

UNCLASSIFIED

RDT&E BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

DATE **FEBRUARY 2000**

BUDGET ACTIVITY
2 - Applied Research

PE NUMBER AND TITLE
0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)

COST (In Thousands)	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
Total Program Element (PE) Cost	62301	97400	73600	83185	84480	74872	76467	Continuing	Continuing
CB2 CHEMICAL BIOLOGICAL DEFENSE (Applied Research)	36563	61726	37721	37445	36871	37057	38307	Continuing	Continuing
TB2 MEDICAL BIOLOGICAL DEFENSE (Applied Research)	12175	22206	21509	30017	31638	22088	22985	Continuing	Continuing
TC2 MEDICAL CHEMICAL DEFENSE (Applied Research)	13563	13468	14370	15723	15971	15727	15175	Continuing	Continuing

A. Mission Description and Budget Item Justification: The use of chemical and biological weapon systems in future conflicts is a steadily increasing threat. Funding under this PE sustains a robust defense which reduces the danger of a chemical and/or biological (CB) attack and enables U.S. forces to survive and continue operations in a CB environment. The medical program focuses on development of vaccines, pretreatment and therapeutic drugs, and on casualty diagnosis, patient decontamination, and medical management. In the non-medical area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection systems. Maintaining state-of-the-art CB defensive systems is critical for force protection and CB weapons deterrence. This program also provides for conduct of applied research in the areas of real-time sensing and immediate biological countermeasures. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. Efforts under this PE transition to and provide risk reduction for Advanced Technology Development (PE 0603384BP), Demonstration/Validation (PE 0603884BP), and Engineering/Manufacturing Development (PE 0604384BP). This project includes non-system specific development directed toward specific military needs and therefore is correctly placed in Budget Activity 2.

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<u>B. Program Change Summary:</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget (FY 2000/FY 2001)	63992	64780	68024
Appropriated Value	63397	99280	
Adjustment to Appropriated Value			
a. Congressional General Reductions			
b. SBIR/STTR	-1055		
c. Omnibus or Other Above Threshold Reductions	78	-197	
d. Below Threshold Reprogramming	-119	-653	
e. Rescissions		-1030	
Adjustments to Budget Years Since FY 2000/2001 PRES BUD			5576
Current Budget Submit (FY2001/PRES BUD)	62301	97400	73600

Change Summary Explanation:

Funding: FY00 - Congressional Adjustments - CB2 (25000) for SAFEGUARD program; for chemical biological point detectors; for chemical biological detection programs; for chemical biological hazard detectors; for chemical biological countermeasures. TB2 (5000) for medical protocols for chemical biological defense. Reprogramming from USMC to Chemical Biological Defense Program IAW P.L. 103-160 - CB2 (4500) for aquifer vulnerability efforts; and probable cause detection system.

Schedule:

Technical:

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2
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COST (In Thousands)	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
CB2 CHEMICAL BIOLOGICAL DEFENSE (Applied Research)	36563	61726	37721	37445	36871	37057	38307	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project CB2 CHEMICAL BIOLOGICAL DEFENSE (Applied Research): This project addresses the urgent need to provide all services with defensive materiel to protect individuals and groups from threat chemical-biological (CB) agents in the areas of: detection; identification and warning; contamination avoidance through reconnaissance; individual and collective protection and decontamination. It also provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and nuclear, biological, chemical (NBC) survivability. This project focuses on horizontal integration of CB defensive technologies across the Joint Services. The techbase uses Defense Technology Objectives (DTOs) as a means to shape the development of selected technologies.

FY 1999 Accomplishments:

- 1568 Chemical Imaging Sensor, DTO - Demonstrated 9-pixel spectrometer at 30 Hz (offline processing of data) with an increase to system sensitivity by a factor of ten. The CIS provides the world's first real time, high-speed chemical imaging system.
- 836 Laser Standoff (S/O), Chemical Detection DTO - Completed evaluation and design for enhanced sensitivity for Mustard agent and transitioned to advanced development for trade-off/integration in brassboard laser upgrade and continued brassboard build for a multi-purpose detector as described for the Joint Service Warning and Identification Light Detection And Ranging (LIDAR) Detector (JSWILD). Demonstrated range-resolved and topographical measurements for a mixture containing two different simulants.
- 732 Joint Warning and Reporting Network (JWARN), DTO - Completed demonstration of DTO with cost target of \$300 per unit, 57.6-kb continuous wireless, and 1-Mb continuous wired data transmission rates using 2 different sensors. Completed tradeoff analysis and documentation, transitioned to JWARN acquisition program.
- 2251 SAFEGUARD - Completed construction of second generation line scanner and high speed Fourier Transform (FT) spectrometer and initiated integration onto platform.

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(APPLIED RESEARCH)**

PROJECT

CB2**FY 1999 Accomplishments (Cont):**

- 3187 Chemical Point Detection Non-DTO - Downselected from over 150 identified candidates for best technology and initiated breadboard design for water monitor. Investigated and evaluated effects of extended exposure durations and low concentration exposures of chemical agents to verify and validate alarm and warning levels/thresholds for detector systems.
- 2717 Biological Sample Preparation System, DTO - New effort initiated to address automation of bio sample preparation procedures for gene-based and mass spectrometric identification/discrimination of biological materials. Effort is scheduled to be completed in FY01 with target transition to Joint Biological Point Detection System (JBPDS) Block II. Demonstrated sensitivity levels of spore methodologies at or near target metrics. Developed methods for release, detection of spore protein biomarkers in 20 minutes by mass spectrometry (MS). Developed methods for sample cleanup for MS. Evaluated several chemical and physical spore disruption methods for Polymerase Chain Reaction (PCR) detection.
- 1318 Biological Point Detection, Non DTO - Developed force differentiation analyzer assays for simulants at or near sensitivity goals for fielded biological identifiers. Developed new integrated waveguide approach and molded fluidics assembly for multiagent immunosensor. Tested multiple commercial and developmental biosensors at Joint Field Trials (JFT) for comparative value.
- 2352 Biological Early Warning Detection, Non DTO - Downselected among candidate fluorescence based triggers/detectors. Collected lab and field data to evaluate candidate new standoff biodetection approaches. Using single particle fluorescence studies, demonstrated linear response to particle size. Expanded database on optical constants and potential impact of encapsulation on fluorescence based approaches.
- 1869 Biological Genetic Technology, Non DTO - Evaluated prototype human superlibrary for value in providing effective antigen recognition elements using a comprehensive library of antibodies representing the entire human immune response (otherwise known as superlibrary). Continued development, test, and transition of new recombinantly-derived antibody-based recognition elements. Tested botulinum toxin recombinant antibody using dendrimer support on ticket format which demonstrated improved performance over standard ticket implementations.
- 523 Advanced Lightweight Chemical Protection, DTO - Combined advanced membranes with lightweight shell fabrics and novel closure systems into a lightweight CB duty uniform concept.
- 836 Advanced Adsorb Protection Application, DTO - Performed extensive characterization of the agent filtration performance of the layered adsorbed bed concept(s). Layered adsorbed bed concepts are identified as offering the greatest potential of providing high agent capacity and low pressure drop for the Joint Service General Purpose Mask (JSGPM) filter.
- 2300 Individual Protection Non-DTO - Designed and fabricated of integrated mask/helmet models, demonstrated comprehensive respirator encumbrance model, determined mechanisms for heat and mass transport through membranes and textiles, and developed improved laboratory test methods for CB clothing materials.

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(APPLIED RESEARCH)**

PROJECT

CB2**FY 1999 Accomplishments (Cont):**

- 2477 Collective Protection, Non-DTO - Completed testing of full scale Pressure Swing Absorption (PSA) system on USMC Amphibious Vehicle test bed. Completed full scale testing of Non Developmental Item (NDI) cleanable/regenerable High-Efficiency Particulate Arresting (HEPA) filters. Completed improvement studies/concepts analysis to support the Joint Transportable Collective Protection System (JTCOPS) and Joint Collective Protection equipment (JCPE). Completed initial evaluation of Surface Acoustic Wave (SAW) Residual Life Indicator (RLI) development effort using simulants; initiated CW agent testing of SAW RLI sensor and simulant studies of chemiresistor and photoionization RLI detectors. Completed investigation of CW agent elution from carbon following agent exposure.
- 836 Decontamination, DTO - Initiated genetic reengineering of organophosphorus hydrolase (OPH) and organophosphorus acid anhydrolase (OPAA) enzymes to enhance V-agent hydrolysis. Enhanced Mustard agent (HD) hydrolysis by dendrimer polymer and phase transfer catalysts.
- 3309 Decontamination, Non DTO - Conducted studies on supercritical fluids and non-ozone depleting fluorocarbon solvent systems for sensitive equipment (items) decontamination. Completed joint DoD/DOE evaluation of atmospheric pressure plasma jet system for potential to decontaminate interior spaces. Conducted solution decontamination research focusing upon oxidative and nucleophilic processes in mixed solvent media with additives such as surfactants. Initiated studies to develop new dry powder decontaminants that can be used in a non-developmental applicator system. Initiated a multi-phase program to develop the next generation of reactive sorbent decontaminant based initially upon zeolites and high surface area solids containing oxidation/reduction couples.
- 3056 Supporting Science and Technology, Non DTO - Published 20 reports on threat chemistry including theoretical studies on oximes, thiranes, and salvation in organophosphorus reactions, closed system flash point measurements suitable for highly toxic substances, and replacement of K-125 thickener with Russian analog. Completed International Task Force (ITF) 33 Report containing the technical evaluation by tri-national (US, UK, CAN) scientists of laboratory data on six emerging chemical threat compounds. Threat biology conducted studies of prions, Yersinia plasmids pCad, pFra, pPst, and published analyses of glanders and melioidosis. Completed sealed nose-only rodent exposure facility for evaluating inhalation toxicology of high-risk substances. Aerosol technology demonstrated unique capability to characterize quantitative, particle size dependent transmission efficiency and aspiration efficiency of aerosol inlets up to 60 mph. Characterized three Biological Integrated Detection System (BIDS) inlets and two Joint Biological Point Detection System (JBPDS) Block I brassboard inlets. Identified technical approaches to advanced aerosol collector and inlet technology with promise to overcome tech barrier shortcomings of the existing equipment with respect to meeting future (JBPDS Block II, Joint Biological Remote Early Warning System (JBREWS), Joint Chemical and Biological Universal Detector (JCBUD)) requirements. Deployed transportable aerosol containment sleeve ("stealth tube") with supporting controlled aerosol generation to field tests for standoff biodetection development for JBREWS.

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PROJECT

2 - Applied Research**0602384BP CHEMICAL/BIOLOGICAL DEFENSE
(APPLIED RESEARCH)****CB2****FY 1999 Accomplishments (Cont):**

- 2926 Modeling and Simulation (MOD/SIM) - Continued model development for simulation of joint force operations in a CBW environment. Developed models for Joint Service CB defense equipment for application in Simulation Based Acquisition (SBA). Continued simulation and wargaming of chemical and biological attack profiles with distribution of vapor, liquid, and solid tracking (VLSTRACK) version 3.0. Initiated development of coupled CB environment/meteorological models for use with forward-deployed weather forecast operations.
- 3370 Man-portable Detectors - Explored and developed polymer film chemistries and advanced Semiconducting Metal-Oxide (SMO) arrays for the detection of CB agents and other chemicals of interest. This effort included fabrication of devices using this technology and laboratory challenge using toxic chemicals.

Total 36563

FY 2000 Planned Program:

- 660 Biological Point Detection, Non-DTO - Downselect to a single exploratory antibody-based biosensor, the Force Amplified Biosensor (FABS). FABS effort is to automate sample prep/processing and enhance assay sensitivity to JBPDS requirement levels. Initiate joint effort with Department of Energy (DOE) Chemical and Biological Nonproliferation Program to collect into single data base ambient background data from multiple U.S. and international sources.
- 2950 Bio Sample Preparation System (BSPS), DTO - Demonstrate fully automated 2 cu ft BSPS concept coupled with gene probe sensor and next-generation mass spectrometer.
- 1000 Chemical Standoff (S/O) Detection, Non-DTO - Evaluate photo-elastic modulator technology for use in standoff detection systems. Initiated feasibility studies to develop concepts for use and evaluate cost to benefit for use of non-traditional chemical biological (disparate) sensors to cue for early warning.
- 820 Biological Early Warning Detection, Non-DTO - Initiate effort to enhance reliability (false detection reduction) and increase discrimination capability of optical analyzers by adding shape/size analysis. Initiate examination of pyrolysis-gas chromatography-ion mobility spectrometry (Py-GC/IMS) as JCBUD candidate, with emphasis on determining chemical identity of signature markers for simulant bioagents. These approaches are being pursued as candidate technology solutions for implementation in arrayed detector networks.
- 1520 Biological Genetic Technology - Complete revised human superlibrary, assess recombinant antibodies using biosensor testbeds. Evaluate methodologies for turn-around time to develop new Antigen Binding Fragment from "unknowns." Assess value of human superlibrary approach to antibody development. Initiate evaluation of combinatorial peptides as alternative recognition molecules.

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(APPLIED RESEARCH)**

PROJECT

CB2**FY 2000 Planned Program (Cont):**

- 590 Advanced Lightweight Chemical Protection, DTO - Integrate improved closure systems with selectively permeable garment. Fabricate final concept lightweight CB duty uniforms and conduct limited field testing.
- 890 Advanced Adsorb Protection Application, DTO - Complete screening of candidate adsorbent materials for JSGPM. Conduct study and analysis of regenerative filtration designs for JTCOPS/JCPE. Initiate investigations of candidate adsorbent materials for protection against Toxic Industrial Materials (TIMS).
- 4500 Individual Protection, Non-DTO - Conduct interface testing of prototypes and downselect to best helmet/mask interface design. Conduct Joint Service Aviation Mask (JSAM) prototype evaluation and create design guidelines. Combine membrane structural and chemical studies with computer models to identify dominant factors controlling high permselectivity. Identify materials and treatments for aerosol threat mediation. Develop prototype, lightweight textiles utilizing nanofiber technology and incorporating agent reactive catalyst.
- 3610 Collective Protection, Non-DTO - Test low-cost, lightweight tentage materials and transition to JTCOPS. Conduct simulant and CW agent testing of chemiresistor-type RLI and conduct simulant testing of photoionization-type RLIs. Initiate studies to examine the performance of immobilized adsorbent beds. Initiate studies to develop and verify performance models and design rules for advanced regenerative adsorption processes.
- 3318 Chemical Point Detection, Non-DTO - Complete breadboard design and initiate breadboard fabrication for water monitor. Complete baseline for comparison of historical data to new methodology and initiate multi-species animal studies for studying toxicological effects of extended exposure duration and low concentration exposures to validate and verify alarm and warning levels/thresholds for detector systems.
- 1870 Chemical Imaging Sensor, DTO - Demonstrate a 16-pixel spectrometer at 100 Hz (offline process of data). Will be the first system capable of collecting and processing data at these speeds. 100 scans per second represents a factor of 20 improvement over current developmental systems.
- 790 Decontamination, DTO - Continue to increase the activity of enzymes known to have hydrolytic activity on V-agents by genetic engineering. Modify the excellent G-agent enzyme by genetic engineering to also hydrolyze V-agents. Identify new enzymes with V-agent activity. Identify and optimize chemical catalysts for H-agent hydrolysis that are compatible with enzyme technologies. Examine mild oxidants that would convert HD to its sulfoxide which would then be de-chlorinated with enzymes.
- 5645 Decontamination, Non-DTO - Incorporate neutralization processes into the supercritical fluid extraction and non-ozone depleting fluorocarbon systems being developed for sensitive equipment decontamination systems. Demonstrate validity of the techniques for down selection into FY01 Joint Service Sensitive Equipment Decontamination System (JSSED) Block I development program. Conduct studies on novel approaches to achieve decontamination of interiors (JSSED Block II). Optimize solution decontaminants under evaluation and prepare for demonstration phase. Initiate studies using oxidative approaches. Continue studies to formulate dry powder decontaminants to be mixed with aqueous based solvents on-site. Continue work on zeolites and high surface area reactive solids and incorporate reactive nano-particle technology.

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**0602384BP CHEMICAL/BIOLOGICAL DEFENSE
(APPLIED RESEARCH)**

PROJECT

CB2**FY 2000 Planned Program (Cont):**

- 2690 Supporting Science and Technology, Non-DTO - CB Threat - Identify and technically evaluate emerging chemical threat agents by literature, quantitative structure-activity relationships (QSAR), synthesis of identified new threat materials and toxicology experiments. Design quantitative powder aerosol generator for use in the nose-only exposure chamber with adequate containment for studying high-risk (no antidote) aerosol substances. Disseminate detailed technical information developed on specific new substances, which is needed to guide detection, protection, and vulnerability work, via Joint Service, NATO, and Tri-Partite panels, working groups, and data exchange agreements. Aerosol Technology - Measure performance of candidate aerosol collectors for JCBUD technology, emphasis will be placed on low temperature techniques including non-liquid collection methods. Initiate design and testing of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the particle size range from 1-10 micrometers diameter and wind speeds of 2-60 mph. Provide controlled biosimulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for the Joint Field Trials.
- 2632 Modeling and Simulation (MOD/SIM) - Continue model development for simulation of joint force operations for incorporation into advanced simulations like Joint Conflict and Tactical Simulation (JCATS), Joint Simulation System (JSIMS), Joint Modeling and Simulation System (JMASS), and Joint Warfare Simulation (JWARS). Continue development of coupled CB environment/meteorological models for incorporation of CBW hazard prediction and tracking into forward-deployed meteorological forecast operations. Develop advanced CBW environment models for more accurate atmospheric transport and fate predictions for battlespace awareness. Continue development of models for Joint Service CB defense equipment for application in Simulation Based Acquisition (SBA).
- 2440 SAFEGUARD, Non DTO - Upgrade sensors and software and complete airborne platform integration in support of an Advanced Warfighting Experiment (AWE) or entry into an Advanced Concept Technology Development (ACTD).
- 7395 Man-portable Detectors, Non-DTO - Develop and optimize polymer coated surface acoustic wave (SAW) and chemiresistive conducting devices that are sensitive and selective to nerve, blister, and blood agent simulants as well as toxic industrial chemicals. Develop impedance and fluorescence-based biosensors employing immunological and DNA detection probes. Integrate hybrid sensor array devices and electronics, neural networks, and other data acquisition and display hardware/software into a prototype detection system for chemical agents. Demonstrate an integrated prototype detector system for CW/BW agents and toxic industrial chemicals under laboratory and field conditions. The goal of these efforts is to develop a man transportable detector with low power and no field maintenance requirements.
- 1970 CB Chemical Hazard Detection, Non-DTO - Develop a deployable CB detection system that can integrate multiple detection technologies such as ion trap spectrometry, electromagnetic energy, neutron-based sensing, for use in detecting nuclear, biological, and chemical weapons.
- 1480 Aquifer Vulnerability, Non-DTO - Investigate vulnerability of aquifers from employment of CB agents on the battlefield.

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2 - Applied Research**0602384BP CHEMICAL/BIOLOGICAL DEFENSE
(APPLIED RESEARCH)****CB2****FY 2000 Planned Program (Cont):**

- 2753 Probable Cause Detection System, Non-DTO - Develop an effective detection system for detecting and identifying CB agents and toxic industrial chemicals as deployed weapons.
- 11311 CB Countermeasures, Non-DTO - Individual Protection - Develop non-woven techniques to construct fabrics suitable for personal CB protective clothing. Investigate the use of synthetics and natural materials for protective fabric. Decontamination - Investigate the use of electron beam, ultra-violet light, infrared, or microwave radiation for CB decontamination applications. Develop a suite of microorganisms capable of detoxifying CB contaminated soil. Modeling and Simulation - Construct a virtual reality high-rise office building and develop models and visualization methods to monitor the spread of CB agents. Model airborne transport hazard using advanced atmospheric monitoring systems and numerical techniques. Bio Detection - Validate and expand the use of advanced Fourier transfer infrared monitoring technology for rapid detection of airborne mycotoxins. Use polypeptides as targets for the isolation of antibodies in vitro. Use synthetic chemistry to create libraries of unnatural biopolymers that function as nucleic acid binding to develop optical and electrochemical sensor elements. Use low cost electronics to demonstrate the feasibility of rapid and selective detection of specific microorganisms. Consequence Management - Develop a sensor that can detect and characterize deeply buried underground facilities that contain CB materials. Develop a communication architecture that can disseminate information to WMD first responders.
- 892 SBIR/STTR.

Total 61726

FY 2001 Planned Program:

- 2080 Chemical Imaging Sensor (CIS), DTO - Demonstrate a 16-pixel spectrometer in real-time operation at 100 Hz (Online process of data). Represents the first time high performance computers have been used on line for this application. System will also be capable of being mounted on platforms with speeds in excess of 1,000 Miles Per Hour with an imaging capability.
- 1500 Chemical Point Detection, Non-DTO - Continue breadboard fabrication and initiate planning for demonstration of the water monitor. Complete G series agents and initiate V series agents for studying toxicological effects of extended exposure duration and low concentration exposures for validation and verification of alarm and warning levels/thresholds for detector systems.
- 765 Chemical Standoff (S/O) Detection, Non-DTO - Complete concept for use development and cost to benefit analysis of disparate sensor.
- 2788 Biological Sample Preparation System (BSPS), DTO - Incorporate microscale approaches to reduce size of BSPS by 35% while maintaining overall sensitivity on both platforms against eight bacterial and viral materials. Reduce sample preparation time to 15 minutes.

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2 - Applied Research**0602384BP CHEMICAL/BIOLOGICAL DEFENSE****CB2****(APPLIED RESEARCH)****FY 2001 Planned Program (Cont):**

- 1400 Biological Point Detection, Non-DTO - Complete automation of Force Amplified Biosensor (FABS) and evaluate in Joint Field Trial lab test. Complete analysis of accumulated ambient background data and identify data gaps for further study as indicated by analysis.
- 1760 Biological Early Warning Detection, Non-DTO - Refine discrimination algorithms for optical fluorescence/shape analysis and pyrolysis-gas chromatography-ion mobility spectrometry detectors and subject to chamber and/or field test with bioagent simulants. Identify new Joint Chem Bio Universal Detector (JCBUD) candidates.
- 1558 Biological Genetic Technology, Non-DTO - Assuming prior year assessment supports validity of approach, continue to transition recombinantly derived FABS (antigen-binding antibody fragments) for test, integration into biosensor testbeds. Assess combinatorial peptides against established molecular recognition standards.
- 1100 Advanced Adsorb Protection Application, DTO - Select regenerative filtration designs for JTCOPS/JCPE. Screen candidate adsorbents for TIMs applications.
- 3760 Individual Protection, Non-DTO - Fabricate final helmet/mask interface concept baseline model and conduct systems testing. Investigate the feasibility of increasing polymer permselectivity by ion implantation. Fabricate and test clothing items employing aerosol threat mediation technologies. Characterize prototype, lightweight textiles using nanofiber technology and incorporating agent reactive catalyst.
- 4308 Collective Protection, Non-DTO - Complete RLI sensor screen for chemiresistor and photoionization sensors. Conduct RLI Tech Demo and down-select to one candidate technology. Complete immobilized bed studies. Conduct lab scale testing of an advanced regenerative filtration system. Fabricate and test optimized hermetic seals. Initiate an effort to develop concepts for improving shelter deployability.
- 800 Decontamination, DTO - Produce sufficient V- and H-agent enzymes and reactive polymers to optimize their use in foams, detergent solutions or other types of dispersion systems.
- 5607 Decontamination, Non-DTO - Complete demonstration of sensitive equipment decontamination methodology and transition to the phase I of the JSSED program. Select technologies to be demonstrated for the decontamination of sensitive interiors (JSSED Block II). Continue research of candidate solution chemistry systems to satisfy the requirements for the Superior Decontamination System (SDS) program. Continue the evaluation of novel solid matrices to satisfy the requirements of the Next Generation Decontamination Kit program. Initiate an effort to evaluate alternative approaches to meet this requirement.

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(APPLIED RESEARCH)**

PROJECT

CB2**FY 2001 Planned Program (Cont):**

- 2695 Supporting Science and Technology, Non-DTO - CB Threat - Identify and technically evaluate emerging chemical threat agents by literature, quantitative structure-activity relationships (QSAR), synthesis of identified new threat materials and toxicology experiments. Identify emerging mid-spectrum bio threats and analytical microbiology capability. Disseminate detailed technical information developed on specific new substances, which is needed to guide detection, protection, and vulnerability work, via Joint Service, NATO, and Tri-Partite panels, working groups, and data exchange agreements. Aerosol Technology - Measure performance of candidate aerosol collectors for JCBUD technology, emphasis will continue to be placed on low temperature, including non-liquid, collection methods and high collection efficiencies. Include chemical simulant aerosol measurements to build technical base for supporting JCBUD aerosol collection requirements. Provide controlled biosimulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for the Joint Field Trials.
- 2600 Modeling and Simulation (MOD/SIM) - Continue model development for simulation of joint force operations for incorporation into advanced simulations like JCATS, JSIMS JMASS and JWARS. Continue development of coupled CB environment/meteorological models for incorporation of CBW hazard prediction/tracking into forward-deployed meteorological forecast/nowcast operations. Continue development advanced CBW environment models for more accurate, higher-resolution atmospheric transport and fate predictions for battlespace awareness and contamination avoidance. Continue development of models for Joint Service CB defense equipment for application in Simulation Based Acquisition (SBA).
- 1500 Novel Bio Sensor Concepts: Identify and qualify for application novel concepts for networked standoff and point chemical and biological sensors for enhanced early warning capability. Novel approaches will include currently fielded non-CB sensors that can provide CB use signatures, such as radar and acoustic sensors, as well as extension of chem standoff approaches to bio detection through optical signatures not presently employed. Point sensors having simultaneous chem and bio detection capabilities will be identified. Networking of these disparate sensors will be accomplished through emerging information management processes.
- 1500 Protection Technologies: Evaluate Ion Implantation as a means of enhancing the permselectivity of polymers. Pursue the most promising respiratory and percutaneous technologies (identified in the FY00 IP Front-End-Analysis) to the reduce respiratory resistance imposed by mask filters and the thermal load imposed by protective clothing. Pursue technologies to support the rapid deployment/establishment of CP Shelters thus reducing the logistical burden normally associated with CP shelters.
- 1000 Simulants for C/B Agents: Evaluate simulant requirements in light of new technology, testing procedures, and environmental and medical issues. Prepare breakthrough simulants for novel and emerging agents for which no simulants currently exist. These new simulants will reduce costs and result in improved testing and evaluation of new defensive equipment.

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PROJECT CB2		
FY 2001 Planned Program (Cont):		
• 1000	Biological Detection Technologies: Develop technologies for highly multiplexed identification of biological agents implemented on platforms such as PCR and flow cytometry. This effort will greatly expand the number of agents identifiable in ensemble ID suites with transitions to JBPDS Blk II and to upgrade of fielded systems. The effort will also develop capability to characterize "unknown" biological agents (i.e., agents for which no assay exists).	
Total	37721	
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TB2
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COST (In Thousands)	FY 1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
TB2 MEDICAL BIOLOGICAL DEFENSE (Applied Research)	12175	22206	21509	30017	31638	22088	22985	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TB2 MEDICAL BIOLOGICAL DEFENSE (Applied Research): This project funds applied research (pre-MS 0) on the development of vaccines, therapeutic drugs and diagnostic capabilities to provide an effective medical defense against validated biological threat agents including bacteria, toxins, viruses and other agents of biological origin. Innovative biotechnological approaches and advances will be incorporated to obtain medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Broad categories for this project include countermeasures (vaccines and therapeutics) to bacteria, toxins, and viruses; diagnostics; and broad spectrum generic medical countermeasures (not agent specific). A subset activity underlying each category is the development of an understanding of the pathogenesis (mechanisms of disease) of these agents to include an understanding of functional genomics of threat agents. Acquiring complete genetic information of validated and novel threat agents provides a strong foundation for development of future medical countermeasures and rapid diagnostics. The broad categories may occasionally address more than a single agent group (i.e., bacterial/viral countermeasures reflects a focus on both groups of agents).

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2 - Applied Research**0602384BP CHEMICAL/BIOLOGICAL DEFENSE
(APPLIED RESEARCH)****TB2****FY 1999 Accomplishments:**

- 591 Bacterial Countermeasures - Evaluated virulence and protective efficacy of live attenuated Brucellae mutant vaccines in animal models and identified two new model systems in which to assess attenuated mutants of Burkholderia mallei (glanders).
- 3754 Bacterial Countermeasures - Identified adjuvants to enhance immunogenicity of glanders vaccine candidates; constructed recombinant vaccine candidates and evaluated mechanisms for attenuating the agent for typhus vaccine; characterized genetic vectors for plague antigens (F1 and V); and studied host responses to additional plague antigens. Explored use of attenuated anthrax as a vector on other vaccine antigens and conducted comparative serologic study of five species of laboratory animals immunized with licensed anthrax vaccine.
- 1970 Toxin Countermeasures - Tested long-term efficacy of Staphylococcal enterotoxin B (SEB) vaccine candidates and demonstrated that mucosal vaccination elicits protective immunity.
- 500 Toxin Countermeasures - Developed in vitro models and bioassays for evaluating ricin vaccine candidate characteristics and therapeutic compounds.
- 1839 Viral Countermeasures - Identified promising antiviral compounds by screening for therapeutic activity against filoviruses and orthopox viruses in animal models of infection and identified protective monoclonal antibody for Ebola; demonstrated utility of DNA vaccine for orthopox virus immunization.
- 519 Toxin Countermeasures - Determined first complete high resolution crystal structure for botulinum neurotoxin in support of therapeutic drug design and identified promising inhibitors of botulinum toxin enzymatic activity.
- 557 Diagnostics - Applied advanced diagnostic technologies for research in diagnostics tests and devices. Determined methods to extract target molecules for diagnostics from multiple types of biological samples (urine, blood, nasal swabs, etc.).
- 1594 Diagnostics - Developed methods to evaluate mechanisms for increasing the stability (shelf-life) of immunological and nucleic acid diagnostic reagents for field use; demonstrated rapid specimen processing of whole blood using portable automatic device and solid phase methods for purification of nucleic acids without use of hazardous chemicals.
- 851 Bacterial/Viral/Toxin Countermeasures - Incorporated various genes coding for antigens from Bacillus anthracis protective antigen (PA), botulinum toxin, and plague into the virus replicon vector and tested for gene expression using in vitro systems for developing multi-agent vaccines.

Total 12175

RDT&E BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)

DATE

FEBRUARY 2000

BUDGET ACTIVITY

2 - Applied Research

PE NUMBER AND TITLE

**0602384BP CHEMICAL/BIOLOGICAL DEFENSE
(APPLIED RESEARCH)**

PROJECT

TB2**FY 2000 Planned Program:**

- 699 Bacterial Countermeasures - Evaluate antimicrobial agents for treatment of infections caused by aerosolized *B. mallei*, the causative agent of glanders.
- 2489 Bacterial Countermeasures - Characterize plague virulence factors as vaccine antigen candidates; explore surrogate markers of protection for validated bacterial threat agents; evaluate new generation of antibiotics for therapeutic efficacy against bacterial threat agents.
- 1740 Viral Countermeasures - Define surrogate markers of immunity and other assessment modalities for filovirus immunity, additional strains of equine encephalitis viruses (VEE, EEE, and WEE), and a common vaccine platform leading to a multivalent equine encephalitis vaccine.
- 436 Viral Countermeasures - Analyze and characterize candidate antiviral compounds generated from previous assessment studies for therapeutic activity against orthopox viruses and filoviruses; explore feasibility of DNA-based orthopox virus vaccines.
- 1302 Toxin Countermeasures - Develop therapeutics (peptides and synthetic compounds) for SEB, botulinum neurotoxin, and ricin toxin based on rational drug design and molecular structure of the toxins.
- 2174 Bacterial/Viral Countermeasures - Investigate cellular mediators (cytokines, chemokines and cell surface receptors) during infection and evaluate immunomodulation as a potential countermeasure approach; evaluate the immune response to filoviruses for potential exploitation of immunomodulation as a countermeasure to threat agents.
- 1071 Bacterial/Viral Countermeasures - Establish the correlation of known surrogate markers of immunity with efficacy of existing vaccines and therapeutics in established model systems (two animal models). Establish usefulness of candidate medical countermeasures to potential genetically engineered microbes and emerging threat agents.
- 4716 Bacterial/Viral Countermeasures/Diagnostics (Medical Biological Defense Protocols) - Develop protocols to enhance biological defense by sequencing information on virulence factors, whole organism genomes, and antibiotic resistance markers and obtain information from existing databases and previously conducted and concurrent basic research to generate a comprehensive BW threat agent database; evaluate data for evidence of common patho-physiological mechanisms among threat agents; exploit information in development of novel medical countermeasures and diagnostic platforms.
- 1044 Diagnostics - Define and characterize immunological and nucleic acid-based methodologies leading to the development of rapid diagnostic capabilities for all biological threat agents.
- 2133 Diagnostics - Define nucleic-based screening methodologies to allow rapid identification and genetic association of relatedness/distance between biological agents.
- 2340 Generic Medical Countermeasures/Diagnostics - Apply sample processing technologies to develop diagnostic tests and devices. Apply agent pathogenesis and protective immunology to establish candidate countermeasures. Establish biochemical or molecular target sites for intervention from genomic sequencing information.

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DATE

FEBRUARY 2000

BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

2 - Applied Research**0602384BP CHEMICAL/BIOLOGICAL DEFENSE****TB2****(APPLIED RESEARCH)****FY 2000 Planned Program (Cont):**

- 1740 Bacterial/Viral/Toxin Countermeasures - Evaluate prior studies performed with individual and combined vaccine candidate components (antigens, DNA, viral vectors, etc.) and determine components to be incorporated into combined multi-agent vaccine candidate.
- 322 SBIR/STTR.

Total 22206

FY 2001 Planned Program:

- 2054 Toxin Countermeasures - Continue defining animal models for aerosol exposure to SEB, botulinum neurotoxin, and ricin toxin. Explore laboratory preparations of candidate botulinum toxin, ricin toxin, and/or SEB vaccines using various adjuvants to enhance immunogenicity.
- 443 Viral Countermeasures - Continue exploration of DNA-based vaccines for orthopox viruses and of the role of antibodies in protection from filoviruses.
- 3759 Toxin Countermeasures - Define protective end-points and surrogate markers for determining the effectiveness of therapies for botulinum neurotoxin and Staphylococcal enterotoxin (SE) threats.
- 1771 Viral Countermeasures - Continue analysis and characterization of candidate antiviral compounds for therapeutic activity against filoviruses and orthopox viruses.
- 1062 Diagnostics - Continue characterization of immunological and nucleic acid-based diagnostic platform methodologies leading to the development of rapid diagnostic device(s) able to identify all biological threat agents.
- 2833 Diagnostics - Develop and evaluate diagnostic assays for virulence factors from Yersinia pestis and other validated bacterial threat agents.
- 4812 Generic Medical Countermeasures - Refine diagnostic technologies (sample and agent processing) as applied directly to the diagnostic tests and devices, emphasizing specific genetic targets. Define therapeutic interventions at the molecular or biochemical level based on genomic sequencing. Refine basic research studies applying technologies to develop novel vaccines or therapies against genetically engineered threats. Define the correlation of known surrogate markers of immunity with efficacy of existing vaccines and therapeutics in established model systems. Characterize promising generic medical countermeasures against threat agents for exploratory development studies in suitable model systems.
- 2423 Bacterial Countermeasures - Continue defining animal models for aerosol exposure to B. mallei (glanders). Explore laboratory formulations of candidate glanders vaccines using various adjuvants to enhance immunogenicity.
- 887 Viral Countermeasures - Evaluate potential interference effects of combined candidate vaccine components in multi-agent vaccines. Select multi-agent vaccine candidates that protect against three or more different threat agents.

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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	
PROJECT TB2		
FY 2001 Planned Program (Cont):		
<ul style="list-style-type: none"> • 	1465 Bacterial Countermeasures - Continue research on surrogate markers of protection for validated bacterial threat agents and evaluate new generation antibiotics for therapeutic efficacy against bacterial threat agents.	
Total	21509	

UNCLASSIFIED

RDT&E BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)	DATE FEBRUARY 2000
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BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT TC2
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COST (In Thousands)	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
TC2 MEDICAL CHEMICAL DEFENSE (Applied Research)	13563	13468	14370	15723	15971	15727	15175	Continuing	Continuing

A. Mission Description and Budget Item Justification:

Project TC2 MEDICAL CHEMICAL DEFENSE (Applied Research): This project funds medical chemical defense applied research, and emphasizes the prevention of chemical casualties through application of pharmaceuticals for prevention and treatment of the toxic effects of nerve, blister, respiratory, and blood agents. This project supports applied research of prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic compounds that will counteract the lethal, physical, and behavioral toxicities of chemical agents. It also supports development of medical chemical defense materiel that ensures adequate patient care, field resuscitation, and patient management procedures.

FY 1999 Accomplishments:

- 5430 Diagnostics - Evaluated analytical procedures in animal models to diagnose and monitor vesicant-induced injury using commercially available instrumentation. Therapeutics - Determine novel mechanisms of action of vesicant agents.
- 1936 Therapeutics - Developed animal models to evaluate skin graft and antimicrobial wound dressings and treatments for blister agents. Assessed the efficacy of antibiotic/steroid ophthalmic preparations for HD-induced injury. Optimized formulations for sponges, towelettes, and surgical pads containing scavenger enzymes for use in wound decontamination.
- 1201 Pretreatments and Therapeutics - Developed enhanced scavengers for nerve agents, characterized the structural alterations of physiologically significant enzymes that are inhibited by nerve agents.
- 1353 Pretreatments and Therapeutics - Assessed the efficacy of leading reactive components of a reactive topical skin protective barrier cream and developed animal decontamination models.
- 3078 Pretreatments and Therapeutics - Developed biological markers to monitor long-term effects of low dose or chronic exposure to CW agents. Evaluated FDA approved pharmaceuticals as potential nerve agent anticonvulsants. Developed an improved electroencephalogram (EEG) test model to evaluate anticonvulsant action of leading compounds against acute and chronic nerve agent poisoning.

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DATE

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BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

2 - Applied Research**0602384BP CHEMICAL/BIOLOGICAL DEFENSE****TC2****(APPLIED RESEARCH)****FY 1999 Accomplishments (Cont):**

- 565 Therapeutics and Diagnostics - Designed and tested an enzyme-based skin and wound decontamination system. Developed far-forward, rapid diagnostic tests for blister and nerve agents for real-time analysis of clinical samples.

Total 13563

FY 2000 Planned Program:

- 3940 Diagnostics - Identify promising analytical procedures for diagnosis and dosimetry of vesicant-induced inflammation.
- 757 Diagnostics - Assess the efficacy of far-forward, rapid diagnostic tests for blister and nerve agents for real-time analysis of clinical samples on the battlefield.
- 1144 Pretreatments - Identify best candidates of genetically engineered scavengers as next generation antidotes for nerve agents.
- 5151 Therapeutics - Assess the efficacy of new, improved countermeasures to vesicant exposure in several model systems, both in vitro and in vivo. Assess the efficacy of antibiotic/steroid ophthalmic preparations for HD-induced injury. Optimize formulations for sponges, towelettes, and surgical pads containing scavenger enzymes for use in wound decontamination.
- 644 Pretreatments and Therapeutics - Estimate the protection achievable by existing countermeasures to novel threat agents.
- 1637 Therapeutics and Diagnostics - Identify pharmacological, physiological, or toxicological methods for monitoring long-term, low-level effects of chemical warfare agents.
- 195 SBIR/STTR.

Total 13468

FY 2001 Planned Program:

- 2442 Pretreatments - Test best candidates of genetically engineered scavengers using advanced test systems, e.g., transgenic or knockout species.
- 4568 Therapeutics - Employing identified models, determine pharmacological, physiological, and toxicological effects of long-term, low-level chemical warfare agents.
- 883 Therapeutics - Assess the efficacy of antibiotic/steroid ophthalmic preparations for HD-induced injury. Optimize formulations for sponges, towelettes, and surgical pads containing scavenger enzymes for use in wound decontamination.

RDT&E BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)		DATE FEBRUARY 2000
BUDGET ACTIVITY 2 - Applied Research	PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	
FY 2001 Planned Program (Cont):		
<ul style="list-style-type: none"> • • 	<ul style="list-style-type: none"> 2217 Pretreatments and Therapeutics - Assess the efficacy of fielded, advanced development, and exploratory development countermeasures to novel threat agents. 4260 Pretreatments and Therapeutics - Using a drug decision approach (decision tree network), evaluate the efficacy of lead vesicant countermeasure compounds identified in earlier screening efforts. 	PROJECT TC2
Total	14370	