

# UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Chemical and Biological Defense Program											Date: March 2014	
Appropriation/Budget Activity					R-1 Program Element (Number/Name)							
0400: Research, Development, Test & Evaluation, Defense-Wide I BA 3: Advanced Technology Development (ATD)					PE 0603384BP I CHEMICAL/BIOLOGICAL DEFENSE (ATD)							
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
Total Program Element	-	214.226	144.847	132.674	-	132.674	136.597	149.496	147.556	143.867	Continuing	Continuing
CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	-	23.247	15.401	17.722	-	17.722	16.123	16.968	16.250	15.844	Continuing	Continuing
NT3: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)	-	30.784	21.702	21.574	-	21.574	23.037	23.387	21.889	21.343	Continuing	Continuing
TM3: TECHBASE MED DEFENSE (ATD)	-	160.195	101.827	87.610	-	87.610	90.079	100.916	101.559	99.018	Continuing	Continuing
TT3: TECHBASE TECHNOLOGY TRANSITION	-	-	5.917	5.768	-	5.768	7.358	8.225	7.858	7.662	Continuing	Continuing

# The FY 2015 OCO Request will be submitted at a later date.

## 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. The PE funds advanced technology development for Joint Service and Service-specific requirements in both medical and physical sciences CBR defense areas.

In the physical sciences area, Project CB3 focuses on demonstrations of CB defense technologies, including biological detection, chemical detection, information system technology for hazard prediction and systems performance, and protection, and decontamination. The Project continues to pursue solutions against traditional agents.

All non-traditional agent (NTA)-dedicated research (both medical and non-medical) is consolidated in Project NT3. This Project includes NTA chemical diagnostics, medical pretreatments, therapeutics, detection, and protection and hazard mitigation.

The medical program in Project TM3, aims to produce biological diagnostic assays and reagents, diagnostic device platforms, pretreatments and therapeutics for bacterial, viral, and toxin threats as well as for chemical threats, 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.

Project TT3, Techbase Technology Transition, pursues efforts to enhance military operational capability, concepts of operation, WMD elimination, and hazard mitigation following a biological warfare or chemical warfare attack.

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<b>Appropriation/Budget Activity</b> 0400: <i>Research, Development, Test &amp; Evaluation, Defense-Wide / BA 3: Advanced Technology Development (ATD)</i>	<b>R-1 Program Element (Number/Name)</b> PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>
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The PE is dedicated to conducting proof-of-principle field demonstrations, and testing system-specific technologies to meet specific military needs. Work conducted under this PE will transition to and will provide risk reduction for PE 0603884BP/PE 0604384BP activities.

<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO</b>	<b>FY 2015 Total</b>
Previous President's Budget	234.280	170.847	154.659	-	154.659
Current President's Budget	214.226	144.847	132.674	-	132.674
Total Adjustments	-20.054	-26.000	-21.985	-	-21.985
• Congressional General Reductions	-0.309	-			
• Congressional Directed Reductions	-14.784	-26.000			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-1.842	-			
• SBIR/STTR Transfer	-3.119	-			
• Other Adjustments	-	-	-21.985	-	-21.985

**Change Summary Explanation**

Funding: FY13: Reductions of \$14.8M impacted efforts supporting threat agent sciences, medical countermeasures and diagnostics device development.

FY14: Reductions of \$26.0M delay key physical and medical program technology development efforts in threat agent sciences, early warning/remote detection, biosurveillance informatics, medical countermeasure pretreatments, diagnostics, and hazard mitigation capabilities.

FY15: Reductions of \$22.0M impact medical countermeasure candidates, diagnostic device technology evaluations, and brassboard prototypes supporting genomic sequencing capabilities.

Schedule: N/A

Technical: N/A

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COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	-	23.247	15.401	17.722	-	17.722	16.123	16.968	16.250	15.844	Continuing	Continuing
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Project CB3 develops technology advancements for joint service application in the area of information systems and modeling and simulation technologies. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. Information systems advanced technology focuses on areas of advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2013	FY 2014	FY 2015	
Title: 1) Biosurveillance (BSV)									-	1.117	-	
Description: Integrate existing disparate military and civilian data sets into advanced warning systems, and leverage and enhance epidemiological models and algorithms for disease prediction, impact and biological threat assessment. Contribute to the development of global, near real-time, disease monitoring and surveillance systems that address secondary infection, fuse medical syndromic, environmental, and clinical data, and feed into agent-based epidemiological modeling, medical resource estimation and decision support tools. Focus on agent-based epidemiological modeling and fusion of disease surveillance data.												
FY 2014 Plans:												
Complete effort initiated in Project TM3 (Diagnostics and Disease Surveillance) - of Verification and Validation (V&V) of existing agent-based epidemiological models, to include underlying population data and disease spread algorithms, along with biosurveillance data fusion, for use in robust adaptive decision making. Demonstrate data stream (inclusive of point of need diagnostic data) integration for early warning and analytical capabilities of the BSV Ecosystem. Develop analytic capabilities to synthesize and interrogate multiple sources of data to provide high confidence in the prediction, early warning and forecasting (inclusive of mitigation strategies) of infectious disease outbreaks. Continue the development of a scalable, replicable framework to serve as the basis for a biosurveillance cloud for government data. Continue development of an infrastructure and integrated set of tools and methods for the collection, storage, recall, and cross comparison of a wide array of biologic-related data emerging from research, clinical testing, and diagnostics, and other diverse sources.												
Title: 2) Detection									5.756	2.262	4.174	
Description: Focuses on the detection and identification of chemical and biological threats in near real-time at a distance from the detector. Future programs focus on the improvement of algorithms, excitation sources, and detector elements to increase range, reduce false positives, increase sensitivity, and reduce cost.												

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<b><i>FY 2013 Accomplishments:</i></b> Continued processes of validating ground truth systems for detection technologies (genomic and proteomic technology) field assessments.					
<b><i>FY 2014 Plans:</i></b> Continue processes of validating ground truth systems for detection technologies (genomic and proteomic technology) field assessments.					
<b><i>FY 2015 Plans:</i></b> Continue processes of validating ground truth systems for detection technologies (genomic and proteomic technology) field assessments.					
<b><i>Title:</i></b> 3) Hazard Prediction  <b><i>Description:</i></b> 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.			4.199	3.210	3.685
<b><i>FY 2013 Accomplishments:</i></b> Continued implementation of new numerical schemes for transport and dispersion models. Continued enhancement of urban transport and dispersion models which transitioned from CB2. Continued with work on configuration management prototype to establish upgraded capabilities listed as valid requirements for JEM. Completed development on the high altitude post-missile intercept effects model. Continued with field transport and dispersion databases and websites for accessible permanent test archiving. Continued implementation and testing of new numerical schemes for future establishment of 64-bit/multi-core capable models.					
<b><i>FY 2014 Plans:</i></b> Continue implementation of new numerical schemes and performance optimization for transport and dispersion models. Continue enhancement of high fidelity urban transport and dispersion. Continue with work on configuration management of science and technology prototype to establish upgraded capabilities listed as valid requirements for Hazard Prediction and Assessment Capability/JEM (HPAC/JEM). Initiate final development and integration of the missile intercept/functioning missile effects model (i.e., hazard predictions given an missile intercepted in flight and hazard predictions given a missile that correctly delivers its payload). Continue providing field transport and dispersion databases and websites for community accessible permanent test archiving. Continue implementation and testing of new numerical schemes for future establishment of 64-bit/multi-core capable models.					
<b><i>FY 2015 Plans:</i></b>					

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
Continue implementation of new numerical schemes and performance optimization for transport and dispersion models. Continue enhancement of high-fidelity urban transport and dispersion. Continue configuration management of science and technology prototype to establish upgraded capabilities listed as valid requirements for Hazard Prediction and Assessment Capability/Joint Effects Model (HPAC/JEM) at a slowed pace. Initiate next-generation development of missile intercept/functioning missile effects model. Complete implementation and testing of new numerical schemes for future establishment of 64-bit/multi-core-capable models.					
<b>Title:</b> 4) Data Analysis  <b>Description:</b> Develop chemical, biological, radiological and nuclear data-sharing capabilities.  <b>FY 2013 Accomplishments:</b> Continued to develop the Chemical and Biological Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB agents on equipment, personnel, and operations. Concluded development of initial versions of systems performance models in collective protection, individual protection, contamination avoidance and decontamination. Initiated system performance model integration with advanced development for program-wide exploitation.  <b>FY 2014 Plans:</b> Integrate additional chapters of the Chemical and Biological Warfare Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB warfare agents on equipment, personnel, and operations. Initiate construction of a secure and capable framework for CB-1 within the Defense Threat Reduction Information Analysis Center (DTRIAC) Next Gen Scientific and Technical Information Archival and Retrieval System (STARS).  <b>FY 2015 Plans:</b> Integrate additional chapters of the Chemical and Biological Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB agents on equipment, personnel and operations. Complete construction of a secure and capable framework for CB-1 within the Defense Threat Reduction Information Analysis Center (DTRIAC) Next Gen Scientific and Technical Information Archival and Retrieval System (STARS).			1.757	2.690	2.043
<b>Title:</b> 5) Operational Effects  <b>Description:</b> Develop decision support tools and information management capabilities for planning and real-time analysis to determine and assess operational effects, risks, and overall impacts of CBRN incidents on decision-making. Focus areas include consequence management, population modeling, and knowledge management.  <b>FY 2013 Accomplishments:</b>			1.379	1.717	3.713

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
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<b>FY 2014 Plans:</b> Continue system performance model integration with advanced development programs and initiate development of second generation versions of systems performance models in individual protection.				
<b>FY 2015 Plans:</b> Continue system performance model integration with advanced development programs. Complete second generation system performance model for multiple decontamination systems.				
<b>Title:</b> 6) Filtration  <b>Description:</b> 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.  <b>FY 2013 Accomplishments:</b> Continued the integration and demonstration of latest generation 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. Continued transition of these technologies to the Joint Service General Purpose Mask(JSGPM) and Joint Service Aircrew Mask (JSAM) programs.  <b>FY 2014 Plans:</b> Continue the integration and demonstration of latest generation 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. Continue transitioning these technologies to the JSGPM and JSAM programs.  <b>FY 2015 Plans:</b> Transition a synthetic nano-structured material focused on toxic industrial chemical removal, including ammonia.		1.674	0.937	1.102
<b>Title:</b> 7) Respirators  <b>Description:</b> 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.  <b>FY 2014 Plans:</b> Develop prototype respirator and conduct testing in a relevant environment.  <b>FY 2015 Plans:</b>		-	0.467	0.360

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
Continue the development of a prototype respirator and conduct testing in a relevant environment.					
<b>Title:</b> 8) Fabrics  <b>Description:</b> Demonstration of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform.  <b>FY 2013 Accomplishments:</b> Continued to integrate next phase of integrated textile systems into a complete second generation candidate ensemble for the Uniform Integrated Protective Ensemble (UIPE) Phase II program as well as other applicable Advanced Technology Demonstrations that may materialize. Continued the trade-space analysis of all government, industrial, and academic candidate materials for use in future UIPE phase initiations. Continued to transition the human performance tool set to the Advanced Development - UIPE program so that it can be used in the optimization of protective ensemble design.  <b>FY 2014 Plans:</b> Continue to integrate next phase of integrated textile systems into a complete second generation candidate ensemble for the UIPE Phase II program as well as other applicable Advanced Technology Demonstrations that may materialize. Transition new fabric technologies to the UIPE program. Scale-up fabrics to ensemble prototypes and test in a relevant environment. Continue the trade-space analysis of all government, industrial, and academic candidate materials for use in future UIPE phase initiations. Complete transition of the human performance tool set to ACD&P - UIPE program so that it can be used in the optimization of protective ensemble design.  <b>FY 2015 Plans:</b> Complete all demonstration activities of the developed fabric technologies.			3.316	1.809	1.474
<b>Title:</b> 9) Decontamination  <b>Description:</b> Demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application.  <b>FY 2013 Accomplishments:</b> Continued the development, demonstration, and transition of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. Continued to integrate and demonstrate robust surface chemistry and decontamination process analysis using ultra high vacuum system into technology maturation process for hazard mitigation. Continued to develop coatings, innovative chemistries/processes, enzyme approaches to hazard mitigation,			1.500	1.192	1.171

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
human remains decontamination processes, and radiological/nuclear decontamination/hazard mitigation capabilities. Transitioned quantitatively evaluated interim capability for radiological/nuclear decontamination/hazard mitigation.  <b>FY 2014 Plans:</b> Continue the development, demonstration, and transition of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. Continue to integrate and demonstrate robust surface chemistry and decontamination process analysis using ultra high vacuum system into technology maturation process for hazard mitigation. Continue to develop coatings, innovative chemistries/processes, enzyme approaches to hazard mitigation, human remains decontamination processes, and radiological/nuclear decontamination/hazard mitigation capabilities. Transition quantitatively evaluated interim capability for radiological/nuclear decontamination/hazard mitigation.  <b>FY 2015 Plans:</b> Continue S&T efforts related to Dial-a-Decon and Enzyme Decon projects. Investigate non-aqueous formulations and responsive coatings.			
<b>Title:</b> 10) Test and Evaluation (T&E) <b>Description:</b> Develop CBRN data sharing capabilities and simulation tools.  <b>FY 2013 Accomplishments:</b> Continued to develop the Test & Evaluation components of the Chemical and Biological Warfare Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB warfare agents on equipment, personnel, and operations. Concluded development of initial versions of systems performance models in collective protection, individual protection, contamination avoidance and decontamination.	3.666	-	-
<b>Accomplishments/Planned Programs Subtotals</b>	23.247	15.401	17.722

<b>C. Other Program Funding Summary (\$ in Millions)</b>											
<u>Line Item</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015 Base</u>	<u>FY 2015 OCO</u>	<u>FY 2015 Total</u>	<u>FY 2016</u>	<u>FY 2017</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• CA4: CONTAMINATION AVOIDANCE (ACD&P)	5.713	24.853	40.088	-	40.088	34.229	29.355	-	-	-	134.238
• DE4: DECONTAMINATION SYSTEMS (ACD&P)	11.463	14.978	2.900	-	2.900	-	-	-	10.000	Continuing	Continuing
• IS4: INFORMATION SYSTEMS (ACD&P)	15.728	8.199	6.169	-	6.169	3.684	1.637	0.100	0.100	Continuing	Continuing



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<b>C. Other Program Funding Summary (\$ in Millions)</b>											
<b>Line Item</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO</b>	<b>FY 2015 Total</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
• TE4: <i>TEST &amp; EVALUATION (ACD&amp;P)</i>	5.164	15.671	21.188	-	21.188	23.334	18.386	18.933	18.933	Continuing	Continuing
• TT4: <i>TECHBASE TECHNOLOGY TRANSITION (ACD&amp;P)</i>	3.205	-	-	-	-	-	-	-	-	-	3.205
<b>Remarks</b>											
<b>D. Acquisition Strategy</b> N/A											
<b>E. Performance Metrics</b> N/A											

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COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
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# The FY 2015 OCO Request will be submitted at a later date.												
A. Mission Description and Budget Item Justification												
Project NT3 develops future capabilities against emerging and novel threats and verifies current capabilities against Non-Traditional Agents (NTAs). This project focuses on demonstrating fast and agile scientific responses to enhance or develop capabilities that address emerging threats. Efforts in this project support an integrated approach to develop new or enhanced countermeasures against novel and emerging threats through innovative science and technology (S&T) solutions for detection, protection, decontamination and medical countermeasures (MCMs). Efforts supply test methodologies and supporting science to verify capabilities, develop protection and hazard mitigation options, expand hazard assessment tools, and develop MCMs against NTAs. This project is a comprehensive and focused effort for developing NTA defense capabilities, coordinated with specific interagency partners for doctrine, equipment, and training for the Warfighter and civilian population for defense against NTAs. This project funds advanced technology development of NTA defense science and technology initiatives and transitions them to Budget Activities 4 and 5.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2013	FY 2014	FY 2015	
Title: 1) Diagnostics - Medical									0.398	0.574	0.667	
Description: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to non-traditional agents in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.												
FY 2013 Accomplishments: Refined mature technologies that can quickly diagnose pre-symptomatic NTA exposure.												
FY 2014 Plans: Continue development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. Begin transition method development for identification and validation of NTAs in clinical samples to the Laboratory Response Network.												
FY 2015 Plans: Continue development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure.												
Title: 2) Pretreatments - Medical									0.501	3.960	6.175	
Description: Develop nerve agent enzyme pretreatments that provide protection against non-traditional agents. Enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high catalytic efficiency for												

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules of nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent.					
<b>FY 2013 Accomplishments:</b> Continued exploitation of alternative expression systems for production of recombinant butylcholinesterase (rBuChE). Completed study of use of plasma derived human butylcholinesterase (huBChE) as prophylactic for all nerve agents.					
<b>FY 2014 Plans:</b> Continue exploitation of alternative expression systems for production of rBuChE. Pursue novel in-silico and/or in vitro methods to facilitate high throughput screening and development of medical countermeasures.					
<b>FY 2015 Plans:</b> Continue efforts to demonstrate feasibility of intra-muscular (IM) stoichiometric bioscavenger. Reduce scope in alternate manufacturing processes for recombinant human butyrylcholinesterase. Contributes to the research efforts at the ADME Research Center of Excellence, with Tier 0, 1 and 2 assay potential (with a reduced scope) at DoD Laboratories as a core program capability.					
<b>Title:</b> 3) Therapeutics - Medical			8.669	8.889	2.305
<b>Description:</b> 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.					
<b>FY 2013 Accomplishments:</b> Continued formulation and stability studies. Began safety studies in small animal model using selected formulation.					
<b>FY 2014 Plans:</b> Reduced scope of formulation and stability studies of therapeutic compounds. Further examine small animal model safety studies of limited selected formulations of centrally active reactivator or anti-cholinergic compounds.					
<b>FY 2015 Plans:</b> Continue development of technology to facilitate delivery of therapeutic regimen to the brain. Further refine small animal model.					
<b>Title:</b> 4) Detection			14.153	5.322	9.034
<b>Description:</b> Detection NTA: Focuses on technologies to provide NTA detection capabilities.					
<b>FY 2013 Accomplishments:</b>					

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
Continued the development of test methodology to validate signatures for chemical aerosol threat materials. <b>FY 2014 Plans:</b> Continue the development of test methodology to validate signatures for chemical aerosol threat materials. <b>FY 2015 Plans:</b> Continue the development of test methodology to validate signatures for chemical aerosol threat materials.					
<b>Title:</b> 5) Modeling & Simulation <b>Description:</b> This effort develops non-traditional agent (NTA) technology advancements for joint service application in the area of information systems and modeling and simulation technologies. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. Information systems advanced technology focuses on areas of advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling. <b>FY 2014 Plans:</b> Conduct analysis and oversight of NTA simulant testing related to creating and verifying NTA modeling source terms, for defense against CBRN hazards. <b>FY 2015 Plans:</b> Complete analysis of NTA simulant testing.			-	0.288	0.239
<b>Title:</b> 6) Air Purification <b>Description:</b> Study and assessment of filter technologies. <b>FY 2013 Accomplishments:</b> Continued development, verification and demonstration of novel materials to improve performance against NTAs. Transitioned these technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs. <b>FY 2015 Plans:</b> Re-establish funding for this effort in NT3. Assess the performance of novel adsorbents and develop specific functionalities of NTAs.			0.288	-	0.388
<b>Title:</b> 7) Percutaneous Protection <b>Description:</b> Study and assessment of protective technologies. <b>FY 2013 Accomplishments:</b>			0.289	0.962	0.862

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Chemical and Biological Defense Program			Date: March 2014		
Appropriation/Budget Activity 0400 / 3		R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) NT3 / TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2013	FY 2014	FY 2015
Continued the verification of protective fabrics against non-traditional agents. Demonstrated and began transition of low burden technologies (such as reduced thermal-burden fabrics, and lighter weight fabrics) to improve overall protective clothing performance against NTAs.  <b>FY 2014 Plans:</b> Continue verification, demonstration and transition of low burden technologies to improve overall protective clothing performance against NTAs. Transition technologies to the Uniform Integrated Protective Ensemble (UIPE) program.  <b>FY 2015 Plans:</b> Assess and optimize technologies to improve whole system performance against NTAs.					
<b>Title:</b> 8) Decontamination  <b>Description:</b> Study and assessment of decontamination technologies.  <b>FY 2013 Accomplishments:</b> Continued verification and demonstration of decontamination technologies against NTAs. Continued to develop and demonstrate enzyme technology for low-impact decon of NTAs. Continued to enhance NTA related understanding and capabilities of current decontamination and hazard mitigation technologies and develop additional processes for NTA hazard mitigation.  <b>FY 2014 Plans:</b> Continue verification, demonstration, and transition of decontamination technologies against NTAs to the Advanced Development - Decontamination Family of Systems (DFoS) program. Continue to develop and demonstrate enzyme technology for low-impact decontamination of NTAs, and transition these technologies. Continue to enhance NTA-related understanding and capabilities of current decontamination and hazard mitigation technologies and develop additional processes for NTA hazard mitigation.  <b>FY 2015 Plans:</b> Continue to assess performance and unique aspects of full spectrum of NTAs and develop technologies to optimize performance against NTAs.			0.290	0.872	1.109
<b>Title:</b> 9) Test & Evaluation  <b>Description:</b> Develops test and evaluation technologies and processes in support of NTA activities.  <b>FY 2013 Accomplishments:</b> Continued initial select agent testing, and continued further prioritized agent testing.  <b>FY 2014 Plans:</b>			6.196	0.835	0.795

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Chemical and Biological Defense Program										<b>Date:</b> March 2014		
<b>Appropriation/Budget Activity</b> 0400 / 3				<b>R-1 Program Element (Number/Name)</b> PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				<b>Project (Number/Name)</b> NT3 / <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i>				
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>										<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
Complete initial select agent testing, and continue further prioritized select agent testing.												
<b>FY 2015 Plans:</b> Continue further prioritized select agent testing.												
<b>Accomplishments/Planned Programs Subtotals</b>										30.784	21.702	21.574
<b>C. Other Program Funding Summary (\$ in Millions)</b>												
<b>Line Item</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO</b>	<b>FY 2015 Total</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	
• CA4: <i>CONTAMINATION AVOIDANCE (ACD&amp;P)</i>	5.713	24.853	40.088	-	40.088	34.229	29.355	-	-	-	134.238	
• DE4: <i>DECONTAMINATION SYSTEMS (ACD&amp;P)</i>	11.463	14.978	2.900	-	2.900	-	-	-	10.000	Continuing	Continuing	
• IP4: <i>INDIVIDUAL PROTECTION (ACD&amp;P)</i>	0.550	1.208	6.811	-	6.811	4.680	0.300	-	-	-	13.549	
• MC4: <i>MEDICAL CHEMICAL DEFENSE (ACD&amp;P)</i>	-	2.000	-	-	-	-	3.750	10.692	25.089	Continuing	Continuing	
• TE4: <i>TEST &amp; EVALUATION (ACD&amp;P)</i>	5.164	15.671	21.188	-	21.188	23.334	18.386	18.933	18.933	Continuing	Continuing	
<b>Remarks</b>												
<b>D. Acquisition Strategy</b> N/A												
<b>E. Performance Metrics</b> N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Chemical and Biological Defense Program										Date: March 2014		
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COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
TM3: TECHBASE MED DEFENSE (ATD)	-	160.195	101.827	87.610	-	87.610	90.079	100.916	101.559	99.018	Continuing	Continuing
# The FY 2015 OCO Request will be submitted at a later date.												
A. Mission Description and Budget Item Justification												
Project TM3 funds preclinical and early phase clinical development of vaccines, therapeutic drugs, and diagnostic capabilities to provide safe and effective medical defense against validated biological threat agents or emerging infectious disease biothreats including bacteria, toxins, and viruses. Innovative biotechnology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents will be evaluated. In addition this project 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. Entry of candidate vaccines, therapeutics, and diagnostic technologies into advanced development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) processes, DoD acquisition regulations, and the oversight of early phase clinical trials in accordance with FDA guidelines. This project also supports the advanced development of medical countermeasures to protect the Warfighter against radiological/nuclear exposure.												
The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, providing a dedicated, cost-effective, reliable, and sustainable MCM process that meets the Warfighter and national security needs. MCMI efforts within science and technology (S&T) are concentrated in advancing two areas: 1) regulatory science and 2) flexible manufacturing technologies and processes for MCMs. Efforts conducted in these areas are enablers supporting the DoD Medical Countermeasures Advanced Development and Manufacturing (MCM-ADM) capability.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2013	FY 2014	FY 2015	
Title: 1) Assays and Reagents									27.924	9.445	19.709	
Description: Development and verification of rapid, sensitive, and specific tests for the identification of Biological Warfare Agents (BWAs) and their expressed pathogens and toxins in clinical specimens from Warfighters for the diagnosis of exposure/infection. Discovery of host biomarkers generated in response to exposure to biological threat agents.												
FY 2013 Accomplishments: Translated laboratory, data fusion informatic methodologies and specimen pipelines into robust and well-characterized signatures required to identify and bio-type emerging, re-emerging, and synthetic threat agent strains, identify antibiotic resistant mutations and phenotypes, and therapeutic and vaccine response markers. Developed and transition thermostable reagents/scale-up protocols to advanced development for use in austere biosurveillance environments. Transitioned agent characterization dossiers to developers of: Medical Counter Measures, microbial forensics capabilities, and assays developers to augment existing biosurveillance infrastructure performing vector surveys, zoonotic epidemiology and provide a direct link between medical												

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Chemical and Biological Defense Program			<b>Date:</b> March 2014		
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
diagnostic, disease surveillance and MCM development. Submit pre-Emergency Use application data packages to FDA Office for in vitro diagnostics.					
<b>FY 2014 Plans:</b> Continue to develop laboratory, data fusion informatics methodologies and specimen pipelines into robust and well-characterized signatures required to identify and bio-type emerging, re-emerging, and identify antibiotic resistant mutations and phenotypes. Develop and transition an additional thermostable reagents/scale-up protocols to advanced development for use in austere biosurveillance environments. Collaborate with the Centers for Disease Control (CDC) to improve diagnostic and surveillance capabilities needed to counter traditional, engineered, emerging and biological threats.					
<b>FY 2015 Plans:</b> Continue to develop and transition an additional thermostable reagents/scale-up protocols to advanced development for use in austere biosurveillance environments. Continue to collaborate with the CDC to improve diagnostic and surveillance capabilities needed to counter traditional, engineered, emerging and biological threats. Complete development and transition signature analysis and assay/device for strain identification and genotyping of Burkholderia pseudomallei and CCHF virus. Continue development of Mass spectrometry protocol capable of identifying HHA false positive triggers on multiple toxin lateral flow assays.					
<b>Title:</b> 2) Bacterial Therapeutics			5.100	13.590	15.521
<b>Description:</b> Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents.					
<b>FY 2013 Accomplishments:</b> Evaluated FDA approved compounds for efficacy in non-human primate models against aerosolized challenge of Y. pestis. Evaluated small molecule inhibitors of the electron transport chain and the ATP synthase bacterial biothreat agents. Performed pharmacokinetic studies of humanized CapD in mouse models. Continued pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the bacterial therapeutics product pipeline.					
<b>FY 2014 Plans:</b> Evaluate FDA approved compounds for efficacy in non-human primate models against aerosolized challenge of B. anthracis. Continue evaluation of efficacy of novel topoisomerase inhibitor against Y. pestis and F. tularensis. Develop novel ribosome inhibitors and additional novel topoisomerase inhibitors as therapeutics for priority antimicrobial resistant bacterial pathogens. Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the bacterial therapeutics product pipeline.					
<b>FY 2015 Plans:</b>					



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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Chemical and Biological Defense Program		<b>Date:</b> March 2014		
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
Evaluate FDA approved compounds for efficacy in non-human primate models against aerosolized challenge of B. anthracis. Develop novel ribosome inhibitors as therapeutics for priority bacterial pathogens. Continue pre-clinical research required to submit IND applications to the FDA for additional products. Continue non-clinical work utilizing the Animal Rule for the submission of Supplemental New Drug Applications (sNDAs), reducing the focus to novel topoisomerase inhibitors and addressing a limited number of priority pathogens.				
<b>Title:</b> 3) Bacterial/Toxin Vaccines  <b>Description:</b> Evaluate the best single agent bacterial and toxin vaccines for effectiveness against aerosol challenge in large animal models.  <b>FY 2013 Accomplishments:</b> Deliver final data package for ricin vaccine. Completed a phase I clinical trial with the lead ricin vaccine candidate (RV Ec).  <b>FY 2014 Plans:</b> Coordinate with the advanced developer to fulfill S&T needs in support of the ricin vaccine transition. Continue to test mutants of RVEc as backup candidates for improved safety and efficacy.  <b>FY 2015 Plans:</b> Coordinate with the advanced developer to fulfill S&T needs in support of the ricin vaccine transition. Down-select to a back-up candidate to RV Ec.		0.604	0.459	9.900
<b>Title:</b> 4) Bacterial/Toxin Vaccines  <b>Description:</b> Develops medical countermeasures to protect the Warfighter against radiological/nuclear exposure. The Department of Defense is the only governmental agency currently developing medical prophylaxis to protect Warfighters or other responders in the event of a radiological incident.  <b>FY 2013 Accomplishments:</b> Explored the development of a biodosimetry hand-held diagnostic device that is minimally invasive, accurate, rapid, high-throughput and suitable for medical triage.		0.172	-	-
<b>Title:</b> 5) Biosurveillance  <b>Description:</b> Integrate existing disparate military and civilian data sets into advanced warning systems, and leverage and enhance epidemiological models and algorithms for disease prediction, impact and biological threat assessment. Contribute to the development of global, near real time, disease monitoring and surveillance systems that address secondary infection, fuse		1.327	-	0.936

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<p>medical syndromic, environmental, and clinical data, and feed into agent-based epidemiological modeling, medical resource estimation and decision support tools. Focus on agent-based epidemiological modeling and fusion of disease surveillance data.</p> <p><b>FY 2013 Accomplishments:</b> Continued effort of Verification and Validation (V&amp;V) of existing agent-based epidemiological models, to include underlying population data and disease spread algorithms, along with biosurveillance data fusion, for use in robust adaptive decision making.</p> <p><b>FY 2015 Plans:</b> Complete the development of a scalable, replicable framework to serve as the basis for a biosurveillance cloud for government data. Continue the development of analytic capabilities to synthesize and interrogate multiple sources of data to provide high confidence in the prediction, early warning and forecasting (inclusive of mitigation strategies) of infectious disease outbreaks.</p>				
<p><b>Title:</b> 6) Chemical Diagnostics</p> <p><b>Description:</b> Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.</p> <p><b>FY 2013 Accomplishments:</b> Expanded the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs.</p> <p><b>FY 2014 Plans:</b> Continue to expand the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs in clinical samples.</p> <p><b>FY 2015 Plans:</b> Continue to expand the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs in clinical samples</p>		0.399	0.460	0.395
<p><b>Title:</b> 7) Diagnostic Device Platforms</p> <p><b>Description:</b> Diagnostic device development to include systems able to harness next generation technologies to revolutionize clinical diagnostics in care facilities and in hospital laboratories. This investment will incorporate capabilities such as next generation sequencing and advanced biomolecular methods to harness both host and pathogen biomarkers in a threat agnostic approach that will serve all echelons of military medical care.</p> <p><b>FY 2013 Accomplishments:</b></p>		15.292	29.211	19.711

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Chemical and Biological Defense Program			<b>Date:</b> March 2014		
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<p>Provided documented assessments of candidate devices potential for transition to advanced developers to support the deployment of point of care diagnostic capabilities. Verified clinical utility of host and pathogen biomarkers and integrate onto diagnostic platform prototype(s) that confers the ability to identify and type novel infectious agents as a function of their relationship to previously characterized pathologies.</p> <p><b>FY 2014 Plans:</b> Continue to develop candidate devices for potential transition to advanced developers to support the deployment of point of care diagnostic capabilities. Development of hardware solutions and assay formats to enable point of need diagnostic capabilities. Verify clinical utility of host and pathogen biomarkers and integrate onto diagnostic platform prototype(s) that confers the ability to identify and type novel infectious agents as a function of their relationship to previously characterized pathologies.</p> <p><b>FY 2015 Plans:</b> Evaluate candidate host biomarker diagnostic targets in clinical test environments. Develop point-of-need diagnostic platforms with host biomarker diagnostic assays and test performance. Evaluate metrics of host-based diagnostic approach by comparing with pathogen detection approaches (infection to detection time, sensitivity, specificity, etc.) in analytical and/or clinical environments. Continue to develop candidate devices for potential transition to support the deployment of point of care diagnostic capabilities. Continue development of hardware solutions and assay formats to enable point of need diagnostic capabilities. Verify clinical utility of host and pathogen biomarkers and integrate onto diagnostic platform prototypes that confer(s) the ability to identify and type novel infectious agents as a function of their relationship to previously characterized pathologies.</p>					
<p><b>Title:</b> 8) Medical Countermeasures Initiative</p> <p><b>Description:</b> The MCMI will integrate the regulatory science and manufacturing technologies and processes developed into the Advanced Development and Manufacturing (MCM-ADM) as enablers of the advanced development and flexible manufacturing capability.</p> <p><b>FY 2013 Accomplishments:</b> Furthered the development of human in vitro immune mimetic assays for FDA acceptance to enable rapid and accurate prediction of the human response to experimental vaccines and other MCMs. Continued to develop and make practical improvements to existing agile, flexible, manufacturing bioprocesses for the purpose of accelerating access to biodefense MCMs. Continued the development of a plant-based virus-like particle (VLP) vaccine. Identified additional ex vivo cell/tissue mimetics such as precision cut tissue slices to serve as predictive surrogates for accelerated MCM efficacy and safety evaluation.</p> <p><b>FY 2014 Plans:</b> Continue development of human in vitro immune mimetic assays for FDA acceptance to enable rapid and accurate prediction of the human response to experimental vaccines and other MCMs. Continue to develop and make practical improvements to existing agile, flexible, manufacturing bioprocesses for the purpose of accelerating access to biodefense MCMs. Continue the</p>			16.654	12.759	9.642

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>
development of a plant-based VLP vaccine. Identify additional ex-vivo cell/tissue mimetics such as precision cut tissue slices to serve as predictive surrogates for accelerated MCM efficacy and safety evaluation.			
<b>FY 2015 Plans:</b> Continue development of human in vitro immune mimetic assays for FDA acceptance to enable rapid and accurate prediction of the human response to experimental vaccines and other MCMs. Continue to develop and make practical improvements to existing agile, flexible, manufacturing bioprocesses for the purpose of accelerating access to biodefense MCMs. Continue the development of a plant-based VLP vaccine.			
<b>Title:</b> 9) Multiagent Medical Countermeasures  <b>Description:</b> Continues efforts previously funded under the Transformational Medical Technologies Initiative to develop candidate countermeasures for Hemorrhagic Fever Virus (HFV) and Intracellular Bacterial Pathogen (IBP). Focuses on the initiation and completion of preclinical studies for candidate countermeasures, to include safety, toxicity, efficacy, and scalability work in accordance with the product's intended use. The ability to formulate Good Manufacturing Practices (GMP), pilot lots and further mature promising drug candidates will be the focus of activities in this capability area. The preclinical drug discovery process culminates in the submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), to determine if candidate countermeasures are suitable for safety evaluation in humans.  <b>FY 2013 Accomplishments:</b> Continued pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the Hemorrhagic Fever Virus (HFV), Intracellular Bacterial Pathogen (IBP) and Emerging Infectious Disease (EID) product pipelines. Continued planning for Phase 1 clinical trials and additional studies for INDs as required by the FDA prior to safety evaluation in humans. Continued the development of animal models for future advanced development of MCMs currently in the S&T phase of development, incorporating feedback from the FDA and Services into requirements.		34.101	-
<b>Title:</b> 10) Nerve Agent Pretreatments  <b>Description:</b> Develop pretreatments that provide protection against all organophosphorous nerve agents. The enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high enzymatic efficiency for the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent.  <b>FY 2013 Accomplishments:</b>		2.519	-

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
Continued characterization of recombinant human butyrylcholinesterase (rHuBChE) bioscavenger product of selected alternative expression systems.				
<b>Title:</b> 11) Neurologic Therapeutics  <b>Description:</b> Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to chemical warfare agents (CWA). This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. Supports eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties.  <b>FY 2013 Accomplishments:</b> Completed studies developing appropriate animal models. Maintained core capability for in vitro and in vivo testing. This core capability for product testing, using standardized methodologies under well-controlled laboratory conditions (e.g., Good Laboratory Practice or GLP), is needed to ensure quality and consistency of study test data submitted in applications to FDA in support of regulatory actions.  <b>FY 2014 Plans:</b> Maintain reduced core capability for in vitro and in vivo testing efforts supporting regulatory science to facilitate FDA licensure including in vitro and in vivo testing.  <b>FY 2015 Plans:</b> Reduced emphasis on continuing efforts supporting regulatory science to facilitate FDA licensure including in vitro and in vivo testing.		9.166	4.585	1.670
<b>Title:</b> 12) Next Generation Diagnostics  <b>Description:</b> Development of next generation diagnostic technologies including portable diagnostic platforms, highly parallel and informative testing formats, and nanotechnology applications. Development of novel assay formats and hardware solutions to enable point of need diagnostic capabilities, allowing for rapid guidance of medical decisions.  <b>FY 2013 Accomplishments:</b> Performed pre-clinical validation studies in relevant animal models and human/zoonotic disease states to stratify pre-symptomatic biomarker panel positive and negative predictive values.		12.872	-	-
<b>Title:</b> 13) Toxin Therapeutics  <b>Description:</b> Identify, optimize and evaluate potential therapeutic candidates effective against biological toxin threat agents.  <b>FY 2013 Accomplishments:</b>		1.645	0.412	1.000

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<p>Evaluated small molecule non-peptidic inhibitors for pharmacokinetic and toxicology profiles. Tested novel small molecule inhibitors in mouse model of BoNT A intoxication for efficacy.</p> <p><b>FY 2014 Plans:</b> Continue evaluation of small molecule non-peptidic inhibitors for pharmacokinetic and toxicology profiles. Test novel small molecule inhibitors in mouse model of BoNT A intoxication for efficacy.</p> <p><b>FY 2015 Plans:</b> Continue evaluation of small molecule non-peptidic inhibitors for pharmacokinetic and toxicology profiles. Test novel small molecule inhibitors in mouse model of BoNT A intoxication for efficacy.</p>					
<p><b>Title:</b> 14) Vaccine Platforms and Research Tools</p> <p><b>Description:</b> Use novel technology and methods to support development of vaccine candidates. Conduct studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods, and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identify correlates of protection in humans, and predict the success of lead vaccine candidates in humans.</p> <p><b>FY 2013 Accomplishments:</b> Continued formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continued to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continued to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilized clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity.</p> <p><b>FY 2014 Plans:</b> Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity.</p> <p><b>FY 2015 Plans:</b> Emphasize alternative production platforms applying them to current CBDP vaccine needs. Utilize clinical samples from Filovirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity.</p>			3.788	2.423	3.826
<b>Title:</b> 15) Viral Therapeutics			6.100	14.066	2.000

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<b>Appropriation/Budget Activity</b> 0400 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	<b>Project (Number/Name)</b> TM3 / <i>TECHBASE MED DEFENSE (ATD)</i>		
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<p><b>Description:</b> Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.</p> <p><b>FY 2013 Accomplishments:</b> Continued evaluation of immunotherapies for Filoviruses in non-human primate models. Developed immune modulators for the treatment of Filovirus infection. Continued screening program to determine efficacy of FDA approved compounds against emerging infectious diseases. Therapeutic efforts were primarily focused on Alphavirus and Filovirus families. Continued pre-clinical research required to submit Investigational New Drug (IND) applications to the FDA for additional products or additional product indications to refresh the viral therapeutics product pipeline.</p> <p><b>FY 2014 Plans:</b> Evaluate immunotherapies for Filoviruses in non-human primate models. Continue development of antibody-based therapies for Filovirus infections. Continue screening program to determine efficacy of FDA approved compounds against emerging infectious diseases. Evaluate FDA-approved host-directed tyrosine kinase inhibitors for efficacy against Alphavirus, Filovirus, Flavivirus, Arenavirus, Bunyavirus, and Orthopoxvirus. Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the viral therapeutics product pipeline.</p> <p><b>FY 2015 Plans:</b> Evaluate immunotherapies for filoviruses in non-human primate models. Continue and repurposing screening program to determine efficacy of FDA approved compounds against emerging infectious diseases. Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the viral therapeutics product pipeline.</p>				
<p><b>Title:</b> 16) Viral Vaccines</p> <p><b>Description:</b> Evaluates the best vaccine candidates for Alphaviruses and Filoviruses for effectiveness and duration of protective immune response against aerosol challenge in large animal models. Animal models will be developed to support FDA licensure of mature vaccine candidates.</p> <p><b>FY 2013 Accomplishments:</b> Coordinated with the advanced developer to fulfill S&amp;T needs in support of the Filovirus vaccine transition. Continued development of Filovirus and Alphavirus immunological assays to support product development. Submitted IND for Phase I clinical trial of Venezuelan Equine Encephalitis (VEE) DNA vaccine delivered by in vivo electroporation via intra-muscular or intra-dermal administration. Completed pre-clinical studies on a trivalent VEE, Eastern and Western Equine Encephalitis (EEE, WEE) DNA formulation. Continued to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced developer. Continued the development of animals models for Alphaviruses (VEE, EEE, and WEE), and Filoviruses (Ebola Sudan,</p>		22.532	14.417	3.300

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Chemical and Biological Defense Program									Date: March 2014		
Appropriation/Budget Activity 0400 / 3				R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) TM3 / TECHBASE MED DEFENSE (ATD)			
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2013	FY 2014	FY 2015
Ebola Zaire, Ebola Bundibugyo, and Marburg), to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure. Although the Filovirus vaccines transitioned in FY11, work continued on the selected candidate(s) to fill knowledge gaps.  FY 2014 Plans: Continue development of Alphavirus immunological assays to support product development. Conduct Good Lab Practices (GLP) animal efficacy studies of the VEE DNA vaccine delivered by in vivo electroporation via intra-muscular or intra-dermal administration. Continue to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced developer. Continue the development of animals models for Alphaviruses (EEE and WEE), to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure.  FY 2015 Plans: Conduct Good Lab Practices (GLP) animal efficacy studies of the VEE DNA vaccine delivered by in vivo electroporation via intra-muscular or intra-dermal administration. Continue to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced developer. Complete GLP natural history studies for Alphaviruses (W/E/VEEV). Continue the development of animals models for Alphaviruses (EEE and WEE), to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure. Begin a Phase 1 clinical trial with a multivalent Alphavirus DNA vaccine candidate.											
Accomplishments/Planned Programs Subtotals									160.195	101.827	87.610
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
• MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&P)	111.415	122.328	102.080	-	102.080	101.019	60.981	32.683	48.277	Continuing	Continuing
• MC4: MEDICAL CHEMICAL DEFENSE (ACD&P)	-	2.000	-	-	-	-	3.750	10.692	25.089	Continuing	Continuing
• MB5: MEDICAL BIOLOGICAL DEFENSE (EMD)	173.505	246.436	169.497	-	169.497	138.224	154.851	179.989	168.644	Continuing	Continuing
• MC5: MEDICAL CHEMICAL DEFENSE (EMD)	17.396	55.087	58.529	-	58.529	65.966	40.880	33.205	1.550	Continuing	Continuing
• MB7: MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)	0.490	0.499	13.414	-	13.414	14.551	9.816	7.277	16.496	Continuing	Continuing
Remarks											



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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Chemical and Biological Defense Program		<b>Date:</b> March 2014
<b>Appropriation/Budget Activity</b> 0400 / 3	<b>R-1 Program Element (Number/Name)</b> PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	<b>Project (Number/Name)</b> TM3 / <i>TECHBASE MED DEFENSE (ATD)</i>
<b><u>D. Acquisition Strategy</u></b> N/A		
<b><u>E. Performance Metrics</u></b> N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Chemical and Biological Defense Program										Date: March 2014		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) TT3 / TECHBASE TECHNOLOGY TRANSITION			
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
TT3: TECHBASE TECHNOLOGY TRANSITION	-	-	5.917	5.768	-	5.768	7.358	8.225	7.858	7.662	Continuing	Continuing

# The FY 2015 OCO Request will be submitted at a later date.

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

Project TT3 validates high-risk/high-payoff technologies, concepts-of-operations, and a new Joint Combat Development concept development and experimentation process that could significantly improve Warfighter capabilities in preparation for transition of mature technologies to advanced development programs requiring chemical and biological (CB) defense technologies. These programs offer an opportunity to identify and efficiently mature emerging technologies including limited objective experiments, laboratory experiments, risk reduction efforts, engineering and integration. These demonstrations and programs seek to demonstrate the potential for enhanced military operational capability and/or cost effectiveness. This project addresses four family of products areas: Biological Resiliency, Weapons of Mass Destruction (WMD) Elimination, Hazard Mitigation and Facilities Protection. Biological resiliency efforts are targeted to reduce biological threats by: (1) improving Department of Defense (DoD) access to the life sciences to combat infectious disease regardless of its cause; (2) establishing and reinforcing DoD concept of operations (CONOPS) against the misuse of the life sciences; and (3) instituting a suite of coordinated DoD and interagency activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences. WMD Elimination addresses detection, identification, verification and baseline assessments in support of expeditionary forces deployed in non-permissive environments. Hazard Mitigation 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. Facilities protection transitions mature technologies to improve individual and critical infrastructure protection capabilities for U.S. and coalition Warfighters.

Three demonstrations will be ongoing in FY15: Joint Biological Agent Decontamination System (JBADS) JCTD- Demonstration of the operational utility of a interior-exterior airframe decontamination capability; Thermal Imaging Dual-Use for Aerosol Monitoring Alarms and Security (TIDAMAS)- Evaluation of a dual capability that can perform chemical standoff detection and ISR; and Joint Concept Development and Experimentation (JCDE)/Rapid Military Utility Assessment Initiative - a partnership with Maneuver Support Center of Excellence (MSCOE) to better ensure S&T solutions address warfighter needs.

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<b>Title:</b> 1) Experiment & Technology Demonstrations	-	5.917	5.768
<b>FY 2014 Plans:</b> Conduct technical and operational demonstrations for persistent and contagious bio agent scenarios in the US European Command Area of Responsibility (EUCOM AOR). Conduct and complete a series of vignettes addressing sampling and analysis (to include forensics preparation), wide area decontamination and medical/epidemiological management. Complete Coalition Warfare Program science and technology (S&T) efforts with international partner in EUCOM AOR. Conduct a field experiment process to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer and with			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Chemical and Biological Defense Program								<b>Date:</b> March 2014			
<b>Appropriation/Budget Activity</b> 0400 / 3				<b>R-1 Program Element (Number/Name)</b> PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>			<b>Project (Number/Name)</b> TT3 / <i>TECHBASE TECHNOLOGY TRANSITION</i>				
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>								<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	
<p>outcomes to support the creation of an initial capabilities document (ICD). Demonstrate decontamination technologies for the interior of airframes against bio agents as part of a Joint Combat Technology Demonstration (JCTD) initiative with US Transportation Command (TRANSCOM). Initiate analysis and market research for a complete facilities protection system that is rapidly deployable, to include threat detection, building hardening, and personal protection.</p> <p><b><i>FY 2015 Plans:</i></b>            Initiate Advanced Technology Demonstration (ATD) for Rapid Response and Recovery thrust area, which includes the WMD Elimination mission space. Conduct extended user evaluation of recently transitioned capabilities for persistent and contagious bio agent scenarios in the US European Command Area of Responsibility (EUCOM AOR). Initiate bio-resiliency S&amp;T development in additional AORs. Conduct early warning/remote detection S&amp;T efforts with international partner in the US Pacific Command (PACOM) AOR. Conduct a rapid military utility assessment and field experiment process to assess early technology capability contributions across combating WMD (C-WMD) mission areas, in collaboration with the CBDP Joint Combat Developer and with outcomes to support CBDP requirements and capability development. Complete demonstration of decontamination technologies for the interior of airframes against bio agents as part of a JCTD initiative with US TRANSCOM.</p>											
<b>Accomplishments/Planned Programs Subtotals</b>								-	5.917	5.768	
<b>C. Other Program Funding Summary (\$ in Millions)</b>											
<b>Line Item</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015 Base</b>	<b>FY 2015 OCO</b>	<b>FY 2015 Total</b>	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
• TT4: <i>TECHBASE TECHNOLOGY TRANSITION (ACD&amp;P)</i>	3.205	-	-	-	-	-	-	-	-	-	3.205
<b>Remarks</b>											
<b>D. Acquisition Strategy</b> N/A											
<b>E. Performance Metrics</b> N/A											