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Exhibit R-2, PB 2010 Chemical and Biological Defense Program RDT&E Budget Item Justification								DATE: April 2009		
APPROPRIATION/BUDGET ACTIVITY					R-1 ITEM NOMENCLATURE					
0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 3 - Advanced Technology Development (ATD)					PE 0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)					
COST (\$ in Millions)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
Total Program Element	238.220	324.769	282.235						Continuing	Continuing
CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	18.839	19.183	25.403						Continuing	Continuing
CI3: CONGRESSIONAL INTEREST ITEMS (ATD)	63.987	50.700	0.000						Continuing	Continuing
TB3: MEDICAL BIOLOGICAL DEFENSE (ATD)	95.996	188.748	204.576						Continuing	Continuing
TC3: MEDICAL CHEMICAL DEFENSE (ATD)	24.183	26.482	29.092						Continuing	Continuing
TE3: TEST & EVALUATION (ATD)	23.824	26.579	13.363						Continuing	Continuing
TR3: MEDICAL RADIOLOGICAL DEFENSE (ATD)	2.152	4.863	2.413						Continuing	Continuing
TT3: TECHBASE TECHNOLOGY TRANSITION	9.239	8.214	7.388						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

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detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD Chemical/Biological Warfare (CBW) defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Also research efforts are planned to evaluate technologies for Weapons of Mass Destruction Civil Support Teams (WMD-CSTs). Work conducted under this PE transitions to and provides risk reduction for System Integration/Demonstration (PE 0603884BP/PE 0604384BP) activities. 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.

**B. Program Change Summary (\$ in Millions)**

	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
Previous President's Budget	245.591	337.927	311.052	
Current BES/President's Budget	238.220	324.769	282.235	
Total Adjustments	-7.371	-13.158	-28.817	
Congressional Program Reductions	0.000	-63.858		
Congressional Rescissions				
Total Congressional Increases	0.000	50.700		
Total Reprogrammings	-4.336	0.000		
SBIR/STTR Transfer	-3.035	0.000		
Other Adjustments	0.000	0.000	-28.817	

**Congressional Increase Details (\$ in Millions)**

**Project:** CI3, CONGRESSIONAL INTEREST ITEMS (ATD)

<b>FY 2008</b>	<b>FY 2009</b>
0.000	50.700

**Change Summary Explanation**

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

Schedule: N/A

Technical: N/A

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	18.839	19.183	25.403						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 (formerly decontamination and protection), and technology transition efforts in these capability areas. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. 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. Starting in FY10, Decontamination and Protection capability areas will be merged into a new capability area called Protection and Hazard Mitigation. 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 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). This project also funds development of methodologies and capabilities for test and evaluation of the advanced technologies.

**B. Accomplishments/Planned Program (\$ in Millions)**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Regenerative and Reactive Air Purification: 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.	0.850	0.000	0.000	
FY08 - Completed evaluation of the swing adsorption filtration including pressure/thermal swing adsorption (PTSA) and electro thermal swing adsorption (ESA) prototype.				
Detection Capabilities for Non-Traditional Agents: Develop detection technologies for Non-Traditional Agents.	2.000	1.494	2.000	
FY08 - Completed impact studies to incorporate modifications to standard Lightweight Chemical Detectors (LCD's) design and transitioned recommendations to advanced development programs such as the Joint Chemical Agent Detector (JCAD) program (see BA5.) Completed the studies necessary to fill the identified				

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
gaps from the analytical studies on the impact of threat environments on the properties of neat agents. Completed the development of agent to simulant correlations in support of test and evaluation needs.  FY09 - Assess and demonstrate antibodies assays in handheld format for small chemical molecules.  FY10 - Develop detection test methodology and design parameters for the NTA test chamber.				
Technology Transition - Conduct competitive assessments of all mature technology from outside the Chemical and Biological Defense Program (CDBP) and assist in transition of promising technology efforts.  FY08 - Completed transition of Department of Homeland Security's (DHS's) Low-cost Biological Aerosol Detector Systems (LBADS) to the Department of Defense's (DoD's) Joint Biological Tactical Detection Systems (JBTDS - see Budget Activity 4, Project CA4; Budget Activity 5, Project CA5). Continued competitive assessment of all mature technology from outside of the CDBP for rapid technology insertion into the capability areas.  FY09 - 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 CDBP for rapid technology insertion into the capability areas.  FY10 - 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 CDBP for rapid technology insertion into the capability areas.	2.960	2.878	4.724	
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.  FY08 - Demonstrated and transitioned first-generation outdoor Sensor Placement Tool (SPT) to advanced development programs such as the Joint Warning and Reporting Network (JWARN) and the Joint Operational	0.293	0.592	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Effects Federation (JOEF) (see BA4, Project IS4; BA5, Project IS5). Demonstrated prototype building interior Source Term Estimation (STE). Demonstrated prototype of second-generation outdoor SPT algorithm to include optimal hazard prediction capability.  FY09 - Transition first generation outdoor STE/Hazard Refinement (HR) and second-generation SPT software to the Joint Effects Model (JEM), JWARN and JOEF. Transition first-generation building interior STE and HR software to JEM and JOEF.  FY10 - Sensor Data Fusion efforts will be re-aligned to Advanced Warning and Reporting.				
Solid Phase: Demonstration of improved chemical and biological decontamination formulations that are compatible with the current family of decontamination systems.  FY08 - Completed research efforts to develop reactive sorbent nano-active suspensions and sprayable powders and transition to advanced development programs such as the Joint Service Transportable Decontamination System (JSTDS). Developed, tested, and completed nano-active powders for use as adsorptive/reactive layers in a human remains pouch and transitioned to Human Remains Decon System (HRDS) program.	0.869	0.000	0.000	
Lightweight Integrated Fabric: Demonstration of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform.  FY10 - 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.	0.000	0.000	0.639	
SBIR - FY09 - Small Business Innovative Research.	0.000	0.214	0.000	
Alternative Processes: Demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application.	0.786	1.957	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>FY08 - Completed research to develop a gaseous chemical and biological decontamination system combining hot air and modified vaporous hydrogen peroxide; determined efficacy effects on decontamination of chemical and biological agents; and determined candidate formulation and application combinations and transitioned to advanced development programs. Initiated efforts to investigate reactive materials and nanotechnology for decontamination processes.</p> <p>FY09 - Continue efforts to investigate reactive materials and nanotechnology for decontamination processes.</p> <p>FY10 - Efforts will be re-aligned to Protection and Hazard Mitigation.</p>				
<p>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.</p> <p>FY08 - Integrated protective mask designs with developmental helmet systems to provide seamless compatibility of chemical and biological protection with ballistic protection, and integration of communication and optical systems. Initiated development of initial high fidelity prototypes for early assessment of human and operational compatibility.</p> <p>FY09 - 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. Continue to develop initial high fidelity prototypes for early assessment of human and operational compatibility during the Uniform Integrated Protective Ensemble (UIPE) Demonstration.</p> <p>FY10 - Efforts will be re-aligned to Protection and Hazard Mitigation.</p>	0.795	1.441	0.000	
<p>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.</p> <p>FY08 - Transitioned Inter-LAN Socket Connection Manager and Joint Warning and Reporting Network (JWARN) Component Interface Device (JCID) on a Chip to the JWARN program. Transitioned Sensor</p>	0.847	0.549	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Alert Verification for Operational Response (SAVIOR), a false alarm reduction capability, to the advanced development program for contamination avoidance.  FY09 - Transition 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 to JWARN.  FY10 - Battle Space Management efforts will be re-aligned to Advanced Warning and Reporting.				
Chemical and Biological Stand-off Technology: Emphasis 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.  FY08 - Completed the development of test methodology to evaluate and assess the value of new signatures in broad regions of the electromagnetic spectrum. Completed prototype designs and initiate fabrication of enhanced biological standoff system based upon this new information to enhance selectivity for interference rejection.  FY09 - Complete the fabrication, conduct a demonstration and transition technology to meet Joint Biological Standoff Detection System (JBSDS) Increment 2 technology based upon the new information in the infrared electromagnetic spectrum to enhance selectivity for interference rejection. Initiate new effort to develop the next generation of standoff chemical technology to meet change in the threat environment.  FY10 - 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.	6.138	5.893	11.884	
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	0.000	0.646	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY10 - Initiate brassboard prototype development efforts for the next generation filter for individual protection from CB agents, Toxic Industrial Chemicals (TIC's) and Non Traditional Agents (NTA' s), 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).				
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.  FY10 - 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	0.000	0.527	
Advanced Warning and Reporting: Develop 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 programs.  FY10 - Transition enhanced version of first-generation building interior Source Term Estimation (STE) and Hazard Refinement (HR) software to the Joint Effects Model (JEM) and the Joint Operational Effects Federation (JOEF).	0.000	0.000	0.114	
Integrated Ensemble Development: Demonstration of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform.  FY08 - Integrated protective mask designs with developmental helmet systems to provide seamless compatibility of CB protection with ballistic protection, and integration of communication and optical systems. Initiated development of initial high fidelity prototypes for early assessment of human and operational compatibility.	0.820	1.481	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY09 - Continue integration of the protective mask designs with developmental helmet systems to provide seamless compatibility of chemical and biological protection with ballistic protection, and integration of communication and optical systems. Continue to develop initial high fidelity prototypes for early assessment of human and operational compatibility during the Uniform Integrated Protective Ensemble (UIPE) Demonstration.  FY10 - Efforts will be re-aligned to Protection and Hazard Mitigation.				
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.  FY08 - Continued enhancement and testing in the Geographic Environmental Database Information System (GEDIS) 2.2 release. Completed initial interior building transport modeling algorithm and software development. Initiated improved Toxic Industrial Chemicals/Toxic Industrial Materials (TIC/TIM) prototype integration into the Joint Effects Model (JEM). Began extension of the Stationary Wind Fit with Turbulence (SWIFT) and provided updated mass consistency wind models and advanced urban models to JEM. Integrated advanced numerical weather prediction techniques for coastal, complex terrain and urban environments into JEM.  FY09 - Transition GEDIS 2.3 to JEM. Validate and verify building interior dispersion model. Complete improved TIC/TIM prototype integration into JEM. Transition multi-scale four-dimensional data assimilation model to operational centers. Deliver complete variable resolution database containing highly refined estimates of climatological and typical atmospheric conditions for any given location and time to JEM. Test and evaluate the use of the existing Weather Research and Forecast/Urban Canopy Model (WRF/UCM) forecasts to drive JEM transport and dispersion prediction. Transition fully extended SWIFT mass consistency wind model to JEM.  FY10 - 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	0.800	1.042	1.848	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
implement the configuration management prototype for transition of project results to advanced development programs.				
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.  FY10 - Initiate brassboard prototypes development of down-selected media-less technologies.	0.000	0.000	0.433	
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.  FY08 - Transitioned Toxic Industrial Chemicals/Toxic Industrial Materials (TIC/TIM), long-term radiological effects, and Allied Medical Publication 8 (AMedP-8) nuclear models. Continued refinement of validation and verification (V&V) documentation from NBC Casualty Resource Estimation Support Tool (NBC CREST) to the Joint Operational Effects Federation (JOEF). Developed a biological and a chemical agent human response model accounting for particle size distribution (PSD) effects. Developed, implemented and tested additional agent response models accounting for PSD effects and initiated delivery of V&V software. Continued transition of NATO's AMedP-8 chemical and biological models from NBC CREST to JOEF.  FY09 - Verify and incorporate models for casualty estimates for infectious/contagious diseases into JEM. Validate models for predicting effects due to infectious/contagious diseases for JEM with real-world and simulation data. Complete transition of NATO's AMedP-8 chemical and biological models from NBC CREST to JOEF.  FY10 - CBDP Decision Capability efforts will be re-aligned to Simulation Analysis and Planning.	0.830	0.821	0.000	
General Purpose Formulations for Decontamination: Demonstration of improved chemical and biological decontamination formulations that are compatible with the current family of decontamination systems.	0.000	0.000	0.717	

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FY10 - Perform coupon tests, material compatibility and small item effectiveness evaluations for solid oxidants and green solvent/surfactant systems. Transition to Joint Portable Decon System (JPDS) and Joint Service Transportable Decon System (JSTDS) programs (see BA5, Project DE5).				
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.  FY08 - Initiated delivery of Output Analysis Tool (OAT), Chemical Hazard Estimation Method Risk Assessment tool (CHEMRAT) version 1.6, Chemical Convoy Operations Risk Vulnerability Estimation Tool (CORVET), and Simulated Training and Analysis for Fixed Facilities/Sites (STAFFS) tactical aircraft upgrades to the Joint Operational Effects Federation (JOEF).  FY09 - Deliver chemical, biological, radiological, and nuclear (CBRN) operational effects methodologies for tactical and theater levels to JOEF. Deliver building interior modeling for JOEF. Complete transition of Agent Fate model to the Joint Effects Model (JEM). Transition mobile forces and shipboard models for CB effects on military operations to JOEF. Begin validation of decision support tools for CBRN for eventual transition to JOEF.  FY10 - Chemical and Biological Warfare Effects on Operations will be re-aligned to Simulation Analysis and Planning.	0.851	0.821	0.000	
Decontamination System-of-Systems: Demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application.  FY10 - 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	0.000	0.200	
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.	0.000	0.000	1.114	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>				<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>			
FY10 - 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 to JOEF. Transition improved Incident Management/Consequence Management (IM/CM) tools and capabilities to advanced development programs.										
Systems Performance Modeling: Develop Chemical, Biological, Radiological and Nuclear (CBRN) data sharing capabilities. FY10 - Prototype a data collection and exchange capability. Develop processes and policies for collection and insertion of data into CBRN Data Backbone.				0.000	0.000	0.557				
<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
CA4/CONTAMINATION AVOIDANCE (ACD&P)	3.621	7.792	39.554						Continuing	Continuing
DE4/DECONTAMINATION SYSTEMS (ACD&P)	4.151	8.643	0.000						Continuing	Continuing
IS4/INFORMATION SYSTEMS (ACD&P)	0.000	0.000	0.000						Continuing	Continuing
TE3/TEST & EVALUATION (ATD)	23.824	26.579	13.363						Continuing	Continuing
TE4/TEST & EVALUATION (ACD&P)	13.776	6.335	28.894						Continuing	Continuing
TT4/TECHBASE TECHNOLOGY TRANSITION (ACD&P)	13.218	17.267	26.761						Continuing	Continuing
<b>D. Acquisition Strategy</b>										
N/A										

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>		<b>DATE:</b> April 2009
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<b>E. Performance Metrics</b> N/A		

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>									<b>DATE:</b> April 2009	
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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
CI3: CONGRESSIONAL INTEREST ITEMS (ATD)	63.987	50.700	0.000						Continuing	Continuing

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

The efforts listed in Section B of this justification include congressional interest programs for FY08 and FY09.

**B. Accomplishments/Planned Program (\$ in Millions)**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>CBDP Initiative Fund Applied Research: The CBDIF goal is to fund new and innovative chemical and biological science and technology projects across a wide range of military operations. Established in FY 2003, it is congressionally directed with the intent to provide funds via a competitive acquisition to non-Government entities.</p> <p>FY08 - Solicited proposals from degree-granting universities, nonprofit organizations, or commercial concerns to include small businesses, in support of the CBDP to fund chemical and biological defense science and technology projects across a wide-range of military operations. Upon technical evaluation and selection of proposals, provide a report detailing the number of projects funded and areas of research.</p>	7.891	0.000	0.000	
<p>SBIR - FY09 - Small Business Innovative Research.</p>	0.000	0.565	0.000	
<p>Fraunhofer USA Center for Molecular Biology -</p> <p>FY08 - Delivered a combined multivalent one-shot vaccine that protects the Armed Forces and civilian communities against plague and anthrax.</p>	0.987	0.000	0.000	
<p>Hand-held Nanotechnology Enabled Bio-Warfare Agent Identification System -</p> <p>FY08 - Produced a light-weight, hand-held device defense-wide for identification of biological warfare agents.</p>	2.368	0.000	0.000	
<p>Long Range Stand Off System for Detection of Biological Materials -</p> <p>FY08 - Conducted research to develop an eye-safe standoff detection system using laser technology.</p>	1.105	0.000	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Carbon Nanotube Chemical Detector -  FY08 - Built upon the previous research (FY07) in developing a prototype arrayed single-walled carbon nanotube (SWNT) CWA detector.  FY09 - Address improvements in sensitivity and selectivity through chemometric/principal component analyses and the development of artificial neural network (ANN) real-time optimum signature selection.	0.987	0.791	0.000	
Surface Enhanced Infrared Detection of Threats -  FY08 - Developed a handheld biological and chemical agent detection device based on surface enhanced infrared detection methods.  FY09 - Continued to develop a handheld biological and chemical agent detection device based on surface enhanced infrared detection methods.	2.604	1.187	0.000	
Small Accelerators and Detection Systems for Homeland Defense and National Security Applications -  FY08 - Continued research from FY06 and FY07 for the development of a new high-power, mobile accelerator systems for CB agent detection and defeat.	1.579	0.000	0.000	
Total Perimeter Surveillance (TPS) -  FY08 - Conducted research for the development of an unattended chem./bio threat detection system.  FY09 - Demonstrate a prototype of the system.	1.578	0.989	0.000	
Photo Catalytic Oxidation (PCO) Demonstration for Water Reuse -  FY08 - Continued research begun in FY06 to address the removal of NBC agents in drinking water in-line with existing water purification units.	1.973	2.373	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY09 - Continuation of research to determine the water purification unit's performance in the removal of high threat CBRN agents and TICs.				
Environmental Bioterrorism Detection Program -  FY08 - Developed a comprehensive bio-surveillance monitoring system.	1.973	0.000	0.000	
Mobile Rapid Response Prototype -  FY08 - Continued in the partnership of Hackensack University Medical Center with the Defense Threat Reduction Agency (DTRA), the Chemical Biological & Radiological Technology Alliance.  FY09 - Continuation of the partnership of Hackensack University Medical Center with the Defense Threat Reduction Agency (DTRA), the Chemical Biological & Radiological Technology Alliance.	3.945	1.582	0.000	
Mobile Real-time, non-specific Viral Agent Detector -  FY08 - Conducted research in the development of a real-time biological agent detector.	1.480	0.000	0.000	
Next Generation Gas Chromatographic Mass Spectrometer for WMD Civil Support Teams -  FY08 - Improved commercially available GC-MS systems to provide chemical analysis and identification in the field which currently does not exist in person-portable form. This effort was directed toward instrument development and testing.	0.789	0.000	0.000	
NIDS Automated Bio Agent Identifier -  FY08 - Conducted research for the development of multiplex handheld immunoassay tickets that are both human visually and machine read.  FY09 - Continuation of research begun in FY08.	2.959	1.582	0.000	
Portable Rapid Bacterial Warfare Detection Unit -	4.341	3.956	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY08 - Conducted research to detect and identify microorganisms of military significance. Optimized a standardized process for real-time detection and identification of Bacterial Warfare Agents (BWA).  FY09 - Develop a field deployable system based on IR spectroscopy.				
Continuation of Unmanned Vehicle CBRNE Unitary Sensor Suite Development and Demonstration -  FY08 - Continued improvement and demonstration of chemical, biological, radiological, nuclear and toxic industrial material sensing technologies.	1.578	0.000	0.000	
UCLA High Speed and High Volume Laboratory Network for Infectious Diseases -  FY08 - Continued prior research (FY07) to develop a new high speed, high throughput bioagent screening and genotyping capability. Implemented an automated phenotyping system and supporting capabilities.  FY09 - Expand capability to include other biothreat agents, including bacterial and/or viruses (dual-use).	3.945	4.944	0.000	
Myeloid Progenitor for Acute Radiation Syndrome - (This effort was transferred to CBMS)  FY08 - Accelerated development of CLT-008, a product offering an immediate treatment option for forward deployed military personnel who may be exposed to high doses of radiation on the battlefield.	2.368	0.000	0.000	
Antioxidant Micronutrient Therapeutic Countermeasures for Chemical Agents -  FY08 - Continued research started in FY07 to determine if ingestion of antioxidants prior to exposure to non-lethal levels of sulfur mustard will reduce lung damage.  FY09 - Test 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.	0.987	0.792	0.000	
Anthrax Monoclonal Antibody Therapeutic and Prophylaxis Program -  FY08 - Conducted research to support safety and efficacy studies evaluating the co-administration of MDX-1303 and vaccine.	1.579	0.000	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Plant Vaccine Development -  FY08 - Conducted research to establish infrastructure and processes for cGMP production of vaccine candidates and to develop a combined multivalent one-shot vaccine formulation that protect against anthrax and plague.  FY09 - Produce vaccine lots under cGMP and evaluate safety and toxicity and confirm protective efficacy of identified dual agent vaccines. Develop technology transfer and implementation programs.	2.960	1.582	0.000	
Advanced Emergency Medical Response Training Program -  FY08 - Developed emergency medical response training program for consequence management of chemical or biological events.	1.579	0.000	0.000	
Multi-Purpose Biodefense Immunoarray -  FY08 - Continued research that began in FY06 to develop a multi-purpose biodefense immunoarray.  FY09 - Continuation of research from FY08.	0.987	0.792	0.000	
Improved CBR Filters -  FY08 - Continued development and demonstration of alternative filters that would provide Toxic Industrial Chemicals (TIC) protection in addition to the standard chemical warfare agent (CWA) protection.  FY09 - Initiate engineering phase with the goal of developing final design configurations that can be easily incorporated into new and existing filtration systems.	1.579	1.582	0.000	
Develop & Test Environmentally Safe Biocides for Bio-Defense -  FY08 - Developed and tested new biocidal technologies for disinfection in bio-defense, environmental and marine contexts.	0.494	0.000	0.000	
Regenerative Chemical Biological Filtration Systems -	2.466	0.000	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY08 - Researched, developed, tested and evaluated regenerative chemical biological filtration systems.				
Warfighter Personnel Decontamination -  FY08 - Continued FY07 RDT&E which had been focused on demonstrating the effectiveness of the Multipurpose Wipe system on skin surrogates. Effort will focused on demonstrating this same efficacy on surfaces.	0.789	0.000	0.000	
Reactive Coatings Enhanced to Resist Chem/Bio Contamination -  FY08 - Continued FY07 research which was completed for the development of reactive coatings by developing an understanding of the requirements for such coatings, identifying potential active/activator technologies, developing test system hardware, and establishing the appropriate analytic methods to measure the performance of the candidate technologies.	1.736	0.000	0.000	
Chemical Warfare Agent Fate Model Verification and Validation Phase II -  FY08 - Continued verification and validation of CWA agent fate evaporation model.	0.987	0.000	0.000	
Acinetobacter Baumannii Research -  FY08 - Developed therapies against pathogens of biodefense concern, including developing new medicines that allow antibiotics to overcome resistance, designing drugs that kill bacteria through novel mechanisms, and reengineering existing antibacterial drugs to defeat resistant bugs.  FY09 - Continue the preclinical development of these agents by developing improved syntheses techniques.	1.973	1.978	0.000	
Strategic Bioterrorism Response for Battlefield Survival -  FY08 - Developed a system, method and infrastructure, to determine if a person has been exposed to a pathogen or toxin and development of a method and device for use in a "point of care" analysis in the theater of war.	1.421	0.000	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Bio Agent Early Warning Detector -  FY09 - Conduct advanced development of a stand-off bio agent detection system.	0.000	1.978	0.000	
Biological Agent Identifiers -  FY09 - Continuation of industry research into biological agent identifiers without wet reagents.	0.000	1.582	0.000	
Eye-Safe Long Range Stand-off System for Detection of Chemical and Biological Weapons -  FY09 - Continuation of research for eye-safe, laser based stand-off Chem/Bio detection systems.	0.000	1.483	0.000	
Mobile Continuous Air Monitor (MCAM) -  FY09 - Continuation of research for a portable continuous monitor for biodetection.	0.000	1.582	0.000	
Rapid Response Institute -  FY09 - TBD.	0.000	3.164	0.000	
Liquid Crystal Sensor Technology Research and Development for Force Protection -  FY09 - Continuation of development of a passively operated sensor that rapidly detects toxins in the immediate environment.	0.000	2.373	0.000	
Biodefense Vaccine Development and Engineering of Antiviral Peptides -  FY09 - TBD.	0.000	1.583	0.000	
Center for Advanced Emergency Response -  FY09 - Continuation of development of emergency medical response training program for consequence management of chemical or biological events.	0.000	4.350	0.000	
ViriChip Rapid Virus Detection Systems -	0.000	1.582	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY09 - Research on the use of nanoscience technology for a virus detection system.				
Protective Self-Decontaminating Surfaces -  FY09 - Previous RDT&E has demonstrated the technology to instantly neutralize chemical agents and kill a number of microbial entities. This effort will produce an advanced prototype to be capable of providing immediate on-site protection with multi-threat applicability.	0.000	1.582	0.000	
Contaminated Human Remains Pouch -  FY09 - Conduct prototype development activities to test a contaminated human remains transportable container.	0.000	1.582	0.000	
Recombinant BChE Formulation Program -  FY09 - TBD.	0.000	1.582	0.000	
Joint Material Decon System -  FY09 - Reactive Overlay and Removable CBRN Coatings.	0.000	1.582	0.000	
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A				
<b>D. Acquisition Strategy</b> N/A				
<b>E. Performance Metrics</b> N/A				

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TB3: MEDICAL BIOLOGICAL DEFENSE (ATD)	95.996	188.748	204.576						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 core science efforts in biological based research and technology programs areas in 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 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 treat exposure to biological threats such as bacterial (plague, anthrax, glanders), viral (smallpox, encephalitic alphaviruses), and toxin (ricin, botulinum neurotoxin, staphylococcal enterotoxin).

This project also includes efforts such as the Transformational Medical Technologies Initiative (TMTI). The Transformational Medical Technologies Initiative (TMTI) was launched in FY 2006 as a key Quadrennial Defense Review initiative 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)**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Multiagent (Broad Spectrum) Medical Countermeasures - This effort is mainly dedicated to 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 maturation of promising	55.240	152.105	126.883	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>drug candidates will be the focus of activities in this capability area. Ultimately, the preclinical drug discovery process culminates in the submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), who 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.</p> <p>FY08 - Continued to identify potential IND candidate drugs for development. Initiated studies necessary to support up to four applications for an IND with the FDA. Completed pre-clinical research necessary to submit two IND applications to the FDA for antiviral drugs against hemorrhagic fever viruses (HFV), specifically targeted against the viral genes in both Ebola and Marburg. (Note: both IND applications were later accepted by the FDA, which will allow the candidate drugs to move into Phase I clinical trials). Continued drug discovery efforts for antisense ribonucleic acid (RNA) therapeutic candidate drugs against HFV pathogens. Developed technology to target molecules of common pathways within the host. Continued investigating use of existing of FDA-approved drugs to enhance effectiveness of current biological warfare (BW) agent countermeasures.</p> <p>FY09 - Continue to identify potential IND candidate drugs for development. Complete pre-clinical research necessary to submit up to ten additional applications for an IND with the FDA. Accelerate drug discovery efforts, incorporating new technology to expand the number of potential drug compounds suitable for advanced development. Implement use of the previously validated transgenic and other animal model systems to replicate human disease and disease response pathways. Begin implementation of test platforms for drug discovery, development, and manufacturing technologies. Continue investigating use of existing of FDA-approved drugs to enhance effectiveness of current BW agent countermeasures.</p> <p>FY10 - 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 a New Drug Application (NDA) with the FDA. Continue investigating use of existing of FDA-approved drugs to enhance effectiveness of current BW agent countermeasures.</p>				

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>Therapy for Ebola and Marburg Virus Infections: Identify, optimize and evaluate potential therapeutic candidates effective against Filovirus infection including Ebola and Marburg Viruses.</p> <p>FY08 - Initiated testing in relevant small and large animal models to support Investigational New Drug (IND) application submission and Food and Drug Administration (FDA) licensure under the animal rule. Down-selected leading technologies based on results from animal studies in coordination with the advanced developer.</p> <p>FY09 - Complete FDA required studies to support the preclinical development and characterization of other leading therapeutic technologies against the Ebola virus and Marburg virus.</p>	5.797	5.370	0.000	
<p>Vaccine Research Support: Assess the effectiveness of candidate vaccines in animal models and perform preliminary evaluations of safety and duration of protective immunity.</p> <p>FY08 - Completed animal effectiveness studies for toxin vaccines. Down-selected filovirus vaccine candidates. Continued safety and effectiveness studies in animals. Began immunity duration studies; initiated stability testing. Evaluated filovirus vaccines for vaccine interference problems between components.</p> <p>FY09 - Further characterize safety, toxicity, and immunity duration studies in animals for filovirus vaccines. Optimize dose, route, and regimen for maximum effectiveness. Assess alphavirus and filovirus vaccines for issues of vaccine interference. Conduct stability and toxicity studies for lead alphavirus vaccine candidates. Complete stability and toxicity studies for toxin vaccines, prepare production lots, and begin Investigational New Drug (IND) application preparation for Food and Drug Administration (FDA) evaluation. Analyze effectiveness, duration of immunity, and dosing regimens of second-generation vaccine against bacterial pathogens (including anthrax, plague, and tularensis).</p> <p>FY10 - Vaccine Research Support efforts will be re-aligned to Bacterial/Toxin and Viral Vaccines.</p>	8.007	7.740	0.000	
<p>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</p>	7.080	9.021	11.508	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>generation diagnostic technologies including portable instrument platforms, highly parallel and informative testing formats, and nanotechnology applications.</p> <p>FY08 - Continued to test optimal matrices/tissues for diagnostic testing using assays with advanced development programs such as the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Block I assays. Used this data to augment the advanced developer's Food and Drug administration (FDA) assay submission packages. Applied new biosynthetic (recombinant) techniques for developing antibody-based diagnostic agents. Adapted real time Polymerase Chain Reaction (PCR) assays identifying genes responsible for antibiotic resistance in bio-threat agents to applicable instrumentation. Assessed enzymatic cascade signal amplification methods to enhance sensitivity of hybridization microarray platforms. Critically analyzed/ applied the results of the decision matrix to testing of next generation diagnostic devices with emphasis on technologies capable of integrating sample processing, nucleic acid, and antibody-based diagnostic testing. Accelerated development and testing of next generation diagnostic devices with the goal of transitioning two candidates to the advanced developer in FY09.</p> <p>FY09 - Transition two candidates for a next generation diagnostic device to the advanced developer. Continue to utilize the decision matrix to identify and evaluate new technologies more effective for diagnosing exposure to bio-threat agents. Validate real time PCR assays identifying genes responsible for antibiotic resistance in bio-threat agents. Perform 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.</p> <p>FY10 - 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 for validation of assay performance and as correlate reference materials from</p>				

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
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.				
SBIR - FY09 - Small Business Innovative Research.	0.000	2.123	0.000	
Development of Platform Technologies - Advanced technology and development activities for Platform Technologies include the maturation of components that in the near future will begin the process of integrating a countermeasure response pipeline. In addition, animal models will reach their highest maturity and be authenticated against challenge material and ready for 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 will focus in on the type of specific therapeutics under development.  FY10 - 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 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.	0.000	0.000	32.945	
Multiagent Vaccines, Western and Eastern Equine Encephalitis (WEE/EEE), and Vaccine Candidates for a Combined Equine Encephalitis Vaccine (Former DTO CB58): Evaluate alphavirus vaccine platforms for safety and effectiveness.	4.153	0.000	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY08 - Completed duration of immunity duration studies for each platform, compared individual constructs, and combined WEE/EEE formulations. Initiated studies to address the issue of interference between vaccine components and the immune response. Concluded safety and effectiveness studies in animal models. Down-selected alphavirus vaccine candidates. Completed DTO CB58.				
<p>Viral Therapeutics: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.</p> <p>FY08 - Initiated animal studies to support FDA submissions, milestone approval, and product transition to advanced development. Completed development of a treatment algorithm for severe Ebola infection. Continued studies to develop two oral therapeutics for orthopox viruses. Conducted FDA required non-human primate studies to support FDA licensure of two oral therapeutics for orthopox virus infection.</p> <p>FY09 - Continue studies to support FDA submissions, milestone approval, and product transition to advanced development programs. Perform FDA required non-human primate studies necessary to complete the development of two oral therapeutics for orthopox viral infection.</p> <p>FY10 - 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 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.</p>	6.114	5.885	9.652	
<p>Multiagent Vaccine Platforms: Evaluate the safety and effectiveness of vaccine platforms for immunization against multiple biothreat agents.</p> <p>FY08 - Evaluated safety and effectiveness of anthrax/plague/toxin vaccines in large animals. Examined the effects of short nucleic acid chain immune stimulating formulations in animals.</p>	3.074	2.322	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY09 - Evaluate safety and effectiveness of multi-agent vaccines (e.g., anthrax/plague/melioidosis); complete studies to determine interference between vaccine components and the immune response; conduct immunity duration studies. Down-select multiagent vaccine platforms, determine dosage, and route of administration.  FY10 - Multi-agent Vaccine efforts will be re-aligned to Vaccine Platforms and Research Tools.				
Bacterial Therapeutics: identify, optimize, and evaluate potential therapeutic compounds effective against bacterial threat agents.  FY08 - Conducted advanced safety and efficacy studies in non-human primates, considering FDA requirements for licensure of new therapeutics and approved therapeutics with a new indication. Coordinated efforts with advanced development programs to ensure the appropriate studies are conducted.  FY09 - Test and evaluate FDA approved antibiotics for efficacy against aerosol exposure to bacterial threat agents in non-human primate models of plague. Initiate advanced safety and effectiveness studies for a new single domain antibody that is smaller than conventional antibodies against plague.  FY10 - 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.	4.135	2.478	2.700	
Toxin Therapeutics: identify, optimize and evaluate potential therapeutic candidates effective against biological toxin threat agents.  FY08 - Evaluated lead compounds in support of FDA submissions, milestone approval, and future transition to advanced development. Developed therapeutic delivery systems in accordance with FDA requirements.  FY09 - Continue optimization and structural activity relationship studies for BoNT small molecule therapeutics to achieve improved pharmacological properties. Test intraneuronal delivery of small molecules using prototype therapeutic delivery system. Evaluate immune modifying compounds for pre and post-exposure therapy for SEB intoxication.	2.396	1.704	1.500	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY10 - 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.				
Bacterial/Toxin Vaccines: Evaluate single agent bacterial and toxin vaccines for effectiveness in animal models.  FY10 - Plan, prepare, and conduct Phase I clinical trial with the Ricin vaccine.	0.000	0.000	1.000	
Viral Vaccines: Lead vaccine candidates for alphaviruses and filoviruses will be evaluated for effectiveness and duration of protective immune response. Animal models will be developed for vaccine validation.  FY10 - 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.	0.000	0.000	16.638	
Vaccine Platforms and Research Tools: studies will be conducted to determine immune interference between candidate vaccines, characterize alternative delivery mechanisms of mature vaccine candidates, and determine effects of vaccine stabilization on efficacy in large animals.  FY10 - Research multiagent vaccines, immune interference, immune stimulating formulations, vaccine delivery/stabilization, and efforts 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	0.000	0.000	1.750	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>								<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
mature Marburg vaccine candidates ready for transition to the advanced developer using the laboratory based human artificial immune system (i.e., MIMIC) technology.											
<b>C. Other Program Funding Summary (\$ in Millions)</b>											
	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	
MB4/MEDICAL BIOLOGICAL DEFENSE (ACD&P)	4.742	5.600	101.265						Continuing	Continuing	
MB5/MEDICAL BIOLOGICAL DEFENSE (SDD)	69.231	89.424	64.478						Continuing	Continuing	
<b>D. Acquisition Strategy</b> N/A											
<b>E. Performance Metrics</b> N/A											

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TC3: MEDICAL CHEMICAL DEFENSE (ATD)	24.183	26.482	29.092						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 capability areas, such as, pretreatments, diagnostics, and Therapeutics to address Chemical Warfare Agent (CWA) exposure and Non-Traditional Agents (NTAs).

**B. Accomplishments/Planned Program (\$ in Millions)**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
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 nerve agents resulting in the need for a small quantity of catalytic bioscavenger to protect against large doses of nerve agents.	5.207	6.636	7.948	
FY08 - Completed all remaining supportive studies for recombinant Bioscavenger Increment 2. Continued to evaluate animal expression systems for binding protein delivery. Pursued structural studies of potential catalytic bioscavengers. Optimized Physiological Based Pharmacokinetic (PBPK) models that predict the effectiveness of bioscavengers in animals. Conducted efficacy studies of catalytic bioscavengers.				
FY09 - Optimize animal expression systems for binding protein delivery. Complete structural studies of potential catalytic bioscavengers. Utilize PBPK models that predict efficacy of bioscavengers in animals for novel catalytic bioscavengers. Evaluate catalytic bioscavengers for safety, efficacy, stability, and immune system stimulation.				

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY10 - Develop formulations for improved PBPK and reduced immune system stimulation of catalytic bioscavengers. Investigate improved drug-delivery systems for 1st generation catalytic bioscavengers. Conduct supportive studies toward licensure of catalytic bioscavengers.				
<p>Cutaneous and Ocular: Minimize injuries to dermal and ocular tissues resulting from exposure to chemical warfare agents (CWA). This involves the development of effective practical field and clinical management strategies and physical and pharmacological interventions to treat the injury processes. 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.</p> <p>FY08 - Continued pivotal studies to support FDA licensure of wound healing products and anti-blister agents. Optimized dosing schemes, evaluated the body's effects on the drug, and refined approaches for potential human use. Down-selected new decontamination formulations and evaluated for efficacy in compliance with FDA regulations.</p> <p>FY09 - Initiate animal studies to determine long term effects of down-selected wound healing products and blister agents, in coordination with the advanced developer.</p> <p>FY10 - 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.</p>	4.063	3.933	3.525	
<p>Diagnostic Technologies: Develop 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.</p> <p>FY08 - Performed method validation studies for the improved nerve agent detection method and initiated animal model exposure tests to characterize the assay. Continued metabolic profile studies in animal exposure models by examining the blood from agent exposed guinea pigs and assessed the feasibility of the</p>	0.671	0.701	1.461	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>methodology as a potential diagnostic technique. Initiated method validation for optimized sulfur mustard blood protein assay. Performed good laboratory practices validation studies on developed whole blood cholinesterase assay.</p> <p>FY09 - Conclude validation of the optimized sulfur mustard blood protein assay. Initiate validation of the urine byproduct assay. Conclude metabolic profile study and conduct data analysis. Complete validation of procedure to assess the presence of chemical warfare analytes from hair samples.</p> <p>FY10 - 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. Initiate a capability to pre-symptomatically diagnose Non-Traditional Agent (NTA) exposure.</p>				
SBIR - FY09 - Small Business Innovative Research.	0.000	0.296	0.000	
<p>Neurologic: Therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to CWAs. This 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.</p> <p>FY08 - Tested novel and FDA approved neuroprotectants against nerve agents in one or more animal models with a focus on requirements to support the submission of investigational new drug applications and licensure documentation to the FDA for their approval. Initiated safety/side effect/dosing and the body's effects on the drug evaluation of new compounds.</p> <p>FY09 - Accelerate 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.</p> <p>FY10 - 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,</p>	10.195	10.966	13.467	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
neuroprotectants, anti-epileptics, and receptor competitors and neutralizing agents for neuroprotective activity against nerve agents in animal models.				
<p>Medical Toxicology (Non-Traditional Agents (NTAs) and Other agents): Investigate common mechanisms of agent injury. Determine 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.</p> <p>FY08 - Verified and validated new generation computational tools for predictive modeling.</p> <p>FY09 - Develop, validate, and complete practical clinical strategies to aid in management of NTA casualties.</p>	3.047	2.950	0.000	
<p>CWA Operational Exposure Hazard Assessment Research: Work is designed to support FDA licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties.</p> <p>FY08 - Conducted toxicity modeling to support animal-to-human extrapolations of toxicity and to predict toxicity with various routes and durations of exposure.</p> <p>FY09 - Complete data analysis and deliver dataset to define the operational effects from chemical agent contact and inhalation exposure.</p>	1.000	1.000	0.000	
<p>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. This involves the development of 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.</p> <p>FY10 - 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.</p>	0.000	0.000	1.330	
	0.000	0.000	1.361	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>							<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>Non Traditional Agents (NTAs): Develop common mechanisms of agent injury. Determine the toxic effects of agents by probable routes of field exposure and refine standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanisms of toxicity.</p> <p>FY10 - Develop and evaluate novel and FDA licensed products as post-exposure therapeutics against NTA poisoning in advanced animal models.</p>										
<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<u><b>FY 2008</b></u>	<u><b>FY 2009</b></u>	<u><b>FY 2010</b></u>	<u><b>FY 2011</b></u>	<u><b>FY 2012</b></u>	<u><b>FY 2013</b></u>	<u><b>FY 2014</b></u>	<u><b>FY 2015</b></u>	<u><b>Cost To Complete</b></u>	<u><b>Total Cost</b></u>
MC4/MEDICAL CHEMICAL DEFENSE (ACD&P)	19.778	8.155	9.478						Continuing	Continuing
MC5/MEDICAL CHEMICAL DEFENSE (SDD)	14.149	22.068	14.086						Continuing	Continuing
<b>D. Acquisition Strategy</b>										
N/A										
<b>E. Performance Metrics</b>										
N/A										

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TE3: TEST & EVALUATION (ATD)	23.824	26.579	13.363						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. These methodologies support development testing and operational testing with regard to advanced development programs that have unique chemical and biological defense requirements. These new methodologies and testing capabilities include the development of protocol and standards for use of chemical and biological simulants.

**B. Accomplishments/Planned Program (\$ in Millions)**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
SBIR - FY09 - Small Business Innovative Research.	0.000	0.305	0.000	
Test and Evaluation, Detection: Develop, test, and evaluate technologies and processes in support of detection capability testing.	7.666	7.156	6.000	
FY08 - Transitioned critical reagent program antigen variability research to Biosafety Level (BSL)-2 and BSL-3 production facilities. Completed and transitioned standard for background interferent references and test procedures. Completed range test validation system. Completed previous effort in optical acceptance measurement for test and evaluation antigens. Initiated decontamination and materials efforts in the design of a Non-Traditional Agent (NTA) chamber.				
FY09 - Continue development of methodologies and capabilities for test and evaluation of technologies currently in early stages of tech-base development. Initiate and complete Quality Assurance (QA) implementation and checkpoints for scaled-up antigen production runs and post-production conformance tests. Continue NTA chamber design effort by conducting liquid dissemination development and proof of principle tests with several agents and address questions regarding the safety of unprotected personnel using the chamber post decontamination.				
FY10 - 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				

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
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.				
<p>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.</p> <p>FY08 - Incorporated Non-Traditional agent data to define and developed improved NTA simulants that will address test and evaluation needs. Identified requirements for and initiated development of new simulants for chemical and biological (CB) warfare agents for use in test and evaluation efforts. Conducted experiments, scaled-up commercially available biopesticidal virus preparation and transition methods and reagents to Critical Reagent Program. Evaluated simulants developed to reflect masking/encapsulation technology used with CB agents. Evaluated standard protocols and analyzed results from the hazard assessment and correlation studies. Initiate TIC/battlefield contaminants methodologies study.</p> <p>FY09 - Continue development of simulants for specified NTAs to be used in test and evaluation efforts. Complete standard protocol evaluation. Continue development of masking/encapsulation simulants for CB agents. Complete TIC/battlefield contaminants methodologies study.</p> <p>FY10 - 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.</p>	3.410	3.891	1.558	
<p>Test and Evaluation, Information System Technology: Develop test and evaluation technologies and processes in support of Information System Technology activities.</p> <p>FY08 - Conducted requirements collection and review for systems performance models. Continued development on decontamination efficacy prediction model. Continued development on collective protection systems performance model. Continued development on individual protection equipment performance model.</p>	2.644	3.825	5.605	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>FY09 - Continue development on decontamination efficacy prediction model. Transition first module of decontamination model. Integrate state-of-the-art transport and dispersion models and visualization software into collective protection systems performance model. Integrate relevant analytical tools into individual protective equipment performance model. Initiate verification and validation processes on emerging test and evaluation models. Begin development of contamination avoidance systems performance model.</p> <p>FY10 - Develop and transition 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.</p>				
<p>Test and Evaluation, Protection (FY08-09), Protection and Hazard Mitigation (FY10): Develop test and evaluation technologies and processes in support of Protect and Hazard Mitigation activities.</p> <p>FY08 - Continued 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). Continued standard procedures for IPE Assessment. Continued 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.</p> <p>FY09 - Complete 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). Complete standard procedures for IPE Assessment. Complete real-time sampling/detector system swatch test methodology for use in CBARTS, test methodology standards and guidance for air purification technologies, IPE field operations effects standard, and IPE air flow mapping.</p> <p>FY10 - Initiate methodology/source data effort to simulate IP durability test in lab and relate to field durability.</p>	8.529	9.992	0.200	
	1.575	1.410	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>							<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>Test and Evaluation, Decontamination (FY08-09): Develop test and evaluation technologies and processes in support of Decontamination activities.</p> <p>FY08 - Completed decontamination hazard byproduct and residual agent test standards and low level detection of residual agents in reaction products and deliver standard test methods to Service laboratories and other supporting test laboratories. Completed test protocols for decontamination hazard byproduct and residual test standards and write and published test operations procedures.</p> <p>FY09 - Initiate and complete test and evaluation methodologies and protocols for assessing reactivity of alternative reactive material technologies and processes. Initiate and complete processes for relevant environment and relevant equipment testing for live agents and calculations for small item contact test that incorporates toxicological considerations.</p>										
<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TE4/TEST & EVALUATION (ACD&P)	13.776	6.335	28.894						Continuing	Continuing
TE5/TEST & EVALUATION (SDD)	48.238	42.020	41.466						Continuing	Continuing
TE7/TEST & EVALUATION (OP SYS DEV)	6.887	7.119	4.891						Continuing	Continuing
<b>D. Acquisition Strategy</b> N/A										
<b>E. Performance Metrics</b> N/A										

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TR3: MEDICAL RADIOLOGICAL DEFENSE (ATD)	2.152	4.863	2.413						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 first 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)**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>Radiation Medical Countermeasures: Develop 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 and/or first responders in the event of a radiological incident.</p> <p>FY08 - Evaluated multiple promising drug candidates to assess animal survival rate when exposed to lethal radiation. Initiated efficacy and safety analysis in non-human primates (NHP) and the assessment of drug mechanism of action and initial determination of formulation. Initiated evaluation of products and therapeutic regimens that mitigate and/or treat radiological injury, with emphasis on broad spectrum activity, ease of administration, and safety. Initiated evaluation of additional promising radioprotectant prophylaxis and post-irradiation therapeutic agents that prevent/mitigate lethal effects of radiological exposure.</p> <p>FY09 - Continue to evaluate at least two promising drug candidates to assess animal survival rate when exposed to lethal radiation. Evaluate 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 NHPs. Continue to evaluate the preclinical efficacy and safety studies in NHPs, an assessment</p>	2.152	4.809	2.413	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>							<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
of drug mechanism of action, and the determination of drug formulation according to the FDA animal rule. Evaluate promising radioprotectants and post-irradiation therapeutic agents. FY10 - Evaluate mature and promising agents for respiratory and gastrointestinal damage and repair. Demonstrate efficacy and safety in non-human primates (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.										
SBIR - FY09 - Small Business Innovative Research.							0.000	0.054	0.000	
<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<u><b>FY 2008</b></u>	<u><b>FY 2009</b></u>	<u><b>FY 2010</b></u>	<u><b>FY 2011</b></u>	<u><b>FY 2012</b></u>	<u><b>FY 2013</b></u>	<u><b>FY 2014</b></u>	<u><b>FY 2015</b></u>	<u><b>Cost To Complete</b></u>	<u><b>Total Cost</b></u>
MR4/MEDICAL RADIOLOGICAL DEFENSE	6.579	8.129	0.000						Continuing	Continuing
MR5/MEDICAL RADIOLOGICAL DEFENSE	0.000	2.936	8.311						Continuing	Continuing
<b>D. Acquisition Strategy</b> N/A										
<b>E. Performance Metrics</b> N/A										

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TT3: TECHBASE TECHNOLOGY TRANSITION	9.239	8.214	7.388						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 (ATD's) and Joint Concept Technology Demonstrations (JCTD's). 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 ATD's and JCTD's 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 ATD's and JCTD's to advanced development efforts located in Budget Activity 4 (Project TT4).

**B. Accomplishments/Planned Program (\$ in Millions)**

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY08 - Completed Manufacturing Readiness Assessment (MRA) process. Conducted Technology Readiness Evaluation in support of the ART IBRD ATD.	2.050	2.666	2.430	
FY09 - Conduct 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.				
FY10 - 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 to demonstrate system				

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
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.				
<p>Advanced Remediation Technologies (ART):</p> <p>FY08 - Performed candidate technology maturation research/testing in preparation for the HaMMER ATD. Performed candidate technology maturation testing in preparation for Automated Detailed Equipment Decontamination for Land Vehicles (Auto Decon) efforts. Continued technology evaluations and gap analysis for Interagency Biological Remediation Demonstration (IBRD).</p> <p>FY09 - Complete biological decontamination technology and decision support system evaluations for IBRD. Complete biological technology demonstrations for IBRD. Complete testing of candidate technologies for Auto Decon. Continue testing of candidate technologies for the HaMMER ATD. IBRD and Auto Decon Efforts continue in and transition to Budget Activity 4 (See Project TT4).</p> <p>FY10 - Continue testing of candidate technologies for HaMMER ATD.</p> <p>Early Warning Military Applications in Reconnaissance Systems (EW-MARS):</p> <p>FY08 - Initiated an evaluation of early warning technologies to improve capability to detect and react to initial chemical or biological (CB) attack and prevent a second attack.</p> <p>FY09 - Analyze 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 (ie. MARS-JPF).</p> <p>FY10 - 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-</p>	7.189	5.455	4.958	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>								<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
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.											
SBIR - FY09 - Small Business Innovative Research.								0.000	0.093	0.000	
<b>C. Other Program Funding Summary (\$ in Millions)</b>											
	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>Cost To Complete</u>	<u>Total Cost</u>	
TT4/TECHBASE TECHNOLOGY TRANSITION (ACD&P)	13.218	17.267	26.761						Continuing	Continuing	
<b>D. Acquisition Strategy</b>											
N/A											
<b>E. Performance Metrics</b>											
N/A											

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