

**UNCLASSIFIED**

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)</b>	DATE <b>February 2003</b>
---	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/          BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED          RESEARCH)</b>
---	---

COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	145706	173362	106451	104385	101916	88711	86059	85014	Continuing	Continuing
CB2 CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	93534	113169	65872	63494	66507	52915	49249	50169	Continuing	Continuing
TB2 MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	34195	40977	22699	22622	15415	15692	16442	13095	Continuing	Continuing
TC2 MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	17977	19216	17880	18269	19994	20104	20368	21750	Continuing	Continuing

Line No: 017	Page 1 of 70 Pages	Exhibit R-2 (PE 0602384BP)
--------------	--------------------	----------------------------

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)</b>	DATE <b>February 2003</b>
---	------------------------------

BUDGET ACTIVITY  
**RDT&E DEFENSE-WIDE/  
BA2 - Applied Research**

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

**A. Mission Description and Budget Item Justification:** The use of chemical and biological weapon systems in future conflicts is an increasing threat. Funding under this PE sustains a robust program, which reduces the danger of a 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. This program also provides for conduct of applied research in the areas of real-time sensing and immediate biological countermeasures. This PE also provides concept and technology demonstrations of new system concepts that will shape the development for environmental monitoring, medical surveillance, and data mining/fusion/analysis subsystems. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. Efforts under this PE transition to and provide risk reduction for Advanced Technology Development (PE: 0603384BP), Advanced Component Development and Prototypes (PE: 0603884BP) and System Development and Demonstration (PE: 0604384BP). This project includes non-system specific development directed toward specific military needs and therefore is correctly placed in Budget Activity 2.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)</b>	DATE <b>February 2003</b>
---	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>
---	--

<b>B. <u>Program Change Summary:</u></b>	<b><u>FY 2002</u></b>	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>
Previous President's Budget (FY 2003 PB)	146431	262177	95242	94494
Current Biennial Budget Estimates (FY 2004/2005)	145706	173362	106451	104385
Total Adjustments	-725	-88815	11209	9891
a. Congressional General Reductions	-4225	-143615	0	0
b. Congressional Increases	3500	54800	0	0
c. Reprogrammings	0	0	0	0
d. SBIR/STTR Transfer	-775	0	0	0
e. Other Adjustments	0	0	11209	9891

**Change Summary Explanation:**

**Funding:** FY03 - Transfer to the Department of Homeland Security Bioterrorism initiatives (-\$137,000K HS2).

FY03 - Adjustment for CBD (+\$42,900K CB2; +\$9,800K TB2; +\$2,100K TC2; ) to fund high priority programs.

FY04 - Adjustment to provide for special investigations into Chem Bio defense technology to include threat agents, operational sciences, modeling, simulants, and nuclear, biological, chemical survivability (CB2 - \$+\$13,000K).

FY05 - Adjustment to provide for special investigations into Chem Bio defense technology to include threat agents, operational sciences, modeling, simulants, and nuclear, biological, chemical survivability (CB2 - \$+\$12,000K).

**Schedule:**

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

DATE **February 2003**

BUDGET ACTIVITY  
**RDT&E DEFENSE-WIDE/  
BA2 - Applied Research**

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

**Technical:**

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
---	---	-----------------------

COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
CB2 CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	93534	113169	65872	63494	66507	52915	49249	50169	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 via reconnaissance, individual and collective protection, and decontamination. The project provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and nuclear, biological, chemical (NBC) survivability. This project focuses on horizontal integration of CB defensive technologies across the Joint Services. The Defense Technology Objectives (DTOs) provide a means to shape the development of selected technologies within this project.

**B. Accomplishments/Planned Program**

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Detection	29820	27349	18900	16800

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments:**

- 2200 Chemical Imaging Sensor (DTO-CB19) - Demonstrated a 16-pixel spectrometer operating at 360 Hz with off-line processing of data.
- 1600 Biological Sample Preparation System (BSPS) for Biological Identification (DTO-CB20) - Initiated evaluation of a new series of taggant chemistry for multi-agent, multiplexing Polymerized Chain Reaction (PCR) assays to reduce overall number of needed assays. Evaluated fluidic systems from PCR breadboard to reduce processing time, target was 20 minutes for sample processing.
- 4905 Detection of Agent in Water (DTO-CB37) - Completed construction of initial breadboard component candidates. Completed testing of component candidates to identify shortfalls. Initiated a limited military utility assessment to demonstrate technology.
- 3815 Point Detection, Biological Identification - Continued development of Force Discrimination Assay (FDA). Continued development of concepts for automation and initiated testing of chip-based phylogenetic analysis of biological materials. Initiated evaluation of quantum dot technology for application to enhance antibody ticket technology for improved stability and sensitivity. Identified combinatorial peptides as potential simulants for biological agents.
- 1690 Point Detection, Detector Modifications - Initiated modification of point detection systems to enhance performance against new chemical targets. Initiated assessment of modifications on system impacts to power usage, reliability, and overall system life expectancy. Broadened spectral knowledge base to predict performance of active and passive IR sensors for detection of surface contamination. Initiated evaluation of novel materials and material treatment solutions to decrease penetration of aerosol particulates through overgarments. Transitioned to Advanced Technology Development (6.3).

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments (Cont):**

- 6560 Point Detection, Integrated CB Detection - Initiated characterization of biomarkers observed in Py-GC-IMS sensors against performance matrix of sensitivity, selectivity, and interference rejection for optimal design trade-off analysis. Initiated evaluation and development of novel concepts, methodologies, and techniques for biological discrimination, advanced aerosol handling, and triggering capabilities for chemical aerosols.
- 6400 Standoff Detection, Biological Standoff - Investigated new and novel methods for detecting biological aerosols. Technologies included Brillouin Spectroscopy, Passive Interferometry, and Polarized Light Scattering.
- 1300 Standoff Detection, Chemical Standoff - Collected quantitative vapor and diffuse reflectance data on chemical simulants.
- 1350 Standoff Detection, Integrated CB Detection - Initiated a program to develop technology to detect the presence of CBW contaminants on surfaces for use in vehicular and handheld systems Joint Service Chemical Detector (JSCD). Initial studies focused on active and passive optical technologies that could be employed on or from a vehicular platform. Conducted assessment of standoff technologies that may be implemented simultaneously against chemical and biological agents. Initiated a program to develop a wide agent spectral range technology to detect the presence of CBW vapors, aerosols, and rains (WideSpec).

**Total** 29820

**FY 2003 Planned Program:**

- 900 End-of-Service-Life Indicators for NBC Mask Filters (DTO-CB36) - Complete baseline evaluations of candidate technologies. Downselect best candidate technologies. Fabricate and evaluate ESLI/filter concept models. Optimize baseline design and determine optimum ESLI location.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program (Cont):**

- 4500 Standoff Biological Aerosol Detection (DTO-CB35) - Initiate construction and characterization of breadboards to demonstrate the capability to detect and discriminate (bio vs. non-bio) biological agents at a concentration of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km based on the results of the downselect and user input.
- 1800 Wide Area Aerial Reconnaissance for Chemical Agents (DTO-CB53) - Perform airborne phenomenology tests with existing hyperspectral imaging sensors (100-Hz, 2x8 TurboFT and 0.3-Hz, 128x128 AIRIS). Complete engineering designs for a 30-Hz, 64-pixel TurboFT, and a 3-Hz, 128x128 AIRIS.
- 5900 Integrated CB Standoff Detector (DTO-CB49) - Conduct initial downselection of potential technologies based on market survey and user input. Downselection process will involve user community as well as internal and external technical experts and will include factors such as performance, logistics, platform, operational concerns, maturity, and cost. Initiate the development and testing of higher risk subcomponents to minimize the risk in the later breadboard development phase to demonstrate the capability to detect chemical agents at a concentration of 135 mg/m<sup>2</sup> and biological agents at a concentration of 3,000 agent containing particles per liter of air (ACPLA) at a range of 1 km.
- 1300 Decontamination, Solution Chemistry - Optimize formulations for chemical and biological decontamination systems. Initiate material compatibility and efficacy testing on an expanded test bed for promising approaches. Optimize an innovative catalytic buffering system to provide pH control in solution decon formulations. Complete final kinetics and panels testing for the combined enzyme decontamination system.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program (Cont):**

- 1400 Biological Sample Preparation System (BSPS) for Biological Identification (DTO-CB20) - Continue development of new taggant chemistry for multi-agent, multiplexing PCR assays. Conduct a feasibility analysis on what is required to make multiplex and multi-agent assays cost effective. Conduct an analysis of alternatives based on feasibility study to design an optimized platform using multi-agent, multiplexing PCR assays.
- 2700 Detection of Agent in Water (DTO-CB37) - Complete downselection of technology for the detection of chemical agents in potable water. Continue technology development of detection of biological agents in potable water to include sample processing and preparation.
- 4100 Point Detection, Biological Identification - Complete development of Force Discrimination Assay (FDA). Continue development and testing automation of chip-based phylogenetic analysis of biological materials. Demonstrate quantum dot technology for application to enhance antibody ticket technology for improved stability and sensitivity. Conduct evaluation and development of database for protein markers from biological agents for mass spectroscopy based systems. Evaluate the potential of aptamers as substitutes for antibodies in current platforms.
- 3650 Lightweight Integrated CB Detection - Develop and evaluate technologies. Develop and populate database for downselection criteria. Initiate an analysis of alternatives to downselect best technologies to meet the requirements of the Joint Modular CB Detector. Focus on physical methodologies like optical spectroscopy and pyrolysis gas chromatography ion mobility spectroscopy to address the requirements.
- 1099 Point Detection, Integrated CB - Initiate exploration of new concepts for small, combined chemical and biological identifiers. Continue evaluation and development of millimeter wave spectroscopy and data fusion techniques to combine chemical and biological detection requirements.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
--	--	-----------------------

**FY 2003 Planned Program (Cont):**

**Total 27349**

**FY 2004 Planned Program:**

- 4500 Standoff Biological Aerosol Detection (DTO-CB35) - Complete construction and characterization of breadboards to demonstrate the capability to detect and discriminate (bio vs. non-bio) biological agents at a concentration of 1,000 agent containing particles per liter of air (ACPLA) at a range of 1 km.
- 1500 Wide Area Aerial Reconnaissance for Chemical Agents (DTO-CB53) - Develop a 30-Hz frame rate, 64-pixel Fourier transform infrared (FTIR) hyperspectral imager (TurboFT). Perform sensor characterization tests. Develop off-line algorithms and signal processing techniques.
- 3700 Integrated CB Standoff Detector (DTO-CB49) - Complete development and testing of the higher risk subcomponents to project the capability to detect chemical agents at a concentration of 135 mg/m<sup>2</sup> and biological agents at a concentration of 3,000 agent containing particles per liter of air (ACPLA) at a range of 1 km. Complete the final downselection of the most promising technology(ies). The final downselection will be supported by the results and data obtained in the previous subcomponent development phase.
- 7200 Detection of CB Contamination on Surfaces (DTO-CB52) - Complete construction and conduct initial characterization of breadboard(s) to demonstrate the capability to detect chemical agents at a deposition of 0.5 g/m<sup>2</sup> and operationally significant biological agent contamination levels. Perform final downselection.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

<b>BUDGET ACTIVITY</b> <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	<b>PE NUMBER AND TITLE</b> <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	<b>PROJECT</b> <b>CB2</b>
---	---	------------------------------

**FY 2004 Planned Program (Cont):**

- 2000 Point Detection, Biological Identification - Complete development and testing automation of chip-based phylogenetic analysis of biological materials. Identify engineering/manufacturing issues for the transition of quantum dot technology to the Critical Reagent Program for application to enhance antibody ticket technology for improved stability and sensitivity.

**Total** 18900

**FY 2005 Planned Program:**

- 2600 Standoff Biological Aerosol Detection (DTO-CB35) - Optimize overall system performance based on test results obtained from testing.
- 1500 Wide Area Aerial Reconnaissance for Chemical Agents (DTO-CB53) - Develop a 3-Hz, 128x128 tunable hyperspectral imager (AIRIS). Perform sensor characterization tests. Develop off-line algorithms and signal processing techniques.
- 4100 Integrated CB Standoff Detector (DTO-CB49) - Initiate breadboard construction of the final downselected technology(ies) to demonstrate the capability to detect chemical agents at a concentration of 135 mg/m<sup>2</sup> and biological agents at a concentration of 3,000 agent containing particles per liter of air (ACPLA) at a range of 1 km.
- 4500 Detection of CB Contamination on Surfaces (DTO-CB52) - Upgrade and test breadboard(s) based on results of characterization. Demonstrate the capability to detect chemical agents at a deposition of 0.5 g/m<sup>2</sup> and operationally significant biological agent contamination levels.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
--	--	-----------------------

**FY 2005 Planned Program (Cont):**

- 4100 Point Detection, Integrated CB Point Detection - Initiate exploration and concept development for new concepts for small, combined chemical and biological identifiers. Conduct feasibility studies and perform a cost to benefit analysis on "low consumable or reagentless" concepts. Initiate breadboard system and component design for a fieldable detector at ambient conditions. Complete testing of novel algorithms for improved chemical and biological discrimination.

**Total** 16800

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Protection	9976	8250	5700	6528

**FY 2002 Accomplishments:**

- 1100 Advanced Adsorbents for Protection Applications (DTO-CB08) - Developed an improved/modified ASZM-TEDA adsorbent that enhances the protection against ammonia and formaldehyde. Identified adsorbent bed compositions that provided reduced JSGPM/JSAM encumbrance (pressure drop; weight; size). Evaluated chemical removal performance of ASZM-TEDA adsorbent and approximately 500 other novel adsorbent materials against design limiting Toxic Industrial Chemicals (TICs). Developed initial concept compositions and transitioned novel adsorbents for removal of TICs for incorporation into the JSGPM.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments (Cont):**

- 800 End-of-Service-Life Indicator for NBC Mask Filters (DTO-CB36) - Initiated development of baseline data characterizing the performance of the most promising End-of-Service-Life Indicator (ESLI) technologies. Assessed performance parameters including reaction time, range of detection, and effects of temperature and humidity using carbon bed test cells.
- 1200 Self-Detoxifying Materials for Clothing Applications (DTO-CB45) - Assessed enzymes, polyoxometalates, and cyclodextrins for their incorporation into nanofibers for agent deactivation. Identified candidate reactive nanoparticle candidates for incorporation into films and fibers for improved barrier protection. Developed a process to bind N-halamines to target clothing material, and initiated testing to characterize and quantify the reactivity of treated materials.
- 2201 Collective Protection, Filtration - Completed single pass filtration model validation and evaluated candidate adsorbents against high priority TICs and for use in regenerative filtration applications. Demonstrated single pass filter concepts using nano-materials. Initiated proof-of-principle testing and evaluation of 50 CFM pressure-temperature swing adsorption filter to validate model. Evaluated and identified best performing candidate adsorbents for use in regenerative filtration (P/TSA) applications. Initiated evaluation of electrostatic filter particulate and aerosol capture enhancement and degradation effects of TICs on HEPA filters and ways to mitigate. Initiated trade study assessment on the feasibility and application of open and closed circuit air supply and rebreather technologies. Developed Residual Life Indicator (RLI) test beds at Naval Research Lab (NRL) and Edgewood Chemical and Biological Center (ECBC), continued chemical sensor RLI testing, and started physical sensor testing.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments (Cont):**

- 1222 Collective Protection, Shelters - Completed Collective Protection Front End Analysis and Master Plan. Continued development and evaluation of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals). Developed new CB skin material, identified and evaluated commercial waterproof zippers, developed and designed prototype linear track profiles, assessed four hermetic sealing methodologies for current set of shelter materials. Initiated development and assessment of chemistries for self-decontaminating shelter materials. Provided initial assessment of failure mechanisms of shelter materials to conventional weapons blast pressure effects.
  
- 1924 Individual Protection, Clothing - Optimized aerosol threat mediation material (nanofiber web) and processes resulting in a more durable fabric system. Initiated the testing of fielded and developmental protective garment materials to evaluate their effectiveness against TICs. Conducted laboratory trials to enhance the permselectivity of membranes by ion implantation, and characterized the material physical properties and CB agent protection capabilities of those trial membranes. Demonstrated through a DUST effort the large scale production of protective membrane-based garments for military and civilian applications and submitted candidates to the JSLIST Alternate Source Qualification program for consideration. Identified the most promising permselective membrane candidates and initiated the characterization of those candidates. Examined novel materials and material treatment solutions to decrease penetration of non-traditional threat agents (NTA) aerosols through overgarments.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments (Cont):**

- 1529 Individual Protection, Masks - Completed concept studies for the long-term integrated mask/helmet. Completed preliminary technology feasibility studies for advanced mask concepts. Compared existing filtration media with reactive iodine media with respect to physical properties (such as pressure drop and dust/particulate removal), and transitioned further development to the Air Purification Systems project. Screened candidate sorbent media structures to evaluate their critical properties, and identified the three best candidates for further development. Screened candidate advanced lens materials to evaluate their critical properties and downselected to three materials for further development. Identified available technologies that can be used for assessing mask characteristics critical for improved protection, flow dynamics, heat and moisture transfer, and fogging.

**Total** 9976

**FY 2003 Planned Program:**

- 1200 Advanced Adsorbents for Protection Applications (DTO-CB08) - Complete database and model of adsorption equilibrium and rate processes for four agent classes. Identify at least one adsorbent bed composition that provides the level of protection required by the JSGPM, JCPE, and JTCOPS programs for all CW agents and the highest priority TICs. Develop at least one adsorbent bed composition providing for effective P/TSA system performance (meeting JCPE requirements) for all chemical warfare agents and all high priority TICs.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program (Cont):**

- 1900 Collective Protection, Filtration - Complete database and model of adsorption equilibrium and rate processes for high priority TICs. Complete development of initial pressure, temperature, and electrical swing adsorption (P/T/E/SA) regeneration models and fabrication of test stands. Complete proof-of-principle testing and evaluation of 50 CFM pressure-temperature swing adsorption filter to validate model. Initiate 200 CFM pressure-temperature swing adsorption filter to assess scalable model and applicability for advanced system integration. Optimize candidate adsorbents for use in regenerative filtration (P/T/ESA) applications that are effective against a wide spectrum of TIC and Chemical Warfare Agents (CWA). Complete evaluation of electrostatic and biocidal filter enhancement for aerosol and particulate capture and deactivation. Evaluate degradation effects of TICs on HEPA filters and ways to mitigate. Initiate literature review for developing hybrid air purification systems incorporating technologies providing broad protection. Finish trade study assessing feasibility and application of open and closed circuit air supply and rebreather technologies. Complete chemical and physical Residual Life Indicators sensor testing.
  
- 900 Collective Protection, Shelters - Continue development and evaluation of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals). Test new CB skin material including constructed shelter systems. Continue development and testing of chemistries for self-decontaminating shelter materials. Complete initial assessment and modeling of shelter materials failure mechanisms to conventional weapons blast pressure effects and transition to JCPE.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program (Cont):**

- 1500 Self-Detoxifying Materials for Clothing Applications (DTO-CB45) - Continue to assess new reactive compounds and treatments for improved detoxification in membranes. Develop concepts for nanoreactors and surface-migrating phases for improved agent breakdown within membranes and coatings. Select relevant reactive nanoparticles and polymeric materials for subsequent processing and testing studies. Characterize the reaction kinetics and loading capacity of N-halamines treated materials with CWA simulants.
  
- 1050 Individual Protection, Clothing - Complete testing of fielded and developmental protective garment materials to evaluate their effectiveness against TICs, and provide recommendations to the user community. Characterize the surface phenomena occurring in ion implanted polymers and determine the transport properties of moisture and chemicals of those polymers. Complete transport and physical characterization of selected candidate permselective membranes, and initiate detailed analysis of structure-property relationships. Optimize materials and material treatment solutions for overgarments to improve protection against Non Traditional Agents (NTA) aerosols. Identify sampling techniques and assess clothing air velocities as an initial step in evaluating the effects of atmospheric temperature and wind on agent penetration of individual protective equipment (IPE). Validate recent research which indicates that intermittent cooling to various body regions can provide as much cooling benefit (in terms of core temperature reduction) as cooling continuously, but at a fraction of the Maneuver Control System (MCS) capacity.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program (Cont):**

- 1700 Individual Protection, Masks - Begin development of advanced mask concepts focusing on lightweight system integration, a wider range of protection, and improved thermal attenuation. Assemble advanced mask concept prototypes for preliminary human factor studies. Initiate optimization of candidate sorbent media structures by the testing of media properties and the modification of that media to improve performance. Optimize candidate lens materials through the evaluation of chemical and physical properties and the modification of that material to enhance performance. Develop and evaluate new and improved mask technologies to improve protection through novel sealing and pressurization options. Identify appropriate aerosol generation and detection equipment, develop and validate test procedures, and conduct protection factor study using mask headform tester and controlled leaks.

**Total** 8250

**FY 2004 Planned Program:**

- 1100 Advanced Adsorbents for Protection Applications (DTO-CB08) - Validate model of single-pass and regenerative filtration adsorption models. Complete performance verification of adsorbents for use in NBC filtration systems. Selected adsorbent beds will undergo performance verification testing to fully assess the performance constraints expected in the host filter system. These evaluations will consider adsorbent bed performance under a wide range of agent challenge concentration scenarios and environmental conditions.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
--	--	-----------------------

**FY 2004 Planned Program (Cont):**

- 500 Collective Protection, Filtration - Characterize constraints of mature candidate adsorbent compositions, including aging, cyclic flow capacity, relative humidity, temperature and material compatibility. Assess chemical removal performance of prototype JSGPM filters containing adsorbent developed under DTO-CB08. Characterize constraints of mature candidate adsorbent compositions against a wide range of TIC and CWA including aging, chemical reaction regeneration cycles, relative humidity, temperature, and material compatibility. Optimize regenerative process (including, temperature, pressure, ECS, cycle time) using verified candidate adsorbent materials. This task will mature the technology for future consideration as an advanced technology demonstrator. Complete literature review and technical workshop for developing hybrid air purification systems incorporating technologies providing broad protection. Downselect anti-microbial aerosol/particulate media, complete initial testing and develop enhanced prototype.
- 1100 Collective Protection, Shelters - Continue development and testing of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals) and constructed shelter systems. Identify and test optimal chemistries for self-decontaminating shelter materials and applications.
- 900 End-of-Service-Life Indicators for NBC Mask Filters (DTO-CB36) - Fabricate and evaluate first-generation ESLI prototype demonstrator units against the target agents to validate achievement of performance goals. The evaluation will include environmental testing to assess the effects of temperature and humidity extremes, long-term storage, and rough handling on ESLI performance.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
<p><b>FY 2004 Planned Program (Cont):</b></p> <ul style="list-style-type: none"> <li>• 1500 Self-Detoxifying Materials for Clothing Applications (DTO-CB45) - Evaluate durability of carbon-loaded melt blown/electrospun liners; measure breakthrough, speed and extent of reaction of agent simulants in scaled up membranes; develop adhesive bonding methodology for elastic detoxifying membrane adhesion to woven and knit fabrics; develop fabric/clothing design to maximize reactive treatments. Prepare and evaluate polymeric films, fibers, and/or permselective membranes with incorporated reactive nanoparticles of selected types and different loading levels. Treat full garments with N-halamines and other oxidative compounds and assess the physical and chemical characteristics of those garments.</li> <li>• 600 Individual Protection, Masks - Refine advanced mask system concepts using actual technologies to the maximum extent possible. Optimize candidate mask sealing options and assess anti-fogging and moisture control technologies.</li> </ul> <p><b>Total 5700</b></p> <p><b>FY 2005 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 1500 Collective Protection, Filtration - Develop hybrid air purification systems that incorporate mature adsorptive regenerative, and catalytic technologies for the purpose of providing broader protection than current single pass filter technology. Develop a matrix model for hybrid air purification systems that can address wide application requirements by providing the optimal mix of technologies. Test advance aerosol/particulate filters providing enhanced biological protection.</li> <li>• 1000 Collective Protection, Shelters - Continue development and testing of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals) and constructed shelter systems. Perform full scale testing of self-decontaminating shelter systems.</li> </ul>		
Project CB2/Line No: 017	Page 20 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

<b>BUDGET ACTIVITY</b> <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	<b>PE NUMBER AND TITLE</b> <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	<b>PROJECT</b> <b>CB2</b>
---	---	------------------------------

**FY 2005 Planned Program (Cont):**

- 1528 Individual Protection, Clothing - Optimize ion implantation conditions for maximum permselectivity and demonstrate optimized membranes. Complete analysis of membrane structure-property relationships, optimize the most promising membranes, evaluate the properties of modified membranes, and produce and evaluate fabric systems which include the optimized membranes. Conduct testing of full garments protected against NTA aerosols, and assess and optimize garment design. Develop swatch test technology for assessing role of wind speed, temperature in challenge penetration of IPE. Initiate development of advanced ensemble closure technologies to reduce/prevent aerosol penetration. Identify thermal management technologies for protective ensemble applications.
- 2500 Individual Protection, Masks - Develop advanced mask system prototypes using enhanced technologies to the maximum extent possible. Continue optimization of candidate sorbent media structures by testing of the properties of the media and modification of that media to improve performance. Continue optimization of candidate lens materials through the evaluation of chemical and physical properties and the modification of that material to enhance performance. Develop at least three technology concepts by integrating best-option technologies and conduct both laboratory and human factor evaluations. Prepare human-use protocol, and conduct human protection factor study with monodisperse inert aerosols.

**Total** 6528

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Decontamination	5829	4100	3500	3400

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments:**

- 900 Decontamination, Enzymatic Decontamination (DTO-CB09) - Completed characterization of H-agent enzymes. Conducted initial efficacy testing of a combined enzyme formulation.
- 1600 Decontamination, Oxidative Decontamination Formulation (DTO-CB44) - Optimized oxidative formulations using a peroxycarbonate-based approach and began kinetics, toxicity, and material compatibility testing. Developed several candidate formulations and evaluated commercial catalysts to improve oxidation rates for a peracid-based decontaminant.
- 1350 Decontamination, Sensitive Equipment - Continued developmental efforts to address Joint Service Sensitive Equipment Decon Program (JSSED) Block II and III approaches focusing on plasma technology and spot cleaning methodology using emerging solvents and solid/solvent suspensions.
- 904 Decontamination, Solid Phase Chemistry - Evaluated the physical limitations of novel solid phase technology for decontamination operations. Efforts focused on nanoscale metal oxides and zeolites. Implemented these findings into other areas of the decon program and determined the best future uses for these materials.
- 1075 Decontamination, Solution Chemistry - Completed a feasibility study examining the potential to combine multiple developmental solution chemistry approaches into single formulations. Initiated live agent screening using dioxiranes. Optimized enzymes effective against GV and other organophosphorous agents.

**Total** 5829

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
<p><b>FY 2003 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 2100 Decontamination, Oxidative Decontamination Formulation (DTO-CB44) - Conduct contact hazard and off-gas testing on coupons and continue material compatibility testing for the peroxy carbonate approach. Optimize formulations using the peracid approach and conduct live agent testing with candidate formulations. Integrate other oxidative approaches into the DTO.</li> <li>• 1200 Decontamination, Sensitive Equipment - Conduct feasibility studies for decontamination technology solutions for JSSSED Block II and III using plasma technology and spot cleaning methodology using reactive solid/solvent suspensions.</li> <li>• 800 Decontamination, Solid Phase Chemistry - Develop and demonstrate novel solid and sorbent decontamination applications using nanoscale metal oxides, solvents, and reactive additives.</li> </ul> <p><b>Total 4100</b></p> <p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 2200 Decontamination, Oxidative Decontamination Formulation (DTO-CB44) - Conduct chamber testing over operational temperature range, finish material compatibility testing, and formulate peroxy carbonate and peracid candidates into a dry powder and/or concentrated liquid. Finalize formulation of newly added oxidative approaches and conduct material compatibility and agent testing.</li> <li>• 500 Decontamination, Sensitive Equipment - Complete plasma technology demonstration for applications in JSSSED Blocks II/III</li> <li>• 800 Decontamination, Solid Phase Chemistry - Conduct materials compatibility studies and coupon validation studies on promising solid phase efforts identified in FY02-03.</li> </ul> <p><b>Total 3500</b></p>		
Project CB2/Line No: 017	Page 23 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
---	---	-----------------------

**FY 2005 Planned Program:**

- 2300 Decontamination, Oxidative Decontamination Formulation (DTO-CB44) - Continue chamber testing over operational temperature range, finish material compatibility testing, and formulate new oxidative approaches into a dry powder and/or concentrated liquid.
- 300 Decontamination, Sensitive Equipment - Conduct technology watch for potential JSSED product improvements.
- 800 Decontamination, Solid Phase Chemistry - Conduct a science and technology level analysis of alternatives on reactive and sacrificial coating materials.

**Total** 3400

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Supporting Science and Technology	14871	12610	18400	18100

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
<p><b>FY 2002 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 2558 Aerosol Technology - Measured quantitative performance of six candidate aerosol collectors for advanced point biological detection technology. Initiated design of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range at wind speeds up to 60 mph. Initiated the design of a new generation of aerosol concentrators using mini-machining technology to reduce size, power consumption, and weight, in order to meet stringent requirements for advanced detection systems. Continued to provide controlled biological simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for Technology Readiness Evaluation (TRE).</li> <li>• 3731 Threat Agents - Continued assessment of gaps in threat agent data, and identified requirements for improved simulants in CB defense materiel development. Initiated a program of small-quantity synthesis for defensive RDT&amp;E, toxicology screening, and characterization of new threat materials (to include persistence properties of novel agents) identified as urgent needs while continuing assessment of long-term needs. Initiated validation studies on simulant BG spores, improvement of simulant Erwinia herbicola, exploration of novel "peptide-based" bio simulants, and selection of new simulants for novel chemical agent aerosols. Initiated research on persistence of bacteria and spores. Initiated establishment of an agent/simulant knowledge base technical information system.</li> <li>• 4405 Low Level Operational Toxicology - Completed miosis threshold studies for second generation agents in rats over extended exposure durations. Completed GF and GB potency ratio studies on rats. Initiated non-rodent animal studies on G agents to support the extrapolation of data to humans. Developed methodology for VX inhalation studies to characterize Ct relationships for low level longer duration exposures. Developed CWA tissue dose metric to quantify exposure and predict toxicological response.</li> </ul>		
Project CB2/Line No: 017	Page 25 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
--	--	-----------------------

**FY 2002 Accomplishments (Cont):**

- 4177 Environmental Fate of Agents - Prepared the agent fate research program master plan. Completed Phase 1 literature survey of reports relevant to the fate of chemical agents deposited onto surfaces. Converted the surface evaporation database to Oracle and expanded to include additional data for use in model development, calibration, and validation. Developed a stand-alone version of current surface evaporation methodology and used for a parameter sensitivity analysis to better focus agent fate laboratory studies. Developed CHEMRAT as an operational analysis tool using existing surface evaporation methodology and threat scenarios. Draft reports have been completed for the Czech 2000/2001 outdoor field trials, and the Czech 2002 field trials have been performed. Constructed wind tunnel facility in the UK has been constructed and is undergoing characterization testing. Techniques appropriate for live agent laboratory testing have been established. An Oversight Panel review has been supported and responded to.

**Total** 14871

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program:**

- 2500 Aerosol Technology - Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological and chemical detection technology, which operates at the Joint Service low temperature requirement (-28 degrees F). Fabricate and test the first brassboards of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range and wind speeds up to 60 mph. Fabricate and test the first brassboards of a new generation of aerosol concentrators and collectors using mini-machining technology to reduce the size, power consumption, and weight of aerosol components in order to meet the stringent requirements for advanced detection systems. Continue to provide controlled biosimulant aerosol challenges and begin providing chemical agent simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for Technology Readiness Evaluation.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program (Cont):**

- 4350 Threat Agents - Complete the assessment of long-term needs in threat agent data and needs for improved simulants in CB defense materiel development. Participate in a collaborative inter-agency laboratory program to fill data gaps and improve simulants. Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials. Identify data gaps for established chemical and biological threat agents. Initiate characterization of fundamental properties of *Y. pestis*. Develop a secure database environment for bioinformatics. Continue assessment of bacteria persistence. Initiate characterization of fundamental properties of a viral family selected by biodefense priorities. Complete research on new simulants for novel chemical threat agents. Continue research on simulant BG spores, exploration of novel "peptide-based" bio simulants, and improvement of simulant *Erwinia herbicola*. Initiate research for a new viral simulant. Continue development of an agent/simulant knowledge base technical information system with emphasis on collection of biological agent and simulant data and quality assessment of chemical and biological agent and simulant data.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program (Cont):**

- 5760 Environmental Fate of Agents - Conduct Phase 2 of the literature survey and analysis effort. A matrix of planned number of tests versus agent and substrate for laboratory, wind tunnel, and open-air scales will be completed. Techniques for formulation and dispersal of thickened agent will be established and documented. The surface evaporation database will be completed to include data found by the literature survey and for painted and other surfaces. Laboratory studies, wind tunnel tests, and field trials for live agents on concrete will be performed and documented. Data will address rates of evaporation, ad/absorption, desorption, decay, and droplet spread; chemical adsorption effects on equilibrium; and contact transfer as a function of time. Data analysis, testing, and modeling will be done to correlate wind tunnel flow conditions to those existing in the outdoor boundary layer. A baseline improved surface evaporation inhalation and contact hazard model will be developed. CHEMRAT will use the baseline model and new threat scenarios.

**Total** 12610

**FY 2004 Planned Program:**

- 2300 Aerosol Technology - Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological and chemical detection technology, which operates at the Joint Service low temperature requirements (-28 degrees F). Design an omnidirectional inlet that performs satisfactorily under all conditions, including high wind speeds. Optimize design, and begin to fabricate second generation brassboards using mini-machining technologies to reduce size, power consumption, and weight of aerosol components in order to meet the stringent requirements for advanced detection systems. Continue to provide biological and chemical simulant aerosols and expand capability to include wider range of aerosol sizes and feed stocks in preparation for Technology Readiness Evaluation.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2004 Planned Program (Cont):**

- 5000 Threat Agents - Publish a Front End Analysis (FEA) based on the prior year assessment of long-term needs in threat agent data and needs for improved simulants in CB defense materiel development. Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continue to characterize fundamental properties of Y. pestis and initiate work on B. mallei. Complete characterization of fundamental properties of a viral family and initiate characterization on a second viral family selected by biodefense priorities. Load bioinformatics database with fundamental non-medical properties. Complete validation studies on simulant BG spores and continue improvement of Erwinia herbicola antigenicity, exploration of novel "peptide-based" bio simulants, and research on a new viral simulant. Continue development of an agent / simulant knowledge base technical information system with emphasis on environmental impact and toxicology data.
- 5500 Low Level Operational Toxicology Studies - Complete inhalation data sets GF in swine and VX in rodent models. Continue to resolve technological challenges generating and sampling very low concentrations of VX for non-rodent models. Test preliminary dosemetric model in swine for cross route extrapolation.
- 5600 Environmental Fate of Agents - Laboratory studies, wind tunnel tests, and field trials for live agents on asphalt will be performed and documented. Wind tunnel tests and field trials will also be done on live grass. Neat and thickened agent will be used, and decay, equilibrium shifts, droplet spread, absorption rate, and contact transfer will be measured in addition to vapor flux versus time.

**Total** 18400

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2005 Planned Program:**

- 2600 Aerosol Technology - Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological and chemical detection technology, which operates at the Joint Service low temperature requirements (-28 degrees F). Complete fabrication and test second generation aerosol concentrators and collectors that use mini-machining technology to reduce the size, power consumption, and weight of aerosol components in order to meet the stringent requirements for advanced detection systems. Demonstrate proof of principle hardware for advanced concentrators and collectors using technologies such as acoustic, electrostatic, and micro fiber. Continue to provide controlled biological and chemical simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for Technology Readiness Evaluation.
  
- 4500 Threat Agents - Continue to synthesize small quantities for defensive RDT&E, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continue to characterize fundamental properties of *Y. pestis* and *B. mallei* and initiate work on *F. tularensis*. Complete characterization of fundamental properties of a second viral family selected by biodefense priorities. Complete improvement of *Erwinia herbicola* antigenicity, and continue exploration of novel "peptide-based" bio simulants and research on a new viral simulant. Initiate characterization of fundamental properties on a viral family selected by biodefense priorities. Continue upgrading the data in the agent/simulant knowledge base technical information system.
  
- 5500 Low Level Operational Toxicology Studies - Complete cross-validation studies for routes of exposure using GB. Develop vapor generation and analytical systems for GD. Initiate VX inhalation data sets in swine.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
---	---	-----------------------

**FY 2005 Planned Program (Cont):**

- 5500 Environmental Fate of Agents - Perform laboratory studies for live agents on soil. Wind tunnel tests and field trials will use live agents on brackish water or alternate substrates. Agents and substrates will address data gaps and current threat situations based on periodic program status evaluation. The final surface evaporation model will be completed and used with CHEMRAT and will transition to the Battle Management acquisition programs. An accuracy estimation for model predictions will also be provided based on model performance versus data assembled under this program.

**Total** 18100

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Information Technology Systems	11801	6301	7492	8000

**FY 2002 Accomplishments:**

- 3393 Bioinformatics - Developed an open source data base with the capacity to acquire genomics (DNA sequencing, DNA array, and genotyping) and proteomics data. Integrated software tools for gathering, statistically assessing and analyzing quantitative proteomics data (from the isotope coded affinity tag [ICAT] approach) in a high throughput proteomic environment. Developed co-precipitation of protein complexes as means to identify protein-protein interactions

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments (Cont):**

- 1808 Battle Management - Conducted Battle Management Front End Analysis (FEA) which identified optimum investment strategy. Completed analysis/and report on tests of non-CB sensors against CB simulant disseminations. Expanded database on non-CB sensor performance through measurement against additional dissemination approaches. Conducted study which assessed value added through data fusion of networked multiple same-type disparate sensors and multiple different disparate sensors.
- 3237 Environment - Completed methodology documentation and validation of VLSTRACK. Increased computational speed and concentration fluctuation representation in next-generation hazard evolution model MESO (small scale used to measure atmospheric motion) with concurrent validation. Improved high resolution computational fluid dynamics model (CBW-CFX) to address realistic droplet size distributions and biological agent decay. Initiated coupling of numerical weather prediction models with existing CB dispersion codes. Initiated refinement of hazard evolution codes to better incorporate effects of the environment on chemical agents.
- 1980 Planning, Training and Analysis - Initiated simulation hazard modeling for systems and forces via distributed simulations systems. Initiated examination of sensitivity of hazard evolution/prediction models for agent toxicity.
- 1383 Simulation Based Acquisition - Identified and planned for highest priority prototyping demonstrations. Initiated coupling of CBD commodity area object models with demonstrated prototyping system. Initiated definition of performance and technical specifications of an eventual virtual prototype system to improve acquisition CBD materiel.

**Total** 11801

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2003 Planned Program:**

- 1200 Planning, Training and Analysis (DTO-CB43) - Complete and demonstrate initial operational capability of APOD module. Conduct independent Validation and Verification (V&V) of fighter base module. Initiate development and testing of Sea Port of Debarkation (SPOD) module.
- 1664 Environment (DTO-CB55) - Improve next-generation model (MESO) to include wet biological modifications, improve accuracy over rough terrain, and further improvements to boundary layer atmospheric physics. Evaluate performance of computational fluid dynamics model (CBW-CFX) on ships and fixed land structures and identify areas for improvement. Demonstrate performance of coupled weather/CBW dispersion model. Evaluate performance of hazard evolution codes updated by agent environmental effects data.
- 700 Planning, Training and Analysis - Demonstrate HLA or DIS application of hazard models. Conduct statistical analysis of results of agent toxicity load variation in several hazard prediction models for fixed site application.
- 1350 Sim Based Acquisition - Initiate testing of prototyping models against highest priority CBD objects. Develop and demonstrate a breadboard virtual prototype system.
- 1387 Battle Management - Expand studies to address data fusion approaches for multiple sensors. Assess value added at system-level (multiple networked CB sensors and non-CB sensors) through modeling and demonstration. Initiate examination of methods to improve real-time, network-aided decision making, and visualization of network responses.

**Total** 6301

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

<b>BUDGET ACTIVITY</b> <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	<b>PE NUMBER AND TITLE</b> <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	<b>PROJECT</b> <b>CB2</b>
---	---	------------------------------

**FY 2004 Planned Program:**

- 2492 Battle Management - Initiate efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses.
- 2000 Planning, Training and Analysis - Test and finalize Aerial Port of Debarkation (APOD) and Seaport of Debarkation (SPOD) representation. Define Contamination Avoidance for Seaports of Debarkation (CASPOD) data requirements. Populate SPOD representation. Support JOEF Block I demonstration. Perform independent validation and verification on core model. Begin module definition and design for Marine Expeditionary Force HQ, depot and railhead modules.
- 2000 CB Hazard Environment Prediction (DTO-CB55) - Transition advanced predictive capabilities (MESO) to JEM Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging.
- 1000 Simulation Based Acquisition - Gain user acceptance of next-higher priority CBD object (Bat Mgmt or Protection) and evaluate application of model.

**Total** 7492

**FY 2005 Planned Program:**

- 3500 Battle Management - Continue efforts to optimize data fusion and decision-making across networks and to provide visualization of network sensor responses
- 2500 Planning, Training and Analysis (DTO-CB43) - Test and finalize toward JOEF Block II transition. Develop Marine Expeditionary Force HQ, depot, and railhead modules. Perform internal validation and verification (V&V).

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
--	--	-----------------------

**FY 2005 Planned Program (Cont):**

- 1500 Environment - Enhance the complex terrain and flow around structures modeling capability to address variable surface characterization and solar effects on agent evaporation. Perform code optimization and validation of the complex terrain and flow around structures tools.
- 500 Simulation Based Acquisition - Evaluate application of prototype model against next-higher priority CBD object.

**Total 8000**

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Applied Research	21237	52981	11880	10666

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments:**

- 3500 Bioinformatics - Adapted bioinformatic approaches developed for the human genome project to produce meaningful generalizations about the large number of candidates that can be potentially used for biological threat agents and their varied or engineered properties. Initiated integrating comprehensive and interactive databases maintained and updated with fundamental properties of biological agents of military interest. Initiated development of data mining tools to analyze microbial information specifically tailored to military assessment and decision making for CB defense. Initiated the development of predictive algorithms embedded into databases developed above to understand biological threats, allow generalizations, assess risk of emerging biological threats, and suggest the course of defense response under specific circumstances (e.g., pathogenic genes in unnatural host context or potential threat of engineered genomes).
- 2715 Air Purification Systems - Developed methodology for testing anti-microbial filters/treatments for collective and individual protection. Established R&D contract for reactive filter media. Initiated design of test apparatus to challenge reactive media with biological aerosol simulants. Conducted modeling and testing of lab- and sub-scale anti-microbial air purification devices, which have potential to enhance bio-safety and reduce operating costs associated with air purification.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments (Cont):**

- 8719 Joint Biological and Chemical Terrorism Response Project - Completed development of rapid anthrax test method for blood and environmental samples initiated in CB countermeasures. Initiated development of rapid test for smallpox and plague. Completed revision of medical training and reference for treatment of chemical and biological exposures for non-military hospitals. Continued development and initial testing of the wide area biological counterterrorism surveillance and detection tool. Developed protocols for safe transport of biologically contaminated clinical samples. Continued development and initial testing of a transportable fiber optic detector for a wide variety of biological threat agents found in the field. Continued research into identification of the genetic factors affecting bioterrorism toxicants and toxins. Continued practical recommendations for hospital hygiene practices dealing with bioterrorism. Completed the initial selection of biological and chemical isolation suits for bioterrorism response.
- 970 Common Asset for Biological Security - Developed genome based bioinformatics tools, assessed performance, and applied to gene chip detection/identification technologies.
- 3393 CB Countermeasures - Continued investigations into mechanisms of cell death after exposure to chemical and biological agents. Developed and initiated testing of new, non-woven protective suits for response to chemical and biological threats. Continued investigations into feasibility of employing selenium bound receptors to destroy and eliminate infectious biological agents. Continued development of embedded miniature chemical detectors for employment in critical and sensitive sites.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>

**FY 2002 Accomplishments (Cont):**

- 970 Integrated Detection of Energetic and Hazardous Materials (ITMS) - Developed arrays of Cylindrical Ion Traps Mass Spectrometers and the methodologies to analyze the spectra in parallel. Investigated the ITMS methodologies for the point detection of BW agents. Tested the limits of detection via neutron initiated gamma-ray spectroscopy and compared to the theoretical results. Investigated application of advanced transforms on multi-sensor detection models.
- 970 CB Regenerative Air Filtration System - Constructed a facility for toxic and chemical agent testing on one-half scale regenerative pressure/temperature swing adsorption (P/TSA) air filtration devices. A manufacturer supplied a prototype filtration unit. Initiated testing on this unit to identify the performance limits and develop concepts for an optimized design.

**Total** 21237

**FY 2003 Planned Program:**

- 5000 Low Level Operational Toxicology Studies - Complete inhalation data sets to define longer time, lower level operational effects for sarin (GB) in swine and a second generation agent (GF) in rats. Develop a valid marker (dosemetric) for nerve agent exposure suitable for predicting agent effects across species to refine operational human health risk assessment. Complete short-term behavioral and physiological effect studies in rodents using sarin (GB). Extend low-dose exposures to varying durations to assess the potential impact on operational readiness in humans. Initiate integration studies to extend the ability to predict physiological effects across exposure routes and species.
- 3000 Countermeasures to Biological and Chemical Threats - Create and assess innovative strategies for training civilian and military personnel responding to a chemical and biological agent terrorist attack.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
<p><b>FY 2003 Planned Program (Cont):</b></p> <ul style="list-style-type: none"> <li>• 2000 Polymer Based Chemical and Biological Sensors - Develop and validate polymer based chemical and biological sensor technologies that enhance current state of the art approaches.</li> <li>• 964 Bioinformatics - Create tailored approaches to the extraction and rapid analysis of biological data to enhance the study of chemical and biological threat agent effects.</li> <li>• 4000 Air Purification Collective and Individual Protection - Develop and evaluate filter material formulations for efficacy against biological threat agents.</li> <li>• 2000 Bio-Compact Disk Application Development - Explore and develop bio-compact disk technology.</li> <li>• 1000 Air Containment Monitoring System - Develop systems for contained air monitoring for chemical agents.</li> <li>• 25000 Chem-Bio Defense Initiatives Fund - Develop technologies and methodologies for the rapid detection of, and protection from biological agents utilizing both point and standoff platforms.</li> <li>• 4717 National Consortium for Countermeasures to Biological and Chemical Threats - Develop multiple technologies and implementations to counter the threat of attack using chemical and biological threat agents against civilian and military populations.</li> </ul>		
Project CB2/Line No: 017	Page 40 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
<p><b>FY 2003 Planned Program (Cont):</b></p> <ul style="list-style-type: none"> <li>5300 Anthrax Bio Defense Technologies - Develop and commercialize an inexpensive and robust hand-held sensor that can be used by military field personnel with minimal training to detect low levels of bio warfare (BW) agents. The technology is based on antibodies supported on Love Shear horizontal acoustic wave devices. Preliminary data has shown that this technology has the potential to provide biological identification at an enhanced sensitivity of 10 to 100 times over current systems, within a few minutes, in a hand-held unit. This effort is supported by industry, who will combine its state of the art materials and manufacturing expertise to mass produce real-time, highly sensitive, hand-held bio sensors.</li> </ul> <p><b>Total 52981</b></p> <p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>11880 Non Traditional Agent - Expand and accelerate applied research level of effort to develop advanced countermeasures, detection and protection strategies for non-traditional agents and perform agent fate studies.</li> </ul> <p><b>Total 11880</b></p> <p><b>FY 2005 Planned Program:</b></p> <ul style="list-style-type: none"> <li>10666 Non Traditional Agent - Continue expansion and acceleration of applied research level of effort to develop advanced countermeasures, detection and protection strategies for non-traditional agents and continue to perform agent fate studies.</li> </ul> <p><b>Total 10666</b></p>		
Project CB2/Line No: 017	Page 41 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>CB2</b>
---	---	-----------------------

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	1578	0	0

**FY 2003 Planned Program:**

- 1578 SBIR

**Total** 1578

<b>C. <u>Other Program Funding Summary:</u></b>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>To Compl</u>	<u>Total Cost</u>
CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD)	18531	47349	33414	33027	25908	30903	31328	31914	Cont	Cont
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	11791	11075	4714	5257	4575	4122	3196	3255	Cont	Cont

**UNCLASSIFIED**

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>								DATE <b>February 2003</b>
--	--	--	--	--	--	--	--	------------------------------

<b>BUDGET ACTIVITY</b> <b>RDT&amp;E DEFENSE-WIDE/</b> <b>BA2 - Applied Research</b>				<b>PE NUMBER AND TITLE</b> <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE</b> <b>(APPLIED RESEARCH)</b>				<b>PROJECT</b> <b>TB2</b>
---	--	--	--	---	--	--	--	------------------------------

	COST (In Thousands)	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	Cost to	Total Cost
		Actual	Estimate	Complete							
TB2	MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	34195	40977	22699	22622	15415	15692	16442	13095	Continuing	Continuing

**A. Mission Description and Budget Item Justification:**

**Project TB2 MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH):** This project funds applied research on the development of vaccines, therapeutic drugs, and diagnostic capabilities to provide an effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. Innovative biotechnological approaches and advances will be incorporated to obtain medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include Defense Technology Objectives (DTO); science and technology programs in medical biological defense (diagnostic technologies, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines); and directed research efforts (Medical Countermeasures, Genetically Engineered Threat Countermeasures, Vaccines, Monoclonal Antibody Based Research, Needle-less Delivery Methods for Recombinant Protein Vaccines, and Organic Vaccine Production).

**B. Accomplishments/Planned Program**

	<b><u>FY 2002</u></b>	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>
Therapeutics	16825	17835	11080	10984

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
<p><b>FY 2002 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 1685 Therapeutics, Bacterial - Optimized and correlated in vitro assays with animal models for selected antibiotic and other therapeutics for bacterial threat agents and examined effects of selected therapies on multiple agent exposures in an animal model. Studied the effect of immunomodulators on the host response to <i>B. mallei</i> and <i>Y. pestis</i> candidate vaccines and identified modulators effective in enhancing candidate vaccines.</li> <li>• 7270 Therapeutics, Toxin - Initiated structural stabilization and optimization studies on selected lead inhibitors of botulinum neurotoxin and staphylococcal enterotoxin B (SEB) toxin activity; optimized the structure of best peptide-based inhibitor of botulinum neurotoxin serotype A. Tested more than 2,800 compounds for the potential to inhibit botulinum neurotoxin serotype A. Produced and evaluated prototype activity-based assays to screen inhibitors of botulinum neurotoxin serotypes D, E, and F. Applied botulinum neurotoxin activity-based assay technology toward the development of an activity-based assay for inhibitors of anthrax lethal toxin. Refined ex vivo and standardized in vitro screening models for botulinum toxin and SEB intoxication.</li> <li>• 3370 Therapeutics, Viral - Assessed the potential for immunotherapy against Ebola virus in higher animal species models. Completed investigation of mechanisms of Ebola virus pathogenesis in higher animal species models to characterize promising surrogate markers of efficacy for therapies. Initiated research for development of a variola (smallpox) animal model at the Centers for Disease Control and Prevention (CDC).</li> <li>• 1500 Therapeutics, Medical Countermeasures - Enhanced applied research efforts toward the development of broad-spectrum therapeutic countermeasures for exposure to various classes of biological threats.</li> </ul>		
Project TB2/Line No: 017	Page 44 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
--	--	-----------------------

**FY 2002 Accomplishments (Cont):**

- 3000 Therapeutics, Genetically Engineered Threat Medical Countermeasures - Expanded genetic and protein databases to identify and catalogue the various virulence factors, toxic motifs, and host regulatory proteins responsible for the pathologic effects of biological threat agents. Continued curating the genetic information database, evaluating mechanisms of pathophysiology associated with toxin threats, and developing critical proteomics capability.

**Total** 16825

**FY 2003 Planned Program:**

- 1624 Therapeutics, Bacterial - Evaluate novel antibiotics and other therapeutics in established in vitro assays and animal models. Establish a database of therapeutic profiles for various species of bacterial threat agents.
- 7278 Therapeutics, Toxin - Continue high-throughput assessment of candidate therapeutic inhibitors for botulinum neurotoxin. Complete testing and development of cell-free assay for assessment of candidate therapeutic inhibitors of staphylococcal enterotoxin (SE). Select lead candidate inhibitors based upon results in cell-free and cell-based assays and prepare toxin-inhibitor crystals for x-ray diffraction analysis. Evaluate the outcome of structural stabilization and optimization studies on lead inhibitors of botulinum and SE.
- 1320 Therapeutics, Viral - Continue assessing the potential for immunotherapy against Ebola virus in higher animal species models. Identify pharmacological compounds provided by industry that disrupt filovirus growth in cell culture. Assess therapeutic action of compounds in mouse and higher animal models of filovirus infection. Continue research for development of a variola animal model at CDC.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
--	--	-----------------------

**FY 2003 Planned Program (Cont):**

- 1438 Therapeutics, Medical Countermeasures - Accelerate research to define criteria for successful therapeutics against toxins and viruses to obtain diverse compounds such as inhibitors, channel-blockers, natural product extracts, and peptides that show promise as potential therapeutics against botulinum neurotoxins, staphylococcal enterotoxin, ricin toxin, and viruses. Continue characterizing and refining the smallpox higher animal model for use in determining the effectiveness of post-exposure therapies.
- 2875 Therapeutics, Genetically Engineered Threat Medical Countermeasures - Accelerate research efforts directed toward compiling and prioritizing function-related structural elements that constitute known toxins and virulence factors of biological threat agents. Continue developing integrated databases of protein domains or three-dimensional structural elements identified as virulence factors in biological threat organisms.
- 1000 Therapeutics, Monoclonal Antibody Based Technology - Continue research toward development of a proprietary Heteropolymer (HP) system as a potential therapeutic for acute anthrax intoxication. Conduct in vivo assessment of the HP system in a transgenic mouse strain expressing the human CR-1 receptor on red blood cells. Perform in vivo assessments comparing therapeutic capability of monoclonal antibody 14B7, which has high affinity for anthrax toxin, alone and with the HP system.
- 2300 Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopoxviruses (DTO) - Determine optimum dose of cidofovir in the appropriate higher animal species model using both the lethal pulmonary and lesional infection models with monkeypox. Characterize disease pathogenesis in both animal models. Perform studies to establish the therapeutic window in the variola model developed with the CDC.

**Total** 17835

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>

**FY 2004 Planned Program:**

- 1495 Therapeutics, Bacterial - Perform additional in vivo studies on efficacy of selected antimicrobial compounds against various bacterial threat agents in small animal models.
- 6450 Therapeutics, Toxin - Initiate testing of lead inhibitors of botulinum neurotoxin and SE using in vivo model systems for assessment of therapeutic efficacy. Standardize in vivo model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy.
- 835 Therapeutics, Viral - Continue the assessment for immunotherapy for filoviruses. Identify pharmacological compounds provided by industry that may intervene in filovirus-induced shock. Assess therapeutic action of compounds in mouse models of filovirus infection. Complete research for development of a variola animal model at CDC.
- 2300 Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopoxviruses (DTO) - Continue preclinical virology studies (including animal efficacy studies) required for a supplemental New Drug Application for cidofovir and provide technical data and support to the drug license holder. Compare the variola animal model to the monkeypox animal model and human monkeypox to qualify models to be proposed under the Food and Drug Administration (FDA) animal efficacy rule.

**Total** 11080

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
---	---	-----------------------

**FY 2005 Planned Program:**

- 1498 Therapeutics, Bacterial - Perform therapeutic efficacy studies in higher animal species models. Continue studies on selected FDA-licensed antimicrobial compounds to support consideration for changing label indications for use against BW threat agents.
- 6462 Therapeutics, Toxin - Develop surrogate endpoints of human clinical efficacy for botulinum neurotoxin and SE therapeutics. Test combinations of monoclonal antibodies against multiple botulinum neurotoxin serotypes for efficacy using cell-based culture systems.
- 2724 Therapeutics, Viral - Complete the assessment for immunotherapy for filoviruses. Assess therapeutic action of pharmacological compounds provided by industry in mouse and primate models of filovirus infection.
- 300 Therapeutics, Therapy for Smallpox and Other Pathogenic Orthopoxviruses (DTO) - Complete preclinical virology studies (including animal efficacy studies) required for a supplemental New Drug Application for cidofovir and provide technical data and support to the drug license holder.

**Total** 10984

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Diagnostics	5366	6712	4228	4236

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
<p><b>FY 2002 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 600 Diagnostics, Common Diagnostic Systems (DTO) - Completed system integration and verification of approaches, reagents, and protocols for portable devices capable of detecting and identifying nucleic acids from a broad range of biological threat agents in clinical specimens.</li> <li>• 4766 Diagnostic Technologies - Continued preparation of diagnostic reagents to enhance the depth and diversity of current approaches for the rapid recognition of infection by potential biological threat agents. Assessed preclinical models and standards for evaluating medical diagnostic systems prior to transition to the regulatory compliant medical laboratory.</li> </ul> <p><b>Total 5366</b></p> <p><b>FY 2003 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 6712 Diagnostic Technologies - Apply new diagnostic approaches to the early recognition of infection, adapting the technologies to current and future comprehensive integrated diagnostic systems. Apply new technological approaches for diagnosis of potential biological warfare threat agents in laboratory studies using relevant clinical samples. Apply new technological approaches for concentrating and processing clinical samples to support rapid biological agent identification. Apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.</li> </ul> <p><b>Total 6712</b></p>		
Project TB2/Line No: 017	Page 49 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
---	---	-----------------------

**FY 2004 Planned Program:**

- 4228 Diagnostic Technologies - Continue to apply new diagnostic approaches directed toward early recognition of infection, selecting technologies that can be adapted to current and future comprehensive integrated diagnostic systems. Continue laboratory studies using relevant clinical samples to apply new technological approaches for diagnosis of potential biological warfare threat agents. Continue to apply new technological approaches for concentrating and processing clinical samples to support rapid agent identification and to apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.

**Total** 4228

**FY 2005 Planned Program:**

- 4236 Diagnostic Technologies - Continue applying new diagnostic approaches to the early recognition of infections. Technologies will be adapted to current and future comprehensive integrated diagnostic systems. Continue applying new technological approaches for diagnosis of potential biological warfare threat agents in laboratory studies using clinical samples. Apply new technological approaches for processing clinical samples and apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples.

**Total** 4236

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Vaccines	12004	15749	7391	7402

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>

**FY 2002 Accomplishments:**

- 350 Vaccines, Medical Countermeasures for Brucella (DTO) - Tested most efficacious vaccine candidate against Brucella abortus (B. abortus) and B. suis in the mouse lung infection model. Tested efficacy of additional live vaccine candidates against B. melitensis in the mouse lung infection model. Continued to develop and validate in vitro systems in mice and higher animal species to reliably quantify the intensity of potentially protective immune responses and determine the immune system components that eliminate infection with candidate live, attenuated vaccines.
- 200 Vaccines, Medical Countermeasures for Encephalitis Viruses (DTO) - Completed development of higher animal species models for Venezuelan equine encephalitis (VEE) virus type 3A. Redirected eastern equine encephalitis (EEE) and western equine encephalitis (WEE) virus vaccine development back to discovery and focused DTO on a multivalent VEE vaccine candidate.
- 300 Vaccines, Multiagent Vaccines for Biological Threat Agents (DTO) - Completed improvements to the naked DNA and VEE replicon vaccine delivery platforms to optimize their use as multiagent vaccines and combined VEE replicon vaccine platforms for botulinum neurotoxin A, anthrax protective antigen, and Marburg virus into a multiagent vaccine construct.
- 593 Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO) - Evaluated formulations for intranasal, inhalational, and transdermal application of recombinant proteins intended for use as vaccines. Evaluated novel commercial adjuvants in combination with vaccine candidates. Evaluated in animal models, proprietary vaccine delivery devices with commercial partners.
- 230 Vaccines, Recombinant Plague Vaccine Candidate (DTO) - Completed determination of the range of protection of the recombinant plague vaccine candidate against other virulent strains of Yersinia pestis (plague) in animals.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>

**FY 2002 Accomplishments (Cont):**

- 500 Vaccines, Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate (DTO) - Completed the evaluation of isoform biological activity. Completed the determination of formaldehyde requirement for stable rPA vaccine preparations. Continued to develop the mouse potency assay and determination of the in vitro correlate of immunity for the rPA vaccine candidate. Developed antibodies to rPA in higher animal species to support continuing passive immunity studies. Provided technical summaries to the information package supporting entry of the rPA vaccine into component advanced development.
- 4119 Vaccines, Bacterial - Optimized in vitro correlate assays for candidate vaccines against various bacterial threat agents and evaluated the efficacy of additional novel component vaccine candidates (i.e., fusion proteins and antigen cocktails). Optimized formulation and dosage regime of selected vaccine candidates in animals. Determined whether plasmids expressing foreign genes in a virulent Brucella lead to suitable attenuation and immunogenicity in mice.
- 1840 Vaccines, Toxin - Demonstrated that recombinant vaccine candidates, based on the botulinum toxin heavy chain (Hc) subunit, can elicit protective immunity in mice against neurotoxins produced by various strains of Clostridium botulinum.
- 2372 Vaccines, Viral - Determined that markers of immunity (i.e., antibody) did not correlate with protection against disease from divergent strains of Marburg virus. Developed higher animal species models for western equine encephalitis (WEE) virus.
- 1500 Vaccines - Enhanced applied research toward innovative approaches for the development and delivery of next generation and generation-after-next vaccines and strategies to enhance the immune response to various classes of biological threats.

**Total** 12004

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>

**FY 2003 Planned Program:**

- 350 Vaccines, Medical Countermeasures for Brucella (DTO) - Determine whether over-expression of vaccine antigens in candidate live vaccines increases protective efficacy. Continue to develop and validate in vitro systems in mice and higher animal species to reliably quantify the intensity of potentially protective immune responses and determine the immune system components that eliminate infection complications following use of live attenuated candidate vaccines.
- 200 Vaccines, Medical Countermeasures for Encephalitis Viruses (DTO) - Complete studies on production of the live, attenuated VEE vaccine virus constructs, their genetic stability, and transmission potential of candidate VEE virus vaccines in competent vector mosquitoes.
- 628 Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO) - Downselect formulations for intranasal, inhalational, and/or transdermal delivery of recombinant protein vaccines. Propose commercial or proprietary device for delivery of vaccines.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>

**FY 2003 Planned Program (Cont):**

- 4589 Vaccines, Bacterial - Develop mutants in various agents for in vivo expressed genes to examine role in virulence. Characterize the mechanism(s) of vaccine resistance in selected strains of various agents. Determine mechanisms and correlates of protection with efficacious glanders vaccines. In support of rPA vaccine candidate entry into component advanced development, complete evaluation of immunogenicity and efficacy of rPA isoform species in the rabbit model; continue to develop reagent standards for use in an in vitro potency assay; and complete collection of immune serum for evaluation in a higher animal species passive transfer study. In support of recombinant plague vaccine development, complete development of anti-V antigen competitive enzyme-linked immunosorbent assay (ELISA) and cytotoxicity inhibition assays; complete determination of the range of protection of the vaccine candidate against other virulent strains of *Y. pestis* in animals; and complete studies in mice on alternate vaccine administration routes, dose, formulation and mucosal adjuvants.
  
- 3245 Vaccines, Viral - Assess mechanism of immunity that protects against disease from Ebola virus in lower animal models. Develop assays to measure markers to validate the efficacy of vaccine candidates in established model systems for Ebola virus. Develop higher animal species models for EEE virus.
  
- 1437 Vaccines - Evaluate additional vaccine candidates for delivery using the multiagent delivery platform. Develop virus constructs and obtain commercially produced humanized mouse monoclonal antibodies to evaluate protective immune responses. Investigate the potential of live vaccine candidates for bacterial threat agents.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

<b>BUDGET ACTIVITY</b> <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	<b>PE NUMBER AND TITLE</b> <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	<b>PROJECT</b> <b>TB2</b>
---	---	------------------------------

**FY 2003 Planned Program (Cont):**

- 1000 Vaccines, Delivery Methods for Recombinant Protein Vaccines - Assess novel, minimally invasive delivery technologies for the administration of protein subunit biodefense vaccine candidates, including recombinant protective antigen and recombinant staphylococcal enterotoxin (SE) B vaccines, and either recombinant SE A vaccine or recombinant F1-V fusion protein plague vaccine.
- 2500 Vaccines, Organic Vaccine Production - Evaluate and determine the usefulness of methods/technologies to develop vaccines through alternative or unconventional means.
- 1800 Vaccines, Ricin Vaccine by Protein Engineering (DTO) - Complete efficacy studies on recombinant ricin toxin A-chain (rRTA) vaccine candidates and downselect to two lead candidates. Scale up process development for rRTA vaccine candidates; conduct analytical test qualification for identity and stability studies of rRTA candidates; and develop potency assay for rRTA vaccine candidates.

**Total** 15749

**FY 2004 Planned Program:**

- 3655 Vaccines, Bacterial - Continue to evaluate potential live-attenuated glanders vaccine candidates in small animal models. Perform preliminary studies in the development of an acellular brucella vaccine candidate. Continue to perform in vitro and in vivo studies to support advanced development of the rPA vaccine candidate (i.e., phase 2 clinical trials).

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>

**FY 2004 Planned Program (Cont):**

- 1632 Vaccines, Toxin - Initiate studies on the ability of intact catalytic and translocation domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Initiate studies to increase immunogenicity of recombinant BoNT heavy chain (Hc) subunit vaccine candidates by varying adjuvant and/or method of delivery. Continue developing in-process and release assays for recombinant BoNT Hc vaccine candidates. Qualify in vivo and in vitro concept model systems for assessment of recombinant ricin vaccine candidate efficacy and surrogate endpoints of human clinical efficacy.
- 2104 Vaccines, Viral - Initiate applied research to define correlates of immunity that protect against disease from filoviruses (Marburg and Ebola viruses) and from alphaviruses (EEE and WEE viruses).

**Total** 7391

**FY 2005 Planned Program:**

- 3661 Vaccines, Bacterial - Test selected glanders virulence determinants for their ability to elicit protective immunity in a small animal model. Continue applied research studies on development of an acellular brucella vaccine candidate. Continue to perform in vivo studies to support advanced development of the rPA vaccine candidate in its progress toward FDA-licensure.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
---	---	-----------------------

**FY 2005 Planned Program (Cont):**

- 1634 Vaccines, Toxin - Continue studies on the ability of intact catalytic and translocation domains of botulinum neurotoxins (BoNT) to elicit protective immunity in animal models. Continue studies to increase immunogenicity of existing recombinant BoNT vaccine candidates via adjuvants and/or delivery methods. Complete developing in-process and release assays for recombinant BoNT vaccine candidates. Continue recombinant ricin vaccine candidate stability testing. Develop surrogate endpoints of clinical efficacy for higher animal species ricin vaccine adjuvant studies. Test novel adjuvants with lead ricin vaccine candidate in vivo.
- 2107 Vaccines, Viral - Continue applied research to define correlates of immunity that protect against disease from filoviruses (Marburg and Ebola viruses) and from alphaviruses (EEE and WEE viruses).

**Total** 7402

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	681	0	0

**FY 2003 Planned Program:**

- 681 SBIR

**Total** 681

**UNCLASSIFIED**

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>								DATE <b>February 2003</b>
--	--	--	--	--	--	--	--	------------------------------

BUDGET ACTIVITY <b>RD&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TB2</b>
---	--	-----------------------

<b>C. <u>Other Program Funding Summary:</u></b>										
---	--	--	--	--	--	--	--	--	--	--

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>To Compl</u>	<u>Total Cost</u>
TB3 MEDICAL BIOLOGICAL DEFENSE (ATD)	34554	35515	49939	44621	39530	39527	42528	38573	Cont	Cont

--	--	--	--	--	--	--	--	--	--	--

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
---	---	-----------------------

COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
TC2 MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	17977	19216	17880	18269	19994	20104	20368	21750	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. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Pretreatments, Therapeutics, and Diagnostics), and directed research efforts (Low Level Chemical Warfare Agent Exposure, Non-Traditional Agents (NTA), and Mustard Gas Antidote).

**B. Accomplishments/Planned Program**

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Low Level Chemical Warfare Agent Exposure	1000	2000	2500	2500

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
<p><b>FY 2002 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 1000 Low Level Chemical Warfare Agent (CWA) Exposure - Continued to study biological markers of low dose exposures and investigated selectivity of the markers for CWAs. Evaluated potential genetic and central nervous system perturbations following low level CWA exposures. Initiated studies of the effects of chronic exposure to low doses of CWAs in cellular energy systems and esterases in guinea pig brain. Developed a behavioral component model in guinea pig for studying the effects of low dose chronic exposure to CWAs.</li> </ul> <p><b>Total 1000</b></p> <p><b>FY 2003 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 2000 Low Level Chemical Warfare Agent Exposure: Effects and Countermeasures (DTO) - Assess short-term behavioral, physiological, and neuropathological effects of sarin (GB) nerve agent in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness.</li> </ul> <p><b>Total 2000</b></p> <p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 2500 Low Level Chemical Warfare Agent Exposure: Effects and Countermeasures (DTO) - Assess short-term behavioral, physiological, and neuropathological effects of VX nerve agent in rodents following low-dose exposures for varying durations and their potential impact on human operational readiness. Initiate studies on the effects of current prophylactic and therapeutic treatments on the maximum tolerated dose for repeated chemical warfare agent exposures and on other indices of chemical agent toxicity.</li> </ul> <p><b>Total 2500</b></p>		
Project TC2/Line No: 017	Page 60 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
---	---	-----------------------

**FY 2005 Planned Program:**

- 2500 Low Level Chemical Warfare Agent Exposure: Effects and Countermeasures (DTO) - Assess VX nerve agent and sulfur mustard (HD)-induced changes in respiratory function produced by low-dose exposures of varying duration. Complete assessments of the short-term effects of VX nerve agent on higher order behavioral tasks in higher animal species following a range of low-dose exposures for varying durations to improve estimates of impact on human operational readiness. Complete assessments of the effects of current chemical warfare agent treatments on toxicity at low doses of exposure.

**Total** 2500

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Pretreatments	5633	5387	5810	5511

**FY 2002 Accomplishments:**

- 1000 Pretreatments, Chemical Agent Prophylaxis II (DTO) - Identified sources of human butyrylcholinesterase (HBuChE) for purification. Prepared sufficient amounts of purified HBuChE to test efficacy in two animal models.

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
--	--	-----------------------

**FY 2002 Accomplishments (Cont):**

- 4633 Pretreatments - Continued investigation of potential transgenic/bioengineered enzyme for production of next generation nerve agent catalytic scavenger. Identified/developed animal models for tests of new scavenger candidate(s). Initiated preliminary efficacy studies with scavengers of nerve agents. Renewed identification of a cyanide pretreatment/treatment compound. Pursued the expression and purification of a recombinant human carboxylesterase for crystallization. Purified a potential pretreatment enzymatic antidote for organophosphate poisoning.

**Total** 5633

**FY 2003 Planned Program:**

- 5387 Pretreatments - Develop physiological pharmacokinetic models of CWAs. Evaluate the safety and circulatory stability of recombinant bioscavengers. Determine specific carbohydrate structures of human serum butyrylcholinesterase for reference material for Good Laboratory Practices (GLP) and current Good Manufacturing Practices (cGMP) production. Generate serum carboxylesterase-deficient mice for use in testing efficacy of nerve agent bioscavengers. Evaluate several classes of compounds that behave by different mechanisms of action, to include methemoglobin formers and sulfur donors, to pursue development of a cyanide pretreatment.

**Total** 5387

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
---	---	-----------------------

**FY 2004 Planned Program:**

- 5810 Pretreatments - Determine toxicokinetics of CWAs and the impact of pretreatment in guinea pigs. Determine x-ray crystallographic structure of catalytic scavengers.

**Total** 5810

**FY 2005 Planned Program:**

- 5511 Pretreatments - Complete development of transgenic animal model that can produce sufficient amounts of recombinant enzyme scavengers for clinical trials. Complete feasibility testing of vector/gene combinations to validate the concept of gene therapy for bioscavengers.

**Total** 5511

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Non-Traditional Agents	4500	3500	4000	5000

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
<b>BUDGET ACTIVITY</b> <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	<b>PE NUMBER AND TITLE</b> <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	<b>PROJECT</b> <b>TC2</b>
<p><b>FY 2002 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>4500 Non-Traditional Agents (NTAs) - Assessed the efficacy and prioritized potential approaches for improving the effectiveness of newly proposed nerve agent countermeasures. Evaluated oxime effectiveness against NTAs. Evaluated newly identified anticonvulsants for improved survival after exposure to NTAs. Assessed the effects of in vivo persistence of NTAs on current countermeasure efficacy. Confirmed cardiac pathology seen after exposure to NTAs. Initiated mechanistic studies of oxime reactivation of novel agents-inhibited butyrylcholinesterase. Studied the effectiveness of pretreatment and treatment countermeasures on emerging organophosphorous compounds.</li> </ul> <p><b>Total</b> 4500</p> <p><b>FY 2003 Planned Program:</b></p> <ul style="list-style-type: none"> <li>2500 Non-Traditional Agents - Evaluate cardiac toxicity following NTA exposure in cardiac muscle cells and animal models. Consider anti-organophosphate antibodies as an NTA treatment strategy. Evaluate bioscavenger pretreatment as medical countermeasure against NTAs in guinea pigs.</li> <li>1000 Non-Traditional Agents, Improved Oxime (DTO) - Initiate chemical assay development to detect candidate oxime(s) for use against traditional nerve agents and non-traditional agent (NTAs) in biological fluids, stability studies, and studies to identify and characterize a surrogate marker for efficacy, drawing from an array of promising compounds already identified.</li> </ul> <p><b>Total</b> 3500</p>		
Project TC2/Line No: 017	Page 64 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
<p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 3000 Non-Traditional Agents - Document cardiac toxicity following NTA exposure in cardiac muscle cells and animal models, and recommend appropriate countermeasures. Continue evaluations of bioscavenger pretreatment as medical countermeasures against NTAs in guinea pigs. Develop surrogate markers for alternative NTA countermeasures in guinea pigs. Determine efficacy of candidate NTA countermeasures in higher animal species.</li> <li>• 1000 Non-Traditional Agents, Improved Oxime (DTO) - Continue assay development, stability studies, and studies to identify and characterize a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and NTAs.</li> </ul> <p><b>Total 4000</b></p> <p><b>FY 2005 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 1000 Non-Traditional Agents, Improved Oxime (DTO) - Complete assay development and stability studies. Complete the identification and characterization of a surrogate marker for efficacy of candidate oxime(s) for use against traditional nerve agents and NTAs.</li> <li>• 4000 Non-Traditional Agents - Continue evaluations of bioscavenger pretreatment as medical countermeasure against NTAs in guinea pigs. Continue studies to determine efficacy of candidate NTAs medical countermeasures in higher animal species. Initiate pre-formulation stability studies of candidate medical countermeasures. Investigate surrogate markers in higher animal species.</li> </ul> <p><b>Total 5000</b></p>		
Project TC2/Line No: 017	Page 65 of 70 Pages	Exhibit R-2a (PE 0602384BP)

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
---	---	-----------------------

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Therapeutics	5494	5605	3614	3412

**FY 2002 Accomplishments:**

- 3000 Therapeutics, Medical Countermeasures for Vesicant Agents II (DTO) - Evaluated improved animal models for screening candidate combination therapies for sulfur mustard (HD) exposure. Defined side effects, established adversity levels, and collated available industrial documentation on vesicant countermeasures. In addition, evaluated potential treatments for HD-induced pulmonary injury under controlled conditions. Studied the hairless mouse as a model for evaluating the effectiveness of pretreatments and therapies against cutaneous HD exposure. Tested antagonists of apoptosis and studied their effectiveness in blocking HD-induced cytotoxicity.
- 2494 Therapeutics - Developed criteria for evaluating neuronal damage and recovery after status epilepticus. Evaluated improved animal models for screening combinations of anticonvulsant candidate therapies. Determined the potential effect(s) of combinations of anticonvulsants. Determined the essential ingredients for a rinse solution to optimally treat HD-induced ocular injury. Investigated modulation of intracellular calcium as a strategy for protecting against soman-induced seizure related brain damage. Evaluated commercially available licensed wound healing products.

**Total**    5494

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>

**FY 2003 Planned Program:**

- 1000 Therapeutics, Medical Countermeasures for Vesicant Agents II (DTO) - Identify therapeutic window for administering compounds to mitigate the effects of HD exposure. Evaluate combination therapies for HD exposure in animal models.
- 2505 Therapeutics - Evaluate new Food and Drug Administration (FDA)-approved drugs for treatment of HD-induced ocular injury. Optimize formulation for an ocular rinse that treats HD-induced ocular injury. Evaluate treatments for HD-induced pulmonary injury. Develop experimental protocol to evaluate drugs, drug combinations and drug treatment protocols with potential to control nerve agent-induced seizures. Evaluate ability of midazolam and anticholinergics to terminate nerve agent-induced seizures in a higher animal species model. Evaluate antagonists of apoptosis and the blockade of HD-induced toxicity. Examine modulation of intracellular calcium to protect against soman-induced seizure related brain damage. Develop and test neuroprotectant drugs to protect against status epilepticus following nerve agent exposure. Assess alternate higher animal species as models for nerve agent toxicity and medical countermeasures.
- 2100 Therapeutics, Mustard Gas Antidote - Explore the use of antioxidant liposomes as a medical countermeasure to sulfur mustard agent exposure.

**Total**    5605

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>	DATE <b>February 2003</b>
--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE                  (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
---	---	-----------------------

**FY 2004 Planned Program:**

- 3614 Therapeutics - Determine efficacy of midazolam and anticholinergic drug combinations against seizures and lethality caused by nerve agents. Test FDA-approved drugs shown to be neuroprotective in both anatomic and behavioral studies. Conduct screening of candidate antivesicant compounds. Determine minimal amount of atropine needed to sustain survival in higher animal species exposed to nerve agent. Develop in vitro and in vivo models to support efficacy studies of new antivesicant countermeasures.

**Total 3614**

**FY 2005 Planned Program:**

- 3412 Therapeutics - Define in vitro and in vivo models for study of improved nerve agent countermeasures. Define pharmacological categories for points of intervention in vesicant injury process. Screen potential antivesicant compounds.

**Total 3412**

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Diagnostics	1350	2441	1956	1846

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
<p><b>FY 2002 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>1350 Diagnostics - Modified cholinesterase testing assay technology to generate diagnostic information on large sample sizes with rapid throughput of samples.</li> </ul> <p><b>Total</b> 1350</p> <p><b>FY 2003 Planned Program:</b></p> <ul style="list-style-type: none"> <li>2441 Diagnostics - Pursue development of an ocular device for self-examination of pupillary response to nerve agent exposure. Continue development of analytical methods to measure biological matrices (e.g., blood, urine, tissue) following CWA exposure. Develop confirmatory forensic diagnostic capabilities and rapid screening technology for field applications.</li> </ul> <p><b>Total</b> 2441</p> <p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>1956 Diagnostics - Initiate development of diagnostic applications for miniaturized mass spectrometer. Investigate applicability of ocular device for self-examination of pupillary response. Develop diagnostics that can be used to diagnose exposure via respiratory route. Refine analytical methods to measure scopolamine levels in blood and tissue.</li> </ul> <p><b>Total</b> 1956</p>		
Project TC2/Line No: 017	Page 69 of 70 Pages	Exhibit R-2a (PE 0602384BP)

UNCLASSIFIED

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2a Exhibit)</b>		DATE <b>February 2003</b>
--	--	------------------------------

BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA2 - Applied Research</b>	PE NUMBER AND TITLE <b>0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</b>	PROJECT <b>TC2</b>
--	--	-----------------------

**FY 2005 Planned Program:**

- 1846 Diagnostics - Continue development of diagnostic applications for miniaturized mass spectrometer. Continue to investigate applicability of ocular device for self-examination of pupillary response.

**Total** 1846

	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	283	0	0

**FY 2003 Planned Program:**

- 283 SBIR

**Total** 283

<b>C. <u>Other Program Funding Summary:</u></b>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>To Compl</u>	<u>Total Cost</u>
	TC3 MEDICAL CHEMICAL DEFENSE (ATD)	10672	11470	13199	13489	12571	12644	12818	13058	Cont