemical and biological decontamination system combined hot air and modified vaporous hydrogen peroxide, determine efficacy effects on decontamination of chemical and biological agents, and determine candidate formulation and application combinations to support Joint Platform Interior Decontamination (JPID).

**Total** 4781

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
Detection	27730	20731	20466

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## **FY 2005 Accomplishments:**

- 1290 Testing and Trials Hot Lightweight Chemical Detector (LCD) BCA# 20/31/33- Initiated efforts to characterize and assess the performance of a breadboard (heated inlet version of the United Kingdom fielded LCD) against non-traditional agents and traditional agents. The breadboard assessment is the basis for the design and build of a prototype that will be assessed for transition suitability to the acquisition program Joint Chemical Agent Detector (JCAD).
- 4352 Detection Test Capabilities for Non-Traditional Agents BCA# 33 Initiated development of agent to simulant correlations in support of detection T&E needs. Conducted analytical studies on the impact of threat environments on the properties of neat agents. Developed facility for detector testing of NTAs.
- Lightweight Integrated CB Detection (DTO CB50) BCA# 3/4/21/31 Down-selected technologies to the best three approaches for pyrolysis-GC-IMS. Prepared preliminary design concepts based on these approaches.
- 4820 Chemical/Biological Agent Water Monitor (DTO CB37) BCA# 31 Completed prototype build for biological detection requirements and assessment methodology. Continued development of chemical detection portion of the program with an objective of a Milestone A in FY06.
- 1990 Point Detection, Biological Identification BCA# 21 Initiated micro-array concept for high throughput laboratory bio detection/identification. Completed prototype build for an automated antibody multiplex assay system with reader to reduce consumable cost for Joint Biological Point Detection System (JBPDS).

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### **FY 2005 Accomplishments (Cont):**

- 1990 Laser Induced Surface Analysis (LISA) Prototype BCA# 28 Assessed the performance of the first generation detection algorithm under operational environments. Developed the second generation detection algorithm based on the assessed shortfalls of the first generation algorithm. Supported transition of technology into Chemical Unmanned Ground Reconnaissance (CUGR) Advanced Concept Technology Development (ACTD).
- System Performance Modeling BCA# 7/10/21 Conducted analytical feasibility studies on the technical parameters in the detection of CB contamination on surfaces in post decontamination applications. Initiated the development of databases containing spectral infrared backgrounds suitable for standoff applications (includes imaging techniques). Conducted analytical feasibility studies on the minimum acceptable technical parameters for a stand-alone low cost/low power biological trigger system for early warning.
- 1595 Stand-off, Sensor Assessment Non-Traditional Agent (NTA) BCA# 33 Completed spectral database of NTAs. Completed enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs.
- 2000 Technology Readiness Assessment Initiated Technology Readiness Evaluation (TRE) of detection equipment.
- 457 Chemical Biological Defense Program Initiative Fund.

**Total** 27730

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## **FY 2006 Planned Program:**

- 4567 Point Detection, Biological Identification Complete and demonstrate transition into micro-array system for high throughput laboratory biological detection/identification. Demonstrate the prototype for an antibody multiplex assays system for Joint Biological Point Detection System (JBPDS) technology insertion.
- 5500 Lightweight Integrated CB Detection (DTO CB50) Assess ability of technology to meet Joint Biological Tactical Detection System (JBTDS) requirements and as a technology insertion to the Joint Biological Point Detection System (JBPDS) and Reconnaissance Systems as spiral enhancements/replacement for the biological trigger systems. The technology will also meet the need to detect/identify chemical aerosols. Initiate fabrication of brassboards. Develop a UV florescence detector that exploits Semiconductor Ultra Violet Optical Sources (SUVOS) developed by DARPA as a competing technology for JBTDS.
- Chemical/Biological Agent Water Monitor (DTO CB37) BCA# 31 Complete the development of the chemical detection portion of the requirements. Demonstrate and conduct a Milestone A at the end of FY06 on the chemical requirements. Complete, demonstrate, and conduct a Milestone B for the advanced prototype for the biological detection requirements by the end of FY06. The DTO supports the Joint Chemical Biological Radiological Agent Water Monitor (JCBRAWM).
- 1250 System Performance Modeling BCA# 1/28 Complete the database development of infrared spectral backgrounds. Conduct and finalize an analytical feasibility study to determine the minimal performance parameters needed for a standoff biological detection system for on-the-move capability for a mobile platform like Stryker vehicle program.

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### FY 2006 Planned Program (Cont):

- 3454 Detection Test Capabilities for Non-Traditional Agents BCA# 33 Continue the development of agent to simulant correlations in support of T&E needs. Initiate the studies necessary to fill the identified gaps from the analytical studies on the impact of threat environments on the properties of neat agents. Priority will be for biological materials followed by chemical materials.
- 1000 Biological Stand-off Technology BCA# 1 Initiate the development of test methodology to evaluate and assess the value of new signatures in board regions of the electromagnetic spectrum. Initiate development of a prototype system.
- 1360 Chemical Stand-off Technology BCA# 7/10 Initiate the development of test methodology to evaluate and assess the value of new signatures to reduce the false alarm rate and to increase the detection range.

**Total** 20731

## **FY 2007 Planned Program:**

- 5231 Lightweight Integrated CB Detection (DTO CB50) BCA# 3/4/21/31 Demonstrate the technology and transition for technology insertion into Joint Biological Point Detection System (JBPDS) and Reconnaissance Systems as enhancements/replacement for the biological trigger systems to detect/identify chemical aerosols. Complete fabrication, and test and evaluation of brassboards.
- Total Lightweight Imaging System for Reconnaissance BCA# 7/10/28 Initiate the development of a prototype system based on
  the enabling technology demonstration from DTO CB52. Continue the development of a prototype system that meets the
  requirements from the analytical feasibility system conducted in FY06 for an on-the-move capability for biological standoff
  on a mobile reconnaissance platform.

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### FY 2007 Planned Program (Cont):

- 3644 Detection Test Capabilities for Non-Traditional Agents BCA# 33 Continue the development of agent to simulant correlations in support of T&E needs. Continue the studies necessary to fill the identified gaps from the analytical studies on the impact of threat environments on the properties of neat agents. Priority will be for biological materials followed by chemical materials.
- 2070 Chemical Stand-off Technology BCA# 7/10 Continue the development of test methodology to evaluate and assess the value of new signatures to reduce the false alarm rate and to increase the detection range.
- 1800 Biological Stand-off Technology BCA# 1 Continue the development of test methodology to evaluate and assess the value of new signatures in broad regions of the electromagnetic spectrum.

**Total** 20466

	FY 2005	<u>FY 2006</u>	FY 2007
Modeling and Simulation Battlespace Management	1300	7032	10147

## **FY 2005 Accomplishments:**

• 750 Chemical and Biological Hazard Environment Prediction (DTO CB55) BCA# 5/6 - Transitioned advanced predictive capabilities (MESO) to Joint Effects Model (JEM) program. Enhanced the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging.

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**BA3 - Advanced Technology Development (ATD)** 

### **FY 2005 Accomplishments (Cont):**

- 450 Chemical and Biological Warfare Effects on Operations (DTO CB43) BCA# 5/6/8/9 Tested and transitioned DTO efforts to Joint Operational Effects Federation (JOEF) Block II. Performed internal Verification and Validation.
- 100 Battlespace Management BCA# 8/9 Developed a shared Common Operating Picture (COP) in support of Joint Warning and Reporting Network (JWARN).

**Total** 1300

## **FY 2006 Planned Program:**

- 1100 Chemical and Biological Warfare Effects on Operations (non-DTO) BCA# 5/6/8/9 Conduct a current capability
  demonstration of sensor siting around a selected DoD facility. Conduct a data model study and initiate the web-services
  component of the IMPACT model framework. Demonstrate automated CBRN data import/export tool for use with the Joint
  Operational Effects Federation (JOEF) prototype.
- 3231 Chemical and Biological Hazard Environment Prediction (DTO CB55) BCA# 5/6 Complete DTO CB55. Transition CBW-CFX capabilities to the Joint Effects Model (JEM) program. Restructure the RUSTIC model for installation of the SOC model. Conduct a current capability demonstration of sensor sites around a selected DoD facility. Improve ruggedization and testing and evaluation in the GEDIS 2.0 release. Perform sensitivity and uncertainty analysis for the atmospheric chemistry of the Toxic Industrial Chemicals (TICs) database.

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PROJECT

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0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

CB3

**BA3 - Advanced Technology Development (ATD)** 

### FY 2006 Planned Program (Cont):

- 1701 Battlespace Management BCA# 2/3/4/8/9 Enhance enterprise level definition, development, release and transition of fully developed RPM capability. Provide integrated demonstration and assess user feedback on the Common Operating Picture (COP) for HLS and HLD. Demonstrate in a simulated environment the Inter-LAN socket connection manager. Conduct live real-time demonstration of JWARN Compliant Interface Device (JCID) compliance on examples of fielded JWARN sensors. Produce final report, user manual and prepare to transition JCID compliant thin server technology. Field test the intelligent agent decision design for next generation CB battle management.
- 1000 CBDP Decision Capability BCA# 1-39 Design and develop a common user graphic user interface (GUI) for the CB Simulation Suite. Develop data and documents for independent verification and initiate verification activities.

**Total** 7032

## **FY 2007 Planned Program:**

• 2690 Chemical and Biological Warfare Effects on Operations (non-DTO) BCA# 5/6/8/9 - Test and verify the Simulated Training and Analysis for Fixed Facilities/Sites (STAFFS) and CONTAM model linkages. Conduct a simulation and analysis of the Chemical-Improvised Explosive Device (C-IED) model. Enhance the rapid mission impact assessment tool software and test on additional missions. Execute final implementation of the web-services interface and data model of the IMPACT framework.

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**BA3 - Advanced Technology Development (ATD)** 

### FY 2007 Planned Program (Cont):

- 2316 Chemical and Biological Hazard Environment Prediction (non-DTO) BCA# 5/6 Develop the surface heat flux model for water. Verify the model and test the code for speed enhancements. Enhance sensor siting tool to include DoD defined siting metrics. Develop a second generation siting tool and demonstrate. Include more data types, tailor application support and canopy parameterizations in the GEDIS 2.1 release. Conduct lab-scale validation of Toxic Industrial Chemicals (TICs) chemistry model. Develop methodology for undefined TICs.
- 2974 Battlespace Management BCA# 2/3/4/8/9 Demonstrate increased maturity and readiness of the Inter-LAN socket connection manager for transition to the Joint Warning and Reporting Network (JWARN) program. Incorporate warfighter feedback and transition the next generation CB battle management capability. Complete development, implement, test and transition the sensor alert verification for incident operational response capability.
- 2167 CBDP Decision Capability BCA# 1-39 Complete the independent verification of the CB Simulation Suite. Conduct demonstrations and exercises in targeted user communities. Prepare to transition capability to the Joint Operational Effects Federation (JOEF) program.

**Total** 10147

	FY 2005	<u>FY 2006</u>	<u>FY 2007</u>
Protection	474	8462	8797

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**BA3 - Advanced Technology Development (ATD)** 

### **FY 2005 Accomplishments:**

• 474 Collective Protection, Air Purification - Assessed the impact of pollutants on aerosol/particulate filters and transitioned to the Joint Expeditionary Collective Protection (JECP) Program. Completed development and demonstrated an advanced electrically-enhanced filter that will produce the same results found in breadboard prototypes.

Total 474

### **FY 2006 Planned Program:**

- 1771 Advanced Air Purification System Model (DTO CB61) Initiate assessment of advanced COTS and developmental air purification systems. Measure laboratory- scale design and platform application integration data to evaluate these configurations. Design Advanced Air Purification system configuration for one platform application.
- 1100 Improved Single-Pass Filters Optimize polishing sorbent material and measure design data for CWA/TIC. Integrate ammonia filtration material into current filters. Demonstrate polishing sorbent for CP filters (M98) and transition. Integrate Residual Life Indicator system with COLPRO filter/blower system and perform validation testing. Demonstrate candidate residual life indicators in operational filtration systems.
- 1299 Regenerative and Reactive Air Purification Demonstrate catalytic-based air purification applications by incorporation of commercial or newly developed catalysts for chemical, biological and TICs destruction. Develop a breadboard system with optimized catalyst, post treatment filter, and thermal management. CATOX and regenerative air purification will transition through DTO CB61, EFV ATD and FY08 JECP TRE.
- 900 Shelter Materials, Coatings and Materials Treatments, Reactive or Self-Decontaminating Demonstrate Expedient COLPRO Coatings proof-of-concept for tentage applications.

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### FY 2006 Planned Program (Cont):

- 1792 Shelter Systems Analyze COLPRO TRE results and identify and document critical sub-system components and
  interface/integration issues requiring S&T. Acquire sub-system demo components, address interface/integration issues,
  assemble and test sub-system. Down-select and fabricate prototypes from sub-systems. Conduct physical performance
  testing on prototypes integrated as full COLPRO systems.
- Self-Detoxifying Materials for CB Protective Clothing (DTO CB45) Manufacture prototype garments containing reactive nanoparticles. Measure chemical/aerosol breakthrough of garments. Conduct field testing. Collect user assessments. Conduct CWA simulant and live CWA testing on worn garments to assess durability. Technologies resulting from this effort are applicable to future protection ensemble.

### **Total** 8462

## **FY 2007 Planned Program:**

- Advanced Air Purification Systems Model (DTO CB61) Fabricate system demonstrators. Test and validate the Advanced Air Purification System Model, then optimize for design concepts. Complete test and validation of Advanced Air Purification System Model. Transition initial version of AAP Systems Model for FY08 TRE.
- 1150 Improved Single-Pass Filters Develop a Residual Life Indicator (RLI) prototype capable of determining the integrity, physical adsorption capacity and reaction capacity of in-service CBRN filters. Complete tracer evaluation for filter assessment of chemical reactivity capacity with chemical pulse testing and correlation development. Demonstrate subsystem hardware in current CBRN filter providing capability for determining the residual life of filter and transition to JECP FY08 TRE.

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## FY 2007 Planned Program (Cont):

- Shelter Materials, Coatings and Materials Treatments, Reactive or Self-Decontaminating Apply expedient and reactive coatings to current general-purpose tent fabric as after-treatment and test for transition to JECP FY08 TRE.
- 2138 Shelter Systems and CCA/Airlock/TFA (CCAATFA) Fabricate shelters using novel materials, enhanced closures, and novel
  ingress/egress systems and initiate assessment. Fabricate a prototype general-purpose shelter using improved textiles such as
  PVC/Tedlar/Polyester fabric and conduct a systems simulant test. Fabricate CCAATFA prototypes and test (simulant).
  Conduct shelter system tech demo/testing for transition to JECP FY08 TRE.
- 2100 Self-Detoxifying Materials for CB Protective Clothing (DTO CB45) Optimize garment designs. Manufacture optimized prototype garments containing optimized reactive nanoparticle-loaded fabrics. Measure chemical/aerosol breakthrough of optimized garments. Conduct field-testing and assessments. Down-select candidates. Technologies resulting from this effort will support future protective ensembles.

**Total** 8797

	FY 2005	<u>FY 2006</u>	FY 2007
Test and Evaluation	0	18649	28993

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## **FY 2006 Planned Program:**

- 1600 Standardized Procedure for IPE Assessment Initiate development of real-time sampling/detector system swatch (for use in Chemical and Biological Agent Resistance Test System) and system (for use in Man-in-Simulant Test System). Initiate protocol development for Protective Ensemble Test System.
- 535 IPE Field Operations Effects Standard Develop pressure suit concepts and conduct initial test and evaluation for use in assessing field operations effects on garments.
- B17 Development of Standardized Collective Protection (COLPRO) Shelter Systems Protective Test Evaluation Standards Develop conceptual biological test operating procedures. Draft initial procedures and protocol for chemical, biological, and
  aerosol testing of collective protection systems.
- 600 IPE Airflow Mapping Quantify driving forces influencing air and agent transport inside the garment/mask. Initiate model to predict airflow within the ensemble, and develop test apparatus to validate the model.
- 1806 Test Standard Development for Protection Technologies Develop Concepts For filtration and air purification system test method development. Initiate development of test apparatus for the conduct of evolving test methods.
- 1000 TIC/Battlefield Contaminant Set Standard for IPE and COLPRO Establish TIC and battlefield contaminant lists and down-selection process, and initiate swatch and filter test methods development. Initiate test methodology IP systems/MIST aerosol, COLPRO component and whole systems.
- 1600 Measurement of Natural Interferent Transients (MONITR).
- 1380 Range Test Validation System.

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## FY 2006 Planned Program (Cont):

- 315 Chemical Detector Testing with NTAs in the McNamera Glove Box Facility.
- 300 Optical Acceptance Measurements for Test & Evaluation Antigens.
- 1600 CRP Antigen Variability Research.
- 510 Overarching Contamination Avoidance Model for Test and Evaluation.
- 1132 CREATIVE Decontamination Efficacy Prediction Model.
- 750 Overarching Collective Protection (COLPRO) Model for Test and Evaluation.
- 450 Achieving Low-Level Detection of Residual Agent and Reaction Products.
- 2801 Decon Hazard Byproduct and Residual Agent Test Standards.
- 400 Simulants for Protective Equipment Testing
- 541 Engineered Aerosol Production for Laboratory-Scale Chemical and Biological Test and Evaluation.
- 512 Aerosol Cloud Production and Droplet Delivery technology Protocol.

**Total** 18649

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**BA3 - Advanced Technology Development (ATD)** 

## **FY 2007 Planned Program:**

- 2067 Joint Expeditionary Collective Protection (JECP) Modeling and Simulation Construct prototype model, leverage legacy models, commence validation, verify model via test data, prepare validation reports, and acquire accreditation.
- 4350 JECP Advanced Technologies Tests Continue construction of test fixtures and commence testing of fixtures for RLI, filtration-systems, materials, seams and enclosures fixtures.
- 6187 JECP Advanced Technologies Tests Validate RLI, filtration and materials, seams and enclosures fixtures.
- 2900 JECP Simulant Platform Tests Develop testing and evaluation methods and procedures for non-vapor threats, e.g., aerosols, rains, and other emerging threats.
- 1900 Decontamination System Battlefield Test Conditions, Evaluation and Methodology Procure instrumentation for field decontamination assessment and measurements. Commence testing to validate performance of current methods under battlefield conditions.
- 3800 Individual Protective Equipment (IPE) Bio Mask System Chamber Test Complete modifications for prototype chamber for use with biological materials, toxic industrial materials (TIMs) and non traditional agents (NTAs).
- 2000 IPE Battlefield Test Conditions, Evaluation Methodology Conduct full-range testing to quantify current performance baselines, initiate development of a field mask testing system, initiate development of field IPE-system test procedures.
- 2000 IPE Overarching Model Complete model development, commence verification, validation and accreditation as per DoD requirements.

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### **FY 2007 Planned Program (Cont):**

- 2000 IPE Expanded Simulant System Test Develop real-time Man-in-Suit Test (MIST) sampler, develop aerosol-challenge test capabilities for MIST chamber.
- 1789 Continue CRP Antigen Variability Research.

**Total** 28993

	FY 2005	<u>FY 2006</u>	FY 2007
SBIR/STTR	0	1075	0

### **FY 2006 Planned Program:**

• 1075 SBIR

**Total** 1075

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CB3

**BA3 - Advanced Technology Development (ATD)** 

C. Other Program Funding Summary:									
	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>To</u> <u>Compl</u>	<u>Total</u> <u>Cost</u>
CA4 CONTAMINATION AVOIDANCE (ACD&P)	50885	31140	1000	8031	12368	5624	0	0	109048
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	4869	0	0	0	0	0	0	0	4869
CP4 COUNTERPROLIFERATION SUPPORT (ACD&P)	15853	24239	25452	26152	15083	14344	26674	Cont	Cont
DE4 DECONTAMINATION SYSTEMS (ACD&P)	16950	998	2000	4517	2577	2278	4002	Cont	Cont

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BUDGET ACTIVITY  RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development (ATD)  PE NUMBER AND TITLE  0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)  CM3  CM3									
COST (In Thousands)	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
CM3 HOMELAND DEFENSE (ATD)	3256	0	0	0	0	0	0	0	3256

## A. Mission Description and Budget Item Justification:

Project CM3 HOMELAND DEFENSE (ATD): 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 CSTs) 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 WMD CSTs 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 CSTs knowledge of available local, state and federal resources that can assist in the mitigation of a WMD emergency.

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CM3

**BA3 - Advanced Technology Development (ATD)** 

This program funds the acquisition, validation and testing of commercial off-the-shelf (COTS)/government off-the-shelf (GOTS) components on the existing Table of Distribution and Allowances (TDA) for WMD CSTs as well as those systems or components that are responsive to validated WMD CST requirements. This program also funds the evaluation of new commercial products and capabilities that may meet requirements and may be considered for the WMD CST TDA.

## B. Accomplishments/Planned Program

	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Congressional Interest Items	992	0	0

## **FY 2005 Accomplishments:**

• 992 WMD CST - Center for BioDefense - Conducted component level testing for analytic systems and provide planning support.

**Total** 992

	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
WMD-Civil Support Teams	2264	0	0

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0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

CM3

**BA3 - Advanced Technology Development (ATD)** 

## **FY 2005 Accomplishments:**

• 2264 WMD CST - Conducted component testing of Commercial off-the-shelf (COTS) detection, protections and decontamination equipment.

**Total** 2264

C. Other Program Funding Summary:									
	FY 2005	FY 2006	<u>FY 2007</u>	<u>FY 2008</u>	FY 2009	<u>FY 2010</u>	<u>FY 2011</u>	<u>To</u> <u>Compl</u>	<u>Total</u> <u>Cost</u>
CA4 CONTAMINATION AVOIDANCE (ACD&P)	50885	31140	1000	8031	12368	5624	0	0	109048
CM5 HOMELAND DEFENSE (SDD)	8754	390	0	0	0	0	0	0	9144
CM6 HOMELAND DEFENSE (RDT&E MGT SUPPORT)	1313	1536	1533	0	0	0	0	0	4382
JA0004 WMD - CIVIL SUPPORT TEAM EQUIPMENT	18200	0	0	0	0	0	0	0	18200

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COST (In Thousands)	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	4869	0	0	0	0	0	0	0	4869

## A. Mission Description and Budget Item Justification:

**Project CP3 COUNTERPROLIFERATION SUPPORT (ATD):** The mission of the Counterproliferation Program (CP) is to address shortfalls in the DoD 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 CBDP. Efforts include planning and development of Advanced Concept Technology Demonstrations (ACTD), such as the CBRN Unmanned Reconnaissance (CUGR) in addition to Joint Warfighter Experiments (JWE). Beginning in FY06 efforts under this project have moved to project TT3.

### **B.** Accomplishments/Planned Program

	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
ACTD Planning and Development	2156	0	0

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CP3

**BA3 - Advanced Technology Development (ATD)** 

## **FY 2005 Accomplishments:**

- 1156 ACTD-PD Initiated technology planning for selection of technologies for future ACTD candidates. Initiated planning for the Military Applications in Reconnaissance and Surveillance (MARS) Manned/Unmanned Aerial Vehicle (M/UAV) experimentation program. Initiated planning for the Chemical Biological Networked Early Warning System (CBNEWS) Advanced Technology Demonstration. Initiated feasibility analyses for a proposed information technology system called Situational Awareness and Response Network (STARNET); first is the feasibility to see the signature of a biological attack amongst the medical surveillance systems data, second is the feasibility of being able to process large amounts of data from medical surveillance, intelligence, environmental sensors, and law enforcement data at a Combatant Commander level on a daily basis for a biological defense fusion cell.
- 1000 ACTD-PD Initiated the Military Applications in Reconnaissance and Surveillance (MARS) -Unmanned Ground Vehicle
  (UGV) program testing CBRN detection technologies for use on one man and two man portable UGVs for technology
  insertion into the CBRN Unmanned Ground Reconnaissance (CUGR) ACTD or the transition program for CUGR ACTDs
  UGV portion.

**Total** 2156

	FY 2005	<u>FY 2006</u>	FY 2007
EXPERIMENT AND TECH DEMO (TT3)	2713	0	0

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0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

CP3

**BA3 - Advanced Technology Development (ATD)** 

## **FY 2005 Accomplishments:**

- 1072 ACTD-PD Completed planning for CBRN Unmanned Ground Vehicle (CUGV) systems technical testing and integration for the CBRN Unmanned Ground Reconnaissance (CUGR) Advanced Concept Technology Demonstration (ACTD).
- 391 ACTD-PD Completed integration of technologies for the Biological Network (BIONET) program.
- 1250 ACTD-PD Evaluated test requirements for Non Standard Equipment Review Panel testing. Completed testing on a modified M256 kit enabling low volatility agent detection. Completed testing on Pressure Swing Adsorption technology. Completed testing on Infrared Scanning technology enabling the detection of elevated body temperatures in humans.

**Total** 2713

C. Other Program Funding Summary:								<u>To</u>	Total
	FY 2005	FY 2006	<u>FY 2007</u>	FY 2008	FY 2009	FY 2010	FY 2011	Compl	<u>Cost</u>
CP4 COUNTERPROLIFERATION SUPPORT (ACD&P)	15853	24239	25452	26152	15083	14344	26674	Cont	Cont
TT3 TECHBASE TECHNOLOGY TRANSITION	0	11127	11087	7879	8340	8688	8627	Cont	Cont

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COST (In Thousands)	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
TB3 MEDICAL BIOLOGICAL DEFENSE (ATD)	67899	88830	96736	143039	200722	229218	131723	Continuing	Continuing

## A. Mission Description and Budget Item Justification:

Project TB3 MEDICAL BIOLOGICAL DEFENSE (ATD): 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 development. Entry of candidate vaccines, therapeutics, and diagnostic technologies into development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) and licensure processes and DoD acquisition regulations. Categories for this project include Defense Technology Objectives (DTOs); science and technology program areas in medical biological defense capability areas (Pretreatments, Diagnostics, Therapeutics and Emerging Threats), directed research efforts; and efforts to transition promising medical biological defense technologies from the Defense Advanced Research Projects Agency (DARPA). Categories under this project address the Joint Requirements Office (JRO) critical capability gaps identified in the baseline capability assessment performed in FY03. The specific critical capability gaps addressed are Gap #14 (Medical Prophylaxes - Lack of multi-valent vaccines), Gap #22 (Medical Therapeutics - Limited anti-viral/ toxin development),

Gap #24 (Medical Therapeutics - Lack of FDA Approval for CBRN), Gap #35 (Diagnostics - Lack of portability), Gap #36 (Diagnostics - FDA Approval) and Gap #38 (Diagnostics - Reagent Verification).

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TB3

**BA3 - Advanced Technology Development (ATD)** 

## B. Accomplishments/Planned Program

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
Congressional Interest Items	16017	24810	0

## **FY 2005 Accomplishments:**

- 1984 Bioterrorism Preparedness Educated North Shore- LIJ First Watch Programs Emergency Services on biothreat triggers, deployed new technology to them and then tested the effectiveness of the response procedures through surveillance of phone calls, syndromic data and admissions and laboratory data collected from hospitals and community based physician offices.
- Anthrax and Oral Plague Vaccine Development Developed an oral, live bacterial vectoral plague vaccine; initiate a Phase I/II clinical trial to evaluate the immune response.
- 3818 Bioadhesion Research to Combat Biological Warfare -Developed a non-invasive anthrax vaccine and multiagent vaccines targeting anthrax and other pathogens.
- 992 Oral Adjuvants Developed adjuvants that enhance natural resistance and adaptive immune responses against mucosal pathogens.
- 3471 Plant Vaccine Development Developed safe and efficacious oral multi-agent vaccines from plant-based anthrax and plaque platforms and developed an immediate therapeutic treatment against BW agent epidemics.
- 2975 Polyclonal Human Antibody Production System Continued the process to produce polyclonal antibodies in transgenic cows by evaluating new methods and technologies for downstream purification and viral clearance.

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February 2006

**BUDGET ACTIVITY** 

PE NUMBER AND TITLE

PROJECT

RDT&E DEFENSE-WIDE/

0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

TB3

**BA3 - Advanced Technology Development (ATD)** 

### **FY 2005 Accomplishments (Cont):**

**Total** 16017

## **FY 2006 Planned Program:**

- 991 Clinical Treatment for Sulfur Mustard Agent Burns.
- 991 Heteropolymer Anthrax Monoclonal Antibody.
- 1387 Oral Adjuvants Develop adjuvants that enhance natural resistance and adaptive immune responses against mucosal pathogens.
- 1981 Outbreak Detection Information Network (ODIN).
- 2030 Anthrax Monoclonal Antibody Therapeutic and Prophylaxis Program.
- 2080 Polyclonal Human Antibody Productions System Continue the process to produce polyclonal antibodies in transgenic cows by evaluating new methods and technologies for downstream purification and viral clearance.
- 2971 Dengue Countermeasures.
- 2971 Ebola Countermeasures.
- 3466 Plant Vaccine Development Develop safe and efficacious oral multi-agent vaccines from plant-based anthrax and plaque platforms and developed an immediate therapeutic treatment against BW agent epidemics.
- 5942 UCLA High Speed, High Volume Laboratory Network for Infectious Diseases.

**Total** 24810

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0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

TB3

**BA3 - Advanced Technology Development (ATD)** 

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
Transitional Medical Technology Initiative	0	29093	65006

### **FY 2006 Planned Program:**

29093 Multiagent (Broad Spectrum) Medical Countermeasures - Evaluate therapeutic compounds and small molecule archives for
potential drug interactions against common pathogenesis pathways identified from basic research efforts. Design platforms
for discovery, development and manufacturing technologies that allow the rapid incorporation of medical countermeasure
technologies into robust and very rapid process development and manufacturing scale-up systems.

**Total** 29093

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### **FY 2007 Planned Program:**

• 65006 Multiagent (Broad Spectrum) Medical Countermeasures - This effort is part of the Quadrennial Defense Review (QDR)

"leading edge" investment to develop broad spectrum medical countermeasures against future genetically-engineered
bio-terror threats, for which there are no current defenses. Expand drug discovery efforts such as anti-sense RNA
technology that target common bacterial virulence or house-keeping genes (pathogenicity islands, quorum-sensing molecules,
siderophores, etc.). Evaluate additional therapeutic compounds and small molecule archives for potential drug interactions
against common pathogenesis pathways identified from basic research efforts. Develop transgenic animal models or alternate
animal model systems to better replicate the human-pathodeme, common virulence, and response pathways. Test platforms
for discovery, development and manufacturing technologies that allow the rapid incorporation of medical countermeasure
technologies into robust and very rapid process development and manufacturing scale-up systems. Develop platform
manufacturing technologies that enable rapid regulatory approval and rapid clinical development.

**Total** 65006

	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Diagnostics	11849	4825	6098

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### **FY 2005 Accomplishments:**

- 5599 Diagnostic Technologies Developed tech base assay for detecting anthrax in blood using the Joint Biological Agent Identification and Diagnostic System (JBAIDS), Block I instrument granted FDA approval. Augmented field studies of assays, reagents and platforms for the diagnosis of potential biological warfare threat agents with animal studies. Transitioned assays in support of the JBAIDS acquisition program, Block I and II. Continued plant expression studies for Marburg virus and transitioned baculovirus expressed Ebola for further reagent development. Applied new technological approaches for processing clinical samples to complex matrices and different threat types. Initiated assessment of host response data in order to target the development of specialized gene sets. Completed extensive evaluation of commercial instruments meeting criteria for JBAIDS, Block II, toxin detection and forwarded data to the advanced developer.
- Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Finalized standards for immunodiagnostics assays. Delivered four nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer. Delivered four antigen detection assays and/or supporting reagents to the advanced developer.
- 4805 Diagnostics Technologies, IT Medical Surveillance Assessed integration of medical surveillance information and laboratory testing using the Epidemic Outbreak Surveillance (EOS) model.

**Total** 11849

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### **FY 2006 Planned Program:**

- 3125 Diagnostic Technologies Develop additional multiplexed nucleic acid assays. Invest in improving the sensitivity and specificity of existing assays, developing assays for new targets and new threats, as genomic data and techniques become available. Transition additional assays in support of the Joint Biological Agent Identification and Diagnostic System (JBAIDS) acquisition program Block I and II. Continue to augment field studies of assays, reagents and platforms for the diagnosis of potential biological warfare threat agents with animal studies prior to transition to the advanced developer; develop a more coordinated joint approach to performing animal studies and providing useful feedback to assay developers. Further apply new technological approaches for processing clinical samples to complex matrices and different organisms. Initiate evaluation of a broad range pathogen detection system capable of identifying genetically engineered strains. Continue to apply proteomics to the development of immunologic assays for pathogen detection. Collect data on host response to bacterial pathogens in order to develop gene sets. Continue assessing next generation technologies and adapting for military use.
- Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Deliver four new nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer. Deliver four new antigen detection assays and/or supporting reagents to the advanced developer.

**Total** 4825

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## **FY 2007 Planned Program:**

4298 Diagnostic Technologies - Continue to transition assays in support of the Joint Biological Agent Identification and Diagnostic System (JBAIDS) acquisition program, Block II. Further augment field studies of assays, reagents and platforms for the diagnosis of potential biological warfare threat agents with animal studies prior to transition to the advanced developer. Address more in-depth validation studies complementing DTO CB56; offer these assay development standards as a template for government agencies; assist the advanced developer in gaining Federal Drug Administration (FDA) approval of assays. Analyze data from a multi-center comparison of automated extraction technologies versus JBAIDS, Block I manual kit; make suggestions to advanced developer pertaining to a block improvement. Continue to target improvements in sample preparation techniques. Complete studies/analyze results to identify biomarkers of immunity in individuals vaccinated against biological warfare agents. Validate proteomics microarray for plague. Expand evaluation of a broad range pathogen detection system capable of identifying genetically engineered strains. Utilize proteomics data to develop and test immunologic assays for bioagent detection. Identify gene sets corresponding to early biomarkers of infection caused by selected bacterial biological agents. Develop assays targeting early biomarkers of infections caused by selected viral biological agents and test on existing fielded platforms. Continue to assess components of future comprehensive integrated diagnostic system suitable to both hand held and reference laboratory confirmatory testing; continue to investigate technologies capable integration of nucleic acid and immunodiagnostic testing and proceed with developmental testing in anticipation of support to JBAIDS, Block III.

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**BA3 - Advanced Technology Development (ATD)** 

### FY 2007 Planned Program (Cont):

 1800 Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Deliver four new nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer. Deliver four new antigen detection assays and/or supporting reagents to the advanced developer.

**Total** 6098

	FY 2005	<u>FY 2006</u>	FY 2007
Emerging Threats	10569	566	0

## **FY 2005 Accomplishments:**

• 569 Genetically Engineered Threats - Initiated development of enhanced interferon therapeutics for viral vectored threats. Began development on high throughput microarray based resequencing of B. anthracis. Identified broad spectrum host cell traitor proteins using Ebola as a model.

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### **FY 2005 Accomplishments (Cont):**

• 10000 Defense Advanced Research Projects Agency (DARPA) Program Transition - Expanded medical biological defense technologies transitioned from the DARPA. Developed additional B-cell lines and evaluate the B-cell based diagnostic sensor technology on clinical samples. Developed a blood assay for the superantigen toxin antagonists. Complete development of five additional B-cell lines. Complete development and performance testing of a 16-channel B-cell based diagnostic sensor. Establish formulation for an orally bioavailable superantigen toxin antagonist.

#### **Total** 10569

### **FY 2006 Planned Program:**

• 566 Genetically Engineered Threats - Conduct determination of spore germination inhibitors and their effectiveness. Research continuing into 2007 will be absorbed by the Therapeutics Research Area under Therapeutics for Bacterial Agents and Therapeutics for Viral Agents, as appropriate.

**Total** 566

	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Pretreatments	13053	12013	9018

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### **FY 2005 Accomplishments:**

- 1890 Vaccine Research Support, Alternate Delivery Methods for Recombinant Protein Vaccines (DTO CB32) Demonstrated proof-of-concept for lead alternate vaccine delivery system(s). Completed preclinical research studies and prepared recommendations to support transition of commercial technology for alternate vaccine delivery out of the technology base.
- Vaccine Research Support, Recombinant Ricin Vaccine (DTO CB46) Completed a comprehensive review of results with lead candidate, including potency, efficacy, adjuvant studies, toxicity and pathology studies in rodents. Completed efficacy studies and pathology in higher animal species with the lead vaccine candidate.
- 3070 Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis
  Vaccine (DTO CB58) Continued testing candidates in available animals for EEE vaccine. Determined the compatibility of
  vaccine candidate, V3526 (VEE), and vaccine platforms in animals.
- Multiagent Vaccines, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60) Tested leading vaccine candidates in animals (viral challenge dose, route, pre-existing vector immunity, and variation in viral challenge strain).

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### **FY 2005 Accomplishments (Cont):**

• 5118 Vaccine Research Support - Continued to perform animal studies which support clinical trials of selected vaccine candidates against bacterial threat agents. Initiated technology base studies in support of the development and eventual FDA licensure of the ricin and recombinant plague F1-V vaccine candidates. Initiated evaluation of inactivated BoNT light chain vaccine candidates as well as large-scale truncations of BoNT holotoxins in animal models. Initiated studies on multivalent vaccine candidates to protect against multiple BoNT serotypes, including cloning and expression of genes for novel multivalent vaccine candidates. Tested promising vaccine strategies in higher animal species for ability to protect against filoviruses. Continued testing of next generation Staphylococcal Enterotoxin A (SEA)/ Staphylococcal Enterotoxin B (SEB) immunogen as vaccine candidates to protect against multiple SE serotypes in vivo (inside the organism). Evaluated stability and immunogenicity of SEB toxin vaccine in support of clinical trials. Evaluated promising EEE/WEE vaccine candidates in higher animal species against EEE or WEE virus challenge. Evaluated poxvirus DNA vaccine.

**Total** 13053

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## **FY 2006 Planned Program:**

- 1110 Rapid Detection, Threat Assessment and Attribution of Genetically Engineered Biothreat Organisms Using Microarray-Based Resequencing Technologies (DTO CB64) Provide for rapid, inexpensive, high-throughput, microarray-based DNA resequencing of biothreat agent genomes, whether they are naturally occurring, newly arising, or genetically engineered strains. Develop the capability to perform whole-genome sequencing in single laboratories with minimal space and personnel requirements at less than 1% of the current cost of existing, non-DOD industrial genome sequencing centers. Enable immediate definitive identification of the organism and provides specific data on the presence of any engineered elements. Develop and implement collection procedures and expand biothreat agent strain collection, focusing on Bacillus anthracis and Yersinia pestis. Demonstrate and evaluate two high-density microarray systems.
- Vaccine Research Support, Recombinant Ricin Vaccine (DTO CB46) Complete expression/purification of ricin toxin components in a soluble, immunogenic form and down-selection of vaccine candidates after Non-Human Primates (NHP) efficacy studies (surrogate marker of clinical efficacy). Complete formulation and stability studies. Provide technical data from completed vaccine research studies to the advanced developer for incorporation into an Investigational New Drug (IND) application.
- 3000 Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis
  Vaccine (DTO CB58) Continue evaluating combinations of EEE, WEE, and V3526 (VEE) or alternate VEE constructs
  (the DNA- or replicon-based vaccine platforms) in animal models.

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## **FY 2006 Planned Program (Cont):**

- Multiagent Vaccines, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60) Conduct animal models of aerosol infection with filoviruses. Determine if putative surrogate markers of protection reliably predict mitigation or prevention of disease in animals for optimal vaccine development. Continue recombinant subunit vaccine development for Ebola virus. Evaluate vaccine performance requirements (vaccine dose, route, number of doses) in animal models. Prepare current Good Manufacturing Product (cGMP) grade candidate vaccine materials for pre-IND studies. Prepare for down-selection of filovirus candidate vaccine platform. Prepare pre-IND data package for filovirus vaccine candidate.
- 1000 Multiagent Vaccines (Formerly Resuscitative Intervention) Determine optimum dose mixture and route of entry for protein-based trivalent vaccine and evaluate any potential antigen interference phenomena.

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## FY 2006 Planned Program (Cont):

• 4263 Vaccine Research Support - Evaluate animal studies which support clinical trials of selected vaccine candidates against bacterial threat agents. Continue technology base studies in support of the development and eventual FDA licensure of the ricin candidate vaccine. Expand challenge studies against selected intracellular pathogen candidate vaccines and evaluate the contribution of cell-mediated immunity toward protection. Evaluate studies on multivalent BoNT vaccine candidates to protect against multiple BoNT serotypes. Evaluate next generation Staphylococcal Enterotoxin A/Staphylococcal Enterotoxin B (SEA/SEB) immunogens as vaccine candidates to protect against multiple SE serotypes in vivo. Finalize stability analysis and immunogenicity of SEB toxin vaccine in support of clinical trial. Complete evaluation of promising Western and Eastern Equine Encephalitis (EEE/WEE) vaccine candidates in higher animal species against EEE or WEE virus challenge. Complete evaluation of poxvirus DNA vaccine. Accelerate the evaluation of genetic vaccine candidates in non-human primate model systems for poxviruses (DNA vaccine). Increase the evaluation of the human immune response to selected target antigens.

**Total** 12013

### **FY 2007 Planned Program:**

• 3100 Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58) - Complete duration of immunity studies with lead candidates for each platform, comparing the individual constructs and trivalent formulations. Develop Non-Human Primates (NHP) models of aerosol exposure to all alphaviruses. Begin down-selection of alphavirus vaccine candidate platforms for advanced development.

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**BA3 - Advanced Technology Development (ATD)** 

### FY 2007 Planned Program (Cont):

- Multiagent Vaccines (Formerly Resuscitative Intervention) Evaluate targeted Bacillus spore vaccine in animal models. Evaluate multiagent candidate vaccines in non-human primate (NHP) model for immunogenicity and immune interference, especially adjuvant formulations/systems that enhance the efficacy of molecular vaccines. Continue evaluation and eventual down-selection of various vaccine platform technologies that are amenable to multiagent immunization. Analyze duration of immunity and protective efficacy of multiagent vaccine formulations. Develop final data package for trivalent recombinant protein vaccine combining anthrax, plague and ricin from earlier optimization studies.
- 4918 Vaccine Research Support Continue to evaluate animal studies which support clinical trials of selected vaccine candidates against bacterial threat agents. Proceed with evaluation of generic Bacillus vaccine candidate in higher animal models. Complete technology base studies in support of the development and eventual Food and Drug Administration (FDA) licensure of the ricin vaccine candidate. Begin optimization of new generation intracellular pathogen vaccines, considering alternative adjuvant formulations, routes of administration, and dosage schedules. Continue expanded challenge studies against selected intracellular pathogen candidate vaccines. Continue studies on multivalent BoNT vaccine candidates to protect against multiple BoNT serotypes. Proceed with evaluation of down-selected filovirus vaccine platform in higher animal species for ability to protect against filoviruses. Evaluate ability and characteristics of next generation Staphylococcal Enterotoxin A/Staphylococcal Enterotoxin B (SEA/SEB) immunogens as vaccine candidates to protect against multiple SE serotypes in vivo. Finalize the evaluation of promising EEE/WEE vaccine candidates in higher animal species against EEE or WEE virus challenge. Complete evaluation of poxvirus DNA vaccine for endurance of immunity.

**Total** 9018

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**BA3 - Advanced Technology Development (ATD)** 

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
Therapeutics	16411	16664	16614

### **FY 2005 Accomplishments:**

- 2917 Therapeutics, Bacterial Assessed selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Developed enhance aerobiology capabilities and developed animal model to facilitate bacterial therapeutics research.
- 4384 Therapeutics, Toxin Continued timing and dosage studies in mouse model with steroid candidate compound that prevents the lethality of Staphylococcal Enterotoxin type B (SEB).
- 2200 Therapeutics, Viral Finished characterization of genes identified in random homozygous knock-out screening and their
  evaluation as drug targets. Finished screening for inhibitors of ribonucleic acid (RNA) polymerase. Evaluated novel targets
  obtained from proteomic studies.
- 540 Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) Continued to finish 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.

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**BA3 - Advanced Technology Development (ATD)** 

## FY 2005 Accomplishments (Cont):

- 4430 Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (BoNT) Continued evaluation of high affinity recombinant human antibodies against Botulinum Neurotoxins (BoNT) in vivo. Developed surrogate endpoints of human clinical efficacy for BoNT therapeutics. Initiated evaluation of neuronal drug delivery systems for leading BoNT treatment modalities in vitro and ex vivo.
- 1940 Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63) Determined therapeutic potential of candidate drugs in small animal models, including determination of the optimum dose, route and schedule (DRS) for delivery of the drug and the therapeutic window (latest time treatment can be initiated).

### **Total** 16411

### FY 2006 Planned Program:

- 2677 Therapeutics, Bacterial Continue to advance the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Continue to enhance aerobiology capabilities and aerosol efficiencies as it applies to animal model development in relation to pharmacokinetic and pharmacodynamic profiles to facilitate bacterial therapeutics research efforts.
- 2350 Therapeutics, Toxin Continue to conduct proof-of-concept studies in animal models with lead compounds shown to have potential as inhibitors of target toxins (botulinum neurotoxin, ricin, staphylococcal enterotoxins (SEs)). Continue to enhance aerobiology capabilities and animal model development to facilitate toxin therapeutics research.

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**BA3 - Advanced Technology Development (ATD)** 

### FY 2006 Planned Program (Cont):

- 2855 Therapeutics, Viral Continue evaluating new drug formulations or prodrugs for orthopox viruses. Continue to enhance
  aerobiology capabilities and animal model development to facilitate viral therapeutics research. Perform dose ranging studies
  in primates for lead prodrug compounds for orthopox. Complete studies on short interfering RNA-mediated effects on
  Ebola.
- Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) Perform testing in non-human primates (NHPs) for FDA licensure consideration under the FDA Animal Efficacy Rule. Develop and execute initial steps in plan for licensure and manufacturing of candidate, leading up to milestone approval and transition. Refine and demonstrate, to the extent possible, additional resuscitative technologies that integrate established and emerging orthopox therapeutic modalities into suitable candidate therapies in humans.
- 5700 Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59) Develop a technology from the information generated from this research development plan for nonclinical studies of optimum therapeutic candidates/treatment modalities. Determine and demonstrate the most suitable delivery system for the lead peptide inhibitors. Develop and execute initial steps in plan for licensure and manufacturing with lead compounds, leading up to milestone approval and transition. Refine and demonstrate, to the extent possible, additional resuscitative technologies that integrate established and emerging toxin therapeutic modalities into suitable candidate therapies in humans, specifically as a complement to future vaccination strategies.

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**BA3 - Advanced Technology Development (ATD)** 

### FY 2006 Planned Program (Cont):

- 2300 Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63) Determine the effect of treatment on viral pathogenesis in the mouse Ebola virus model or other more appropriate small
  animal model such as mice and guinea pigs for Marburg. Perform efficacy studies in NHP models that provide the best
  model for evaluation of the potential for treating filoviruses. Develop and execute initial steps in plan for licensure and
  manufacturing with lead compounds, leading up to milestone approval and transition. Refine and demonstrate, to the extent
  possible, additional resuscitative technologies that integrate established and emerging viral therapeutic modalities into suitable
  candidate therapies in humans. Conduct additional efficacy trials, advancing to higher species as appropriate. Initiate
  comprehensive analysis of mechanisms of protection. Complete analysis of studies performed to characterize the
  pathogenesis of Marburg virus (strain Ci67) in nonhuman primates in support of the FDA two animal efficacy rule.
- Resuscitative Intervention Screen available technologies being developed for "golden hour" treatment of combat casualties against current medical countermeasures for nerve agent pre-treatment and therapy for drug interaction effects. Begin development of in silico modeling of patient physiological response to chemical (nerve) agent to establish treatment response guidelines and to assist in evaluation of drug interaction effects.

**Total** 16664

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**BA3 - Advanced Technology Development (ATD)** 

### **FY 2007 Planned Program:**

- 3287 Therapeutics, Bacterial Continue assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Therapeutics studies should include not only treatment in models of active infection but also post-exposure prophylaxis. Continue to enhance aerobiology capabilities and aerosol efficiencies as it applies to improve animal model development in relation to pharmacokinetic and pharmacodynamic profiles in order to facilitate bacterial therapeutic research efforts.
- 6300 Therapeutics, Toxin Finish proof-of-concept studies and aerobiology studies in animal models with lead compounds shown to have potential as inhibitors of target toxins (botulinum neurotoxin, ricin, staphylococcal enterotoxins (SEs)). Define and demonstrate in vivo suitable delivery systems for lead candidate compounds.
- 3888 Therapeutics, Viral Testing of humanized antibodies produced with corporate partners.
- 3139 Therapeutics, Therapy for Ebola and Marburg Virus Infections (DTO CB63) Characterize and compare the utility of therapeutic interventions against Ebola and Marburg viruses in vitro and in animal models. Establish collaborative arrangements with industry partners, correlate all efforts with advance developers through the "product development team" process. Perform appropriate testing in relevant small and later large animal models for eventual FDA licensure.

**Total** 16614

	FY 2005	<u>FY 2006</u>	<u>FY 2007</u>
SBIR/STTR	0	859	0

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**BA3 - Advanced Technology Development (ATD)** 

## FY 2006 Planned Program:

• 859 SBIR

**Total** 859

	C. Other Program Funding Summary:									
ı									<u>To</u>	<u>Total</u>
ı		<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	FY 2011	<u>Compl</u>	<u>Cost</u>
	MB4 MEDICAL BIOLOGICAL DEFENSE (ACD&P)	24215	22574	0	71022	99435	138474	166246	Cont	Cont
	MB5 MEDICAL BIOLOGICAL DEFENSE (SDD)	9843	60612	71834	92533	95113	77377	181423	Cont	Cont

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	COST (In Thousands)	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
TC3	MEDICAL CHEMICAL DEFENSE (ATD)	12125	23863	18893	31812	31656	32621	33785	Continuing	Continuing

## A. Mission Description and Budget Item Justification:

Project TC3 MEDICAL CHEMICAL DEFENSE (ATD): This project supports the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs to protect U.S. forces against known and emerging chemical warfare 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 drug compounds. Entry of candidate pretreatment/prophylaxes, therapeutics, and diagnostic technologies into development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) application and licensure processes and DoD acquisition regulations. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas in medical chemical defense capability areas (Pretreatments, Diagnostics, Therapeutics and Emerging Threats), and directed research efforts (Low Level Chemical Warfare (CW) agent exposure and Non-Traditional Agents (NTAs)). Categories under this project address the Joint Requirements Office (JRO) critical capability gaps identified in the baseline capability assessment performed in FY03. The specific critical capability gaps addressed are Gap #15 (Medical Prophylaxes - Lack of prophylaxes for chemical warfare agents), Gap #22 (Medical Therapeutics - Limited anti-viral/ toxin development), Gap #24 (Medical Therapeutics - Lack of FDA Approval for CBRN), Gap #35 (Diagnostics - Lack of portability), Gap #36 (Diagnostics - FDA Approval) and Gap #38 (Diagnostics - Reagent Verification).

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0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

TC3

**BA3 - Advanced Technology Development (ATD)** 

## B. Accomplishments/Planned Program

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
Diagnostics	593	593	599

## **FY 2005 Accomplishments:**

• Diagnostic Technologies - Performed advanced research aimed at transitioning detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CW agent exposure. Followed-up studies to adapt DoD-developed whole blood cholinesterase assay for organophosphate exposure to automation/high throughput. Matured in vitro chemical and analytical parameters for the fluoride reactivation assay to detect the presence of VX nerve agent and performed preliminary animal work in anticipation of in vivo testing; validated a blood protein assay for detection of sulfur mustard adducts.

**Total** 593

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**BA3 - Advanced Technology Development (ATD)** 

## **FY 2006 Planned Program:**

• 593 Diagnostic Technologies - Continue advanced research experiments aimed at transitioning detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CW agent exposure. Expand studies adapting the DoD-developed whole blood cholinesterase assay for organophosphate exposure to automation and high throughput testing; analyze marker studies. Proceed with in vivo validation of flouride reactivation assay to detect VX nerve agent; investigate potential strategies for incorporation of internal standard to fluoride reactivation assay.

**Total** 593

## **FY 2007 Planned Program:**

• Diagnostic Technologies - Validate improved/novel assays against standard assays published in standard TB MED 296.

Accelerate advanced research experiments aimed at transitioning detection methods in clinical samples for metabolites, adducts and/or other relevant biomarkers resulting from CW agent exposure. Conduct further animal studies to validate assays for detecting biomarkers of CWA exposure in biological samples. Complete automation/high throughput testing protocol the DoD-developed whole blood cholinesterase assay for organophosphate exposure; collate marker studies; expand efforts to adapt method to a hand-held, field deployable device allowing immediate evaluation of exposure to nerve agents, pesticides and other organophosphates. Adapt fluoride reactivation assay standards developed in previous years to additional nerve agents.

Total 599

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0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

TC3

**BA3 - Advanced Technology Development (ATD)** 

	FY 2005	FY 2006	FY 2007
Emerging Threats	1569	10336	0

### **FY 2005 Accomplishments:**

• 1569 Chemical Warfare Agent Defense, Low Level CW Agent Exposure - Evaluated 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.

### **Total** 1569

### FY 2006 Planned Program:

- 2206 Chemical Warfare Agent Defense, Low Level CW Agent Exposure Complete studies on the effects of chronic low dose chemical exposure and possible medical countermeasures.
- 2700 Chemical Warfare Agent Defense, Low Level CW Agent Exposure Effects and Countermeasures (DTO CB51) Complete
  integration studies to determine the long term effects of exposure to low levels of chemical agents and determine their
  relevance to operational risk management hazard assessment. Complete DTO CB51.
- 4000 Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57) Complete studies on the efficacy of barrier skin creams on NTAs and determine the effectiveness of current skin decontamination kits in treating NTA skin contamination. Determine the efficacy of oximes and human butyl cholinesterase against NTAs. Complete DTO CB57.

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TC3

**BA3 - Advanced Technology Development (ATD)** 

### FY 2006 Planned Program (Cont):

1430 Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures - (DTO CB57) - Evaluate the
pharmacokinetics of improved candidate medical countermeasures for comparison to the in vivo (inside the organism)
persistence of NTAs. Conduct studies on human-derived butyrylcholinesterase (plasma and recombinant) as a bioscavenger
protective molecule.

**Total** 10336

	FY 2005	<u>FY 2006</u>	FY 2007
Pretreatments	2828	6301	8697

## **FY 2005 Accomplishments:**

• 2828 Nerve Agent Defense, Biological Scavenger - Completed evaluation of human protein recombinant scavenger as a nerve agent countermeasure. Initiated preparation of technical data package for transition out of the technology base. Continued to evaluate purification protocols for large scale isolation of human plasma-derived butyrylcholinesterase (Block I) - pBioscavenger (Increment I).

**Total** 2828

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TC3

**BA3 - Advanced Technology Development (ATD)** 

### **FY 2006 Planned Program:**

• 6301 Nerve Agent, Bioscavengers - Continue evaluation of catalytic bioscavenger (Block II) efficacy in animal model studies for safety and efficacy. Support studies for recombinant bioscavenger (Block II) transition to investigational new drug (IND) status. Perform advanced studies of in vivo expression systems for the delivery of bioscavengers. Explore utility of peptide drugs as potential catalytic bioscavengers. Continue studies of the 3-D crystallographic structures of human carboxylesterase (CaE) and paraoxynase 1 (PON-1). Initiate use of directed evolution or gene shuffling as an approach to identify cBioscavenger. Determine physiological based pharmacokinetic (PBPK) models to predict bioscavenger efficacy in Non-Human Primates (NHP) models.

**Total** 6301

## **FY 2007 Planned Program:**

• Nerve Agent, Bioscavengers - Expand recombinant and catalytic bioscavenger (Block II) efficacy, immunogenicity, and stability studies. Provide supportive studies for investigational new drug (IND) submission for recombinant bioscavenger candidate (Block II). Continue evaluation of in vivo expression systems for bioscavenger delivery systems. Continue and extend studies of the 3-D crystallographic structures of human carboxylesterase (CaE) and paraoxynase 1 (PON-1). Extend animal model evaluation, significantly reduced immunogenicity, and efficacy studies of recombinant and catalytic bioscavengers.

**Total** 8697

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TC3

**BA3 - Advanced Technology Development (ATD)** 

	FY 2005	<u>FY 2006</u>	FY 2007
Therapeutics	7135	6401	9597

### **FY 2005 Accomplishments:**

- 4256 Nerve Agent Defense, Improved Oxime (DTO CB48) Determined efficacy of oximes against selected Non Traditional Agents (NTA) and traditional nerve agents in non-human primates (NHPs). Completed correlation of oxime efficacy with pharmacokinetics and AChE reactivation in guinea pigs. Completed pharmacokinetics of candidate in guinea pig and determined pharmacokinetics in non-human primate. Completed safety/toxicity studies of candidate oximes in mice and guinea pigs. Completed determination of stability of oximes in aqueous solution. Received Milestone A decision approval and transitioned three candidates to Advanced Development.
- Nerve Agent Defense, Nerve Agent Anticonvulsants Initiated pharmacokinetic (PK) evaluations of most promising anticonvulsants; determined relationship between successful seizure control and therapeutic blood levels.
- 272 Nerve Agent Defense, Neuroprotection Initiated PK evaluations of selected neuroprotectants.
- 1176 Vesicant Agent Defense, Vesicant Medical Countermeasures Initiated PK evaluations of selected antivesicants.
- Vesicant Agent Defense, Cutaneous Therapeutics Completed validation of pig model and evaluated the efficacy of several commercially available wound healing products in promoting improved healing of superficial dermal sulfur mustard injuries using a validated weanling pig model.

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TC3

**BA3 - Advanced Technology Development (ATD)** 

### **FY 2005 Accomplishments (Cont):**

• 272 Chemical Warfare Agent Defense, Skin and Wound Decontamination - Completed the efficacy evaluation and determined the protective ratios for Reactive Skin Decontaminant Lotion (RSDL), Skin decontamination kit M291SDK, 0.5% bleach, and soapy water challenged with nerve agents GD, VX, and two non-traditional agents in the haired guinea pig model.

Completed the efficacy evaluation and determined the protective ratio for Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) challenged with GD, VX, and two non-traditional agents in the haired guinea pig model.

#### **Total** 7135

### **FY 2006 Planned Program:**

- 900 Improved Oxime Perform safety testing and dose range study for new compounds in non-human primate model.
- 1701 Nerve Agent Defense, Nerve Agent Anticonvulsants Maximize use of pharmacologic data obtained to develop improved single or multiple drug regimens to treat nerve agent induced seizures.
- 1100 Nerve Agent Defense, Neuroprotection Complete and compile data for PK evaluations of most promising
  neuroprotectants. Investigate role of novel agents such as huperzineA in central nervous system (CNS) protection.
  Complete evaluation of neurobehavioral effects of nerve agents in non-human primates and rodents to investigate the role
  and efficacy of new therapeutic agents.
- 1300 Vesicant Agent Defense, Vesicant Medical Countermeasures Determine the safety and efficacy of a variety of selected compounds, including protease inhibitors, using a rodent model. Continue PK evaluations of selected antivesicants.

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TC3

**BA3 - Advanced Technology Development (ATD)** 

## FY 2006 Planned Program (Cont):

- 800 Vesicant Agent Defense, Cutaneous Therapeutics Evaluate a wide array of commercially available wound healing products
  for their efficacy in promoting improved healing of superficial dermal sulfur mustard injuries using a validated weanling pig
  model.
- 600 Chemical Warfare Agent Defense, Skin and Wound Decontamination Determine the efficacy of Reactive Skin Decontaminant Lotion (RSDL), Skin decontamination kit M291SDK, soapy water, and 0.5% bleach against non-traditional agents compared to no decontamination.

**Total** 6401

### **FY 2007 Planned Program:**

- 5252 Therapeutics, Neurologic (Note: This area combines areas previously titled Nerve Agent Anticonvulsants, Neuroprotectants, and Improved Reactivators) Initiate studies to evaluate in vivo efficacy of candidate reactivators against lethal intoxication by nerve agents. Establish pharmacokinetic and pharmacodynamic parameters of treatment to determine threshold therapeutic drug levels. Perform neurobehavioral assessment of promising candidate products in the appropriate models.
- 2498 Therapeutics, Cutaneous and Ocular Perform pivotal animal efficacy studies, which will meet Food and Drug Administration (FDA) licensure data package requirements. Evaluate commercially available wound healing products for efficacy in promoting improved healing of superficial dermal sulfur mustard injuries.

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TC3

**BA3 - Advanced Technology Development (ATD)** 

### FY 2007 Planned Program (Cont):

Compare the efficacy of Reactive Skin Decontaminant Lotion (RSDL), Skin decontamination kit M291SDK, soapy water, and 0.5% bleach versus no decontamination against Non Traditional Agent (NTA) exposure. Evaluate additional candidate decontamination systems for NTA exposure. Determine the efficacy of Skin Exposure Reduction Paste against Chemical Warfare Agents (SERPACWA) against non-traditional agents compared to no protection. Evaluate additional candidate formulations to meet protection requirements, if needed.

- 847 Therapeutics, Medical Toxicology NTAs and Other agents Exploratory and comparative studies of emerging non-traditional chemical nerve agents. Focus on models and efficacy of interventions. Further discussion is classified.
- 1000 Chemical Warfare Agent Operational Exposure Hazard Assessment Research (DTO CB69) Extrapolate relevant experimental effects to determine post-exposure health problems that may impact subsequent operational readiness and to design and execute studies to generate scientifically valid data to serve as a basis for reducing the error in health risk assessment predictions for useful military Operational Risk Management (ORM) decisions.

**Total** 9597

	FY 2005	<u>FY 2006</u>	FY 2007
SBIR/STTR	0	232	0

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0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)

TC3

**BA3 - Advanced Technology Development (ATD)** 

## FY 2006 Planned Program:

• 232 SBIR

**Total** 232

(	C. Other Program Funding Summary:									
ı									<u>To</u>	<u>Total</u>
L		<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>Compl</u>	<u>Cost</u>
	MC4 MEDICAL CHEMICAL DEFENSE (ACD&P)	11402	21765	37663	15217	5028	5010	4880	Cont	Cont
	MC5 MEDICAL CHEMICAL DEFENSE (SDD)	1350	5029	6417	38151	29405	14025	11702	Cont	Cont

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COST (In Thousands)	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
TR3 MEDICAL RADIOLOGICAL DEFENSE (ATD)	(	0	2162	4441	4203	4523	6731	Continuing	Continuing

## A. Mission Description and Budget Item Justification:

Project TR3 MEDICAL RADIOLOGICAL DEFENSE (ATD): This project funds preclinical development of safe and effective prophylaxes for pre-exposure to radiological threats. A broad range of technologies involved in the targeting and delivery of prophylactic medical countermeasures is evaluated so that the most effective countermeasures are identified for development. Entry of candidate pretreatment technologies into development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) and licensure processes and DoD acquisition regulations. Program objectives focus on mitigating the health consequences from exposures to ionizing radiation that represent a significant threat to US forces under current tactical, humanitarian, and counter terrorism mission environments. Findings from basic and developmental research are integrated into highly focused advanced technology developments studies to produce the following: (1) protective therapeutic studies; (2) novel biological markers and delivery platforms for rapid, field-based individual dose assessment; and (3) experimental data needed to build accurate models for predicting casualties from complex injuries involving radiation and other battlefield insults. This project addresses the Joint Requirements Office (JRO) critical capability gaps identified in the baseline capability assessment performed in FY03. The specific critical capability gap addressed is gap #16 (Medical Prophylaxes - FDA Approval for radiological prophylaxes).

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TR3

**BA3 - Advanced Technology Development (ATD)** 

## B. Accomplishments/Planned Program

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
Radioprotectants	0	0	2162

## **FY 2007 Planned Program:**

• 2162 Radioprotectants - Continue further testing of a promising candidate drug found to have a dose-reduction factor (DRF) of 1.20 or greater in rodents. Initiate studies, including preclinical efficacy, in a large animal model Non-Human Primates (NHP), including non-clinical toxicological and pharmacokinetic analysis, assessment of drug mechanism, and initial determination of formulation. Determine products and regimens that mitigate and/or treat radiation injury post-exposure, with emphasis on broad activity, ease of administration, and safety. Search for improved antibiotics and antiviral regimens to control post-exposure infection in the context of immunosuppression and trauma, and probiotic therapies to minimize pathogenic infection and restore mucosal health.

**Total** 2162

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TR3

**BA3 - Advanced Technology Development (ATD)** 

C. Other Program Funding Summary:								To	Total
	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	Compl	Cost
MR4 MEDICAL RADIOLOGICAL DEFENSE	0	0	6996	15051	15188	11040	3919	Cont	Cont

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BUDGET ACTIVITY  RDT&E DEFENSE-WIDE/ BA3 - Advanced Technology Development (ATD)  PE NUMBER AND TITLE  0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)  TT3							PROJECT <b>T3</b>		
COST (In Thousands)	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
TT3 TECHBASE TECHNOLOGY TRANSITION	(	11127	11087	7879	8340	8688	8627	Continuing	Continuing

## A. Mission Description and Budget Item Justification:

Project TT3 TECHBASE TECHNOLOGY TRANSITION: This project supports technology transition efforts. These efforts test and demonstrate technologies being developed for transition from the Joint Science and Technology Office (JSTO) to the Joint Program Executive Officer (JPEO). This project, which will be initiated in FY06, is funded by realignment of funds: BA6, Anti Terrorism; BA3, CB3 funds for Technology Readiness Evaluations; BA3, CP3 funds for Counter Proliferation Support Program, ACTD Planning and Development; and BA3, CM3 Homeland Defense, Civil Support Teams. The WMD-CST program (formerly Project CM3 - FY05 and earlier) funds Pre-Systems Acquisition in support of Consequence Management teams around the nation. The Technology Transition program supports Advanced Technology Demonstrations and planning for Advanced Concept Technology Demonstrations in the Experimentation and Technology Demonstration group. The Force Protection program demonstrates and tests technology for Force Protection/Installation Protection and specifically for PM Guardian's Installation Protection Program. The Technology Readiness Assessment program provides for testing on technologies transitioning out of the Physical Sciences and Medical Science and Technology programs to meet specific criteria postulated by the JPEO in Technology Transition Agreements or tests technologies provided in response to a Broad Agency Announcement in order to satisfy an acquisition strategy for a Joint Program Manager working with the JPEO.

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TT3

**BA3 - Advanced Technology Development (ATD)** 

## B. Accomplishments/Planned Program

	FY 2005	FY 2006	<u>FY 2007</u>
TECHBASE - TECH TRANSITION - EXPERIMENT & TECH DEMO	0	5308	6175

## **FY 2006 Planned Program:**

- 1995 ACTD Candidate Initiate the Military Applications in Reconnaissance and Surveillance (MARS) Unattended Ground Sensors (UGS) program testing CBRN detection technologies for use on one-man portable UGSs.
- 1689 ACTD Demonstration Execute the Military Applications in Reconnaissance and Surveillance (MARS) Unmanned Ground Vehicle (UGV) program testing CBRN detection technologies for use on one-man and two-man portable UGVs for technology insertion into the CBRN Unmanned Ground Reconnaissance (CUGR) ACTD or the transition program for CUGR ACTDs UGV portion.
- 1624 ACTD Testing Execute the MARS Manned/Unmanned Aerial Vehicle (M/UAV) program testing CBRN detection technologies for use on small UAVs dedicated to CBRN passive defense or CBRN consequence management, reconnaissance and surveillance applications.

**Total** 5308

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TT3

**BA3 - Advanced Technology Development (ATD)** 

### **FY 2007 Planned Program:**

- 1441 ACTD Candidate Perform candidate technology maturation testing in preparation for a FY08 ACTD candidate.
- 1066 ACTD Demonstration Continue the Military Applications in Reconnaissance and Surveillance (MARS) Unmanned Ground Vehicle (UGV) program testing CBRN detection technologies for use on one-man and two-man portable UGVs for technology insertion into the CUGR ACTD or the transition program for CUGR ACTDs UGV portion.
- 1441 ACTD Testing Continue the MARS Manned/Unmanned Aerial Vehicle (M/UAV) program testing CBRN detection technologies for use on small UAVs dedicated to CBRN passive defense or CBRN consequence management, reconnaissance and surveillance applications.
- 2227 ACTD Testing MARS Continue Unattended Ground Sensors (UGS) program testing CBRN detection technologies for use on one man portable UGSs.

**Total** 6175

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
TECHBASE - TECH TRANSITION - FORCE PROTECTION	0	490	507

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TT3

**BA3 - Advanced Technology Development (ATD)** 

### **FY 2006 Planned Program:**

• 490 Force Protection - Develop and demonstrate medical surveillance technology integration for the installation protection program. This is the first year of a two-year effort.

**Total** 490

### **FY 2007 Planned Program:**

• 507 Force Protection - Develop and demonstrate medical surveillance technology integration for the installation protection program. This is the second year of a two-year effort.

**Total** 507

	FY 2005	<u>FY 2006</u>	FY 2007
TECHBASE - TECH TRANSITION - TECH READINESS ASSESS	0	2832	1981

### **FY 2006 Planned Program:**

- 1305 Technology Readiness Assessment (TRA) Complete Technology Readiness Evaluation (TRE) for Collective Protection in the following focus areas: CB Barrier Material, Quick Erect, COL PRO Support Equipment, and Whole COLPRO Systems.
- 234 TRA Initiate planning of FY07 TREs to include chemical stand-off detection equipment and Joint Warning and Reporting Network technologies.

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TT3

**BA3 - Advanced Technology Development (ATD)** 

## FY 2006 Planned Program (Cont):

- 234 TRA Conduct TRAs for the Military Application in Reconnaissance and Surveillance (MARS-UGV) and the Joint Chemical Biological Radiological Agent Water Monitor (JCBRAWM).
- 1059 TRA Complete performance testing of the Collective Protection Air Purification technologies.

**Total** 2832

## **FY 2007 Planned Program:**

- 1519 Technology Readiness Assessment Conduct Technology Readiness Evaluation (TRE) on chemical stand-off technologies.
   Conduct TREs on warning and reporting network technologies. Conduct TRE for the Joint Chemical Biological Radiological Agent Water Monitor (JCBRAWM).
- 462 Technology Readiness Assessment Plan Technology Readiness Evaluation for increment two of Joint Operational Effects Federation (JOEF).

**Total** 1981

	<u>FY 2005</u>	<u>FY 2006</u>	FY 2007
TECHBASE - TECH TRANSITION - WMD-CST	0	2385	2424

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TT3

**BA3 - Advanced Technology Development (ATD)** 

### **FY 2006 Planned Program:**

- 1515 Weapons of Mass Destruction Civil Support Teams (WMD CST) Continue evaluation and testing of new commercial products being considered in response to WMD CST requirements.
- 313 WMD CST Transition technologies tested in FY05 and FY06 processes through the Joint Program Executive Office Chemical Biological Defense (JPEO-CBD) Non-Standard Equipment Review Panel (NSERP) process.
- 557 WMD CST Perform operational testing and Homeland Defense Demonstrations for WMD CSTs.

### **Total** 2385

## **FY 2007 Planned Program:**

- 1537 Weapons of Mass Destruction Civil Support Teams (WMD CST) Transition technologies tested in FY05 and FY06
  processes through the Joint Program Executive Office Chemical Biological Defense (JPEO-CBD) Non-Standard Equipment
  Review Panel (NSERP) process.
- 887 WMD CST Perform operational testing and Homeland Defense Demonstrations for WMD CSTs.

### **Total** 2424

	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
SBIR/STTR	0	112	0

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TT3

**BA3 - Advanced Technology Development (ATD)** 

## FY 2006 Planned Program:

• 112 SBIR

**Total** 112

C. Other Program Funding Summary:								<u>To</u>	<u>Total</u>
	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	Compl	<u>Cost</u>
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	4869	0	0	0	0	0	0	0	4869
CP4 COUNTERPROLIFERATION SUPPORT	15853	24239	25452	26152	15083	14344	26674	Cont	Cont
(ACD&P)									

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