

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

DATE

February 1999

BUDGET ACTIVITY

PE NUMBER AND TITLE

2 - Applied Research

0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)

COST (In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	69329	63992	64780	68024	81787	83159	74556	77226	Continuing	Continuing
CB2 CHEMICAL BIOLOGICAL DEFENSE	46204	37377	33717	32923	37716	37167	37395	38687	Continuing	Continuing
TB2 MEDICAL BIOLOGICAL DEFENSE	10661	12594	17554	21642	30234	31893	22290	23213	Continuing	Continuing
TC2 MEDICAL CHEMICAL DEFENSE	12464	14021	13509	13459	13837	14099	14871	15326	Continuing	Continuing

A. Mission Description and Budget Item Justification: The use of weapons of mass destruction (WMD) in future conflicts is a steadily increasing threat. Funding under this PE sustains a robust defense which both 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 antidotes and drug treatments and on casualty diagnosis, decontamination and medical management. In the non-medical area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection systems. Maintaining state-of-the-art CB defensive systems is critical for force protection and CB weapons deterrence. This project also provides for conduct of applied research in the areas of real-time sensing and immediate biological countermeasures. The work in this program element is consistent with the Joint Service Research, Development and Acquisition (RDA) Plan. Efforts under this PE transition to and provide risk reduction for Advanced Technology Development (PE 0603384BP), Demonstration/Validation (PE 0603884BP) and Engineering/Manufacturing Development (PE 0604384BP). This project includes non-system specific development directed toward specific military needs.

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B. Program Change Summary:	FY 1998	FY 1999	FY 2000	FY 2001
Previous President's Budget (FY1999 PB)	60023	57683	59232	59962
Appropriated Value	70681	63397		
Adjustments to Appropriated Value				
a. Congressional General Reductions				
b. SBIR/STTR	-1185			
c. Omnibus or Other Above Threshold Reductions				
d. Below Threshold Reprogramming	-167	595		
e. Rescissions				
Adjustments to Budget Years Since FY 1999 PB			5548	8062
Current Budget Submit (FY2000/FY2001 PB)	69329	63992	64780	68024

Change Summary Explanation:

Funding: FY99 - TB2 (595) PDM I plus up for increased USARIID Bio RDTE efforts. FY00 - CB2 (927) for increased RDTE efforts, TB2 (2432) PDM I plus up for increased USAMRIID RDTE efforts, TB2 (3505) moved for increased RDTE efforts, TC2 (-228) moved for higher priority efforts, (-1088) revised economic assumptions. FY01 - CB2 (-160) moved for higher priority efforts, TB2 (4929) PDM I plus up for increased USAMRIID RDTE efforts, TB2 (3850) PDM I plus up for increased bio vaccine RDTE, TB2 (1112) moved for increased RDTE efforts, TC2 (-453) moved for higher priority efforts, (-1216) revised economic assumptions.

Schedule:

Technical:

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BUDGET ACTIVITY 2 - Applied Research				PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)					PROJECT CB2		
COST (In Thousands)		FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
CB2	CHEMICAL BIOLOGICAL DEFENSE	46204	37377	33717	32923	37716	37167	37395	38687	Continuing	Continuing
<p>A. Mission Description and Budget Item Justification:</p> <p>Project CB2 CHEMICAL BIOLOGICAL DEFENSE: This project addresses the urgent need to provide all services with defensive materiel to protect individuals and groups from threat chemical-biological (CB) agents in the areas of: detection; identification and warning; contamination avoidance through reconnaissance; individual and collective protection and decontamination. It also provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and nuclear, biological, chemical (NBC) survivability. This project focuses on horizontal integration of CB defensive technologies across the Joint Services.</p>											
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BUDGET ACTIVITY		February 1999
2 - Applied Research	PE NUMBER AND TITLE	PROJECT
	0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	CB2
FY 1998 Accomplishments:		
<ul style="list-style-type: none"> • 2791 Joint Service Modeling and Simulation: Conducted modeling and simulation of fixed base and naval battlegroup operations. Upgraded wargames and distributed interactive simulation (DIS) capabilities to include evaluation of virtual prototypes of Joint Service CB defense equipment. Continued simulation and wargaming of chemical and biological attack profiles with distribution of vapor, liquid and solid tracking (VLSTRACK) version 2.0. • 744 Decon, DTO: Developed enzymatic decontamination systems for G-agents. Scaled up process to production scale. Identified other candidate enzymes to be incorporated into a multi-component system. Identified effective compatible materials capable of decontaminating BW materials. Performed initial field trials and planned NATO demonstration of vehicular decontamination. • 1016 Chem S/O, Non DTO: Demonstrated a breadboard liquid surface detector in the laboratory. Developed novel algorithm for quantifying passive IR data. • 6217 Bio Point Det, Non DTO: Developed concept front-end sample processors for next-generation biological mass spectrometer based on electrospray ionization. Initiated expansion of bio mass spectrometer (MS) database to include background, growth parameter impacts. Developed a PCR assay for a newly identified structural spore gene DNA sequence that distinguishes B. anthracis from all other Bacilli species. Tested several recombinant antibodies to high priority agent of biological origins (ABOs). Evaluated several approaches to enhance DNA extraction from spores. Streamlined DNA methods to advanced tech demo Automated DNA Detection device. Demonstrated detection of free DNA and soluble antigen in bacterial suspensions. Developed single package reagent mixtures for low-logistics burden on NDI immunoassay platforms. • 2916 Ind Prot, Non DTO: Conducted Milestone 0 IPR for the Joint Service General Purpose Mask (JSGPM), initiated development of the respiratory encumbrance model, identified model polymeric membranes for chemical and moisture vapor transport studies and carried out initial investigations, developed novel closure systems and incorporated into prototype overgarments, determined multicomponent transport through permeable fabrics using new analysis tools, identified laboratory methodologies for improved fabric abrasion and heat stress correlation's with field evaluations. • 418 Agent Impermeable Membrane, DTO: Characterized alternative selectively permeable membrane/fabric material and demonstrated the efficacy and durability of the material. • 804 Respirator Filt Tech, DTO: Optimized prototype design and completed formal design verification testing. • 651 JWARN, DTO: Identified hazard prediction efforts and requirements for computational performance and shell program; initiated tradeoff analysis for cost versus NDI sensor link performance; initiated characterization of 10 NDI systems as candidates for downselect for demonstration and tradeoff study. • 958 Adv Adsorb Prot Applic, DTO: Conducted agent filtration performance evaluation of layered adsorbent beds to identify the most promising concept(s) for engineering of physical properties (pore structure and surface characteristics) and chemical properties (surface chemistry and impregnants) of adsorbent materials applicable to noncombustible filters and regenerative filtration systems. • 2315 Chem Point Det, Non-DTO: Initiated feasibility studies for technologies to detect contaminants in water and of novel concepts for meeting Joint Chem/Bio Universal Detector (JCBUD) requirements. 		
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CB2

FY 1998 Accomplishments (cont):

- 3200 Bio Early Warning, Non DTO: Completed test/evaluation of fluorescence-based early warning detector. Completed development of UV database. Field tested laser-based scattering generic detector approach. Initiated studies of optical constants, impact of encapsulation on optical approaches to detection.
- 1322 Bio Genetic Tech, Non DTO: Increased yields of bot tox and Dengue virus recombinant antigen-binding fragments by 30-fold. Established hand-held assay production based on recombinant Fabs; delivered units of Bot-ALERT hand-held assay to Joint Program Office (JPO) and Technical Escort Unit (TEU). Constructed human-based genetic library for production of next-gen Fabs.
- 3642 Supporting Science and Technology, Non DTO: Participated in planning and UNSCOM inspection in Iraq. Published three technical reports on standard and new chemical threat agents and four technical reports in computational chemistry documenting experimental findings on reaction mechanisms. . Special reports prepared on emerging biological threat agents. Designed and fabricated Class III safety cabinet for high-risk toxic agent studies and tested two nose-only exposure cone designs. Successfully demonstrated an isoaxial and isokinetic aerosol sampler for collecting accurate, unbiased filter samples of aerosols outdoors (e.g., DPG). More than thirteen developmental aerosol collectors evaluated using bioaerosol challenges and standard reference aerosols.
- 1100 Chemical Imaging Sensor, DTO: Demonstrated 9-pixel spectrometer at 30 Hz (offline processing of data).
- 3999 Coll Prot, Non DTO: Conducted study on findings relative to industrial vapor filtration and assessment of Surface Acoustic Wave (SAW) sensors for filterresidual life determination. Validated Pressure Swing Adsorption (PSA) design model for single-layer beds, initiated multi-layer PSA bed modeling effort. Initiated an effort to test full scale NDI cleanable/regenerable High Efficiency Particulate Arresting (HEPA) filters, and initiated a study to identify advanced materials and processes for improving HEPA filtration.
- 3000 SAFEGUARD: Initiated the demonstration of the technology for airborne detection of gases for several Department of Defense high priority targets. The program collected data from open-air experiments on simulants of actual target signatures. Initiated the construction of a second generation specialized line scanner and a second generation high speed Fourier Transform Spectrometer.
- 8000 Chemical sensor enhancements: Reduced the risk on efforts in detection of low levels of contamination, demonstrated technology to predict liquid contamination of surfaces, initiated feasibility studies on new technology (millimeter wave spectroscopy), evaluated sampling systems for chemical aerosol threats, initiated demonstration of a universal chemical ionization source for Ion Mobility Spectroscopy (IMS)/Mass spectrometer detectors, and initiated the demonstration of hardware and software linkage components between detectors and Command, Control Communication, Computers, Information and Intelligence (C4I2) systems.
- 2111 Decon, Non DTO: Installed and evaluated bench scale supercritical fluid extraction unit; initiated materials compatibility studies. Completed gas phase ozone study for interior decontamination and initiated solution studies. Continued solution decon studies and investigate an additional approach based on using dipolar-aprotic solvents. Evaluated effectiveness of existing and development decons against biological warfare (BW) simulants. Sponsored technical workshop to address newly identified user requirements.

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FY 1998 Accomplishments (cont):

- 1000 Laser S/O, Chem Det DTO: Evaluated the feasibility in increasing the range and the sensitivity to mustard and began the design of the brassboard

Total 46204

FY 1999 Planned Program:

- 800 Laser S/O, Chem Det DTO: Design and integrated enhanced sensitivity for mustard in brassboard laser upgrade and continue brassboard build for a multi-purpose detector.
- 500 Adv Lgtwgt Chem Prot, DTO: Combine advanced membranes with lightweight shell fabrics and novel closure systems into a concept lightweight CB duty uniform.
- 700 JWARN, DTO: Complete tradeoff analysis; parameters are cost target of \$300 per unit, 57.6-kb continuous wireless, and 1-Mb continuous wired data transmission rates. Demonstrate using at least 2 different sensors and a minimum of 10 linkages.
- 600 Adv Adsorb Prot Applic, DTO: Perform extensive characterization of the agent filtration performance of the layered adsorbed bed concept(s) identified as offering the greatest potential of providing high agent capacity and low pressure drop for the JSGPM filter. Continue optimization of the physical and chemical properties of candidate adsorbents for potential application to noncombustible filters and regenerative filtration systems.
- 800 Decon, DTO: Down select most promising V-agent enzymes. Begin evaluation of V-agent enzymes in foam-based and other decontamination systems.
- 3271 Chem Point Det Non-DTO: Select best technology and initiate breadboard design for water monitor. Investigate and evaluate effects of sub-lethal concentrations of chemical agents for verifying and validating alarm and warning levels/thresholds for detector systems.
- 2400 Safeguard: Complete construction of second generation line scanner and high speed FT spectrometer and initiate integration onto platform.
- 1718 Bio Point Detection, Non DTO: Continue exploratory development of new, automated biological detection concepts. Continue assay optimization efforts for antibody-based And gene probe systems.
- 2309 Bio Early Warning Detection, Non DTO: Downselect among candidate fluorescence-based point particle detectors. Evaluate potential new standoff early warning approaches.
- 1831 Bio Genetic Technology, Non DTO: Test, evaluate prototype human superlibrary, isolate clones for analysis, assess most promising on biosensor testbeds. Initiate assembly of revised human superlibrary utilizing parallel biopanning approach.
- 2191 Ind Prot Non-DTO: Complete design upgrade and begin baseline model fabrication of integrated mask/helmet concepts for transitioning to Joint Service Aviation Mask (JSAM) and future soldier systems, demonstrate improved closure systems for CB clothing ensemble interface, determine mechanisms of heat and mass transport through membranes and textiles, and develop improved laboratory test methods for CB clothing materials.

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PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT CB2
FY 1999 Accomplishments (cont):		
<ul style="list-style-type: none"> • 2466 Coll Prot, Non-DTO: Transition pulsed light biological decon technology into a shipboard decon system development, integrate a regenerable/cleanable HEPA into a test bed, perform chemical agent testing of NOx adsorbing post treatment filter material for CATOX. Complete testing of full scale PSA system on USMC Amphibious Vehicle test bed. Complete full scale testing of NDI cleanable/regenerable HEPA filters. Complete residual life indicator development effort. • 6632 Supporting Science and Technology, Non DTO: Provide CB Threat and Aerosol Technology. Identify and evaluate emerging threat agents by literature, quantitative structure-activity relationships (QSAR), synthesis and toxicology experiments. Provide a set of standard test materials and methods for chemical agent vulnerability determinations of mil-std paints, polymeric materials (e.g., canopies), and protective garments. Provide wind tunnel and chamber facilities for bio aerosol challenges. Test and demonstrate next generation bio aerosol collectors for the Joint Biological Universal Detector (JBUD). Continue model development for simulation of joint force operations in a CBW environment. Develop models for Joint Service CB defense equipment for application in SIMulation Based Acquisition (SBA). Continue simulation and wargaming of chemical and biological attack profiles with distribution of vapor, liquid and solid tracking (VLSTRACK) version 3.0. Initiate development of coupled CB environment/meteorological models for use with forward-deployed weather forecast operations. • 2961 Decon, Non DTO: Complete studies on supercritical fluids and non-ozone depleting fluorocarbon solvent systems for sensitive equipment (items) decontamination and prepare for transition to development in FY01. Perform evaluations of plasma based systems for interior decontamination. Conduct solution decontamination research focusing upon oxidative and nucleophilic processes in mixed solvent media with additives such as surfactants. Initiate studies to develop new dry powder decontaminants that can be used in a non-developmental applicator system evaluated in FY98. Initiate a multi-phase program to develop the next generation of reactive sorbent decontaminant based initially upon zeolites and high surface area solids containing oxidation/reduction couples, which incorporates reactive nanoparticles in the following year. • 1500 Chemical Imaging Sensor, DTO: Demonstrate a 9-pixel spectrometer in real-time operation at 30 Hz. • 2600 Bio Sample Preparation System, DTO: Demonstrate methodologies to disrupt spores, viruses in 20 min at 1 ACPLA sensitivity measured by DNA probes and protein bio MS. Refine and extend protocols and libraries. • 3476 Man-portable Detectors: Initiate the integration of semiconductor metal oxides, polymers, and biochemical film technology onto piezoelectric, optical, and chemiresistive sensing platforms. Explore enhancements to neural networks and fuzzy logic for CB sensors. • 622 SBIR/STTR 		
Total	37377	
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PROJECT

CB2

FY 2000 Planned Program:

- 900 Adv Adsorb Prot Applic, DTO: Complete screening of candidate adsorbent materials for JSGPM. Select designs for non-combustible filter systems and evaluate.
- 600 Adv Lgtwgt Chem Prot, DTO: Integrate improved closure systems with selectively permeable garment. Fabricate final concept lightweight CB duty uniforms and conduct limited field testing.
- 800 Decon, DTO: Select the best candidate V- and H-agent enzymes and use molecular biology techniques to facilitate their production. Optimize use of reactive polymers for H-agents hydrolysis/oxidation in enzyme-based decontaminants. Acquire commercially available enzymes to enhance effectiveness.
- 2766 Chem Point Det, Non-DTO: Complete breadboard design and initiate breadboard fabrication for water monitor. Initiate trade-off studies on technologies for meeting JCBUD requirements.
- 2512 Chem S/O Det, Non-DTO: Determine feasibility of technologies in meeting a handheld system to detect liquid on surfaces with decontamination levels of sensitivity. Evaluate technology for use in high altitude/space applications.
- 1429 Bio Point Det, Non-DTO: Downselect among active biosensor platforms, with emphasis on optimum sensitivity and identification time. Initiate identification and evaluation of potential reagent-free biosensor technologies.
- 1433 Bio Genetic Technology: Complete revised human superlibrary, assess recomb Abs using biosensor testbeds. Evaluate methodologies for turn-around time to develop new Fab from "unknowns."
- 600 Bio Early Warning Detection, Non-DTO: Downselect among candidate bio standoff detection approaches, evaluate optimum for continued development. Evaluate optimum point biodetector distribution for use through data fusion, networking.
- 2677 Ind Prot, Non-DTO: Conduct interface testing of prototypes and downselect to best helmet/mask interface design. Conduct JSAM prototype evaluation and create design guidelines. Combine membrane structural and chemical studies with computer models to identify dominant factors controlling high permselectivity. Identify materials and treatments for aerosol threat mediation.
- 4287 Coll Prot, Non-DTO: Complete improvement concepts/studies for Joint Transportable Collective Protection System (JTCOPS)/Joint Collective Protection Equipment (JCPE). Transition residual life indicator to JTCOPS/JCPE. Test low cost, lightweight tentage material and transition to JTCOPS.
- 1900 Chemical Imaging Sensor, DTO: Demonstrate a 16-pixel spectrometer at 100 Hz (offline process of data).

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CB2

FY 2000 Accomplishments (cont):

- 5500 Supporting Science and Technology, Non-DTO: CB Threat - Identify and technically evaluate emerging chemical threat agents by literature, quantitative structure-activity relationships (QSAR), synthesis of identified new threat materials and toxicology experiments. Complete nose-only exposure chamber with adequate containment for studying high-risk (no antidote) substances. Identify emerging bio threats and initiate analytical microbiology/ABO capability. Disseminate detailed technical information developed on specific new substances, which is needed to guide detection, protection, and vulnerability work, via Joint Service, NATO, and Tri-Partite panels, working groups, and Data Exchange Agreements.
Aerosol Technology - Measure performance of candidate aerosol collectors for JBUD technology, emphasis will be placed on non-liquid collection methods. Complete isokinetic/isoaxial reference aerosol sampler for use in outdoor trials. Provide controlled biosimulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for Joint Field Trials at DPG. Continue model development for simulation of joint force operations for incorporation into JSIMS JMASS and JWARS. Continue incorporation of CBW hazard prediction model into forward-deployed meteorological forecast operations. Develop advanced CBW environment models for more accurate atmospheric transport and fate predictions for battlespace awareness. Continue Development of models for Joint Service CB defense equipment for application in Simulation Based Acquisition (SBA).
- 5413 Decon, Non-DTO: Incorporate neutralization processes into the supercritical fluid extraction and non-ozone depleting fluorocarbon systems being developed for sensitive equipment decontamination systems. Demonstrate validity of the systems for down selection into FY01 development program. Conduct studies on novel approaches to achieve decontamination of interiors. Optimize solution decontaminants under evaluation and prepare for demonstration phase. Continue studies to formulate dry powder decontaminants to be mixed with aqueous based solvents on-site. Continue work on zeolites and high surface area reactive solids. Extend the sorbent effort to incorporate reactive nano-particle technology.
- 2900 Bio Sample Preparation System, DTO: Demonstrate fully automated two cu ft BSPS concept coupled with gene probe sensor and next-gen bio M for bioaerosol analysis.

Total 33717

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<p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 1100 Adv Adsorb Prot Applic, DTO: Select and initiate testing of regen filtration designs for Joint Transportable Collective Protection System/Joint Collective Protection Equipment (JTCOPS/JCPE). • 800 Decon, DTO: Produce sufficient V- and H-agent enzymes and reactive polymers to optimize their use in foams, detergent solutions or other types of dispersion systems. • 3970 Chem Point Det, Non-DTO: Complete tradeoff analysis and initiate technology downselect for JCBUD. Continue breadboard fabrication and initiate planning for demonstration of the water monitor. • 3095 Chem S/O Det, Non-DTO: Downselect technologies for a handheld system to detect liquids on surface. Initiate trade-off studies on downselected technologies for high altitude/space applications. • 1400 Bio Point Det, Non-DTO: Continue evaluation of reagent-free biosenor approaches. Initiate identification and evaluation of potential fluid-free biosensor approaches. Assess best-potential JCBUD candidates. • 1562 Bio Genetic Technology, Non-DTO: Implement evaluation and integration of human superlibrary into antibody isolation labs. Continue to transition Fabs for testing, incorporation into biosensor testbeds. • 1600 Bio Early Warning Detection, Non-DTO: Refine downselected advanced bio standoff technology. Complete evaluation of optimized networking/data fusion of remoted detectors. Evaluate miniaturized detector concepts. • 2658 Ind Prot, Non-DTO: Fabricate final helmet/mask interface concept baseline model and conduct systems testing. Fabricate and test items employing aerosol threat mediation technologies. • 2992 Coll Prot, Non-DTO: Conduct laboratory investigations of low-power regenerative concepts and filter designs. Fabricate and test optimized hermetic seals. • 5249 Supporting Science and Technology, Non-DTO: CB Threat - Identify and technically evaluate emerging chemical threat agents by literature, quantitative structure-activity relationships (QSAR), synthesis of identified new threat materials and toxicology experiments. Identify emerging bio threats and continue to develop analytical microbiology/ABO capability. Disseminate detailed technical information developed on specific new substances, which is needed to guide detection, protection, and vulnerability work, via Joint Service, NATO, and Tri-Partite panels, working groups, and Data Exchange Agreements. Aerosol Technology - Measure performance of candidate aerosol collectors for JBUD technology, emphasis will continue to be placed on non-liquid collection methods. Include chemical simulant aerosol measurements to build tech base for supporting JCBUD aerosol collection requirements. Provide controlled biosimulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for Joint Field Trials at DPG. • 3597 Decon, Non-DTO: Complete demonstration of sensitive equipment decontamination methodology and transition to the phase 1 of the Joint Service Sensitive Equipment Decontamination (JSSSED) program. Select technologies to be demonstrated for the decontamination of sensitive interiors. Demonstrate candidate solution chemistry systems. 		
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FY 2001 Accomplishments (cont):		
	<ul style="list-style-type: none"> • 2100 Chemical Imaging Sensor (CIS), DTO: Demonstrate a 16-pixel spectrometer in real-time operation at 100 Hz. • 2800 Bio Sample Preparation System, DTO: incorporate microscale approaches to reduce size of BSPS by 35 while maintaining overall sensitivity on both platforms against eight bacterial and viral materials. Reduce sample prep time to 15 minutes. 	
Total	32923	

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COST (In Thousands)		FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
TB2	MEDICAL BIOLOGICAL DEFENSE	10661	12594	17554	21642	30234	31893	22290	23213	Continuing	Continuing
<p>A. Mission Description and Budget Item Justification:</p> <p>Project TB2 MEDICAL BIOLOGICAL DEFENSE: This project funds applied research on the development of vaccines and drugs to provide an effective medical defense against validated biological threat agents including bacteria, toxins, viruses and other agents of biological origin. By employing biotechnology, medical system will be designed to rapidly identify, diagnose, prevent and treat disease due to exposure to biological threat agents.</p> <p>FY 1998 Accomplishments:</p> <ul style="list-style-type: none"> • 1072 Evaluated potential adjuvants for use with plague vaccine candidate. • 912 Determined in a mouse model the virulence/protective efficacy of live attenuated Brucella containing multiple gene deletions. • 1518 Determined immunogenicity potential for glanders and typhus vaccine candidates in animal models and prepared diagnostic reagents. • 1284 Prepared immunological and nucleic acid reagents for emerging diagnostic technologies and tested with preclinical specimens. • 2288 Determined synergistic combination of drugs that block staphylococcal enterotoxin B (SEB) induced effects in vitro and tested subsequently in mouse model. • 982 Tested intranasal liposomal ricin A chain subunit vaccine in animal models. • 1891 Performed final studies on growth kinetics and immunogenicity of candidate vaccine constructs for western equine encephalitis (WEE) and eastern equine encephalitis (EEE) and recombinant filoviruses and initiated animal studies to screen antiviral compounds for post-exposure treatment of smallpox. • 714 Investigated potential modes of treatment that block or reverse the effects of the toxins for Clostridium perfringens. <p>Total 10661</p>											

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TB2

FY 1999 Planned Program:

- 612 Evaluate virulence and protective efficacy of live attenuated brucellae mutant vaccines in animal model.
- 3935 Identify adjuvants to enhance immunogenicity of glanders vaccine candidates and construct recombinant vaccine candidates and evaluate mechanisms for attenuating the agent for typhus vaccine development.
- 2665 Evaluate mechanisms for increased shelf life of immunological and nucleic acid diagnostic reagents for field use.
- 2150 Test long-term efficacy of SEB vaccine candidates.
- 823 Conduct safety preclinical trials of immunization in non-human primates for ricin A chain.
- 1625 Screen potential antiviral compounds for activity against filovirus in animal model of infection.
- 584 Increase efforts in application of advanced diagnostic technologies for applied research in diagnostics tests and devices. Apply existing knowledge of genome sequencing of threat agents and their virulence factors to ongoing exploratory research studies of vaccines and therapeutics. Explore the usefulness of any known biochemical or molecular target sites for intervention with vaccines or therapies as well as targets for diagnostic tests and define knowledge gaps. Refine application of animal models for definition of agent pathogenesis and immunology. Explore the correlation of known immunological markers with efficacy of existing vaccines and therapeutics in model systems. Identify likely characteristics of potential genetically engineered microbes and emerging threat agents and characterize the usefulness of existing candidate medical countermeasures to these threats.
- 200 SBIR/STTR

Total 12594

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FY 2000 Planned Program:

- 1779 Select most promising approach and identify final agents to be incorporated into combined product (multi-agent vaccine).
- 445 Analyze and characterize candidate antivirals against orthopox virus.
- 1779 Define surrogate markers of immunity and other assessment modalities for filovirus immunity.
- 1068 Define and characterize immunological and nucleic acid-based diagnostic platform methodologies.
- 2224 Define common physiologic pathway for potential immunomodulation.
- 2047 Investigate therapeutic countermeasures to aerosolized glanders, botulinum toxin, ricin, and SEB.
- 2181 Define genetic screening methodologies allowing rapid identification of genetic association of relatedness/distance.
- 3639 Initiate renovation on approximately 30 existing USAMRIID Biosafety Level 2/3 facilities to meet the emerging demand to support DARPA Pathogen Countermeasures and BW Agent Detection requiring USAMRIID expertise and capabilities in specific biological agents and associated containment laboratory space and in response to increased demand for diagnostic capability requiring BL2/3 laboratory space.
- 2392 Continue efforts in application of advanced diagnostic technologies in applied research on diagnostic tests and devices. Apply knowledge gleaned from agent pathogenesis and protective immunology against threat agents to establish candidate countermeasures. Continue to establish biochemical or molecular target sites for intervention as ascertained from genomic sequencing of threat agents. Continue to develop animal models that define agent pathogenesis and immunology. Establish the correlation of known surrogate markers of immunity with efficacy of existing vaccines and therapeutics in established model systems. Continue identification of characteristics of potential genetically engineered microbes and emerging threat agents and establish usefulness of candidate medical countermeasures to these threats.

Total 17554

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PE NUMBER AND TITLE 0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT TB2
FY 2001 Planned Program:		
<ul style="list-style-type: none"> • 891 Define surrogate markers of immunity and other assessment modalities for multi-agent vaccines. • 446 Develop scientific data package for antiviral therapy to protect against orthopox threat agents. • 2851 Evaluate diagnostic assays for Y. pestis virulence factors. • 1782 Continue screening of potential antiviral compounds for activity against filoviruses. • 1069 Continue characterization of immunological and nucleic acid-based diagnostic platform methodologies. • 2438 Continue defining animal models for aerosol exposure to glanders, botulinum toxin, ricin, and SEB. • 2067 Continue identification of adjuvants for enhancing immunogenicity of glanders, botulinum toxin, ricin, and/or SEB vaccine candidates. • 3782 Define effectiveness criteria for therapies for botulinum toxin and staphylococcal enterotoxin (SE) threats; initiate screening of candidate therapies for botulinum toxin and staphylococcal enterotoxin threats. • 1474 Initiate renovation on approximately 14 existing USAMRIID Biosafety Level 3 facilities to meet the emerging demand to support DARPA Pathogen Countermeasures and BW Agent Detection requiring USAMRIID expertise and capabilities in specific biological agents and associated containment laboratory space and in response to increased demand for diagnostic capability requiring BL3 laboratory space. • 4842 Refine diagnostic technologies as applied directly to the diagnostic tests and devices, emphasizing specific genetic targets as derived from genomic sequencing. Define therapeutic interventions at the molecular or biochemical level based on knowledge gained from genomic sequencing. Refine basic research studies applying technologies to develop novel vaccines or therapies against genetically engineered threats. Define the correlation of known surrogate markers of immunity with efficacy of existing vaccines and therapeutics in established model systems. Characterize promising generic medical countermeasures against threat agents for exploratory development studies in suitable model systems. 		
Total	21642	
Project TB2		

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

DATE

February 1999

BUDGET ACTIVITY

2 - Applied Research

PE NUMBER AND TITLE

0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)

PROJECT

TC2

COST (In Thousands)	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	Cost to	Total Cost
	Actual	Estimate	Complete							
TC2 MEDICAL CHEMICAL DEFENSE	12464	14021	13509	13459	13837	14099	14871	15326	Continuing	Continuing

A. Mission Description and Budget Item Justification:

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

FY 1998 Accomplishments:

- 4605 Continued to characterize effects of HD (mustard) on multiple points of metabolic disruption.
- 1351 Developed appropriate in vitro and in vivo model systems for screening nerve agent countermeasures.
- 2456 Evaluated the existing skin decontamination methods for use in wound decontamination for vesicant agents.
- 368 Developed early prognostic indicators for successful treatment of pulmonary injury to aid in early return to duty of casualties. Identified available therapies for treatment of vesicant agent ocular effects.
- 1105 Developed a system to analyze products of reaction in the decontamination process for candidate reactive topical skin protectants.
- 614 Evaluated use of cloned human carboxylesterases as nerve agent scavengers.
- 1965 Defined a model system to compare and analyze potential modes of treatment for and/or diagnosis of low dose or chronic exposure to CW agents.

Total 12464

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BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

2 - Applied Research

0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)

TC2

FY 1999 Planned Program:

- 3250 Evaluate promising analytical procedures for vesicant-induced inflammation to levels useful in diagnosis and dosimetry.
- 1876 Continue to characterize alterations of the active-site gorge of acetylcholinesterase resulting from nerve agent inhibition. Evaluate novel drugs developed by academia/industry as potential nerve agent anticonvulsants and develop non-human primate electroencephalogram (EEG) test model to evaluate anticonvulsant action of leading compounds against soman poisoning.
- 4285 Continue to evaluate skin graft and antimicrobial wound dressing and treatments for blister agents.
- 500 Develop far-forward, rapid diagnostic tests for blister and nerve agents for real-time analysis of clinical samples on the battlefield and identify reactive components in the development of a wound decontamination system.
- 1001 Define and characterize the reaction kinetics of leading compounds for reactive topical skin protectants and develop animal wound decontamination models.
- 2876 Develop metrics to monitor long-term effects of low dose or chronic exposure to CW agents.
- 233 SBIR/STTR

Total 14021

FY 2000 Planned Program:

- 5243 Evaluate promising analytical procedures for vesicant-induced inflammation to levels useful in diagnosis and dosimetry.
- 4009 Continue development of metrics and assays for monitoring long-term effects of low dose chronic exposure to CW agents.
- 771 Continue development of far-forward, rapid diagnostic tests for blister and nerve agents for real-time analysis of clinical samples on the battlefield.
- 655 Develop assays for study of countermeasures to novel threat agents and continue to assess efficacy of existing compounds against novel threat agents.
- 1666 Develop models for improved countermeasures to vesicant exposure.
- 1165 Develop assay systems for measuring effectiveness of improved chemical agent prophylaxis strategies.

Total 13509

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DATE

February 1999

BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

2 - Applied Research

0602384BP CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)

TC2

FY 2001 Planned Program:

- 4596 Develop animal models for study of chronic exposure to low doses of CW agents.
- 889 Continue studies of antibiotic/steroid ophthalmic preparations; develop packaging and formulations for sponges, towelettes, and surgical pads containing oxime for use in wound decontamination.
- 1231 Continue development of model systems for testing of countermeasures to novel threat agents.
- 4286 Screen candidate compounds for efficacy as pretreatments/treatments to vesicant exposure.
- 2457 Develop model systems for testing improved chemical agent prophylaxis.

Total 13459