## BUDGET ACTIVITY
3 - Advanced Technology Development

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

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<td>Total Program Element (PE) Cost</td>
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<td>40910</td>
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### A. Mission Description and Budget Item Justification:

This program element demonstrates technologies that enhance U.S. forces' ability to deter, defend against, and survive chemical and biological (CB) warfare. This PE funds advanced technology development for Joint Service and Service-specific requirements in both medical and non-medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as countermeasures against CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination and medical management of casualties. In the non-medical area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD Chemical/Biological Warfare (CBW) defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Work conducted under this PE transitions to and provides risk reduction for Demonstration/Validation (PE 0603884BP) and Engineering/Manufacturing Development (PE 0604384BP) activities. The work in this program element is consistent with the Joint Service Research, Development and Acquisition (RDA) Plan. This program element also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated BW operational awareness and the restoration of operations following a BW/CW attack. This program is dedicated to conducting proof of principle field demonstrations and tests of system-specific technologies to meet specific military needs.
B. Program Change Summary:

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<td>Previous President's Budget (FY1999 PB)</td>
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Adjustments to Appropriated Value

|                      |         |         |         |         |
| a. Congressional General Reductions |         |         |         |         |
| b. SBIR/STTR          | -669    |         |         |         |
| c. Omnibus or Other Above Threshold Reductions |         |         |         |         |
| d. Below Threshold Reprogramming | 4397    | 602     |         |         |
| e. Rescissions        |         |         |         |         |

Adjustments to Budget Years Since FY 1999 PB

|                      |         |         |         |         |
| Current Budget Submit (FY2000/FY2001 PB) | 43517   | 52212   | 40910   | 44881   |

Change Summary Explanation:

Funding:
FY99 - TB3 (602) PDM I plus up for increased USAMRIID Bio RDTE efforts. FY00 - CB3 (-94) moved for higher priority efforts; TB3 (1784) PDM I plus up for increased USAMRIID Bio RDTE efforts, TB3 (-230) moved for higher priority efforts, TC3 (-160) moved for higher priority efforts, CP3 RESTOPS (3726) program restructured to fund upfront efforts for RESTOPS ACTD, (-687) revised economic assumptions. FY01 - CB3 (-171) moved for higher priority efforts; TB3 (4714) PDM I plus up for increased USAMRIID Bio RDTE efforts, TB3 (2000) PDM I plus up to transition DARPA medical diagnostics and therapy, TB3 (-455) moved for higher priority efforts, TC3 (-317) moved for higher priority efforts, CP3 RESTOPS (3398) program restructured to fund upfront efforts for RESTOPS ACTD, (-802) revised economic assumptions.

Schedule:

Technical:
### Project CB3 CHEMICAL BIOLOGICAL DEFENSE (ADV TECH DEV)

**FY 1998 Accomplishments:**

- **5277** Bio ATD - Concluded development and demonstrated the capability of remotely-deployed integrated biodetection network to provide an early warning capability to high value targets. Continued development of Auto DNA Diagnostic (ADD) technology. Developed Bio modules for ATD.
- **773** JS Large Area Decon - Evaluated the efficacy of Non-Developmental decontaminants in laboratory and panel testing procedures. Assessed efficacy of decontaminants in conjunction with applicator systems in chamber studies. Conducted engineering testing and evaluation of novel applicator systems.Performed market survey of Non-Developmental Items (NDI) and identified most promising new leads.
- **1281** JSWILD - Initiated design and fabrication of brassboard system for Joint Service Warning and Identification Lidar Detector (JSWILD).
- **1186** SUBD - Awarded contract to develop and demonstrate microfluidics optical sensor technology.
- **997** SUBD - Awarded contract to optimize fluorochrome based sensor technology for demonstration and test to enhance hand-held detector applications.
- **1242** SUBD - Awarded contract to develop an improved Small Unit Biological Detector using demonstrated improved sensor technology.
- **2690** Biocide Decon - Continued development of advanced biocide CBW protection material and application for personal protection and casualty care. Continued front end analysis and development of a new decontamination master plan.

**Total** 13446
FY 1999 Planned Program:
- **5959** Bio ATD - Conclude development, miniaturization of third-generation UV fluorescence sensor. Complete, evaluate first-generation ADD. Participate, demonstrate in Battle Lab Warfighter Experiment.
- **2961** JSWILD - Continue fabrication of brassboard system and initiate planning for demonstration of system.
- **920** JS Large Area Decon - Complete front end analysis of technologies to address multiple decontamination scenarios which include: skin and personal equipment decontamination, equipment decontamination in the field, equipment decontamination at fixed facilities, key areas at fixed facilities, sensitive equipment decontamination and decontamination of interior spaces containing sensitive items, surfaces and cargo. Identify and prioritize technologies for each functional area and staff a master plan incorporating newly identified leads which will drive the S&T area for the coming developmental cycle.
- **1541** MONOPAC and Service Life Initiatives (Prev: Tractor Dirt) - Prepare a fully permeable single layer (shell and liner) “monopak” chemically protective material for transition to the next joint protective ensemble program. A Chemical Protective Combat Uniform (CPCU) will be constructed using the latest Army/Navy closure concepts for a comprehensive durability (7 day) field trial. There is no field expedient way to access the current condition of chemically protective uniforms. Residual Life Initiative (RLI) addresses this on-going concern and during FY99 plans assess and develop several promising concepts. All material and concept item performance will be fully characterized as part of the transition support package.
- **1500** Biocide Ensembles (ATD) - Continue development of advanced biocide CBW protection material and application for personal protection and casualty care.
- **218** SBIR/STTR

Total 13099

FY 2000 Planned Program:
- **5160** Detection Technologies - Demonstrate brassboard capabilities in field testing with sufficient laser power and detector sensitivity to detect agents at a distance of 20 km (a 400 percent increase from the FY96 baseline).
- **363** MONOPAC and Service Life Initiatives (Prev: Tractor Dirt) - Final transition of "monopak" concept items. Delivery of RLI concept items and/or technology assessment reports. Conduct initial RLI concept item demonstration and transition best efforts to follow-on developmental projects.

Total 5523
<table>
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<th>FY 2001 Planned Program:</th>
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<tr>
<td>5073 Detection Technologies - Initiate design of brassboard system. Initiate planning for demonstration of the Joint Chem/Bio Agent Water Monitor (JCBAWM).</td>
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Total 5073
A. Mission Description and Budget Item Justification:

Project CP3 COUNTERPROLIFERATION SUPPORT: The mission of the Counterproliferation Program (CP) is to address shortfalls in DoD's deployed capability to defend against and counter the proliferation of weapons of mass destruction (WMD). By focusing on short term results, the CP accelerates delivery of new tools, equipment and procedures to combat forces. Under the passive defense pillar, CP enhances the efforts of the Chemical and Biological Defense Program. This program funds a variety of projects to defend our forces against WMD, such as the Air Base/Port Biological Detection Advanced Concept Technology Demonstration (ABPACTD), Biological Detection (BIODET), and Restoration Operations (RestOps).

FY 1998 Accomplishments:

- 930 ABPACTD - Completed development/integration of software/hardware interfaces for biological and chemical detectors. Demonstrated automated warning and reporting from bio-network during Air Base/Port Biological Detection (Portal Shield) ACTD field trials.
- 3492 BIODET - Continued advanced technologies development for a high sensitivity, broadband miniaturized mass spectrometer for identification and classification of biological and chemical agents.
- 500 BIODET - Continued advanced materials and technologies development for the Air Sampler and Concentrator for Biological Materials.
- 1100 BIODET - Continued upconverting phosphor technology development for miniaturized flow cytometer biological agent detection prototype.
- 279 BIO Non Sys - Continued background aerosol particle and liquid sampling for identification of battlefield interferents outside the continental United States (OCONUS) fixed sites assets and established an accessible database.
- 970 RestOps - Initiated preliminary investigation of available technologies to do restoration of operations. Prepared description of actual exercises to baseline current capability to do restoration of operations with emphasis on identifying areas of improvement.

Total 7271
FY 1999 Planned Program:

- 600  BIODET - Transition advanced materials technologies developed for the Miniaturized Environmental Air Sampler and Concentrator for Biological Materials to the combined aerosol sampler and detector.
- 3146  BIODET - Continue advanced technologies development for high sensitivity biological/chemical agent detection using broadband, miniaturized mass spectrometer techniques.
- 985  BIODET - Continue to transition upconverting phosphor technology development for miniaturized flow cytometer biological agent detection prototype.
- 594  BIO Non Sys - Continue background aerosol particle and liquid sampling for identification of battlefield interferents at outside the continental United States (OCONUS) fixed sites assets.
- 1905  RestOps - Continue concept development for technology prototyping with supporting survivability and hazard analysis for restoration of operations.
- 122  SBIR/STTR

Total 7352

FY 2000 Planned Program:

- 984  BIODET - Initiate development of biological identification system using nucleic acids.
- 492  BIODET - Complete transition of upconverting phosphorous technology development for miniaturized flow cytometer biological agent detection prototype.
- 1427  BIODET - Complete first generation of Biological Time-of-Flight (BIOTOF) Mass Spectrometer for transition to field testing.
- 388  CRP - Develop reagents (anti-bodies and antigens) that are critical to the development, testing, and support of CP Biological Detection Systems.
- 1936  BIO Non Sys - Initiate development of automated sample preparation for Polymerase Chain Reaction (PCR) devices.
- 1451  BIO Non Sys - Initiate development of non-specific BW colormetric gene assay.
- 1934  RestOps - Initiate development of next generation chemical/biological transport models (to include complex terrain and urban environment) and simulations for CINC Logistics/Warfighting Planning Tools.
- 1937  RestOps - Initiate development of novel chemical/biological decontaminants.

Total 10549
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<th>FY 2001 Planned Program:</th>
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<tr>
<td>1742  BIODET - Continue development of biological identification system using nucleic acids.</td>
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<td>983   BIODET - Initiate development of new antibodies or their replacements using advanced molecular techniques.</td>
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<td>388   CRP - Continue to develop reagents (anti-bodies and antigens) that are critical to the development, testing, and support of CP Biological Detection Systems.</td>
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<td>1836  BIO Non Sys - Continue development of non-specific BW colorometric gene assay.</td>
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<tr>
<td>1836  BIO Non Sys - Continue development of automated sample preparation for Polymerase Chain Reaction (PCR) devices.</td>
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<td>786   BIO Non Sys - Initiate development for mini-environmental air sampler.</td>
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<td>1353  RestOps - Continue development of next generation chemical/biological transport models (to include complex terrain and urban environment) and simulations for CINC Logistics/Warfighting Planning Tools.</td>
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<tr>
<td>1352  RestOps - Continue development of novel chemical/biological decontaminants.</td>
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**Total** 10276
A. Mission Description and Budget Item Justification:

Project TB3 MEDICAL BIOLOGICAL DEFENSE (INDUSTRIAL BASE): This project funds preclinical development of safe and effective prophylaxes and therapies (vaccines and drugs) for exposure to biological threat agents. This project also supports the advanced technology development of kits to rapidly diagnose exposure to biological agents in clinical samples. To complete the defensive effort, a broad range of technologies involved in the targeting and delivery of prophylactic and therapeutic medical countermeasures is evaluated to ensure the protection of U.S. forces.

FY 1998 Accomplishments:

- **1280** Carried out final preclinical studies required for transition of plague vaccine to demonstration/validation.
- **1553** Performed final evaluation of efficacy of a polyvalent, live, vaccinia-vectored Brucella vaccine in animal model system and established safety of candidate typhus vaccines in animal models.
- **1992** Performed head-to-head comparison of confirmation for advanced development and tested preparation of immunologically and nucleic acid-based diagnostic reagents added to hand-held diagnostic devices specific for BW threat agents.
- **2034** Prepared final data package for botulinum toxin C-fragment vaccine candidate for advanced development.
- **2649** Determined best adjuvant and dose schedule for recombinant staphylococcus enterotoxin B (SEB) vaccine in animal models for lethal and incapacitating effects.
- **2062** Conducted testing of ricin vaccine candidates in animal models for safety and efficacy and evaluated surrogate markers of protection.
- **957** Developed nucleic acid probes and primers for multiple orthopox gene regions to use in definitive diagnostic tests and evaluated neurovirulence of vaccine candidates against western equine encephalitis (WEE) and eastern equine encephalitis (EEE) viruses.
- **349** Completed in vitro testing of filovirus vaccine candidates.

Total 12876
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<td>Compare protective efficacy of live attenuated vs. subunit vaccines, transition Brucella vaccine candidate to Demonstration and Validation phase, and perform initial safety and efficacy studies for typhus vaccine candidates.</td>
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<tr>
<td>2487</td>
<td>Evaluate stability and potential interactions of immunological diagnostic reagents prepared and tested on multiplexed platforms.</td>
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<tr>
<td>756</td>
<td>Begin to construct models for multivalent vaccines including use of viral or bacterial-vectored vaccines, or DNA vaccines.</td>
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<tr>
<td>3060</td>
<td>Determine toxicity of drugs in animal models to evaluate use in treatment of typhus and staphylococcal enterotoxin exposure.</td>
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<tr>
<td>2027</td>
<td>Continue clinical trials of ricin A subunit vaccine candidate for safety and efficacy and evaluate surrogate markers of protection.</td>
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<tr>
<td>918</td>
<td>Develop data package for milestone transition of EEE virus and WEE virus vaccine and construct final early rapid assay and final confirmation-level assay systems for the orthopox viruses to differentiate smallpox.</td>
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<tr>
<td>1597</td>
<td>Evaluate the safety and efficacy of filovirus vaccine candidates in animal models.</td>
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<tr>
<td>591</td>
<td>Expand on comparison of candidate diagnostic technologies in applied research on diagnostic devices and tests. Initiate demonstration of usefulness of existing candidate medical countermeasures applied to emerging threat agents or genetically engineered microbes. Initiate demonstration of efficacy of therapies derived from knowledge of genomic sequences of threat agents and their virulence factors. Compare candidate surrogate markers of immunity for validation as acceptable markers of vaccine efficacy. Develop system for comparison of database created by genomic sequencing of threat agents and their virulence factors. Prepare demonstrations of animal models defining agent pathogenesis and immunology.</td>
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Total 14565
FY 2000 Planned Program:

- **1038** Begin evaluation of immunogenicity for combined products and examine for possible interference effects.
- **807** Transition a multivalent vaccine effective against VEE type 1 A/B/C, 1E, and III.
- **288** Compare efficacy of candidate therapeutic countermeasures against aerosol challenge by orthopox viruses.
- **2306** Compare candidate vaccines for protection against aerosolized filoviruses.
- **1154** Validate immunologically based diagnostic assays for specific BW agents.
- **1961** Prepare a decision package for transition to advanced development of a ricin A subunit vaccine that will protect and reduce lung injury due to inhaled ricin.
- **576** Complete technology data packages supporting transition decisions for candidate vaccine for botulinum toxins.
- **2134** Prepare a decision package for transition of an SEB vaccine to advanced development.
- **1384** Assess and confirm usefulness of new antibiotics against classical threat agents.
- **1754** Continue comparison of candidate diagnostic technologies in applied research on diagnostic devices and tests. Continue advanced screening for efficacy of therapeutic interventions gleaned from genomic sequencing studies, as applied to known threat agents. Continue to develop candidate surrogate markers of immunity for validation as acceptable markers of vaccine efficacy. Compare novel therapies and vaccines developed against genetically engineered threats. Prepare preliminary safety and efficacy data for candidate medical countermeasures to emerging threat agents.

**Total** 15393
UNCLASSIFIED

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

BUDGET ACTIVITY
3 - Advanced Technology Development

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

PROJECT
TB3

FY 2001 Planned Program:
- 1733 Test efficacy of combined products (individually and in combined products).
- 347 Conduct advanced screening for safety, efficacy, and toxicity of candidate medical countermeasures to orthopox viruses.
- 2310 Conduct advanced screening for safety, efficacy, and toxicity of candidate filovirus countermeasures.
- 1155 Develop hand-held device to identify threat agent nucleic acids.
- 3017 Evaluate candidate immunomodulation strategies as countermeasures. Prepare decision package for transition to advanced development of candidate immunomodulation countermeasures.
- 2590 Compare genetic methodologies allowing rapid identification of genetic association/genetic distance of pathogenic agents.
- 2355 Conduct advanced screening of selected compounds for safety and efficacy against biological threat agents.
- 1965 Perform a series of laboratory investigations to obtain data necessary for transition of DARPA-developed technologies to DoD applications: safety studies in animals, efficacy studies in animals, definition of surrogate markers of efficacy, pharmacokinetic studies, formulation studies, assay development, down selection of candidate compounds, Investigational New Drug (IND) submission.
- 4631 Validate animal models defining agent pathogenesis and immunology. Complete comparison of candidate diagnostic technologies in applied research on diagnostic devices and tests. Complete development of surrogate markers of immunity for validation as acceptable markers of vaccine efficacy. Complete screening of therapeutic interventions gleaned from genomic sequencing studies, as applied to known threats and their virulence factors. Complete demonstration of usefulness of existing candidate medical countermeasures applied to emerging threat agents or genetically engineered microbes. Demonstrate animals models defining agent pathogenesis and immunology. Demonstrate promising generic medical countermeasures against threat agents for exploratory development studies in suitable model systems.

Total 20103
Project TC3 MEDICIAL CHEMICAL DEFENSE (LIFE SPT): This project supports the investigation of new medical countermeasures to include antidotes, pretreatment drugs, and topical skin protectants to protect U.S. forces against known and emerging chemical warfare (CW) threat agents. Capabilities are maintained for reformulation, formulation, and scale-up of candidate compounds using current good laboratory practices (cGLP). Analytical stability studies and safety and efficacy screening, in addition to pre-clinical toxicology studies, are performed prior to full-scale development of promising pretreatment or treatment compounds.

FY 1998 Accomplishments:
- **4918** Consolidated the testing profiles of candidate vesicant pretreatments in animal model systems. Performed toxicity and reactogenicity studies.
- **1110** Determined safety and immunologic response in animal models to mutagenized butyrlcholinesterase (BuChE) nerve agent scavengers.
- **373** Conducted demonstration of cyanomethemoglobin level blood monitor for chemical casualty assessment leading to Milestone 0 transition.
- **1768** Evaluated leading compounds for ability to block nerve agent-induced electroencephalographic (EEG) changes and seizures in non-human primate.
- **836** Formulated candidate reactive moieties for reactive topical skin protectant into an acceptable base.
- **919** Evaluated, in animals, the effects of improved intracellular delivery of antioxidants to cells undergoing free radical attack due to mustard gas exposure.

Total **9924**
FY 1999 Planned Program:

- 4869 Perform efficacy and safety studies in appropriate animal model of candidate treatments for vesicant-induced inflammation leading to down-selection for Demonstration and Validation phase.
- 1287 Conduct dose-ranging studies and efficacy studies of candidate nerve agent scavengers in non-human primates.
- 460 Develop and demonstrate computer-assisted expert system for management of chemical casualties to serve as an adjunct to field diagnostics. Determine the efficacy of FDA approved ocular therapies against HD, evaluate available therapeutic interventions to inhalation HD exposure in the pig, and complete testing of therapeutic regimes for HD contaminated wounds.
- 1931 Begin preparation of final data package for advanced anticonvulsant including clinical toxicity, safety and efficacy data for FY00 milestone decision.
- 1010 Perform final reformulation and rank order reactive topical skin protectant candidates. Identify and acquire novel wound decontamination reactive moieties.
- 7353 Chronic low dose efforts will include two National Academy of Sciences Institute of Medicine studies to develop long term research plans as basis for changes in policy and doctrine. Collaborative intramural and extramural efforts will be supported at USAMRICD, USAECBC, AFRRI and selected Universities.
- 286 SBIR/STTR

Total 17196

FY 2000 Planned Program:

- 6048 Test safety and efficacy of selected improved vesicant countermeasure candidates and initiate transition to improved vesicant countermeasure.
- 1061 Establish efficacy of reactive components in decontamination of wounds.
- 554 Test selected compounds for efficacy and safety against novel threat agents.
- 1782 Test safety and efficacy of improved chemical agent immunoprophylaxis.

Total 9445
**RDT&E BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)**

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<td>0603384BP CHEMICAL/BIOLOGICAL DEFENSE</td>
<td>TC3</td>
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**FY 2001 Planned Program:**

- 1616  Test far-forward rapid diagnostic tests in limited field tests.
- 807   Select best candidates and test for safety and efficacy against novel threat agents.
- 2536  Select best candidates and test for efficacy and safety against vesicant agent exposure.
- 4470  Initiate selection of best candidate(s) for improved chemical agent prophylaxis.

**Total** 9429