Exhibit R-2, RDT&E Budget Item Justification: PB 2011 Chemical and Biological Defense Program										DATE: February 2010	
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 2009 Actual**	**FY 2010 Estimate**	**FY 2011 Base Estimate**	**FY 2011 OCO Estimate**	**FY 2011 Total Estimate**	**FY 2012 Estimate**	**FY 2013 Estimate**	**FY 2014 Estimate**	**FY 2015 Estimate**	**Cost To Complete**	**Total Cost**
Total Program Element	307.351	299.680	177.113	0.000	177.113	197.867	187.654	194.471	197.769	Continuing	Continuing
CB3: *CHEMICAL BIOLOGICAL DEFENSE (ATD)*	19.567	25.297	15.410	0.000	15.410	21.450	26.120	36.775	37.148	Continuing	Continuing
CI3: *CONGRESSIONAL INTEREST ITEMS (ATD)*	46.971	18.622	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
TB3: *MEDICAL BIOLOGICAL DEFENSE (ATD)*	180.425	203.723	115.233	0.000	115.233	125.666	109.737	115.049	117.289	Continuing	Continuing
TC3: *MEDICAL CHEMICAL DEFENSE (ATD)*	21.641	28.971	29.134	0.000	29.134	30.401	30.546	31.356	31.877	Continuing	Continuing
TE3: *TEST & EVALUATION (ATD)*	25.761	13.307	11.875	0.000	11.875	11.267	11.160	0.000	0.000	Continuing	Continuing
TR3: *MEDICAL RADIOLOGICAL DEFENSE (ATD)*	4.859	2.403	0.957	0.000	0.957	0.966	1.922	2.901	2.927	Continuing	Continuing
TT3: *TECHBASE TECHNOLOGY TRANSITION*	8.127	7.357	4.504	0.000	4.504	8.117	8.169	8.390	8.528	Continuing	Continuing

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 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Previous President's Budget	324.769	282.235	0.000	0.000	0.000
Current President's Budget	307.351	299.680	177.113	0.000	177.113
Total Adjustments	-17.418	17.445	177.113	0.000	177.113
• Congressional General Reductions		-1.255			
• Congressional Directed Reductions		0.000			
• Congressional Rescissions	0.000	0.000			
• Congressional Adds		18.700			
• Congressional Directed Transfers		0.000			
• Reprogrammings	-9.223	0.000			
• SBIR/STTR Transfer	-3.650	0.000			
• Other Adjustments	-4.545	0.000	177.113	0.000	177.113

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2009	FY 2010
Project: CI3: *CONGRESSIONAL INTEREST ITEMS (ATD)*		
Congressional Add: *Carbon Nanotube Chemical Detector -*	0.791	0.000
Congressional Add: *Surface Enhanced Infrared Detection of Threats -*	0.987	0.000
Congressional Add: *Total Perimeter Surveillance (TPS) -*	0.989	1.593
Congressional Add: *Photo Catalytic Oxidation (PCO) Demonstration for Water Reuse -*	1.373	0.000
Congressional Add: *Mobile Rapid Response Prototype -*	1.082	2.390
Congressional Add: *NIDS Automated Bio Agent Identifier -*	1.000	2.390
Congressional Add: *Portable Rapid Bacterial Warfare Detection Unit -*	3.156	0.000
Congressional Add: *UCLA High Speed and High Volume Laboratory Network for Infectious Diseases -*	4.862	0.000
Congressional Add: *Antioxidant Micronutrient Therapeutic Countermeasures for Chemical Agents -*	0.792	0.000
Congressional Add: *Plant Vaccine Development -*	1.582	1.593
Congressional Add: *Multi-Purpose Biodefense Immunoarray -*	0.792	0.000

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Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2009	FY 2010
Congressional Add: *Improved CBR Filters -*	1.582	0.000
Congressional Add: *Acinetobacter Baumannii Research -*	1.978	0.000
Congressional Add: *Bio Agent Early Warning Detector -*	1.978	0.000
Congressional Add: *Biological Agent Identifiers -*	1.582	0.000
Congressional Add: *Eye-Safe Long Range Stand-off System for Detection of Chemical and Biological Weapons -*	1.483	0.000
Congressional Add: *Mobile Continuous Air Monitor (MCAM) -*	1.582	0.000
Congressional Add: *Rapid Response Institute -*	3.164	0.000
Congressional Add: *Liquid Crystal Sensor Technology Research and Development for Force Protection -*	2.373	0.000
Congressional Add: *Biodefense Vaccine Development and Engineering of Antiviral Peptides -*	1.583	0.000
Congressional Add: *Center for Advanced Emergency Response -*	4.350	0.000
Congressional Add: *ViriChip Rapid Virus Detection Systems -*	1.582	0.000
Congressional Add: *Protective Self-Decontaminating Surfaces -*	1.582	0.000
Congressional Add: *Contaminated Human Remains Pouch -*	1.582	0.000
Congressional Add: *Recombinant BChE Formulation Program -*	1.582	0.000
Congressional Add: *Joint Material Decon System -*	1.582	0.000
Congressional Add: *Multi-Target Shipping Container Interrogation System Mobile Continuous Air Monitor*	0.000	1.593
Congressional Add: *Hand-Held Apparatus for Mobile Mapping and Expedited Reporting*	0.000	2.788
Congressional Add: *Regenerative Chemical Biological Filtration Systems*	0.000	2.689
Congressional Add: *Unified Management Infrastructure System*	0.000	0.797
Congressional Add: *Water Purification System for Natural Disasters*	0.000	0.797
Congressional Add: *CBDP Advanced Development*	0.000	1.992
Congressional Add Subtotals for Project: CI3	46.971	18.622

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Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2009	FY 2010
Congressional Add Totals for all Projects	46.971	18.622

Change Summary Explanation

Funding: N/A - Adjustments less than 10% of total program.

Schedule: N/A

Technical: N/A

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program			DATE: February 2010
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COST ($ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
CB3: *CHEMICAL BIOLOGICAL DEFENSE (ATD)*	19.567	25.297	15.410	0.000	15.410	21.450	26.120	36.775	37.148	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 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 Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR *FY 2010 Plans:* Small Business Innovative Research.	0.000	0.345	0.000	0.000	0.000
2) Decontamination Alternative Processes: Demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application.	1.838	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: Continued efforts to investigate reactive materials and nanotechnology for decontamination processes. *FY 2010 Plans:* Efforts re-aligned to Protection and Hazard Mitigation.					
3) Protection Respiratory/Ocular Protection: 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 2009 Accomplishments:* Continued integration of the protective mask designs with developmental helmet systems to provide seamless compatibility of CB protection with ballistic protection, and integration of communication and optical systems. Continued to develop initial high fidelity prototypes for early assessment of human and operational compatibility during the Uniform Integrated Protective Ensemble (UIPE) Demonstration. *FY 2010 Plans:* Efforts re-aligned to Protection and Hazard Mitigation.	1.263	0.000	0.000	0.000	0.000
4) Protection Integrated Ensemble Development: Demonstration of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform. *FY 2009 Accomplishments:* Continued integration of the protective mask designs with developmental helmet systems to provide seamless compatibility of chemical and biological protection with ballistic protection, and integration	1.481	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
of communication and optical systems. Continued to develop initial high fidelity prototypes for early assessment of human and operational compatibility during the Uniform Integrated Protective Ensemble (UIPE) Demonstration. *FY 2010 Plans:* Efforts re-aligned to Protection and Hazard Mitigation.					
5) Protection & Hazard Mitigation Lightweight Integrated Fabric: Demonstration of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform. *FY 2010 Plans:* Develop systems integration of a complete chemical and biological (CB) ensemble that incorporates emerging designs and prototype concepts. Refine 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). Continue limited field trials in a relevant environment. *FY 2011 Base 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.	0.000	0.628	0.753	0.000	0.753
6) Protection & Hazard Mitigation 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.	0.000	0.635	0.878	0.000	0.878

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2010 Plans: Initiate 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 Base 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 Joint Expeditionary Collective Protection (JECP) and support of collective protection in vehicular/platform systems in Major Defense Acquisition Programs (MDAP).					
7) Protection & Hazard Mitigation 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 Plans:* Continue integration of the protective mask designs with developmental helmet systems to provide seamless compatibility of CB protection with ballistic protection, and integration of communication and optical systems in parallel excursions to the IP Demo.	0.000	0.518	0.000	0.000	0.000
8) Protection & Hazard Mitigation	0.000	0.425	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
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 Plans:* Initiate breadboard prototypes development of down-selected media-less technologies.					
9) Protection & Hazard Mitigation 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 Plans:* Complete coupon tests, material compatibility and small item effectiveness evaluations for solid oxidants and green solvent/surfactant systems. Transition to Decontamination Family of Systems program (see BA5, Project DE5).	0.000	0.704	0.000	0.000	0.000
10) Protection & Hazard Mitigation Decontamination System-of-Systems: Demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. *FY 2010 Plans:* Complete data package for self-decontaminating surfaces. Transition to the Hazard Mitigation for Materials and Equipment Restoration (HaMMER) Advanced Technology Demonstration (see Project TT3, E&TD).	0.000	0.196	0.377	0.000	0.377

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2011 Base 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.					
11) Protection & Hazard Mitigation Innovative Systems Concepts and Analysis *FY 2011 Base 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.	0.000	0.000	0.624	0.000	0.624
12) Information Systems Technology Sensor Data Fusion: Develop scientific techniques for fusing disparate information from multiple sources for insertion into the Joint Effects Model (JEM), Joint Warning and Reporting Network (JWARN), and Joint Operational Effects Federation (JOEF), and other identified acquisition programs. *FY 2009 Accomplishments:* Transitioned first generation outdoor Source Term Estimation (STE)/Hazard Refinement (HR) and second-generation Sensor Placement Tool (SPT) software to the Joint Effects Model (JEM), JWARN and JOEF. Transitioned first-generation building interior STE and HR software to JEM and JOEF. *FY 2010 Plans:* Sensor Data Fusion efforts re-aligned to Advanced Warning and Reporting.	0.592	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
13) Information Systems Technology Battle Space Management: Develop collaborative information management technologies for insertion into the Joint Warning and Reporting Network (JWARN) and Joint Operational Effects Federation (JOEF) acquisition programs. *FY 2009 Accomplishments:* Transitioned to JWARN the capability to exchange and multi-level fusion of actionable information with real world Command and Control (C2) systems in Department of Defense, Coalition and Homeland Security/Homeland Defense (HLS/HLD) domains. *FY 2010 Plans:* Battle Space Management efforts re-aligned to Advanced Warning and Reporting.	0.549	0.000	0.000	0.000	0.000
14) Information Systems Technology Advanced Warning and Reporting: 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 Plans:* Transition enhanced version of first-generation building interior Source Term Estimation (STE) and Hazard Refinement (HR) software to the Joint Effects Model (JEM). *FY 2011 Base Plans:* 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).	0.000	0.114	1.054	0.000	1.054
15) Information Systems Technology	1.042	1.848	1.961	0.000	1.961

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Hazard Prediction and Assessment: 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 to include counterproliferation, chemical and biological weapons, accidents and ground effects from ballistic missiles. *FY 2009 Accomplishments:* Transitioned GEDIS 2.3 to JEM. Validated and verified building interior dispersion model. Completed improved TIC/TIM prototype integration into JEM. Transitioned multi-scale four-dimensional data assimilation model to operational centers. Delivered complete variable resolution database containing highly refined estimates of climatological and typical atmospheric conditions for any given location and time to JEM. Tested and evaluated the use of the existing Weather Research and Forecast/Urban Canopy Model (WRF/UCM) forecasts to drive JEM transport and dispersion prediction. Transitioned fully extended SWIFT mass consistency wind model to JEM. *FY 2010 Plans:* Continue further refinements of the GEDIS data requirements tool with additional types of data such as climatology and population. Complete urban dispersion modeling for transition into JEM. Develop and implement the configuration management prototype for transition of project results to advanced development programs. *FY 2011 Base 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.					
16) Information Systems Technology	0.588	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Chemical Biological Defense Program Decision Capability: Develop tools for decision making for consequence management, human knowledge management, and health/human effects modeling including casualty estimation. *FY 2009 Accomplishments:* Verified and incorporated models for casualty estimates for infectious/contagious diseases into JEM. Validated models for predicting effects due to infectious/contagious diseases for Joint Effects Model (JEM) with real-world and simulation data. Completed transition of NATO's AMedP-8 chemical and biological models from NBC CREST to JOEF. *FY 2010 Plans:* CBDP Decision Capability efforts re-aligned to Simulation Analysis and Planning.					
17) Information Systems Technology Chemical and Biological Warfare Effects on Operations: Develop the science behind the modeling and simulation of operations at the strategic, operational and tactical level in a CBRN environment for mobile forces, tactical aircraft, naval operations and fixed sites. *FY 2009 Accomplishments:* Delivered chemical, biological, radiological, and nuclear (CBRN) operational effects methodologies for tactical and theater levels to JOEF. Delivered building interior modeling for JOEF. Completed transition of Agent Fate model to the Joint Effects Model (JEM). Transitioned mobile forces and shipboard models for CB effects on military operations to JOEF. Began validation of decision support tools for CBRN for eventual transition to JOEF. *FY 2010 Plans:* Chemical and Biological Warfare Effects on Operations re-aligned to Simulation Analysis and Planning.	0.821	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
18) Information Systems Technology Simulation Analysis and Planning: 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, human knowledge management, health/human effects modeling including casualty estimation, and fusion of diseases surveillance data. *FY 2010 Plans:* Verify respiratory tract models for prediction of human response as a function of particle size to improve casualty estimation for CBRN hazards and incorporate these models into the Joint Effect Model (JEM) for currently available agent data. Transition infection/contagious disease model to JEM. Transition sensor placement tool to acquisition programs. Transition CB effects on mobile forces analysis study and prototype for tactical and operational military operations. Transition improved Incident Management/Consequence Management (IM/CM) tools and capabilities to advanced development programs. *FY 2011 Base 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.	0.000	1.114	0.427	0.000	0.427
19) Information Systems Technology Systems Performance Modeling: Develop Chemical, Biological, Radiological and Nuclear (CBRN) data sharing capabilities.	0.000	0.493	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2010 Plans: Complete prototyping a data collection and exchange capability. Complete developing processes and policies for collection and insertion of data into CBRN data backbone efforts.					
20) Detection Detection Capabilities for Non-Traditional Agents: Develop detection technologies for Non-Traditional Agents. *FY 2009 Accomplishments:* Assessed and demonstrated antibodies assays in handheld format for small chemical molecules. *FY 2010 Plans:* Continue to develop supporting technologies and protocols to meet the Initial Operating Capabilities of the Next Generation Test Facility at the Edgewood Chemical and Biological Center. *FY 2011 Base Plans:* All NTA-related efforts re-aligned to the Detection NTA capability area located in this Budget Activity.	2.000	1.964	0.000	0.000	0.000
21) Detection 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 2009 Accomplishments:* Completed the fabrication and demonstration technology to meet Joint Biological Standoff Detection System (JBSDS) Increment 2 technology based upon the new information in the infrared	6.611	11.673	0.496	0.000	0.496

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
electromagnetic spectrum to enhance selectivity for interference rejection. Initiated new effort to develop the next generation of standoff chemical technology to meet change in the threat environment. *FY 2010 Plans:* Conduct a Technology Readiness Assessment and transition active IR and depolarization technologies as a candidate for JBSDS Increment 2. Initiate field trials to validate chemical signature for chemical standoff detection and identification capabilities. Initiate an analysis of alternatives to support efforts in meeting new requirements for the next generation of standoff chemical technology. Initiate 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 Base 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.					
22) Detection NTA Detection NTA: Focuses on technologies to provide NTA detection capabilities. *FY 2011 Base 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.	0.000	0.000	4.200	0.000	4.200
23) Technology Transition	2.782	4.640	4.640	0.000	4.640

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
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 2009 Accomplishments:* Initiated and completed transition of a miniature, lightweight chemical and biological sensor to JPM-BioDetection from DHS. Initiated transition of the Integrated CB Agent Hazard Mitigation program from the Defense Advanced Research Projects Agency (DARPA) to the United States Army Corps of Engineers through component 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 2010 Plans:* Continue transition of the Integrated CB Agent Hazard Mitigation with systems and neutralization efficiency testing in a laboratory environment. Continue competitive assessment of all mature technology from outside of the CBDP for rapid technology insertion into the capability areas. *FY 2011 Base Plans:* 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	19.567	25.297	15.410	0.000	15.410

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• CA4: *CONTAMINATION AVOIDANCE (ACD&P)*	7.703	40.186	63.347		63.347	9.093	10.754	4.742	3.978	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program			DATE: February 2010
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C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• CB2: *CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)*	102.599	110.955	88.897		88.897	100.243	97.979	90.686	91.554	Continuing	Continuing
• DE4: *DECONTAMINATION SYSTEMS (ACD&P)*	4.822	1.792	7.051		7.051	5.748	1.386	0.000	0.000	Continuing	Continuing
• IS4: *INFORMATION SYSTEMS (ACD&P)*	0.000	0.000	11.221		11.221	3.404	4.565	4.676	4.741	Continuing	Continuing
• TE3: *TEST & EVALUATION (ATD)*	25.761	13.307	11.875		11.875	11.267	11.160	0.000	0.000	Continuing	Continuing
• TE4: *TEST & EVALUATION (ACD&P)*	6.261	28.773	19.304		19.304	11.851	28.035	20.266	21.139	Continuing	Continuing
• TT4: *TECHBASE TECHNOLOGY TRANSITION (ACD&P)*	17.065	26.649	26.466		26.466	18.564	18.838	19.294	19.563	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program			DATE: February 2010
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COST ($ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
CI3: *CONGRESSIONAL INTEREST ITEMS (ATD)*	46.971	18.622	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The efforts listed in this project include congressional interest programs for FY09 and FY10.

B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
Congressional Add: Carbon Nanotube Chemical Detector - *FY 2009 Accomplishments:* Addressed improvements in sensitivity and selectivity through chemometric/principal component analyses and the development of artificial neural network (ANN) real-time optimum signature selection.	0.791	0.000
Congressional Add: Surface Enhanced Infrared Detection of Threats - *FY 2009 Accomplishments:* Continued to develop a handheld biological and chemical agent detection device based on surface enhanced infrared detection methods.	0.987	0.000
Congressional Add: Total Perimeter Surveillance (TPS) - *FY 2009 Accomplishments:* Demonstrated a prototype of the system.	0.989	1.593

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
FY 2010 Plans: Continuation of FY09 research.		
Congressional Add: Photo Catalytic Oxidation (PCO) Demonstration for Water Reuse - *FY 2009 Accomplishments:* Continued research to determine the water purification unit's performance in the removal of high threat CBRN agents and TICs.	1.373	0.000
Congressional Add: Mobile Rapid Response Prototype - *FY 2009 Accomplishments:* Continued the partnership of Hackensack University Medical Center with the Defense Threat Reduction Agency (DTRA), the Chemical Biological & Radiological Technology Alliance. *FY 2010 Plans:* Continuation of FY09 research.	1.082	2.390
Congressional Add: NIDS Automated Bio Agent Identifier - *FY 2009 Accomplishments:* Continued research begun in FY08. *FY 2010 Plans:* Conduct research for the development of multiplex handheld immunoassay tickets that are both human visually and machine read.	1.000	2.390
Congressional Add: Portable Rapid Bacterial Warfare Detection Unit -	3.156	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
FY 2009 Accomplishments: Developed a field deployable system based on IR spectroscopy.		
Congressional Add: UCLA High Speed and High Volume Laboratory Network for Infectious Diseases - *FY 2009 Accomplishments:* Expanded capability to include other biothreat agents, including bacterial and/or viruses (dual-use).	4.862	0.000
Congressional Add: Antioxidant Micronutrient Therapeutic Countermeasures for Chemical Agents - *FY 2009 Accomplishments:* Tested the hypothesis that a mixture of antioxidants before and after exposure to sulfur mustard may increase percent survival and survival time by decreasing oxidative damage and inflammation.	0.792	0.000
Congressional Add: Plant Vaccine Development - *FY 2009 Accomplishments:* Produced vaccine lots under cGMP and evaluated safety and toxicity and confirmed protective efficacy of identified dual agent vaccines. Developed technology transfer and implementation programs. *FY 2010 Plans:* Continuation of FY09 Research.	1.582	1.593
Congressional Add: Multi-Purpose Biodefense Immunoarray - *FY 2009 Accomplishments:* Continued research from FY08.	0.792	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
Congressional Add: Improved CBR Filters - *FY 2009 Accomplishments:* Initiated engineering phase with the goal of developing final design configurations that can be easily incorporated into new and existing filtration systems.	1.582	0.000
Congressional Add: Acinetobacter Baumannii Research - *FY 2009 Accomplishments:* Continued the preclinical development of these agents by developing improved syntheses techniques.	1.978	0.000
Congressional Add: Bio Agent Early Warning Detector - *FY 2009 Accomplishments:* Conducted advanced development of a standoff bio agent detection system.	1.978	0.000
Congressional Add: Biological Agent Identifiers - *FY 2009 Accomplishments:* Continued industry research into biological agent identifiers without wet reagents.	1.582	0.000
Congressional Add: Eye-Safe Long Range Stand-off System for Detection of Chemical and Biological Weapons - *FY 2009 Accomplishments:* Continued research for eye-safe, laser based standoff Chem/Bio detection systems.	1.483	0.000
	1.582	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
Congressional Add: Mobile Continuous Air Monitor (MCAM) - *FY 2009 Accomplishments:* Continued research for a portable continuous monitor for biodetection.		
Congressional Add: Rapid Response Institute - *FY 2009 Accomplishments:* Addressed technology related to quickly responding to chemical or biological situation.	3.164	0.000
Congressional Add: Liquid Crystal Sensor Technology Research and Development for Force Protection - *FY 2009 Accomplishments:* Continued development of a passively operated sensor that rapidly detects toxins in the immediate environment.	2.373	0.000
Congressional Add: Biodefense Vaccine Development and Engineering of Antiviral Peptides - *FY 2009 Accomplishments:* Performed vaccine development pertaining to antiviral countermeasures.	1.583	0.000
Congressional Add: Center for Advanced Emergency Response - *FY 2009 Accomplishments:* Continued development of emergency medical response training program for consequence management of chemical or biological events.	4.350	0.000
Congressional Add: ViriChip Rapid Virus Detection Systems -	1.582	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
FY 2009 Accomplishments: Researched on the use of nanoscience technology for a virus detection system.		
Congressional Add: Protective Self-Decontaminating Surfaces - *FY 2009 Accomplishments:* Provided immediate on-site protection with multi-threat applicability to instantly neutralize chemical agents and kill a number of microbial entities.	1.582	0.000
Congressional Add: Contaminated Human Remains Pouch - *FY 2009 Accomplishments:* Conducted prototype development activities to test a contaminated human remains transportable container.	1.582	0.000
Congressional Add: Recombinant BChE Formulation Program - *FY 2009 Accomplishments:* Conducted medical countermeasure technology development.	1.582	0.000
Congressional Add: Joint Material Decon System - *FY 2009 Accomplishments:* Addressed Reactive Overlay and Removable CBRN Coatings.	1.582	0.000
Congressional Add: Multi-Target Shipping Container Interrogation System Mobile Continuous Air Monitor	0.000	1.593

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
FY 2010 Plans: Develop air monitoring system for shipping containers.		
Congressional Add: Hand-Held Apparatus for Mobile Mapping and Expedited Reporting *FY 2010 Plans:* Develop 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.	0.000	2.788
Congressional Add: Regenerative Chemical Biological Filtration Systems *FY 2010 Plans:* Continuation of research funded in FY08 for a regenerative filtration system to reduce costs and provide protection against all chemical warfare agents for military personnel, critical equipment, and strategic facilities.	0.000	2.689
Congressional Add: Unified Management Infrastructure System *FY 2010 Plans:* Develop 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.	0.000	0.797
Congressional Add: Water Purification System for Natural Disasters *FY 2010 Plans:* Develop a water purification system.	0.000	0.797

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010
Congressional Add: CBDP Advanced Development *FY 2010 Plans:* Advanced Development	0.000	1.992
Congressional Adds Subtotals	46.971	18.622

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• CI1: *CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)*	8.090	20.036	0.000		0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• CI2: *CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)*	42.714	16.630	0.000		0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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COST ($ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TB3: *MEDICAL BIOLOGICAL DEFENSE (ATD)*	180.425	203.723	115.233	0.000	115.233	125.666	109.737	115.049	117.289	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TB3) funds preclinical development of vaccines, therapeutic drugs, and diagnostic capabilities to provide safe and effective medical defense against validated biological threat agents 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) licensure processes, DoD acquisition regulations, and the oversight of Phase 1 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) 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 threats such as bacterial (plague, anthrax, glanders), viral (smallpox, encephalitic alphaviruses), and toxin (ricin, botulinum neurotoxin, staphyloccal enterotoxin) agents.

This project also includes efforts such as the Transformational Medical Technologies Initiative (TMTI). The Transformational Medical Technologies Initiative (TMTI) was launched to respond to the threat of emerging or intentionally bioengineered biological threats. TMTI's mission is to protect the Warfighter from genetically engineered 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 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 agents (e.g, developing new and innovative ways to mass produce drugs in the event of a biological incident).

B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR	0.000	2.637	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2010 Plans: Small Business Innovative Research.					
2) Diagnostics 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 2009 Accomplishments:* Transitioned two candidates for a next generation diagnostic device to the advanced developer. Continued to utilize the decision matrix to identify and evaluate new technologies more effective for diagnosing exposure to bio-threat agents. Validated real time PCR assays identifying genes responsible for antibiotic resistance in bio-threat agents. Performed advanced assessment on the use of biosynthetic (recombinant) reagents on existing systems and improved test assays utilizing new technologies and approaches that enhance diagnosis of early exposure to BWAs. *FY 2010 Plans:* Continue development of two additional candidates for a next generation diagnostic device. Develop an automated, prototype polymerase chain reaction system on microarray cartridge using light emitting chemical-based (or other sensitive signal-amplified) technology. Continue to refine and transition strain test panels for viral specificity (inclusivity and exclusivity) characterization. Characterize assay specificity to ensure assays consistently identify the intended target but not related targets. Use 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. Develop and verify assays as per standardized processes. Transition pilot production protocols for biosynthetic (recombinant) antigen production for bacterial BWAs. Maintain an animal tissue bank	9.021	11.307	9.845	0.000	9.845

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
for validation of assay performance and as correlate reference materials from animal BWA exposure studies. Develop and verify single domain biosynthetic (recombinant) antibodies to bacterial and viral BWA targets. Investigate methods of stabilization of BWA biomarkers in clinical samples to extend transport and limit cold chain requirements. *FY 2011 Base 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.					
3) Pretreatments Vaccine Research Support: Assess the effectiveness of candidate vaccines in animal models and perform preliminary evaluations of safety and duration of protective immunity. *FY 2009 Accomplishments:* Further characterized safety, toxicity, and immunity duration studies in animals for filovirus vaccines. Optimized dose, route, and regimen for maximum effectiveness. Assessed alphavirus and filovirus vaccines for issues of vaccine interference. Conducted stability and toxicity studies for lead alphavirus vaccine candidates. Completed stability and toxicity studies for toxin vaccines, prepared production lots, and begin Investigational New Drug (IND) application preparation for Food and Drug	8.128	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Administration (FDA) evaluation. Analyzed effectiveness, duration of immunity, and dosing regimens of second-generation vaccine against bacterial pathogens (including anthrax, plague, and tularensis). *FY 2010 Plans:* Vaccine Research Support efforts re-aligned to Bacterial/Toxin and Viral Vaccines.					
4) Pretreatments Multiagent Vaccine Platforms: Evaluates the safety and effectiveness of vaccine platforms for immunization against multiple biothreat agents. *FY 2009 Accomplishments:* Evaluated safety and effectiveness of multi-agent vaccines (e.g., anthrax/plague/melioidosis); completed studies to determine interference between vaccine components and the immune response; conducted immunity duration studies. Down-selected multiagent vaccine platforms, determine dosage, and route of administration. *FY 2010 Plans:* Multi-agent Vaccine efforts will be re-aligned to Vaccine Platforms and Research Tools.	3.500	0.000	0.000	0.000	0.000
5) Pretreatments Bacterial/Toxin Vaccines: Evaluates the best single agent bacterial and toxin vaccines for effectiveness against aerosol challenge in large animal models. *FY 2010 Plans:* Plan, prepare and conduct Phase I clinical trial with the Ricin vaccine. *FY 2011 Base Plans:* Complete the Phase I clinical trial with the Ricin Vaccine.	0.000	0.984	0.937	0.000	0.937

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
6) Pretreatments	0.000	16.372	10.304	0.000	10.304

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.

FY 2010 Plans:

Initiate 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. Test chemically inactivated and deoxyribonucleic acid (DNA) vaccine candidates against VEE, EEE, and WEE for effectiveness against aerosol delivered doses in animals. Conduct dose, schedule, and aerosol challenge studies in animals with Ebola vaccine candidates. Transition two Marburg virus vaccine candidates to advanced development programs, and determine protection duration studies on these two candidates. Conduct 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. Conduct 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 Base Plans:

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,

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
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.					
7) Pretreatments	0.000	1.722	4.371	0.000	4.371
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.					
FY 2010 Plans: Research multiagent vaccines, immune interference, immune stimulating formulations, vaccine delivery/stabilization to predict the human immune response to vaccine candidates. Initiate 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). Evaluate 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 Base 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					

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
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.					
8) Therapeutics Therapy for Ebola and Marburg Virus Infections: Identifies, optimizes and evaluates potential therapeutic candidates effective against Filovirus infection including Ebola and Marburg Viruses. *FY 2009 Accomplishments:* Completed FDA required studies to support the preclinical development and characterization of other leading therapeutic technologies against the Ebola virus and Marburg virus.	5.302	0.000	0.000	0.000	0.000
9) Therapeutics Viral Therapeutics: Identifies, optimizes and evaluates potential therapeutic candidates effective against designated viral threat agents. *FY 2009 Accomplishments:* Continued studies to support FDA submissions, milestone approval, and product transition to advanced development programs. Performed FDA required non-human primate studies necessary to complete the development of two oral therapeutics for orthopox viral infection. *FY 2010 Plans:* Conduct 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. Conduct remaining FDA required non-human primate studies	5.567	9.493	9.519	0.000	9.519

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
necessary to complete the development of oral therapeutics for orthopox viral infection. Evaluate the efficacy of administering post-exposure therapeutic vaccine in conjunction with therapies that stop blood clotting in animals infected with filovirus. Continue animal studies to support FDA submissions, milestone approval, and product transition to advanced development. *FY 2011 Base 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.					
10) Therapeutics Bacterial Therapeutics: Identifies, optimizes, and evaluates potential therapeutic compounds effective against bacterial threat agents. *FY 2009 Accomplishments:* Tested and evaluated FDA approved antibiotics for efficacy against aerosol exposure to bacterial threat agents in non-human primate models of plague. Initiated advanced safety and effectiveness studies for a new single domain antibody that is smaller than conventional antibodies against plague. *FY 2010 Plans:* Test and evaluate the effectiveness of commercially available antibiotics against animals exposed to aerosol versions of plague and tularemia. Determine antibiotic susceptibility profiles for Yersinia pestis and Francisella tularensis in the laboratory.	2.447	2.656	2.700	0.000	2.700

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2011 Base Plans: Determine the effectiveness of commercially available antibiotics against Francisella tularensis in relevant animal infection models.					
11) Therapeutics Toxin Therapeutics: Identifies, optimizes and evaluates potential therapeutic candidates effective against biological toxin threat agents. *FY 2009 Accomplishments:* Continued optimization and structural activity relationship studies for BoNT small molecule therapeutics to achieve improved pharmacological properties. Tested intraneuronal delivery of small molecules using prototype therapeutic delivery system. Evaluated immune modifying compounds for pre and post-exposure therapy for Staphylococcal Enterotoxin B (SEB) intoxication. *FY 2010 Plans:* Initiate work to develop antitoxin preparation for Ricin and Staphylococcal Enterotoxin B (SEB). Define the therapeutic parameters for Ricin and SEB therapeutic. Test candidate BoNT small molecule therapeutics in animal challenge models. Perform advanced animal testing on small molecules that are protective against a lethal challenge of SEB in relevant animal models. *FY 2011 Base 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.	1.683	1.475	1.500	0.000	1.500

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
12) Transformational Medical Technologies Initiative	144.777	124.132	63.135	0.000	63.135

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. 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.

FY 2009 Accomplishments:

Continued to identify potential IND candidate drugs for development. Completed pre-clinical research necessary to submit up to ten additional applications for an IND with the FDA. Accelerated drug discovery efforts, incorporating new technology to expand the number of potential drug compounds suitable for advanced development. Implemented use of the previously validated transgenic and other animal model systems to replicate human disease and disease response pathways. Began implementation of test platforms for drug discovery, development, and manufacturing technologies. Continued investigating the use of existing of FDA-approved drugs to enhance effectiveness of current BW agent countermeasures.

FY 2010 Plans:

Continue to identify potential IND candidate drugs for development. Complete pre-clinical research necessary to submit up to seven additional applications for an IND with the FDA. Upon submission of an IND to the FDA for further evaluation, DoD Milestone A decisions will take place. Downselect contract performers who have had their IND applications accepted by the FDA. Initiate planning for Phase 1 clinical trials and other studies necessary to support advanced development efforts toward an New Drug Application (NDA) with the FDA. Continue investigating use of existing of FDA-approved drugs to enhance effectiveness of current BW agent countermeasures.

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2011 Base 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, Animal models were previously product licensure under the FDA Animal Rule. 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.					
13) Transformational Medical Technologies Initiative	0.000	32.945	12.922	0.000	12.922
Development of Platform Technologies: 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. In addition, animal models will be authenticated against challenge material and ready to support clinical trials. 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 Plans:* Conduct initial studies to determine dose-response, optimal route of administration and timing/ schedule of administration of product in relevant animal efficacy models. Based on completed studies, initiate development of the bioinformatics platform, which will integrate the various TMTI platforms by electronically structuring all TMTI data for rapid access and analysis. Continue development of rapid					

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
drug discovery and development platform technologies. Accelerate effort to develop and scale-up new rapid manufacturing platform technologies for biological drugs. Development efforts will bring these technologies into compliance with FDA current good manufacturing practices (cGMP) and quality requirements. Generate 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. Begin integration of stand-alone platforms into capabilities that can be demonstrated as a system. Validate test platforms for drug discovery, development and manufacturing technologies that allow the incorporation of medical countermeasure technologies into the TMTI rapid response capability. Support computer models to advance/enhance drug design. High throughput screening assays and technologies and novel platforms for target identification will also be investigated. *FY 2011 Base 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.					
Accomplishments/Planned Programs Subtotals	180.425	203.723	115.233	0.000	115.233

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C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• MB4: *MEDICAL BIOLOGICAL DEFENSE (ACD&P)*	7.910	102.437	136.975		136.975	130.718	131.347	115.985	113.566	Continuing	Continuing
• MB5: *MEDICAL BIOLOGICAL DEFENSE (SDD)*	87.676	57.558	141.680		141.680	161.732	159.144	141.481	111.671	Continuing	Continuing
• TB2: *MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)*	50.485	53.930	43.858		43.858	50.866	51.077	51.051	51.959	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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COST ($ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TC3: *MEDICAL CHEMICAL DEFENSE (ATD)*	21.641	28.971	29.134	0.000	29.134	30.401	30.546	31.356	31.877	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. 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.

B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR *FY 2010 Plans:* Small Business Innovative Research.	0.000	0.373	0.000	0.000	0.000
2) Diagnostics 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.	0.701	1.436	0.226	0.000	0.226

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: Concluded validation of the optimized sulfur mustard blood protein assay. Initiated validation of the urine byproduct assay. Concluded metabolic profile study and conduct data analysis. Completed validation of procedure to assess the presence of chemical warfare analytes from hair samples. *FY 2010 Plans:* Further development of improved reactivation and solvent-free extraction methodologies for definitive CWA byproduct identification. Determine windows of opportunity for biomarker identification and subsequent therapeutic intervention for CWA in laboratory and animal models. *FY 2011 Base 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 Budget Activity.					
3) Chem Diagnostics NTA *FY 2011 Base Plans:* Continue evaluation of mature technologies that can quickly diagnose NTA exposure before symptoms appear and determine the type of agent.	0.000	0.000	0.400	0.000	0.400
4) Pretreatments Nerve Agent, Bioscavengers: Develop pretreatments that provide protection against all organophosphorous nerve agents. Bioscavengers 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. One molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules	6.636	7.811	7.861	0.000	7.861

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent. *FY 2009 Accomplishments:* Optimized animal expression systems for binding protein delivery. Completed structural studies of potential catalytic bioscavengers. Utilized Physiological Based Pharmacokinetic (PBPK) models that predict efficacy of bioscavengers in animals for novel catalytic bioscavengers. Evaluated catalytic bioscavengers for safety, efficacy, stability, and immune system stimulation. *FY 2010 Plans:* Develop formulations for improved pharmacokinetic and reduced immune system stimulation for catalytic bioscavengers. Investigate improved drug-delivery systems for 1st generation catalytic bioscavengers. Conduct supportive studies toward licensure of catalytic bioscavengers. *FY 2011 Base Plans:* Apply 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.					
5) Therapeutics 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.	3.933	3.465	3.689	0.000	3.689

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: Initiated animal studies to determine long term effects of down-selected wound healing products and blister agents, in coordination with the advanced developer. *FY 2010 Plans:* Evaluate commercial off-the-shelf irrigation systems for treatment of CWA exposure in the laboratory and animals. Continue animal studies to examine long-term effects of wound healing products. Down-select newly identified therapeutics with potential for treating mustard agent-induced ocular injury. Begin efficacy testing in compliance with FDA regulations for ocular administration. *FY 2011 Base 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.					
6) Therapeutics Neurologic: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to CWAs. This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. Supports eventual FDA licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. *FY 2009 Accomplishments:* Accelerated efforts 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 according to FDA guidelines.	6.421	13.240	13.137	0.000	13.137

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2010 Plans: Test broad-spectrum reactivators in one or more animal models, with a focus on requirements to support FDA submissions under the animal rule. Initiate safety/side effect/dosing and the body's effects on the drug evaluation of new compounds. Continue 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 Base 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.					
7) Therapeutics Medical Toxicology (Non-Traditional Agents (NTAs) and Other agents): Investigates common mechanisms of agent injury. Determines the toxic effects of agents by probable routes of field exposure as well as standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanism(s) of toxicity. *FY 2009 Accomplishments:* Developed, validated, and completed practical clinical strategies to aid in management of NTA casualties.	2.950	0.000	0.000	0.000	0.000
8) Therapeutics CWA Operational Exposure Hazard Assessment Research: Supports FDA licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties.	1.000	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: Completed data analysis and delivered dataset to define the operational effects from chemical agent contact and inhalation exposure.					
9) Therapeutics Respiratory and Systemic: Supports investigation of the systemic host response to 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 FDA licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. *FY 2010 Plans:* Identify and test potential therapeutics with a focus on FDA approved drugs that are currently used for other indications for treatment of CWA-induced lung damage. Investigate approaches to enhance inhalational delivery of selected candidate therapeutics. Evaluate commercially available aerosol bronchodilators as supportive therapy following acute inhalational exposure to CWAs. *FY 2011 Base 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.	0.000	1.308	1.367	0.000	1.367
10) Therapeutics	0.000	1.338	2.454	0.000	2.454

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
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 Plans:* Develop and evaluate novel and FDA licensed products as post-exposure therapeutics against NTA poisoning in advanced animal models. *FY 2011 Base Plans:* Complete characterization of a novel therapeutic for manufacturability and pharmacology. Establish formulation for safety testing and stability.					
Accomplishments/Planned Programs Subtotals	21.641	28.971	29.134	0.000	29.134

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• MC4: *MEDICAL CHEMICAL DEFENSE (ACD&P)*	19.365	9.438	0.000		0.000	2.973	3.661	5.035	14.670	Continuing	Continuing
• MC5: *MEDICAL CHEMICAL DEFENSE (SDD)*	14.203	14.027	51.856		51.856	47.835	28.771	12.122	8.171	Continuing	Continuing
• TC2: *MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)*	35.008	40.418	33.648		33.648	36.327	36.500	37.475	38.150	Continuing	Continuing

D. Acquisition Strategy

N/A

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E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program			DATE: February 2010
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COST ($ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TE3: *TEST & EVALUATION (ATD)*	25.761	13.307	11.875	0.000	11.875	11.267	11.160	0.000	0.000	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. Starting in FY11, all NTA-dedicated research will be re-aligned into specific capability areas within this project.

B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR *FY 2010 Plans:* Small Business Innovative Research.	0.000	0.176	0.000	0.000	0.000
2) Test and Evaluation (T&E) NTA Develops test and evaluation technologies and processes in support of NTA activities. *FY 2011 Base 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.	0.000	0.000	2.000	0.000	2.000
3) Test and Evaluation (T&E)	6.643	5.896	2.784	0.000	2.784

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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 Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Test and Evaluation, Detection: Develop, test, and evaluate technologies and processes in support of detection capability testing. *FY 2009 Accomplishments:* Continued development of methodologies and capabilities for test and evaluation of technologies currently in early stages of technology development. Initiated and completed Quality Assurance (QA) implementation and checkpoints for scaled-up antigen production runs and post-production conformance tests. Continued NTA chamber design effort by conducting liquid dissemination development and proof of principle tests with a few agents and addressed questions regarding the safety of unprotected personnel using the chamber post decontamination. *FY 2010 Plans:* Continue development of methodologies and capabilities for test and evaluation of technologies currently in early stages of tech-base development. Continue 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 Base Plans:* Complete development of methodologies and capabilities for test and evaluation of technologies currently in early stages of technology development.					
4) Test and Evaluation (T&E) 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.	3.891	1.531	1.391	0.000	1.391

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: Continued development of simulants for specified NTAs to be used in test and evaluation efforts. Completed standard protocol evaluation. Continued development of masking/encapsulation simulants for CB agents. Completed TIC/battlefield contaminants methodologies study. *FY 2010 Plans:* Continue development of NTA Simulants. Provide 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. Identify and develop 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. Develop 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 Base 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.					
5) Test and Evaluation (T&E) Test and Evaluation, Information System Technology: Develop test and evaluation technologies and processes in support of Information System Technology activities.	3.825	5.508	5.600	0.000	5.600

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: Continued development on decontamination efficacy prediction model. Transitioned first module of decontamination model. Integrated state-of-the-art transport and dispersion models and visualization software into collective protection systems performance model. Integrated relevant analytical tools into individual protective equipment performance model. Initiated verification and validation processes on emerging test and evaluation models. Began development of contamination avoidance systems performance model. *FY 2010 Plans:* Develop second module of decontamination model. Continue development and integration relevant to construction of systems performance models for collective protection, contamination avoidance, and individual protection. Build requirements for systems performance model integration and program-wide exploitation. Conduct requirements analysis for inclusion of data from test and evaluation community into CBRN Data Backbone. *FY 2011 Base 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 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.					
6) Test and Evaluation (T&E) Test and Evaluation, Protection and Hazard Mitigation: Develop test and evaluation technologies and processes in support of Protect and Hazard Mitigation activities.	9.992	0.196	0.100	0.000	0.100

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: Completed development of collective protection shelter systems test and evaluation standards, Toxic Industrial Chemicals (TIC), and battlefield contaminant standards for Individual Protection Equipment (IPE) and Collective Protection (COLPRO). Completed standard procedures for IPE Assessment. Completed real-time sampling/detector system swatch test methodology for use in Chemical and Biological Agent Resistance Test System (CBARTS) test methodology standards and guidance for air purification technologies, IPE field operations effects standard, and IPE air flow mapping. *FY 2010 Plans:* Initiate methodology/source data effort to simulate IP durability test in laboratory and relationship to field durability. *FY 2011 Base Plans:* Continue development of methodology/source data effort to simulate IP durability in laboratory and relationship to field durability.					
7) Test and Evaluation (T&E) Test and Evaluation, Decontamination: Develop test and evaluation technologies and processes in support of decontamination activities. *FY 2009 Accomplishments:* Initiated and completed test and evaluation methodologies and protocols for assessing reactivity of alternative reactive material technologies and processes. Initiated and completed processes for relevant environment and relevant equipment testing for live agents and calculations for small item contact test that incorporates toxicological considerations.	1.410	0.000	0.000	0.000	0.000
Accomplishments/Planned Programs Subtotals	25.761	13.307	11.875	0.000	11.875

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• TE4: *TEST & EVALUATION (ACD&P)*	6.261	28.773	19.304		19.304	11.851	28.035	20.266	21.139	Continuing	Continuing
• TE5: *TEST & EVALUATION (SDD)*	37.444	36.593	15.901		15.901	12.243	4.238	14.614	15.300	Continuing	Continuing
• TE7: *TEST & EVALUATION (OP SYS DEV)*	7.037	4.870	4.813		4.813	4.779	4.750	5.660	5.615	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program			DATE: February 2010
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 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TR3: *MEDICAL RADIOLOGICAL DEFENSE (ATD)*	4.859	2.403	0.957	0.000	0.957	0.966	1.922	2.901	2.927	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 Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) Radiological Medical Countermeasures	4.859	2.371	0.957	0.000	0.957

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 2009 Accomplishments:

Continued to evaluate at least two promising drug candidates to assess animal survival rate when exposed to lethal radiation. Evaluated efficacy of three to four therapeutic candidates and regimens that mitigate and/or treat post-radiation exposure, with emphasis on broad spectrum activity, ease of administration, and safety in non-human primates (NHPs). Continued to evaluate the preclinical efficacy and safety studies in NHPs, an assessment of drug mechanism of action,

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
and the determination of drug formulation according to the FDA animal rule. Evaluated promising radioprotectants and post-irradiation therapeutic agents. *FY 2010 Plans:* Evaluate mature and promising agents for respiratory and gastrointestinal damage and repair. Demonstrate efficacy and safety in NHPs. Begin down-selection and prepare 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 FDA license. *FY 2011 Base 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 animals models for radiation exposures useful to support FDA licensure.					
2) SBIR *FY 2010 Plans:* Small Business Innovative Research.	0.000	0.032	0.000	0.000	0.000
Accomplishments/Planned Programs Subtotals	4.859	2.403	0.957	0.000	0.957

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• MR4: *MEDICAL RADIOLOGICAL DEFENSE (ACD&P)*	4.294	0.000	0.000		0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
	3.002	8.276	1.143		1.143	4.817	2.265	0.000	0.000	Continuing	Continuing

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program			DATE: February 2010
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C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• MR5: *MEDICAL RADIOLOGICAL DEFENSE (SDD)*											
• TR2: *MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)*	0.525	2.897	2.884		2.884	1.904	2.855	1.913	1.903	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program			DATE: February 2010
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 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TT3: *TECHBASE TECHNOLOGY TRANSITION*	8.127	7.357	4.504	0.000	4.504	8.117	8.169	8.390	8.528	Continuing	Continuing

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 Concept 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 (new thrust area) 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 (new thrust area) 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 Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR *FY 2010 Plans:* Small Business Innovative Research.	0.000	0.101	0.000	0.000	0.000
2) Experiment & Technology Demonstrations	5.623	4.869	2.175	0.000	2.175

Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: ART Thrust Area Continued biological decontamination technology and decision support system evaluations for IBRD. Conducted biological technology demonstrations for IBRD. Continued testing of candidate technologies for Auto Decon and HaMMER ATDs and for CBRN capability insertion into advanced development programs. EW Thrust Area Analyzed the capability of current- and near-term early warning technologies that may either be capable of or are required to sense CB attacks in preparation for the Early Warning/Military Applications in Reconnaissance/Surveillance ATDs. CIP Thrust Area Performed Design, Test and Evaluation for the IP Demo ATD. *FY 2010 Plans:* EW Thrust Area Conduct technology testing for EW/MARS Rapid Area Sensitive Site Reconnaissance (RASR) ATD. RASR will assess 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). Conduct 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 Analyze the thermal burden for Warfighter protective gear in a CBRN environment as part of the CIP Low Burden Individual Protection Demonstration (IP Demo). Assessment of integrated fabric, low resistance/profile filtration, human performance prediction and assessment and low-burden air					

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
purifying respirator concurrent with the Protection and Hazard 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 Base 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).					
3) Technology Readiness Assessment *FY 2009 Accomplishments:* Conducted Technology Readiness Evaluations in support of remediation and restoration technology demonstrations to identify technologies in support of the ART IBRD ATD and EW MARS-JFP ATD. *FY 2010 Plans:* Continue Technology Readiness Evaluations in support of the EW MARS-JFP ATD. For the EW RASR ATD, assess 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). Build and integrate key technology components integrated	2.504	2.387	2.329	0.000	2.329

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B. Accomplishments/Planned Program ($ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
to demonstrate system level Force Protection capabilities in a Forward Operating Base scenario. Investigate 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 Base 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.					
Accomplishments/Planned Programs Subtotals	8.127	7.357	4.504	0.000	4.504

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• CB2: *CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)*	102.599	110.955	88.897		88.897	100.243	97.979	90.686	91.554	Continuing	Continuing
• TT4: *TECHBASE TECHNOLOGY TRANSITION (ACD&P)*	17.065	26.649	26.466		26.466	18.564	18.838	19.294	19.563	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A