Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Chemical and Biological Defense Program										DATE: February 2011	
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*				R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*							
COST ($ in Millions)	**FY 2010**	**FY 2011**	**FY 2012 Base**	**FY 2012 OCO**	**FY 2012 Total**	**FY 2013**	**FY 2014**	**FY 2015**	**FY 2016**	**Cost To Complete**	**Total Cost**
Total Program Element	304.952	177.113	229.235	-	229.235	244.608	229.593	212.170	212.377	Continuing	Continuing
CB3: *CHEMICAL BIOLOGICAL DEFENSE (ATD)*	26.964	15.410	23.818	-	23.818	30.514	37.806	38.139	38.586	Continuing	Continuing
CI3: *CONGRESSIONAL INTEREST ITEMS (ATD)*	30.172	-	-	-	-	-	-	-	-	0.000	30.172
TB3: *MEDICAL BIOLOGICAL DEFENSE (ATD)*	196.007	115.233	172.636	-	172.636	180.913	167.900	149.413	148.398	Continuing	Continuing
TC3: *MEDICAL CHEMICAL DEFENSE (ATD)*	28.046	29.134	21.582	-	21.582	21.900	22.695	23.193	23.919	Continuing	Continuing
TE3: *TEST & EVALUATION (ATD)*	12.296	11.875	11.199	-	11.199	11.081	0.992	0.991	0.990	Continuing	Continuing
TR3: *MEDICAL RADIOLOGICAL DEFENSE (ATD)*	4.086	0.957	-	-	-	0.200	0.200	0.434	0.484	Continuing	Continuing
TT3: *TECHBASE TECHNOLOGY TRANSITION*	7.381	4.504	-	-	-	-	-	-	-	0.000	11.885

A. Mission Description and Budget Item Justification

This program element (PE) demonstrates technologies that enhance the ability of U.S. forces to deter, defend against, and survive Chemical, Biological, and Radiological (CBR) warfare. This program element (PE) funds advanced technology development for Joint Service and Service-specific requirements in both medical and physical sciences CBR defense areas. The medical program aims to produce drugs, vaccines and medical devices as countermeasures for CBR threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the physical sciences area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination. The work in this PE is consistent with the Joint Service CB Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated biological warfare operational awareness, and the restoration of operations following a biological warfare or chemical warfare attack. This program is dedicated to conducting proof-of-principle field demonstrations, test of system-specific technologies to meet specific military needs. Work conducted under this PE transitions to and provides risk reduction for System Integration/ Demonstration (PE 0603884BP/PE 0604384BP) activities.

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B. Program Change Summary ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
Previous President's Budget	299.680	177.113	197.867	-	197.867
Current President's Budget	304.952	177.113	229.235	-	229.235
Total Adjustments	5.272	-	31.368	-	31.368
• Congressional General Reductions		-			
• Congressional Directed Reductions		-			
• Congressional Rescissions	-	-			
• Congressional Adds		-			
• Congressional Directed Transfers		-			
• Reprogrammings	-2.241	-			
• SBIR/STTR Transfer	-3.664	-			
• Other Adjustments	11.177	-	31.368	-	31.368

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2010	FY 2011
Project: CI3: *CONGRESSIONAL INTEREST ITEMS (ATD)*		
Congressional Add: *Total Perimeter Surveillance (TPS)*	1.593	-
Congressional Add: *Handheld Automated Bio Agent Identifier*	2.390	-
Congressional Add: *Plant Vaccine Development*	1.593	-
Congressional Add: *Multi-Target Shipping Container Interrogation System Mobile Continuous Air Monitor*	1.593	-
Congressional Add: *Hand-Held Apparatus for Mobile Mapping and Expedited Reporting*	2.788	-
Congressional Add: *Regenerative Chemical Biological Filtration Systems*	2.689	-
Congressional Add: *Unified Management Infrastructure System*	0.797	-
Congressional Add: *CBDP Advanced Development*	1.992	-
Congressional Add: *Automated Sample Preparation (ASP) for Biological Detection*	0.797	-
Congressional Add: *High Speed, High Volume Laboratory Network for Infectious Disease*	1.593	-
Congressional Add: *Protective Self-Decontaminating Surfaces*	1.593	-
Congressional Add: *Chemical and Biological Threat Reduction Coating*	2.390	-
Congressional Add: *Self-decontaminating Polymer System for Chemical and Biological Warfare Agents*	2.788	-
Congressional Add: *Contaminated Human Remains Pouch*	1.593	-
Congressional Add: *Portable Rapid Bacterial Warfare Detection Unit*	3.983	-

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Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2010	FY 2011
Congressional Add Subtotals for Project: CI3	30.172	-
Congressional Add Totals for all Projects	30.172	-

Change Summary Explanation

Funding: FY10 - Adjustments less than 10% of total program.

FY12 - Program realignments to support high priority CBDP and DoD program initiatives (+$2,400K CB3; +$47,244K TB3; -$8,819K TC3; -$38K TE3; -$949K TR3; -$8,117K TT3). Economic assumptions (-$32K CB3; -$274K TB3; -$30K TC3; -$17K TE3).

Schedule: N/A

Technical: N/A

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011
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COST ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
CB3: *CHEMICAL BIOLOGICAL DEFENSE (ATD)*	26.964	15.410	23.818	-	23.818	30.514	37.806	38.139	38.586	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (CB3) demonstrates technology advancements for joint service application in the areas of detection, information systems technology, protection/hazard mitigation, and technology transition efforts. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. This project also includes efforts dedicated to developing capabilities to protect against Non-Traditional Agents (NTAs). Starting in FY11, all NTA-dedicated research will be re-aligned into specific capability areas within this project in order to ensure a focused effort on this high priority area. Detection focuses on advanced development of technologies from applied research for standoff and point detection and identification of chemical and biological agents. Information systems advanced technology focuses on areas of advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling. Protection and Hazard Mitigation focuses on advanced development of technologies that protect and reduce the chemical/biological/radiological/nuclear threat or hazard to the Warfighter, weapons platforms, and structures. This project also funds advanced development of chemical and biological defense science and technology initiatives and transitions them to advanced development programs in Budget Activities 4 and 5, through prototypes that are evaluated in Advanced Technology Demonstration (ATDs) and Joint Warfighter Experimentation (JWE).

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Title: 1) Protection & Hazard Mitigation	0.931	0.753	0.657
Description: Lightweight Integrated Fabric: Demonstration of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform. ***FY 2010 Accomplishments:*** Developed systems integration of a complete chemical and biological (CB) ensemble that incorporates emerging designs and prototype concepts. Refined concepts for an integrated ensemble that will transition to advanced development programs such as the Uniform Integrated Protective Ensemble (UIPE) and the Individual Protection Advanced Technology Demonstration (IP Demo - see Project TT3, Experimental & Technology Demonstration and Project TT4). Continued limited field trials in a relevant environment. ***FY 2011 Plans:*** Incorporate lessons from IP Demo and develop final data packages for transition to UIPE and/or Joint Service Lightweight Integrated Suit Technology (JSLIST) programs. ***FY 2012 Plans:*** Incorporate next phase of integrated textile systems into a complete second generation candidate ensemble for the Uniform Integrated Protective Ensemble (UIPE) Phase II program as well as other applicable Advanced Technology Demonstrations that			

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
may materialize. Provide a trade-space analysis of all government, industrial, and academic candidate materials for use in future UIPE phase initiations. Transition human performance initial tool set to JPM protection that can be used in the optimization of protective ensemble design.			
Title: 2) Protection & Hazard Mitigation ***Description:*** Low-Resistance, Low-Profile Filtration: Demonstration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that includes toxic industrial chemicals. ***FY 2010 Accomplishments:*** Initiated brassboard prototype development efforts for the next generation filter for individual protection from CB agents, Toxic Industrial Chemicals (TICs) and Non Traditional Agents (NTAs), in efforts parallel to the IP Demo for collective protection filtration in support of advanced development programs such as the Joint Expeditionary Collective Protection (JECP) and support of collective protection in vehicular/platform systems in Major Defense Acquisition Programs (MDAP). ***FY 2011 Plans:*** Incorporate lessons from the IP Demo and develop final data packages for transition to advanced development programs such as the UIPE, Joint Service General Purpose Mask (JSGPM), and Joint Service Aircrew Mask (JSAM) (see BA5, Project IP5). Continue prototype development in support of JECP and support of collective protection in vehicular/platform systems in MDAP. ***FY 2012 Plans:*** Continue demonstration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that includes toxic industrial chemicals. Transition these technologies to the JSGPM and JSAM programs.	0.942	0.878	0.656
Title: 3) Protection & Hazard Mitigation ***Description:*** Low-Burden Air Purifying Respirator: Demonstration of design alternatives for chemical and biological air-purifying respirators to provide enhanced protection with lower physiological burden and improved interface with mission equipment. ***FY 2010 Accomplishments:*** Continued integration of the protective mask designs with developmental helmet systems to provide seamless compatibility of CB protection with ballistic protection, and the integration of communication and optical systems in parallel excursions to the IP Demo. ***FY 2012 Plans:***	0.768	-	0.703

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Advanced concept CBRN technologies will be integrated within the confines of the Chem/Bio protection component of the Helmet Electronics and Display System - Upgradable Protection (HEADS-UP) Army Technology Objective (ATO) program, which has multi-service participation for ground applications.			
Title: 4) Protection & Hazard Mitigation ***Description:*** Logistically Sustainable Air Purification for Collective Protection: Demonstration of chemical and biological air-purification alternative technologies that minimize or eliminate the need for expendable media within acceptable size, weight and power constraints. ***FY 2010 Accomplishments:*** Initiated breadboard prototypes development of down-selected media-less technologies. ***FY 2012 Plans:*** Demonstrate breadboard concepts of a residual life indicator (RLI) for collective filtration systems.	0.631	-	0.188
Title: 5) Protection & Hazard Mitigation ***Description:*** General Purpose Formulations for Decontamination: Demonstration of improved chemical and biological decontamination formulation that is compatible with the current family of decontamination systems. ***FY 2010 Accomplishments:*** Completed coupon tests, material compatibility and small item effectiveness evaluations for solid oxidants and green solvent/ surfactant systems. Transitioned to Decontamination Family of Systems program (see BA5, Project DE5).	0.980	-	-
Title: 6) Protection & Hazard Mitigation ***Description:*** Decontamination Family-of-Systems (DFoS): Demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. ***FY 2010 Accomplishments:*** Completed data package for self-decontaminating surfaces. Transitioned to the Hazard Mitigation for Materials and Equipment Restoration (HaMMER) Advanced Technology Demonstration (see Project TT3, E&TD). ***FY 2011 Plans:*** Complete additional data packages and technical assessments of technologies to transition to the Joint Program Manager for Decontamination (JPM-Decon) to be incorporated into the Decontamination Family of Systems (DFoS) Program of Record. ***FY 2012 Plans:***	0.272	0.377	1.173

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Continue demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. Integrate robust surface chemistry and decontamination process analysis using ultra high vacuum system into technology maturation process for hazard mitigation. Demonstrate integrated decontaminant test and evaluation system (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursue the optimization of reactive coatings (durable). Transition research efforts "Surfactant Technology for Surface Chemical/Biological Agent Removal" and "Decontamination Assurance Spray."			
Title: 7) Protection & Hazard Mitigation ***Description:*** Innovative Systems Concepts and Analysis: Development and systems analysis of novel system concepts for chemical and biological protection of occupants of buildings and platforms that integrates emerging technologies. ***FY 2011 Plans:*** Focus efforts on most promising approaches and initiate component development to support prototyping and demonstrations. Technologies may include micro fine detoxifying aerosol fogs to facilitate entry and mitigate cross contamination into collective protection systems, internal self-detoxifying surfaces for walls and ductwork, expedient retrofit kits, self-detoxifying and expedient strippable coatings, rapid isolation and purge schemes, and novel and innovative air flow and re-circulation schemes. ***FY 2012 Plans:*** Continuation of Innovative Systems Concepts and Analysis. Transition research effort "Reactive Airlock for Armored Vehicles, Shipboard and Shelter Applications."	-	0.624	0.334
Title: 8) Information Systems Technology ***Description:*** Warning and Reporting Information and Analysis: Emphasis on developing science and technologies for collaborative information management, fusion of disparate information from multiple sources, environmental databases and modeling, fusion of syndromic/diseases surveillance data, and synthetic environments for model performance evaluation and acquisition decisions. ***FY 2010 Accomplishments:*** Transitioned enhanced version of first-generation building interior Source Term Estimation (STE) and Hazard Refinement (HR) software to the Joint Effects Model (JEM). ***FY 2011 Plans:***	1.000	1.054	1.288

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Transition next-generation outdoor STE, HR, and Sensor Placement Tool (SPT) to advanced development programs (JEM - see BA5 Project IS5). Transition first-generation false alarm reduction capability and first generation rapid STE algorithms to advanced development program (JWARN). ***FY 2012 Plans:*** Initiate Verification and Validation (V&V) of STE and HR algorithms for use in complex environments (e.g., variable terrain, urban, water, and building interiors). Transition first-generation false alarm reduction capability. Transition report on the use of meteorological ensemble predictions in dispersion models.			
Title: 9) Information Systems Technology ***Description:*** Hazard Prediction & Information Analysis: Improve battlespace awareness by accurately predicting hazardous material releases, atmospheric transport and dispersion, and resulting human effects. Develop predictive capability for the source term of releases of chemical, biological, and industrial materials from weapons and accidents. ***FY 2010 Accomplishments:*** Continued further refinements of the Geographic Environmental Database and Information System (GEDIS) data requirements tool with additional types of data such as climatology and population. Completed urban dispersion modeling for transition into JEM. Developed and implemented the configuration management prototype for transition of project results to advanced development programs. ***FY 2011 Plans:*** Continue further refinements of the GEDIS data requirements tool. Complete optimization of methods to significantly improve performance of transport and dispersion hazard models for JEM. Continue development and implementation of a configuration management prototype for transition of project results to advanced development programs. Continue advanced development of JEM algorithms to portray and predict Non-Traditional Agent (NTA) hazards in operational environments. ***FY 2012 Plans:*** Further develop the high altitude post-missile intercept effects model for eventual integration into hazard prediction and counterproliferation model frameworks by drawing upon existing modeling of other agencies and handling both successfully intercepted weapons as well as intentionally functioning weapons of a chemical, biological or nuclear payload. Continue with work on configuration management prototype to establish upgraded capabilities listed as valid requirements for JEM.	2.932	1.961	0.913
Title: 10) Information Systems Technology	0.412	0.427	1.465

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Description: Operations Planning & Information Analysis: Develop decision support tools and information management capabilities for planning and real-time analysis to determine and assess operational effects, risks, and impacts of CBRN incidents on decision making. Focus areas include consequence management, population modeling, and human knowledge management. ***FY 2010 Accomplishments:*** Transitioned sensor placement tool to acquisition programs. Transitioned CB effects on mobile forces analysis study and prototype for tactical and operational military operations. Transitioned improved Incident Management/Consequence Management (IM/CM) tools and capabilities to advanced development programs. ***FY 2011 Plans:*** Transition decision support tools for CBRN to the Joint Warning and Reporting Network (JWARN). Transition refined secondary infection and contagious/infectious disease models to the Joint Effects Model (JEM). Transition updated and expanded human effects models. Transition IM/CM tools and capabilities in consequence systems. Transition a fully optimized sensor placement tool. ***FY 2012 Plans:*** Begin development of next generation consequence management software tools that can help to inform both military and civilian first responder commanders regarding (1) CM plan development; (2) shelter-in-place vs evacuation decisions; and (3) operations effects. Develop a route-planning decision aid.			
Title: 11) Information Systems Technology ***Description:*** Systems Performance & Information Analysis: Develop Chemical, Biological, Radiological and Nuclear (CBRN) data sharing capabilities. ***FY 2010 Accomplishments:*** Completed prototyping a data collection and exchange capability. Developed processes and policies for collection and insertion of data into CBRN data management efforts. ***FY 2012 Plans:*** Perform improvements in CBRN data management capabilities, with emphasis on enabling access to information for analysis within CBDP systems performance models. Further enhance analysis toolset which provides the ability to evaluate decontaminants and decontamination systems.	0.100	-	0.350
Title: 12) Information Systems Technology	0.100	-	0.877

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Description: Medical Surveillance & Information Analysis: Integrate existing disparate military and civilian datasets into advanced warning systems, and leverage and enhance epidemiological models and algorithms for disease prediction, impact and biological threat assessment. Contribute to the development of global, near real time, disease monitoring and surveillance systems that address secondary infection, fuse medical syndromic, environmental, and clinical data, and feed into agent-based epidemiological modeling, medical resource estimation and decision support tools. Focus areas include health/human effects modeling including casualty estimation, agent-based epidemiological modeling and fusion of disease surveillance data. ***FY 2010 Accomplishments:*** Verified respiratory tract models for prediction of human response as a function of particle size to improve casualty estimation for CBRN hazards and prepared these models for incorporation into the Joint Effect Model (JEM) for currently available agent data. Transitioned infection/contagious disease model to JEM. ***FY 2012 Plans:*** Transition medical resource estimation and medical countermeasure models. Begin effort to V&V existing agent-based epidemiological models, to include underlying population data and disease spread algorithms, with regard to use in robust adaptive decision making.			
Title: 13) Detection ***Description:*** Detection Capabilities for Non-Traditional Agents: Develop detection technologies for Non-Traditional Agents. In FY11, all NTA-related efforts re-aligned to the Detection NTA capability area located in this Budget Activity. ***FY 2010 Accomplishments:*** Continued developing supporting technologies and protocols to meet the Initial Operating Capabilities of the Next Generation Test Facility at the Edgewood Chemical and Biological Center.	1.985	-	-
Title: 14) Detection ***Description:*** Chemical and Biological Stand-off Technology: Focuses on the detection and identification of chemical and biological threats in near real time at a distance from the detector. Future programs focus on the improvement of algorithms, excitation sources, and detector elements to increase range, reduce false positives, increase sensitivity, and reduce cost. ***FY 2010 Accomplishments:*** Conducted a Technology Readiness Assessment and transitioned active IR and depolarization technologies as a candidate for JBSDS Increment 2. Initiated field trials to validate chemical signature for chemical standoff detection and identification capabilities. Initiated an analysis of alternatives to support efforts in meeting new requirements for the next generation of standoff	11.811	0.496	7.757

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
chemical technology. Initiated efforts in the development of new test methodology for assessing next generation chemical standoff technology to include ground truth systems for field assessments. ***FY 2011 Plans:*** Complete field trial validation of chemical signatures for chemical standoff detection and identification capabilities. Continue development of test methodology for next generation chemical standoff technology. Initiate the process of validating ground truth systems for field assessments. ***FY 2012 Plans:*** Continue development of test methodology for next generation chemical standoff technology. Continue the process of validating ground truth systems for field assessments.			
Title: 15) Detection NTA ***Description:*** Detection NTA: Focuses on technologies to provide NTA detection capabilities. ***FY 2011 Plans:*** Complete the supporting efforts necessary to provide the Initial Operating Capabilities for test facilities. The effort will focus on detection and analytical methodologies to determine sensitivities/thresholds necessary to establish exposure standards needed to create standard operating procedures for the facility. ***FY 2012 Plans:*** Initiate the development of test methodology to validate signatures for chemical aerosols threat materials.	-	4.200	7.457
Title: 16) Technology Transition ***Description:*** Technology Transition - Conduct competitive assessments of promising mature technology from outside the Chemical and Biological Defense Program (CBDP) and assist in transition of promising technology efforts. ***FY 2010 Accomplishments:*** Continued transition of the Integrated CB Agent Hazard Mitigation with systems and neutralization efficiency testing in a laboratory environment. Continued competitive assessment of all mature technology from outside of the CBDP for rapid technology insertion into the capability areas. ***FY 2011 Plans:***	4.100	4.640	-

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Complete transition of the Integrated CB Agent Hazard Mitigation with systems and neutralization efficiency testing in an operational environment. Complete assessment and down-select to two or three best technologies that provides the highest enhancements to capabilities.			
Accomplishments/Planned Programs Subtotals	26.964	15.410	23.818

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• CA4: *CONTAMINATION AVOIDANCE (ACD&P)*	39.396	63.347	33.952		33.952	28.703	24.178	37.476	27.930	0.000	254.982
• CB2: *CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)*	110.937	88.897	97.774		97.774	94.721	89.677	90.823	108.941	Continuing	Continuing
• DE4: *DECONTAMINATION SYSTEMS (ACD&P)*	14.867	7.051	38.737		38.737	30.608	6.430	7.383	12.553	Continuing	Continuing
• IS4: *INFORMATION SYSTEMS (ACD&P)*	13.914	11.221	7.420		7.420	14.682	0.000	0.000	0.000	0.000	47.237
• TE3: *TEST & EVALUATION (ATD)*	12.296	11.875	11.199		11.199	11.081	0.992	0.991	0.990	Continuing	Continuing
• TE4: *TEST & EVALUATION (ACD&P)*	28.412	19.304	5.438		5.438	16.232	12.461	18.369	19.296	Continuing	Continuing
• TT4: *TECHBASE TECHNOLOGY TRANSITION (ACD&P)*	24.937	26.466	3.022		3.022	3.923	4.758	8.467	9.075	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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COST ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
CI3: *CONGRESSIONAL INTEREST ITEMS (ATD)*	30.172	-	-	-	-	-	-	-	-	0.000	30.172

A. Mission Description and Budget Item Justification

The efforts listed in this project include congressional interest programs for FY10.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011
Congressional Add: Total Perimeter Surveillance (TPS) ***FY 2010 Accomplishments:*** Developed a Total Perimeter Surveillance (TPS) solution based on infrared spectroscopy that can provide complete perimeter threat detection and identification with sufficient advanced warning to key DoD infrastructure.	1.593	-
Congressional Add: Handheld Automated Bio Agent Identifier ***FY 2010 Accomplishments:*** Developed a multiplex handheld immunoassay tickets that are both human visually and machine read. This effort utilized an existing immunoassay ticket format to develop nucleic acid-based rapid assays capable of identifying biological agents by species, genus or other category/grouping (e.g., bacteria, toxin, virus). Such a nucleic acid assay will be read by a handheld reader through a "one-button" operation process.	2.390	-
Congressional Add: Plant Vaccine Development ***FY 2010 Accomplishments:*** Developed vaccine lots under cGMP and evaluated safety and toxicity and confirmed protective efficacy of identified dual agent vaccines. Developed technology transfer and implementation programs.	1.593	-
Congressional Add: Multi-Target Shipping Container Interrogation System Mobile Continuous Air Monitor ***FY 2010 Accomplishments:*** Developed an air monitoring system for shipping containers, capable of performing multiple bioassays for live organisms and toxins simultaneously, efficiently, accurately and extremely fast.	1.593	-
Congressional Add: Hand-Held Apparatus for Mobile Mapping and Expedited Reporting ***FY 2010 Accomplishments:*** Developed a tool that enables a rapid, accurate, efficient, low-cost, collection, analysis and dissemination of digital data from multiple sensor suites and rapid reporting for improved situational awareness.	2.788	-
Congressional Add: Regenerative Chemical Biological Filtration Systems	2.689	-

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011
FY 2010 Accomplishments: Developed a regenerative filtration system to reduce costs and provide protection against all chemical warfare agents for military personnel, critical equipment, and strategic facilities. The objective of this project is to mature the technology of regenerable chemical warfare collective protection.		
Congressional Add: Unified Management Infrastructure System ***FY 2010 Accomplishments:*** Developed a secure communication platform to meet military needs in a chemical biological environment, protecting soldiers and first responders on the battlefield using secure mobile communication systems by simultaneously providing what is currently unprecedented: real-time, accurate monitoring of the military's communication devices.	0.797	-
Congressional Add: CBDP Advanced Development ***FY 2010 Accomplishments:*** Conducted advanced development to develop a sensor core adapted from new technology based on high performance Liquid Chromatography detection of molecular interactions on nanostructured surfaces.	1.992	-
Congressional Add: Automated Sample Preparation (ASP) for Biological Detection ***FY 2010 Accomplishments:*** Developed ASP technology to address the challenges of sample preparation for the detection/diagnosis of biological warfare agents. The ASP technology has the ability to process both environmental and clinical biological samples for subsequent analysis on both nucleic acid and/or immunoassay detection/diagnostic systems to detect and identify hundreds of potential targets simultaneously within a single analysis on a single detection/diagnostic platform.	0.797	-
Congressional Add: High Speed, High Volume Laboratory Network for Infectious Disease ***FY 2010 Accomplishments:*** Developed a new high speed, high throughput bioagent screening and genotyping capability that will be able to conduct large scale, data driven research. This resource could be linked with military, government and public institutions and identify epidemiologic and genotypic information of influenza viruses, emerging infectious diseases and bioterrorism.	1.593	-
Congressional Add: Protective Self-Decontaminating Surfaces ***FY 2010 Accomplishments:*** Improved singlet oxygen technology for self-decontaminating surfaces.	1.593	-
Congressional Add: Chemical and Biological Threat Reduction Coating	2.390	-

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011
FY 2010 Accomplishments: Developed a textile laminate that incorporates multifunction fabrics into a textile system including a self-decontaminating fabric layer, a membrane to protect against biological threats, and a sorbent layer.		
Congressional Add: Self-decontaminating Polymer System for Chemical and Biological Warfare Agents ***FY 2010 Accomplishments:*** Enhanced the properties of self-decontaminating materials by defining the relevant mechanisms through experimental and theoretically evaluation of the fundamental characteristics. Continue evolution of these materials through proven engineering approaches.	2.788	-
Congressional Add: Contaminated Human Remains Pouch ***FY 2010 Accomplishments:*** Developed, optimized, and produced an improved gas-tight, liquid-impervious, odor-proof, fluid-absorbing, self decontaminating, and transportable Enhanced Contaminated Human Remains Pouch (ECHRP).	1.593	-
Congressional Add: Portable Rapid Bacterial Warfare Detection Unit ***FY 2010 Accomplishments:*** Used DNA profiling to identify the microorganisms of military significance by obtaining genomic information needed for identification without performing the complicated and expensive sequencing protocols. Optimized these devices for field deployment.	3.983	-
Congressional Adds Subtotals	30.172	-

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• CI1: *CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)*	7.968	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	7.968
• CI2: *CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)*	27.186	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	27.186

D. Acquisition Strategy

N/A

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E. Performance Metrics

N/A

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COST ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TB3: *MEDICAL BIOLOGICAL DEFENSE (ATD)*	196.007	115.233	172.636	-	172.636	180.913	167.900	149.413	148.398	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TB3) funds preclinical and early phase clinical development of vaccines, therapeutic drugs, and diagnostic capabilities to provide safe and effective medical defense against validated biological threat agents or emerging infectious disease biothreats including bacteria, toxins, and viruses. Innovative biotechnology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents will be evaluated. Entry of candidate vaccines, therapeutics, and diagnostic technologies into advanced development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) processes, DoD acquisition regulations, and the oversight of early phase clinical trials in accordance with FDA guidelines. Categories of this project include biological defense capability areas such as Pretreatments, Diagnostics, and Therapeutics. Pretreatment efforts conduct research and development (R&D) of promising vaccines, medications, and technologies provided prior to potential exposure to biological agents. The goal is to reduce or to entirely prevent adverse effects of exposure. Diagnostic efforts are aimed at screening procedures and analytical methods to verify exposure and determine the effects of exposure to biological warfare (BW) or other biothreat agents. Therapeutic efforts provide medical solutions to sustain and protect the Warfighter in biological environments. Specifically, therapeutic efforts are aimed at developing medical countermeasures to treat exposure to biological or emerging threats such as bacterial (plague, anthrax, glanders), viral (smallpox, encephalitic alphaviruses), and toxin (ricin, botulinum neurotoxin, staphylococcal enterotoxin) agents.

This project also includes efforts such as the Transformational Medical Technologies Initiative (TMTI). Effective FY12 this effort is funded as the Transformational Medical Technologies (TMT) Program. The program was launched to respond to the threat of emerging or intentionally engineered biological threats. TMT's mission is to protect the Warfighter from genetically engineered or emerging infectious disease biological threats by providing a rapid response capability from identification of pathogens to the delivery of medical countermeasures. This mission is accomplished through two main efforts: 1) developing broad spectrum (multi-agent) therapeutics against BW or emerging infectious disease agents (e.g. one drug that treats multiple agents); and 2) developing platform technologies to assist in the rapid development of medical countermeasures (MCMs) in response to BW or emerging infectious disease agents (e.g. developing new and innovative ways to mass produce drugs in the event of a biological incident).

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, based on public-private parternship agreements between the government and industry, providing a dedicated, cost-effective, reliable, and sustainable MCM process that meets the warfighter and national security needs. Specifically, the MCMI will provide the capability for the advanced development and flexible manufacturing of biological MCM (to include TMT developed MCMs) to address CBRN threats, including novel and previously unrecognized, naturally-occurring emerging infectious diseases. MCMI efforts within S&T are concentrated in three areas: 1) transition of novel platform/expression systems for MCMs, 2) transition advancement of regulatory science, and 3) integration of novel platforms with MCM advanced development and manufacturing.

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Title: 1) Diagnostics (Biosurveillance)	11.109	9.845	10.328

Description: Diagnostic Technologies: Development and verification of rapid, sensitive and specific tests for the identification of Biological Warfare Agents (BWAs) and their expressed toxins in biological fluids of Warfighters for the diagnosis of exposure/ infection. Discovery of biomarkers of response to exposure. Evaluation of next generation diagnostic technologies including portable instrument platforms, highly parallel and informative testing formats, and nanotechnology applications.

FY 2010 Accomplishments:
Continued development of two additional candidates for a next generation diagnostic device. Developed an automated, prototype polymerase chain reaction system on microarray cartridge using light emitting chemical-based (or other sensitive signal-amplified) technology. Continued to refine and transition strain test panels for viral specificity (inclusivity and exclusivity) characterization. Characterized assay specificity to ensure assays consistently identify the intended target but not related targets. Used highly parallel and informative microarray screening techniques with thoroughly characterized affinity reagents for the discovery of novel biomarkers of host response as targets for assay development. Developed and verified assays as per standardized processes. Transitioned pilot production protocols for biosynthetic (recombinant) antigen production for bacterial BWAs. Maintained an animal tissue bank for validation of assay performance and as correlate reference materials from animal BWA exposure studies. Developed and verified single domain biosynthetic (recombinant) antibodies to bacterial and viral BWA targets. Investigated methods of stabilization of BWA biomarkers in clinical samples to extend transport and limit cold chain requirements.

FY 2011 Plans:
Use decision-based matrix and technology evaluation centers to transition two Technology Readiness Reviews on candidate diagnostic platforms to advanced development programs. Develop atlas/database of phenotypic and genotypic characteristics of relevant BWA bacterial strains. Demonstrate the utility of high informatic content screen-characterized affinity reagents in the discovery of novel biomarkers as targets for assay development. Develop standard methods/protocols for rapid sequencing directly from clinical matrices. Apply bioinformatic and computational methods to verify the utility of host response signatures for pre-symptomatic diagnostic assays. Transition candidate transport media/preservatives and protocols for clinical sample processing. Evaluate developed global-virus and global-microbial microarrays for promising multiplexing and identification of BWAs. Develop and verify production scale-up protocols for single domain biosynthetic (recombinant) antibodies to bacterial and viral BWA targets.

FY 2012 Plans:
Validate and submit pre-EUA (Emergency Use Authorization) data to FDA for high priority BWA and emerging threat assays to preposition for biopreparedness. Transition portable sequence based genetic analyzer and verify assays for top ten priority agents. Transition technology watch report and mature candidate platform technologies of sufficient utility for advanced development as Next Generation Diagnostics System and/or Biosurveillance platform. Transition data packages for detection of

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
antibiotic (Cipro) resistance. Validate and transition scale-up protocols for single domain biosynthetic (recombinant) antibodies to bacterial and viral BWA targets for use in austere environments. Supplement/continue accrual of geographically/genetically representative strain collection and transfer to repository; develop quantitative cell culture for an additional emerging threat agent of high genetic variability. Transition atlas/database of phenotypic and genotypic characteristics of relevant BWA bacterial strains to advanced developer.			
Title: 2) Pretreatments ***Description:*** Bacterial/Toxin Vaccines: Evaluates the best single agent bacterial and toxin vaccines for effectiveness against aerosol challenge in large animal models. ***FY 2010 Accomplishments:*** Planned, prepared and conducted a Phase I clinical trial with the Ricin vaccine. ***FY 2011 Plans:*** Complete the Phase I clinical trial with the Ricin Vaccine. ***FY 2012 Plans:*** Perform final analysis of data from Phase I Clinical trial. Assemble final Ricin vaccine data package.	0.984	0.937	0.799
Title: 3) Pretreatments ***Description:*** Viral Vaccines: Evaluates the best vaccine candidates for Alphaviruses and Filoviruses for effectiveness and duration of protective immune response against aerosol challenge in large animal models. Animal models will be developed to support FDA licensure of mature vaccine candidates. The purpose of developing these animal models is to support pivotal animal studies under the "animal rule". ***FY 2010 Accomplishments:*** Initiated studies to develop/validate animal models for VEE, EEE, and WEE vaccines, as well as for filovirus vaccines, to fulfill future FDA animal rule requirements necessary for vaccine licensure. Tested chemically inactivated and deoxyribonucleic acid (DNA) vaccine candidates against VEE, EEE, and WEE for effectiveness against aerosol delivered doses in animals. Conducted dose, schedule, and aerosol challenge studies in animals with Ebola vaccine candidates. Transitioned two Marburg virus vaccine candidates to advanced development programs, and determined protection duration studies on these two candidates. Conducted studies to further evaluate the effectiveness of combining the individual filoviruses (i.e., Ebola Sudan, Ebola Zaire, Ebola Uganda, and Marburg Angola) vaccines into one multi-agent vaccine. Conducted studies to further evaluate the effectiveness of combining the individual alphavirus (i.e., VEE, EEE, and WEE) vaccines into one multi-agent vaccine. ***FY 2011 Plans:***	14.621	10.304	19.930

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Complete duration studies with the vaccine components against Marburg that transitioned to the advanced development program in FY10. Complete aerosol efficacy studies for the Ebola Zaire and Ebola Sudan vaccine components in non-human primates. Transition the Ebola vaccine components to the advanced development program to combine with the Marburg vaccine component. Determine duration of protection elicited by the Ebola vaccine components. Optimize the dose and immunization schedule to ensure effectiveness of the individual components of the filovirus vaccine when co-administered as a mixture. Complete aerosol efficacy studies of DNA-based vaccines and chemically inactivated/attenuated vaccines against the alphaviruses. Optimize dosing regimens to ensure effectiveness when co-administering the alphavirus vaccine components. Continue the development of animals models for alphaviruses (EEE and WEE), and filoviruses (Ebola Sudan, Ebola Zaire, Ebola Bundibugyo, and Marburg), to fulfill future FDA animal rule requirements necessary for vaccine licensure. For Alphaviruses, determine the median lethal dose of VEE, EEE, and WEE in a distinct type of non-human primate, and test the alphavirus vaccines for immune stimulation capability and efficacy against challenge in this new animal model. For filoviruses, determine the median lethal dose of Ebola Bundibugyo in a distinct type of non-human primate, and begin natural history studies for Ebola Bundibugyo, Ebola Sudan, Ebola Zaire, and Marburg. ***FY 2012 Plans:*** Complete duration studies with the vaccine components against Ebola that transitioned to the advanced development program in FY11. Complete remaining aerosol efficacy studies for the Ebola Zaire and Ebola Sudan vaccine components in non-human primates. Conduct formulation studies of Ebola and Marburg vaccine components. Coordinate with the advanced developer to fulfill S&T needs in support of the filovirus vaccine transition. For Alphavirus DNA vaccines, complete an IND package for the VEE component, submit the IND package to the FDA and initiate a Phase I clinical trial. Manufacture clinical grade (sufficient quality to be administered to humans in a Phase I clinical trial) lots of the EEE and WEE DNA components. Conduct pre-clinical studies on a trivalent VEE, EEE, WEE DNA formulation. For the Alphavirus replicon vaccine, complete an IND package and submit it to the FDA. Continue the development of animals models for alphaviruses (EEE and WEE), and filoviruses (Ebola Sudan, Ebola Zaire, Ebola Bundibugyo, and Marburg), to fulfill future FDA animal rule requirements necessary for vaccine licensure. Although the Filovirus vaccines are transitioning to CBMS in FY11, work will continue on the selected candidate(s) in coordination with CBMS to fill knowledge gaps.			
Title: 4) Pretreatments ***Description:*** Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates themselves. Vaccine	1.722	4.371	4.993

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Platforms and Research Tools utilize novel technologies to stabilize advanced vaccine candidates as well as alternative delivery modalities. ***FY 2010 Accomplishments:*** Researched multiagent vaccines, immune interference, immune stimulating formulations, vaccine delivery/stabilization to predict the human immune response to vaccine candidates. Initiated studies to examine potential immune interference between vaccines (e.g., filovirus interference with alphavirus vaccines; anthrax interference with plague vaccine, etc.) developed by the Department of Defense (DoD). Evaluated mature Marburg vaccine candidates ready for transition to the advanced developer using the laboratory based human artificial immune system (i.e., MIMIC) technology. ***FY 2011 Plans:*** Examine the efficacy of a mature filovirus vaccine in animals previously vaccinated with a mature alphavirus vaccine that was constructed using the same platform technology, to reveal potential immune interference in order to determine whether multiple vaccines using the same platform technologies can be used together. Analyze blood samples collected from individuals in the Former Soviet Union (i.e., vaccinated laboratory workers and/or individuals infected with bio-defense agents endemic to the region) in laboratory assays to determine the antibody and cell-based immune responses elicited by vaccines and/or pathogens of interest, and compare those results to animal studies. Evaluate the safety and immune stimulating capability of mature Filovirus and Alphavirus vaccine candidates in humans by using the MIMIC technology, to support these candidates moving forward into phase I clinical studies by the advanced development program. Conduct pre-formulation studies to produce a thermo-stable, spray-dried formulation of the virus-like particle based Marburg vaccine candidate. ***FY 2012 Plans:*** Continue evaluation of the safety and immune stimulating capability of mature Filovirus and Alphavirus vaccine candidates in humans by using the MIMIC technology. Continue formulation studies to produce a thermo-stable, spray-dried formulation of the virus-like particle based Marburg vaccine candidate. Evaluate additional stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Test alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Evaluate clinical samples from filovirus and alphavirus outbreaks in multiple international locations to determine human immune responses.			
Title: 5) Medical Countermeasures Initiative (MCMI) ***Description:*** The MCMI will begin to integrate the regulatory science and manufacturing technologies and processes developed into the Technical Centers of Excellence (TCE) and advanced development and flexible manufacturing capability. ***FY 2012 Plans:***	-	-	27.581

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Initiate and refine development of multi-product/multi-use MCM technology platforms for the advanced development of MCMs for CBRN threats and emerging infectious diseases. Evaluate and exploit the regulatory advantages of such systems, with the intent that regulatory approval of the platform for one product will simplify subsequent regulatory approvals of other products based on the same system. Initiate and refine development of new technologies and approaches that facilitate and accelerate the development and regulatory review of medical products.			
Title: 6) Therapeutics ***Description:*** Viral Therapeutics: Identifies, optimizes and evaluates potential therapeutic candidates effective against designated viral threat agents. ***FY 2010 Accomplishments:*** Conducted non-human primate studies to determine if anti-inflammatory and anti-thrombotic host factors can be used therapeutically to produce a restorative effect on the blood vessel walls and increase survival from filovirus infection. Conducted remaining FDA required non-human primate studies necessary to complete the development of oral therapeutics for orthopox viral infection. Evaluated the efficacy of administering post-exposure therapeutic vaccine in conjunction with therapies that stop blood clotting in animals infected with filovirus. Continued animal studies to support FDA submissions, milestone approval, and product transition to advanced development. ***FY 2011 Plans:*** Conduct remaining non-human primate studies required for licensure of ST-246, a low-molecular-weight compound that is active against multiple orthopoxviruses. Conduct toxicology studies and analyze efficacy of optimized lead compounds against alphavirus infection in murine and non-human primate challenge models. Characterize the clinical manifestations and virologic/ immunologic parameters of human monkeypox. Determine the effectiveness of pan-alphavirus capsid assembly inhibitors in animal models. ***FY 2012 Plans:*** Evaluate immunotherapies for filoviruses in non-human primate models. Continue evaluation of optimized lead compounds against alphaviruses in animal models of infection. Continue evaluation of filovirus vaccines as treatments for post-exposure filovirus infection. Evaluate FDA approved drug combinations for efficacy against alphaviruses in animal models of infection. Initiate a screening program to determine efficacy of FDA approved compounds against emerging infectious diseases (i.e. alphavirus, filovirus, flavivirus, arenavirus, bunyavirus).	9.577	9.519	6.590
Title: 7) Therapeutics	2.638	2.700	3.795

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Description: Bacterial Therapeutics: Identifies, optimizes, and evaluates potential therapeutic compounds effective against bacterial threat agents. ***FY 2010 Accomplishments:*** Tested and evaluated the effectiveness of commercially available antibiotics against animals exposed to aerosol versions of plague and tularemia. Determined antibiotic susceptibility profiles for Yersinia pestis and Francisella tularensis in the laboratory. ***FY 2011 Plans:*** Determine the effectiveness of commercially available antibiotics against Francisella tularensis in relevant animal infection models. ***FY 2012 Plans:*** Evaluate Protein Design Process optimized anthrax capsule depolymerase (CapD) in murine challenge models of anthrax infection. Transition data package demonstrating efficacy of FDA approved compounds against lethal challenge of aerosolized Y. pestis in nonhuman primate models. Conduct studies to determine efficacy against FDA approved compounds against Burkholderia, Francisella tularensis in murine animal models. Evaluate small molecule inhibitors targeting Y. pestis ATPase enzyme in small animal models.			
Title: 8) Therapeutics ***Description:*** Toxin Therapeutics: Identifies, optimizes and evaluates potential therapeutic candidates effective against biological toxin threat agents. ***FY 2010 Accomplishments:*** Initiated work to develop antitoxin preparation for Ricin and Staphylococcal Enterotoxin B (SEB). Defined the therapeutic parameters for Ricin and SEB therapeutic. Tested candidate botulinum neurotoxin (BoNT) small molecule therapeutics in animal challenge models. Performed advanced animal testing on small molecules that are protective against a lethal challenge of SEB in relevant animal models. ***FY 2011 Plans:*** Test and evaluate FDA approved immunomodulating drugs against exposure to SEB. Develop and determine the therapeutic window of opportunity for novel inhibitors of SEB pathogenesis. Determine initial safety profile and conduct genotoxicity studies for BoNT inhibitors with the goal of improving physiochemical properties and mitigating product liabilities through the use of medicinal chemistry. Conduct pre- and post-challenge of efficacy studies of optimized BoNT inhibitors in mice. Evaluate efficacy of BoNT lead inhibitors using a targeted delivery system in mice. ***FY 2012 Plans:***	0.886	1.500	2.184

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Continue evaluation of FDA approved immunomodulating agents to treat SEB. Initiate a screening program to determine efficacy of FDA approved compounds against BoNT intoxication. Continue evaluation of novel optimized SEB and BoNT inhibitors in small animal models of infection.			
Title: 9) Transformational Medical Technologies Initiative ***Description:*** Multiagent (Broad Spectrum) Medical Countermeasures: Focuses on the initiation and completion of multiple preclinical studies for each new drug, to include safety, toxicity, efficacy, and scalability work in accordance with the product's intended use. The ability to formulate good manufacturing pilot lots and further mature promising drug candidates will be the focus of activities in this capability area. The preclinical drug discovery process culminates in the submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), which conducts reviews and approves new drug candidates. Estimated attrition from preclinical phase to Phase I clinical studies is approximately 50%, thus not all drugs will survive the transition between preclinical development and Phase I studies. Starting in FY10, TMTI initiated an effort targeting Emerging Infectious Diseases (EID), beginning with pandemic influenzas. ***FY 2010 Accomplishments:*** Continued to identify potential IND candidate drugs for development. Completed pre-clinical research necessary to submit up to seven additional applications for an IND with the FDA. Following submission of an IND to the FDA for further evaluation, a DoD Milestone A Decision Review for the Hemorrhagic Fever Virus Class took place. Initiated planning for Phase 1 clinical trials and other studies necessary to support advanced development efforts toward a New Drug Application (NDA) with the FDA. Completed investigating use of existing of FDA-approved drugs to enhance effectiveness of current BW agent countermeasures. Initiated preclinical research to support IND submission for an EID candidate. ***FY 2011 Plans:*** Complete pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications. As MCMs effective as post-exposure prophylaxis and treatment against IBP are matured, an initial DoD Milestone A decision will take place for the IBP Group of MCMs. Initiate planning for Phase 1 clinical trials and additional studies for INDs as required by the FDA prior to safety evaluation in humans. Continue the development of animal models for future advanced development of MCMs currently in the S&T phase of development. This includes exploratory research, identification of supported in the Technologies Portfolio; investment strategy changed for FY11 and beyond to mitigate risk associated with seeking in vivo potency and efficacy critical to the likely product development path, determining dose-response, and the optimal route of administration and timing/schedule of administration of product in relevant animal efficacy models.	101.520	63.135	-
Title: 10) Transformational Medical Technologies Initiative	52.950	12.922	-

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Description: Development of Platform Technologies: Platform Technologies are standalone enabling technologies that support MCM development and when strategically aligned, provide a system of systems response capability to an adverse biological event - from the identification of an unknown pathogen to the development of an approved countermeasure ready for delivery to the Warfighter and the nation. The enabling technologies are divided into five platform areas: Pathogen Characterization, Target Identification, Countermeasure Discovery, Countermeasure Evaluation, and Bioinfomatics. Focuses on advanced technology and development activities for Platform Technologies to include the maturation of components that will begin the process of integrating a countermeasure response pipeline. Off-the-shelf technologies will be identified, evaluated, and refined to demonstrate the ability to provide drug development capabilities. Advanced manufacturing platforms will continue to mature and the technology application will focus on the type of specific therapeutics under development. ***FY 2010 Accomplishments:*** Conducted initial studies to determine dose-response, optimal route of administration and timing/schedule of administration of product in relevant animal efficacy models. Initiated development of the bioinformatics platform, to integrate the various TMT platforms by electronically structuring all TMTI data for rapid access and analysis. Continued development of rapid drug discovery and development platform technologies. Accelerated effort to develop and scale-up new rapid manufacturing platform technologies for biological drugs. Development efforts began to bring these technologies into compliance with FDA current good manufacturing practices (cGMP) and quality requirements. Began generation of Technology Development Strategies that will assist in the development of a roadmap to support efforts that transition to engineering, manufacturing, and development efforts in Budget Activities 4 and 5. Began integration of stand-alone platforms into capabilities that can be demonstrated as a system. Began validation of test platforms for drug discovery, development and manufacturing technologies that allow the incorporation of medical countermeasure technologies into the TMTI rapid response capability. Supported computer models to advance/enhance drug design. High throughput screening assays and technologies and novel platforms for target identification were investigated. ***FY 2011 Plans:*** Continue integration of standalone platforms into capabilities that can be demonstrated as a system. Continue the development of rapid drug discovery and development platform technologies. Integrate the entire system using a robust bioinformatics capability, and validate the integrated bioinformatics platform. Continue to mature and accelerate manufacturing platform technologies for biological drugs to comply with regulatory guidelines. Support compliance and quality measures that are mandatory for future FDA submissions. Continue to integrate pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas into a rapid response capability supported by a centralized bioinformatics capability that ties together geographically separated performers from government agencies, industry and academia.			
Title: 11) Transformational Medical Technologies	-	-	62.851

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TB3: *MEDICAL BIOLOGICAL DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Description: Multiagent (Broad Spectrum) Medical Countermeasures: Continues efforts previously funded under the Transformational Medical Technologies Initiative to develop candidate countermeasures for HFV and IBP. Focuses on the initiation and completion of preclinical studies for candidate countermeasures, to include safety, toxicity, efficacy, and scalability work in accordance with the product's intended use. The ability to formulate Good Manufacturing Practices (GMP), pilot lots and further mature promising drug candidates will be the focus of activities in this capability area. The preclinical drug discovery process culminates in the submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), to determine if candidate countermeasures are suitable for safety evaluation in humans. Starting in FY10, TMT initiated an effort targeting Emerging Infectious Diseases (EID), beginning with pandemic influenzas. ***FY 2012 Plans:*** Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the Hemorrhagic Fever Virus (HFV), Intracellular Bacterial Pathogen (IBP) and EID product pipelines. Continue planning for Phase 1 clinical trials and additional studies for INDs as required by the FDA prior to safety evaluation in humans. Continue the development of animal models for future advanced development of MCMs currently in the S&T phase of development, incorporating feedback from the FDA and Services into requirements.			
Title: 12) Transformational Medical Technologies ***Description:*** Development of Platform Technologies: Continues efforts previously funded under the Transformational Medical Technologies Initiative. Platform Technologies are standalone enabling technologies that support MCM development and when strategically aligned, provide a system of systems response capability to an adverse biological event - from the identification of an unknown pathogen to the development of an approved countermeasure ready for delivery to the Warfighter and the nation. The enabling technologies are divided into five platform areas: Pathogen Characterization, Target Identification, Countermeasure Discovery, Countermeasure Evaluation, and Bioinfomatics. Focuses on advanced technology and development activities for Platform Technologies to include the maturation of components that will begin the process of integrating a countermeasure response pipeline. Off-the-shelf technologies will be identified, evaluated, and refined to demonstrate the ability to provide drug development capabilities. Advanced manufacturing platforms will continue to mature and the technology application will focus on the type of specific therapeutics under development. ***FY 2012 Plans:*** Investment to fund Bio-Surveillance efforts and integrate stand-alone platforms into system-wide capabilities. Further develop rapid drug discovery and development platform technologies, and build upon early success to fully integrate the entire system using robust bioinformatics capabilities, validating the integrated bioinformatics platform. Increase investment to mature and accelerate manufacturing platform technologies for biological drugs to comply with regulatory guidelines. Support compliance and	-	-	33.585

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
quality measures that are mandatory for future FDA submissions. Fully integrate pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas into a rapid response capability supported by a centralized bioinformatics capability that link geographically separated performers together from government agencies, industry and academia.			
Accomplishments/Planned Programs Subtotals	196.007	115.233	172.636

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• MB4: *MEDICAL BIOLOGICAL DEFENSE (ACD&P)*	95.483	136.975	137.653		137.653	150.128	167.604	133.589	119.626	Continuing	Continuing
• MB5: *MEDICAL BIOLOGICAL DEFENSE (SDD)*	57.563	141.680	272.345		272.345	259.039	354.900	331.308	310.104	Continuing	Continuing
• MB7: *MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)*	0.000	0.000	5.448		5.448	0.492	0.493	8.851	15.459	Continuing	Continuing
• TB2: *MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)*	54.858	43.858	84.747		84.747	85.493	76.011	52.527	75.583	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TC3: *MEDICAL CHEMICAL DEFENSE (ATD)*	

COST ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TC3: *MEDICAL CHEMICAL DEFENSE (ATD)*	28.046	29.134	21.582	-	21.582	21.900	22.695	23.193	23.919	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TC3) supports the advanced development of medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs against identified and emerging chemical warfare threat agents. Analytical stability studies, safety and efficacy screening, and preclinical toxicology studies are performed prior to full-scale development of promising pretreatment or treatment drug compounds. Entry of candidate pretreatment/prophylaxes, therapeutics, and diagnostic technologies into advanced development (i.e., efforts funded in Budget Activities 4 and 5) is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) application and licensure processes, as well as Department of Defense (DoD) acquisition regulations. Categories for this project include Pretreatments, Diagnostics, and Therapeutics to address Chemical Warfare Agent (CWA) and Non-Traditional Agents (NTAs) exposure. In FY11, all NTA-dedicated research was re-aligned into specific capability areas within this project in order to ensure a focused effort on this high priority area.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Title: 1) Diagnostics	2.438	0.226	0.262
Description: Diagnostic Technologies: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.			
FY 2010 Accomplishments: Furthered development of improved reactivation and solvent-free extraction methodologies for definitive CWA byproduct identification. Determined windows of opportunity for biomarker identification and subsequent therapeutic intervention for CWA in laboratory and animal models.			
FY 2011 Plans: Optimize the methodology for solvent free extraction of CWA mixtures. Complete blood and urine assay development for CWA exposure. Complete validation of fluoride regeneration method in plasma/blood/RBCs with solid phase extraction for nerve agents. All NTA-specific efforts re-aligned to the Chemical Diagnostics NTA capability area within this Project.			
FY 2012 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Refine methods and expression systems for large-scale production and purification of bioscavengers. Further test improved bioscavenger delivery methods and retention approaches in animal models, including physiologically based pharmacokinetics. Further develop binding proteins in animal models for safety and efficacy.			
Title: 2) Chem Diagnostics NTA ***Description:*** Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to non-traditional agents in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker. ***FY 2011 Plans:*** Continue evaluation of mature technologies that can quickly diagnose NTA exposure before symptoms appear and determine the type of agent. ***FY 2012 Plans:*** Continue evaluation of mature technologies that can quickly diagnose pre-symptomatic NTA exposure.	-	0.400	0.599
Title: 3) Pretreatments ***Description:*** Nerve Agent, Pretreatments: Develop pretreatments that provide protection against all organophosphorous nerve agents. The enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high enzymatic efficiency for the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent. ***FY 2010 Accomplishments:*** Developed formulations for improved pharmacokinetic and reduced immune system stimulation for enzymes. Investigated improved drug-delivery systems for 1st generation enzymes. Conducted supportive studies toward licensure of enzymes. ***FY 2011 Plans:*** Apply physiologically based pharmacokinetics (PBPK) models to improved catalytic bioscavengers. Continue to test improved catalytic bioscavenger delivery methods and retention systems in animal models. Continue to develop binding proteins in animal models for safety and efficacy, using animal testing to down-select candidates for further development. ***FY 2012 Plans:***	3.823	7.861	1.869

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TC3: *MEDICAL CHEMICAL DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Refine methods and expression systems for large-scale production and purification of enzymes. Further test improved pretreatment delivery methods and retention approaches in animal models, including physiologically based pharmacokinetics (PBPK). Further develop binding proteins in animal models for safety and efficacy.			
Title: 4) Chem Pretreatments NTA ***Description:*** Develop nerve agent enzyme pretreatments that provide protection against non-traditional agents. Enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high catalytic efficiency for the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent. ***FY 2012 Plans:*** Further test improved nerve agent enzyme pretreatment delivery methods and retention approaches in animal models, including physiologically based pharmacokinetics. Further develop binding proteins in animal models for safety and efficacy. This work represents a continuation of efforts that were initiated in previous years under the TC3 Chemical Pretreatments capability area prior to the Chemical Pretreatments NTA capability area being established in FY12.	-	-	0.996
Title: 5) Therapeutics ***Description:*** Cutaneous and Ocular: Focuses on minimizing injuries to dermal and ocular tissues resulting from exposure to chemical warfare agents (CWA). This work is designed to support eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. ***FY 2010 Accomplishments:*** Evaluated commercial off-the-shelf irrigation systems for treatment of CWA exposure in the laboratory and animals. Continued animal studies to examine long-term effects of wound healing products. Down-selected newly identified therapeutics with potential for treating mustard agent-induced ocular injury. Began efficacy testing in compliance with FDA regulations for ocular administration. ***FY 2011 Plans:*** Continue to evaluate the effectiveness of various cell-based approaches to facilitate blister agent wound healing in skin and eye. Begin advanced studies focused on down-selecting wound healing products found to be most effective for transition. Continue to assess in animals whether bioengineering and molecular biology approaches may be used to treat blister agent skin and eye injury. Initiate the development of an approach to decontaminate CWAs in penetrating wounds. ***FY 2012 Plans:***	4.900	3.689	3.745

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TC3: *MEDICAL CHEMICAL DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Determine the most effective cell-based approaches to facilitate healing of skin and eye wounds due to sulfur mustard exposure. Complete evaluation of potential wound healing products for advanced development. Evaluate candidate approaches to decontaminate penetrating wounds that have been exposed to CWAs. Further assess molecular biology approaches in animal models to treat skin and eye injuries as a result of sulfur mustard exposure.			
Title: 6) Therapeutics ***Description:*** Neurologic: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to chemical warfare agents (CWA). This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. Supports eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. ***FY 2010 Accomplishments:*** Tested broad-spectrum reactivators in one or more animal models, with a focus on requirements to support FDA submissions under the animal rule. Initiated safety/side effect/dosing and the body's effects on the drug evaluation of new compounds. Continued to evaluate novel and FDA-approved anticonvulsants, neuroprotectants, anti-epileptics, and receptor competitors and neutralizing agents for neuroprotective activity against nerve agents in animal models. ***FY 2011 Plans:*** Continue to evaluate, in animals, novel compounds and FDA-approved drugs not yet evaluated for efficacy against nerve agents. These potential compounds include anticholinergics, neuroprotectants, anticonvulsants, and improved reactivators. Continue efficacy testing on candidates that are designed to support eventual FDA licensure. Continue development of animals models related to nerve exposure with emphasis on FDA animal rule approval. ***FY 2012 Plans:*** Continue animal model evaluation of novel and/or FDA approved drugs not yet tested for treatment of nerve agent exposure. Transition Centrally Active Nerve Agent Therapeutic (scopolamine). Continue development of animal models related to nerve agent exposure. Maintain core capabilities for standardization of in vitro and in vivo testing of therapeutic candidates.	12.676	13.137	4.170
Title: 7) Therapeutics ***Description:*** Respiratory and Systemic: Supports investigation of the systemic host response to chemical warfare agent (CWA) injury via all routes of exposure, with emphasis on the respiratory system and chronic effects of exposure. Develops effective practical field and clinic management strategies, and physical and pharmacological interventions to treat the injury processes. Designed to support eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties.	3.500	1.367	-

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
FY 2010 Accomplishments: Identified and tested potential therapeutics with a focus on FDA approved drugs that are currently used for other indications for treatment of CWA-induced lung damage. Investigated approaches to enhance inhalational delivery of selected candidate therapeutics. Evaluated commercially available aerosol bronchodilators as supportive therapy following acute inhalational exposure to CWAs. ***FY 2011 Plans:*** Continue to evaluate previously identified lead candidate countermeasures for future transition to advanced development. Investigate novel delivery systems for potential inhalational therapeutics against CWA. Continue to investigate efficacy of commercially available aerosol bronchodilators as supportive therapy following pulmonary exposure to CWAs. Research funding has been terminated for future years.			
Title: 8) Therapeutics ***Description:*** Non Traditional Agents (NTAs): Determines the toxic effects of agents by probable routes of field exposure and refines standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanisms of toxicity. ***FY 2010 Accomplishments:*** Developed and evaluated novel and Food and Drug Administration licensed products as post-exposure therapeutics against NTA poisoning in advanced animal models. ***FY 2011 Plans:*** Complete characterization of a novel therapeutic for manufacturability and pharmacology. Establish formulation for safety testing and stability. All NTA-related efforts have been re-aligned to Chemical Therapeutics NTA within this Project in FY12.	0.709	2.454	-
Title: 9) Chem Therapeutics NTA ***Description:*** Non-Traditional Agents (NTA): Determine the toxic effects of agents by probable routes of field exposure and refine standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanisms of toxicity. ***FY 2012 Plans:***	-	-	9.941

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Complete characterization of a novel therapeutic for manufacturability and pharmacology. Establish formulation for safety testing and stability. This work represents a continuation of efforts that were initiated in previous years under the TC3 Chemical Therapeutics capability area prior to the Chemical Therapeutics NTA capability area being established in FY12.			
Accomplishments/Planned Programs Subtotals	28.046	29.134	21.582

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• MC4: *MEDICAL CHEMICAL DEFENSE (ACD&P)*	20.518	0.000	20.804		20.804	3.658	5.045	14.716	3.555	Continuing	Continuing
• MC5: *MEDICAL CHEMICAL DEFENSE (SDD)*	4.126	51.856	26.407		26.407	18.860	18.396	20.824	27.289	Continuing	Continuing
• TC2: *MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)*	38.644	33.648	36.546		36.546	36.993	37.789	38.163	39.395	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TE3: *TEST & EVALUATION (ATD)*	

COST ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TE3: *TEST & EVALUATION (ATD)*	12.296	11.875	11.199	-	11.199	11.081	0.992	0.991	0.990	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TE3) supports the development of test and evaluation methodologies and protocols as new science and technology efforts are discovered and transitioned to advanced development programs. It includes methodology development for chemical and biological defense test and evaluation capabilities, with an emphasis on Non Traditional Agents (NTAs). These methodologies support development testing and operational testing with regard to advanced development programs that have unique chemical and biological defense requirements. These new methodologies and testing capabilities include the development of protocol and standards for use of chemical and biological simulants.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Title: 1) Test and Evaluation (T&E) ***Description:*** Test and Evaluation, Detection: Develop, test, and evaluate technologies and processes in support of detection capability testing. ***FY 2010 Accomplishments:*** Continued development of methodologies and capabilities for test and evaluation of technologies currently in early stages of tech-base development. Continued NTA chamber design effort by conducting dry dissemination development and proof of principle tests with several agents and address the questions regarding the safety of unprotected personnel using the chamber post decontamination. ***FY 2011 Plans:*** Complete development of methodologies and capabilities for test and evaluation of technologies currently in early stages of technology development.	5.610	2.784	-
Title: 2) Test and Evaluation (T&E) NTA ***Description:*** Develops test and evaluation technologies and processes in support of NTA activities. ***FY 2011 Plans:*** Conduct facility design efforts by conducting large particle dissemination development and proof of principle tests with several agents. Complete testing regarding the safety of unprotected personnel using the chamber after decontamination. ***FY 2012 Plans:***	-	2.000	6.460

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Complete facility design efforts by conducting large particle dissemination development and proof of principle tests with several agents. Initiate select agent testing.			
Title: 3) Test and Evaluation (T&E) ***Description:*** Test and Evaluation, Threat Agent Science: Develop test and evaluation technologies and processes in support of Threat Agent Science activities, with a particular emphasis on Non-Traditional Agents. ***FY 2010 Accomplishments:*** Continued development of NTA Simulants. Provided a data base to define the specific characteristic(s) of CWA and BWA threats that must be simulated in order to test the range of types of CBD systems and technologies. Identified and developed simulant or suite of simulants to be used to facilitate field tests of multiple CWA and BWA detectors and/or a multi-purpose BWA/CWA detector. Developed the relationship between aerosolized biological simulants and aerosolized live biological agents for bio standoff detection and discrimination, including identifying the impact of interferents and varying environmental conditions on this relationship. ***FY 2011 Plans:*** Develop methodology and establish the relationship of simulants used in field trials to agents for each CWA detection technology; includes determination of quantity of simulants required to mimic the detector response to agent as well as how interferents and environmental factors impact both simulant and agent. Identify and develop simulants that enable decontamination processes to be monitored to determine its/their progression and efficiency. Develop methodologies that disperse or deposit currently available simulants as if they were agents, which could include adding thickeners or surfactants.	1.457	1.391	-
Title: 4) Test and Evaluation (T&E) ***Description:*** Test and Evaluation, Information System Technology: Develop test and evaluation technologies and processes in support of Information System Technology activities. ***FY 2010 Accomplishments:*** Developed second module of decontamination model. Continued development and integration relevant to construction of systems performance models for collective protection, contamination avoidance, and individual protection. Built requirements for systems performance model integration and program-wide exploitation. Conducted requirements analysis for inclusion of data from test and evaluation community into CBRN Data Backbone. ***FY 2011 Plans:*** Conclude development and integration relevant to construction of collective protection, individual protection, and decontamination models for test and evaluation and transition those models. Continue to build requirements for system performance model	5.142	5.600	4.739

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TE3: *TEST & EVALUATION (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
integration and program-wide exploitation. Collect and federate test data into CBRN Data Backbone prototype. Create processes for entry and authorization of test data in CBRN Data Backbone. Initiate individual protection equipment (IPE) model development to predict system exposure relative to toxicological exposure. ***FY 2012 Plans:*** Further develop CBRN data management capabilities for test and evaluation, with emphasis on enabling access to information for analysis within CBDP systems performance models. Begin Phase 1 of a multi-year effort to create a comprehensive simulation tool for test and evaluation of CBRN defense systems. Further enhance ability to evaluate decontaminants and decontamination systems by continuing to develop simulation capabilities for decontamination processes.			
Title: 5) Test and Evaluation (T&E) ***Description:*** Test and Evaluation, Protection and Hazard Mitigation: Develop test and evaluation technologies and processes in support of Protect and Hazard Mitigation activities. ***FY 2010 Accomplishments:*** Initiated methodology/source data effort to simulate IP durability test in laboratory and relationship to field durability. ***FY 2011 Plans:*** Continue development of methodology/source data effort to simulate IP durability in laboratory and relationship to field durability.	0.087	0.100	-
Accomplishments/Planned Programs Subtotals	12.296	11.875	11.199

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• TE4: *TEST & EVALUATION (ACD&P)*	28.412	19.304	5.438		5.438	16.232	12.461	18.369	19.296	Continuing	Continuing
• TE5: *TEST & EVALUATION (SDD)*	39.372	15.901	11.043		11.043	5.748	11.866	12.217	15.562	Continuing	Continuing
• TE7: *TEST & EVALUATION (OP SYS DEV)*	4.805	4.813	3.597		3.597	3.348	2.888	2.855	2.004	Continuing	Continuing

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	**R-1 ITEM NOMENCLATURE** PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**PROJECT** TE3: *TEST & EVALUATION (ATD)*

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TR3: *MEDICAL RADIOLOGICAL DEFENSE (ATD)*	

COST ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TR3: *MEDICAL RADIOLOGICAL DEFENSE (ATD)*	4.086	0.957	-	-	-	0.200	0.200	0.434	0.484	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TR3) funds advanced technology development of medical countermeasures against radiological exposure. Specifically, innovative technical approaches will be used to develop, refine, and transition promising products to advanced development efforts to mitigate health consequences resulting from Acute Radiation Exposure (ARS) and Delayed Effects of Acute Radiation Exposure (DEARE). Promising products and pertinent science and technology data will be used to support Investigational New Drug (IND) applications and Food and Drug Administration (FDA) licensure processes, with an emphasis on the development of pretreatments to protect military responders in the event of a radiological incident. Research efforts and data are collaboratively shared with other government agencies so that more mature and promising product candidates will be quickly transitioned to advanced development efforts.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Title: 1) Radiological Medical Countermeasures	4.086	0.957	-
Description: Radiation Medical Countermeasures: Develops medical countermeasures to protect the Warfighter against radiological/nuclear exposure. The Department of Defense is the only governmental agency currently developing medical prophylaxis to protect Warfighters or other responders in the event of a radiological incident. ***FY 2010 Accomplishments:*** Evaluated mature and promising agents for respiratory and gastrointestinal damage and repair. Demonstrate efficacy and safety in non-human primates. Began down-selection and prepared for transition of one mature radioprotectant to the advanced developer, using pertinent science and technology data to support an Investigational New Drug (IND) application for eventual Food and Drug Administration (FDA) license. ***FY 2011 Plans:*** Continue to investigate relatively mature candidates for advanced development as medical countermeasures to prevent and treat exposure to radiation. Continue to evaluate diagnostic biodosimetry biomarkers that could be used to potentially screen mass casualties. Continue to explore the development of a biodosimetry hand-held diagnostic device that is minimally invasive, accurate, rapid, high-throughput, and suitable for medical triage. Continue development of animal models for radiation exposures useful to support FDA licensure.			
Accomplishments/Planned Programs Subtotals	4.086	0.957	-

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TR3: *MEDICAL RADIOLOGICAL DEFENSE (ATD)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• MR4: *MEDICAL RADIOLOGICAL DEFENSE (ACD&P)*	2.800	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	2.800
• MR5: *MEDICAL RADIOLOGICAL DEFENSE (SDD)*	0.000	1.143	0.000		0.000	0.000	0.000	0.000	0.000	0.000	1.143
• TR2: *MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)*	1.818	2.884	0.806		0.806	0.605	0.603	0.379	0.335	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TT3: *TECHBASE TECHNOLOGY TRANSITION*	

COST ($ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TT3: *TECHBASE TECHNOLOGY TRANSITION*	7.381	4.504	-	-	-	-	-	-	-	0.000	11.885

A. Mission Description and Budget Item Justification

This project (TT3) supports technology transition, technology experimentation and demonstration efforts, and technology readiness assessments in support of unique chemical and biological Advanced Technology Demonstrations (ATDs) and Joint Capability Technology Demonstrations (JCTDs). Within this project are two primary capability areas: 1) Experiment and Technology Demonstrations; and 2) Technology Readiness Assessment. The Experiment and Technology Demonstrations capability area focuses on integration, testing, and assessing candidate ATDs and JCTDs and includes three thrust areas (two of which are new sub-thrust areas that consolidate legacy systems and are annotated as such below): Advanced Remediation Technologies (ART), Early Warning Military Application in Reconnaissance Systems (EW-MARS), and Comprehensive Innovative Protection (CIP). The ART addresses Chemical, Biological, and Radiological (CBR) remediation and decontamination processes and demonstrates technologies and methods to restore assets such as mobile equipment, fixed sites, critical infrastructures, personal, and equipment to operational status as a result of having reduced or eliminated CBR contamination. The EW-MARS achieves enhanced command and control decision making capabilities as a result of a combined and orchestrated family of chemical and biological defense systems deployed on various platforms in remote locations. The CIP transitions mature technologies to improve individual and collective protection capabilities. The Technology Readiness Assessment capability area focuses on completing manufacturing readiness assessments, technology readiness evaluations, and assessing maturity levels before transitioning ATDs and JCTDs to advanced development efforts located in Budget Activity 4 (Project TT4).

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Title: 1) Experiment & Technology Demonstrations	4.884	2.175	-
FY 2010 Accomplishments: EW Thrust Area Conducted technology testing for EW/MARS Rapid Area Sensitive Site Reconnaissance (RASR) ATD. RASR assessed the capability to rapidly survey large areas (whole rooms, courtyards, fields) and assess and identify contamination with Chemical Warfare Agents (CWAs), Toxic Industrial Chemicals (TICs) or Non-Traditional Agents (NTAs). Conducted a technical assessment to determine if a designated WMD payload was or was not onboard a missile delivery system for the EW/MARS Post Intercept WMD Identification (PIWID) ATD. CIP Thrust Area Analyzed the thermal burden for Warfighter protective gear in a CBRN environment as part of the CIP Low Burden Individual Protection Demonstration (IP Demo). Completed assessment of integrated fabric, low resistance/profile filtration, human performance prediction and assessment and low-burden air purifying respirator concurrent with the Protection and Hazard			

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: *Research, Development, Test & Evaluation, Defense-Wide* BA 3: *Advanced Technology Development (ATD)*	R-1 ITEM NOMENCLATURE PE 0603384BP: *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	PROJECT TT3: *TECHBASE TECHNOLOGY TRANSITION*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2010	FY 2011	FY 2012
Mitigation capability area (see BA2, Project CB2, Protection and Hazard Mitigation), which will support the Uniform Integrated Protective Ensemble (UIPE), and incorporate lessons into further development of integrated fabric. ***FY 2011 Plans:*** ART Thrust Area Perform technical assessments for the ART Hazard Mitigation, Material, and Equipment Restoration (HaMMER) ATD. Incorporate results into HaMMER from testing and transition of solid oxidant and green surfactant and the Decontamination of Family Systems from the Protection and Hazard Mitigation capability area (see BA2, Project CB2, Protection and Hazard Mitigation). EW Thrust Area. Conduct Surety testing, technical demonstrations, and down selects for the RASR ATD. CIP Thrust Area Develop lessons learned from the IP Demo and inform the Protection and Hazard Mitigation capability area for future development (see BA2, Project CB2, Protection and Hazard Mitigation).			
Title: 2) Technology Readiness Assessment ***FY 2010 Accomplishments:*** Continued Technology Readiness Evaluations in support of the EW MARS-JFP ATD. For the EW RASR ATD, assessed the capability to rapidly survey large areas (whole rooms, courtyards, fields) and assess and identify contamination with Chemical Warfare Agents (CWAs), Toxic Industrial Chemicals (TICs) or Non-Traditional Agents (NTAs). Built and integrated key technology components integrated to demonstrate system level Force Protection capabilities in a Forward Operating Base scenario. Investigated the efficacy of rapid biological threat detection coupled with automatic, rapid delivery of supplies, therapeutics, and physiological monitoring equipment via unmanned systems for the CIP JMDSE ATD. ***FY 2011 Plans:*** Continue Technology Readiness Evaluations in support of the EW MARS-JFP ATD. Initiate Technology Readiness Evaluation for the CIP thrust area in preparation for a new ATD. Assess emerging innovations associated with orchestrating the response and capabilities of both individual and collective protection measures within the framework of smart networks and smart materials.	2.497	2.329	-
Accomplishments/Planned Programs Subtotals	7.381	4.504	-

Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
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C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• CB2: *CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)*	110.937	88.897	97.774		97.774	94.721	89.677	90.823	108.941	Continuing	Continuing
• TT4: *TECHBASE TECHNOLOGY TRANSITION (ACD&P)*	24.937	26.466	3.022		3.022	3.923	4.758	8.467	9.075	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A