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Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Chemical and Biological Defense Program **Date:** February 2018

| Appropriation/Budget Activity 0400: <i>Research, Development, Test & Evaluation, Defense-Wide I BA 3: Advanced Technology Development (ATD)</i> | | | | | R-1 Program Element (Number/Name) PE 0603384BP I <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | | | | | | | |
|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| Total Program Element | - | 130.033 | 145.359 | 142.826 | - | 142.826 | 150.168 | 167.402 | 167.679 | 161.133 | Continuing | Continuing |
| CB3: <i>CHEMICAL BIOLOGICAL DEFENSE (ATD)</i> | - | 18.584 | 18.093 | 21.698 | - | 21.698 | 21.675 | 21.735 | 21.740 | 21.737 | Continuing | Continuing |
| NT3: <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i> | - | 16.055 | 23.655 | 22.749 | - | 22.749 | 24.219 | 30.349 | 31.155 | 31.150 | Continuing | Continuing |
| TM3: <i>TECHBASE MED DEFENSE (ATD)</i> | - | 88.629 | 92.846 | 88.188 | - | 88.188 | 93.271 | 104.285 | 103.753 | 97.215 | Continuing | Continuing |
| TT3: <i>TECHBASE TECHNOLOGY TRANSITION</i> | - | 6.765 | 10.765 | 10.191 | - | 10.191 | 11.003 | 11.033 | 11.031 | 11.031 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Demonstrates technologies supporting transition to advanced component development. This includes physical capabilities which cover biological and chemical detection, situational awareness and effects modeling, and protection and hazard mitigation. Other major efforts support enhanced chemical detection capabilities for aerosols and non-traditional agents, expanded capabilities for biosurveillance in pathogen detection and diagnosis, and pretreatments and therapeutics against a broader set of chemical and biological agents. Medical capabilities (pretreatments, therapeutics, diagnostics capabilities, and drug manufacturing and regulatory science technologies), include capabilities against non-traditional agents.

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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| One function of the CBDP S&T Advanced Technology Development budget is to preserve critical core competencies in the DoD Service laboratories which includes: United States Army Edgewood Chemical Biological Center (ECBC), United States Army Medical Research Institute of Infectious Diseases (USAMRIID), United States Army Medical Research Institute of Chemical Defense (USAMRICD), United States Army Natick Soldier Systems Center, Naval Research Lab (NRL), Air Force Research Lab (AFRL), among others. The intent is to maintain strategic partnerships with the DoD Service communities for mission success across the enterprise through collaborative planning and programming maintaining budget assurance. | | | | | | |
| 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. Program Change Summary (\$ in Millions) | | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total |
| Previous President's Budget | | 127.941 | 145.359 | 141.728 | - | 141.728 |
| Current President's Budget | | 130.033 | 145.359 | 142.826 | - | 142.826 |
| Total Adjustments | | 2.092 | 0.000 | 1.098 | - | 1.098 |
| • Congressional General Reductions | | - | - | | | |
| • Congressional Directed Reductions | | - | - | | | |
| • Congressional Rescissions | | - | - | | | |
| • Congressional Adds | | 5.000 | - | | | |
| • Congressional Directed Transfers | | 0.000 | - | | | |
| • Reprogrammings | | -1.099 | - | | | |
| • SBIR/STTR Transfer | | -1.809 | - | | | |
| • Other Adjustments | | 0.000 | - | 1.098 | - | 1.098 |
| Change Summary Explanation | | | | | | |
| Funding: FY17 (+\$5.000M): Congressional add to Medical Biological Pretreatments (TM3). | | | | | | |
| FY17 (-\$1.099M): Program reprogrammings to support high priority CBDP efforts to include Advanced Development and Manufacturing Antibody Technologies. | | | | | | |
| FY17 (-\$1.809M): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts. | | | | | | |
| FY19 (-\$0.902M): Application of revised inflation guidance. | | | | | | |
| FY19 (+\$2.000M): Program adjustments to balance overall portfolio efforts. | | | | | | |
| Schedule: N/A | | | | | | |
| Technical: N/A | | | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | | | | | | | | Date: February 2018 | | |
|---|-------------|---------|---------|--------------|---|---------------|---------|---------|--|---------------------|------------------|------------|
| Appropriation/Budget Activity 0400 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD) | | | | Project (Number/Name) CB3 / CHEMICAL BIOLOGICAL DEFENSE (ATD) | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD) | - | 18.584 | 18.093 | 21.698 | - | 21.698 | 21.675 | 21.735 | 21.740 | 21.737 | Continuing | Continuing |
| A. Mission Description and Budget Item Justification | | | | | | | | | | | | |
| Project CB3 develops technology advancements for joint service application in the area of information systems and modeling and simulation technologies, protection/hazard mitigation and detection. 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. Protection/hazard mitigation works to provide technologies that protect from and reduce the impact of both chemical and biological threats and hazards to the Warfighter, weapons platforms, and structures. Detection strives to develop technologies for point and standoff detection and identification of both chemical and biological agents. | | | | | | | | | | | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | | | | | | | | FY 2017 | FY 2018 | FY 2019 | |
| Title: 1) Expeditionary Collective Protection | | | | | | | | | 0.497 | 0.722 | 0.106 | |
| Description: Develop new technologies for soldiers to determine the remaining chemical vapor service life of their chemical warfare agent (CWA) filters. | | | | | | | | | | | | |
| FY 2018 Plans: | | | | | | | | | | | | |
| Continue filter bed research to investigate how and if various formulation constituents affect coating chemistry and morphology in filter bed. Continue integration and surveillance of Guard Bed and RLI systems. | | | | | | | | | | | | |
| FY 2019 Plans: | | | | | | | | | | | | |
| Continue from FY18 CB3 (Chemical Biological Defense)/Expeditionary Collective Protection integration and surveillance of Guard Bed filters and RLI. Continue to pull satellite cartridges and the primary ColPro filter (M98) filters for surveillance testing and assessment. | | | | | | | | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: | | | | | | | | | | | | |
| Program/project transitioned to Advanced Development. | | | | | | | | | | | | |
| Title: 2) Material Contamination Mitigation | | | | | | | | | 2.347 | 1.696 | 1.912 | |
| Description: Develop highly effective non-traditional or novel decontamination technologies that integrate with current procedures and support non-material improvements of the overall decontamination effort. | | | | | | | | | | | | |
| FY 2018 Plans: | | | | | | | | | | | | |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | | FY 2017 | FY 2018 | FY 2019 |
| <p>Complete agent resistant coatings effort and transition to the Air Force Item manager. Continue to optimize the decontamination parameters for the hot air biological decontamination effort to address sensitive equipment, platform interior, and aircraft decontamination needs. Continue and develop the laboratory scale test to optimize decontamination parameters for the chemical hot air decontamination effort to address sensitive equipment, platform interior, and aircraft chemical warfare agent decontaminant needs. Continue to optimize parameters for responsive and resistant coatings efforts to enhance decontaminability as part of the systems approach to achieving efficacy goals. Continue Wide Area Decontamination of Bacillus anthracis projects, which focus on maturing the biological spore decontamination in a broadened set of outdoor terrains and materials.</p> <p>FY 2019 Plans: Complete and transition sorbent decontaminant formulation effort to advanced development for tactical decontamination, complete vapor and complex surface efficacy performance evaluations and technical demonstration to support relevant data development to transition at TRL6. Continue coatings optimization utilizing new chemical agent resistance method to reduce chemical absorption. Continue Wide Area Decontamination of Bacillus anthracis projects, focusing on varied subscale testing environments. Continue to optimize the decontamination parameters for the hot air biological decontamination effort, including the introduction of germinates to address sensitive equipment, platform interior, and aircraft decontamination needs and reduce the time and logistical burden associated with the process. Continue chemical hot air decontamination effort including the insertion of aerosolized decontaminants to reduce the time and logistical requirements associated with addressing sensitive equipment, platform interior, and aircraft chemical warfare agent decontaminant needs in a relevant environment.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement: Increase due to fact of life change in the program/project.</p> | | | | | |
| <p>Title: 3) Percutaneous Protection</p> <p>Description: Develop advanced ensemble prototypes with state-of-the art materials that address the full spectrum of threats and provide a range of solutions optimized for protection, thermal comfort, and mission performance. The FY18 Percutaneous Protection efforts are expected to continue for 2 years.</p> <p>FY 2018 Plans: Continue development of Level A/B All Hazards ensembles. Develop and scale up novel materials for protection, emerging SCBA technologies, and novel rebreather technologies. Continue to develop biofeedback parameters for enhanced cooling systems. Initiate the development of biocidal fabrics for personal protection in warfighter ensembles. Continued materials development for multifunctional materials with focus on additional materials development and completing performance evaluations.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement:</p> | | | 0.384 | 0.687 | - |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | | FY 2017 | FY 2018 | FY 2019 |
| Decrease due to fact of life change in the program/project. | | | | | |
| Title: 4) Respiratory and Ocular Protection | | | 2.031 | 1.136 | 1.975 |
| Description: Develop novel filtration media that are lighter weight and lower burden while capable of protecting against a broader range of challenges that includes toxic industrial chemicals (TICs). | | | | | |
| FY 2018 Plans: Continue to develop new add-on technologies for SCBA and hybrid system respirators. Continue to demonstrate performance envelop of existing air purification technologies towards emerging threats. Continue to develop nano-structured porous materials for air purification. | | | | | |
| FY 2019 Plans: Continue to acquire and assemble Closed Circuit Self Contained Breathing Apparatus (CC-SCBA) subsystems into a hybrid technology prototype system. Build and test Full-Spectrum Respiratory Protection System (FSRPS) prototypes that include all sensors and control technology solutions. Continue to scale up nano-structured porous materials for air purification. Continue to conduct performance evaluation and demonstration of FSRPS prototypes. Continue to assess novel filtration materials against new emerging threats. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Increase due to change in program/project schedule. | | | | | |
| Title: 5) Biosurveillance (BSV) | | | 2.286 | 2.532 | - |
| Description: Integrate existing disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced warning systems, and leverage and enhance advanced epidemiological models and algorithms for disease prediction, forecasting, 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 disease modeling, medical resource estimation and decision support tools. This effort will be realigned in FY19 to CB3 (Chemical Biological Defense) Threat Surveillance. | | | | | |
| FY 2018 Plans: Complete biosurveillance capabilities aimed at analyzing and facilitating sharing of sequence data, predicting areas of disease reemergence, and visualizing pathogen dynamics in support of the Global Biosurveillance Portal. Initiate the development of analytic applications to acquire, synthesize and interrogate multiple sources of data (open source information, medical diagnostic | | | | | |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | | FY 2017 | FY 2018 | FY 2019 |
| devices, wearable technology, environmental sensors, unmanned platforms and genomic sequences) to provide high confidence in the prediction and early warning of chemical or biological events. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Program/project funding transferred to another funding line. | | | | | |
| Title: 6) Detection Description: Advance and mature technologies and capabilities to detect and identify chemical and biological threats to the point of transitioning to customers for advanced development. This activity can include development of point, remote, or standoff sensors as appropriate, to address both chemical and biological threats. These efforts develop transitionable detection capabilities for early warning of contamination exposure to the warfighter. FY 2018 Plans: Complete the development of genomic sequencing based platforms protocols for comprehensive identification and characterization for field forward capabilities. FY 2019 Plans: Complete the development of sample preparation techniques to enhance environmental detection platforms. Continue the development of proteomic detection capabilities, to include expansion into the methodologies to detect novel threats. FY 2018 to FY 2019 Increase/Decrease Statement: Increase due to change in program/project technical parameters. | | | 3.935 | 3.235 | 6.122 |
| Title: 7) Hazard Prediction Description: 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 toxic industrial materials. FY 2018 Plans: 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 HPAC/JEM. Initiate littoral validation studies for next phase of waterborne transport models. FY 2019 Plans: Continue performance optimization and high fidelity enhancements for transport and dispersion models, particularly for urban environments. Continue configuration management of science and technology prototype for transition of upgraded capabilities to | | | 2.750 | 3.551 | 5.782 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 | FY 2019 |
| Joint Effects Model (JEM). Continue upgrading science and technology prototype to Common CBRN Modeling Interface (CCMI) architecture. Complete validation and verification (V&V) studies for high fidelity source term algorithms. | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Program/project funding transferred to another funding line. | | | | |
| Title: 8) Data Analysis Description: Develop CBRN data-sharing capabilities. Develop 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. Create a framework for implementing CB-1 and provide CBRN defense community access to CB-1. FY 2018 Plans: Continue to provide CBRN defense community access to CB-1. FY 2019 Plans: Complete the digitization effort at the United States Army Heritage and Education Center and make the digitized documents accessible through CB-1s online portal. FY 2018 to FY 2019 Increase/Decrease Statement: Program/project funding transferred to another funding line. | | 0.240 | 0.029 | 0.103 |
| Title: 9) Operational Effects Description: 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 Chemical Biological Radiological and Nuclear (CBRN) incidents on decision-making. Focus areas include consequence management, population modeling, and knowledge management. FY 2018 Plans: Continue operational effects research and analysis efforts to provide objective, quantitative analysis in support of science and technology initiatives, material developments, operational guidance, and requirements settings. Complete verification and validation of Joint Expeditionary Collective Protection System Performance model and initiate transition of these efforts to the Joint Expeditionary Collective Protection (JECPP) program. FY 2019 Plans: | | 4.114 | 4.505 | 2.027 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | | | | | | | | | FY 2017 | FY 2018 | FY 2019 |
| Continue Decontamination and Individual Protection SPM integration and advanced development. | | | | | | | | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Decrease due to change in program/project technical parameters. | | | | | | | | | | | | |
| Title: 10) Threat Surveillance Description: Integrate disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced chemical and biological threat warning systems, tactical decision aids, and leverage and enhance advanced epidemiological models and algorithms for disease prediction, forecasting, impact and biological threat assessment. This effort will be realigned in FY19 from CB3 (Chemical Biological Defense) Biosurveillance and TM3 (Techbase Med Defense) Biosurveillance. FY 2019 Plans: Identify sources for pathogen data and develop tools to mine data sources (PubMed, Google Books, online journals) to create a comprehensive human, animal, and plant pathogen database. Link pathogen database to disease ontologies and develop the capability for automatic pathogen updates from newly published data. Enhance the Biosurveillance Ecosystem (BSVE) framework to support the rapid integration of multiple data sources, tools, algorithms, and services that support chemical and biological defense. FY 2018 to FY 2019 Increase/Decrease Statement: Program/project funding transferred from another funding line. | | | | | | | | | | - | - | 3.671 |
| Accomplishments/Planned Programs Subtotals | | | | | | | | | | 18.584 | 18.093 | 21.698 |
| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | | |
| Line Item | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost | |
| • CA4: CONTAMINATION AVOIDANCE (ACD&P) | 49.313 | 29.211 | 35.094 | - | 35.094 | 27.908 | 20.208 | 16.131 | 17.518 | Continuing | Continuing | |
| • DE4: DECONTAMINATION SYSTEMS (ACD&P) | 0.500 | 9.900 | 7.477 | - | 7.477 | 6.281 | 9.374 | 9.539 | 19.240 | Continuing | Continuing | |
| • IS4: INFORMATION SYSTEMS (ACD&P) | 4.989 | 5.941 | 0.854 | - | 0.854 | 0.291 | 0.075 | 0.071 | 0.068 | Continuing | Continuing | |
| • TE4: TEST & EVALUATION (ACD&P) | 11.747 | 9.157 | 6.581 | - | 6.581 | 5.170 | 5.165 | 3.549 | 3.549 | Continuing | Continuing | |

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C. Other Program Funding Summary (\$ in Millions)

| <u>Line Item</u> | <u>FY 2017</u> | <u>FY 2018</u> | <u>FY 2019</u> <u>Base</u> | <u>FY 2019</u> <u>OCO</u> | <u>FY 2019</u> <u>Total</u> | <u>FY 2020</u> | <u>FY 2021</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
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Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| NT3: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD) | - | 16.055 | 23.655 | 22.749 | - | 22.749 | 24.219 | 30.349 | 31.155 | 31.150 | Continuing | Continuing |

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 supports 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 2017 | FY 2018 | FY 2019 |
|---|----------------|----------------|----------------|
| Title: 1) Expeditionary Collective Protection | 0.200 | - | - |
| Description: Develop new technologies for soldiers to determine the remaining chemical vapor service life of their CWA filters. | | | |
| Title: 2) Material Contamination Mitigation | 0.400 | 1.115 | 0.128 |
| Description: Develop highly effective non-traditional or novel decontamination technologies that integrate with current procedures and support non-material improvements of the overall decontamination effort. | | | |
| FY 2018 Plans: Continue development and optimization of the full range of NTAs into the material contamination mitigation portfolio. Integrate NTA testing into hot air decontamination effort to address sensitive equipment, platform interior, and aircraft NTA decontaminant needs. Continue responsive coatings development and optimization to enhance NTA decontaminability as part of the systems approach to achieving efficacy goals. Continue optimization efforts to develop/enhance NTA mapping (disclosure/assurance) technologies. | | | |
| FY 2019 Plans: Continue responsive coatings optimization against emerging threats under relevant environmental conditions and identifying potential battlefield interferants. Continue development and optimization of the full range of NTAs, including other emerging threats into the material contamination mitigation portfolio under relevant environmental conditions. Continue to integrate NTA | | | |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | | FY 2017 | FY 2018 | FY 2019 |
| testing into hot air decontamination effort to address sensitive equipment, platform interior, and aircraft NTA decontaminant needs in a relevant environment and identifying potential battlefield interferants. Continue optimization efforts to develop/enhance NTA mapping (disclosure/assurance) technologies in simulated relevant environments. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Decrease due to fact of life change in the program/project. | | | | | |
| Title: 3) Personnel Contamination Mitigation | | | 0.300 | 0.807 | 0.354 |
| Description: Develop new technologies to mitigate the risk associated with contaminated human remains and personnel effects (materials) exposed to and contaminated by chemical agents by neutralizing and/or physically removing the residual chemical agents. | | | | | |
| FY 2018 Plans: Transition technology data developed by efforts to develop an alternative to RSDL, including efficacy data against representative NTAs and continue effort to develop a new personnel contamination mitigation formulation (decontaminant). Initiate personnel decontamination efforts to enhance current processes and support mass casualty personnel decontamination warfighter operations, including homeland defense mission, including efficacy data against representative NTAs. | | | | | |
| FY 2019 Plans: Continue personnel decontamination efforts to enhance current processes including efficacy data against representative NTAs and emerging threats in relevant environments and identifying battlefield interferants. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Decrease due to change in program/project technical parameters. | | | | | |
| Title: 4) Respiratory and Ocular Protection | | | 0.350 | 0.357 | 1.811 |
| Description: Development and analysis of design alternatives for chemical and biological air-purifying respirators that provide enhanced protection with lower physiological burden and improved interface with mission equipment. | | | | | |
| FY 2018 Plans: Continue to develop closed circuit SCBA and novel respirator technologies against NTA challenges. | | | | | |
| FY 2019 Plans: Continue to acquire and assemble CC-SCBA subsystems into a hybrid technology prototype system. Build and test FSRPS prototypes that include all sensors and control technology solutions. Continue to scale up nano-structured porous materials for | | | | | |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 | FY 2019 |
| air purification. Continue to conduct performance evaluation and demonstration of FSRPS prototypes. Continue to assess novel filtration materials against new emerging threats. FY 2018 to FY 2019 Increase/Decrease Statement: Increase due to change in program/project schedule. | | | | |
| Title: 5) Pretreatments - Medical Description: Develop pretreatments and prophylactics that provide protection against NTAs and emerging chemical threats. Prophylactic scavengers should rapidly detoxify a broad spectrum of compounds of interest (COIs). FY 2018 Plans: Initiate preclinical studies for adeno associated virus expressed BuChE. Continue to explore whether organophosphorus nerve agents (OPNA) scavengers administered as a post-exposure therapy (either pre- and/or post-symptomatic) affords desired protection. Continue efforts to determine whether co-administration of standard therapy, in conjunction with OPNA scavengers, is substantially more effective after onset of signs of intoxication. FY 2019 Plans: Initiate studies to support clinical development of prophylaxis for selected NTAs if warranted based upon data from FY18 proof-of-concept studies. Continue efforts to develop two organophosphorus nerve agents (OPNA) scavenger enzymes to meet requirements of a prophylactic medical countermeasure. FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments. | | 1.842 | 5.164 | 5.043 |
| Title: 6) Therapeutics - Medical Description: Efforts in this area advance the understanding of mechanisms of action for NTAs and emerging chemical threats by probable routes of field exposure and seek to refine effectiveness of therapeutics to advance therapeutic development. Physiological parameters and pathological assessments will be used to establish the general mode and mechanisms of toxicity required for therapeutic development. FY 2018 Plans: Continue to enable technologies to deliver therapeutics to the brain. Continue evaluating novel therapeutics using high-throughput in vitro screens. Continue lead optimization on novel therapeutic compounds. Continue validating animal models for use in NTA exposure studies. FY 2019 Plans: | | 1.053 | 3.175 | 3.118 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | Date: February 2018 | | |
| Appropriation/Budget Activity 0400 / 3 | | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | | Project (Number/Name) NT3 / <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | | FY 2017 | FY 2018 | FY 2019 |
| Continue investigating technologies to deliver therapeutics to the brain. Continue evaluating novel therapeutics using high-throughput in vitro screens. Continue optimization on novel therapeutic compounds. Continue validating animal models for use in NTA exposure studies. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments. | | | | | |
| Title: 7) Detection | | | 10.153 | 11.840 | 11.283 |
| Description: Detection Non-Traditional Agents (NTA): Focuses on technologies to provide NTA detection capabilities. | | | | | |
| FY 2018 Plans: Continue the advanced development and rapid prototyping of chemical sensors for persistent sensing and chemical reconnaissance applications. Complete and transition the developed low-cost chemical detection capability utilized for identification of liquid threats. | | | | | |
| FY 2019 Plans: Complete the advanced development and rapid prototyping of chemical sensors for persistent sensing and chemical reconnaissance applications. Complete the development of a man worn environmental sensor for detecting exposure to chemical hazards. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments. | | | | | |
| Title: 8) Modeling & Simulation | | | 0.208 | 0.238 | 0.236 |
| Description: This effort develops NTA technology advancements for joint service application in the area of information systems and modeling and simulation technologies. These activities will speed maturation 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. | | | | | |
| FY 2018 Plans: Continue system performance model integration and development for program-wide exploitation for decontamination. | | | | | |
| FY 2019 Plans: Continue system performance model integration and development for program-wide exploitation for decontamination. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: | | | | | |

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|--|---------|---------|-----------------|--|------------------|---------|---------|---|---------|---------------------|------------|---------|
| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | | | | | | | | Date: February 2018 | | |
| 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 2017 | FY 2018 | FY 2019 |
| Minor change due to routine program adjustments. | | | | | | | | | | | | |
| Title: 9) Percutaneous Protection Description: Develop advanced ensemble prototypes with state-of-the art materials that address the full spectrum of threats and provide a range of solutions optimized for protection, thermal comfort, and mission performance. The FY18 NT3 Percutaneous Protection efforts are expected to continue for 2 years. FY 2018 Plans: Initiate evaluation of multifunctional systems for protection in relevant configurations at scale. Continue integration, engineering, and scaling of CB relevant multifunctional materials and garment configurations. FY 2018 to FY 2019 Increase/Decrease Statement: Program/project transitioned to Advanced Development. | | | | | | | | | | 0.855 | 0.157 | - |
| Title: 10) Test & Evaluation Description: Develop test and evaluation technologies and processes in support of NTA activities. FY 2018 Plans: Continue rapid prototyping and evaluation of chemical detection platforms. FY 2019 Plans: Complete the rapid prototyping and evaluation of chemical detection platforms, specifically addressing vapor passive sensing, identification of liquid chemical threats, and the detection of solids. FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments. | | | | | | | | | | 0.694 | 0.802 | 0.776 |
| Accomplishments/Planned Programs Subtotals | | | | | | | | | | 16.055 | 23.655 | 22.749 |
| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | | |
| Line Item | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost | |
| • CA4: CONTAMINATION AVOIDANCE (ACD&P) | 49.313 | 29.211 | 35.094 | - | 35.094 | 27.908 | 20.208 | 16.131 | 17.518 | Continuing | Continuing | |
| • DE4: DECONTAMINATION SYSTEMS (ACD&P) | 0.500 | 9.900 | 7.477 | - | 7.477 | 6.281 | 9.374 | 9.539 | 19.240 | Continuing | Continuing | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | | | | | | | | Date: February 2018 | |
| Appropriation/Budget Activity 0400 / 3 | | | | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | | | | Project (Number/Name) NT3 / <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i> | | | |
| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
| Line Item | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| • IP4: <i>INDIVIDUAL PROTECTION (ACD&P)</i> | 4.517 | 5.145 | 4.000 | - | 4.000 | 2.000 | 2.000 | 3.000 | 0.000 | 0.000 | 20.662 |
| • MC4: <i>MEDICAL CHEMICAL DEFENSE (ACD&P)</i> | 4.816 | 5.165 | 2.790 | - | 2.790 | 4.675 | 3.975 | 7.098 | 7.098 | Continuing | Continuing |
| • TE4: <i>TEST & EVALUATION (ACD&P)</i> | 11.747 | 9.157 | 6.581 | - | 6.581 | 5.170 | 5.165 | 3.549 | 3.549 | Continuing | Continuing |
| Remarks | | | | | | | | | | | |
| D. Acquisition Strategy | | | | | | | | | | | |
| N/A | | | | | | | | | | | |
| E. Performance Metrics | | | | | | | | | | | |
| N/A | | | | | | | | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | | | | | | | | Date: February 2018 | | |
|--|-------------|---------|---------|--------------|---|---------------|---------|---------|---|---------------------|------------------|------------|
| 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) | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| TM3: TECHBASE MED DEFENSE (ATD) | - | 88.629 | 92.846 | 88.188 | - | 88.188 | 93.271 | 104.285 | 103.753 | 97.215 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Project TM3 supports 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.

B. Accomplishments/Planned Programs (\$ in Millions)

| | FY 2017 | FY 2018 | FY 2019 |
|---|----------------|----------------|----------------|
| Title: 1) Assays and Reagents 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. This effort will be realigned in FY19 to TM3 (Techbase Med Defense) Medical Diagnostics. FY 2018 Plans: Continue efforts and studies on host response biomarker classifiers. Continue the development and production of thermostable reagents. Continue the development of assays and technologies for biological and chemical agent detection and characterization. Continue verification and testing performance of biomarker assays and reagents for point-of-need diagnostic platforms. Continue to optimize pipelines to improve unbiased pathogen discovery and/or detection in clinical and environmental samples. Continue optimization and enhancement of updated bioinformatics platform to support genomic and clinical (biomedical) informatics. Continue evaluating optimization and enhancement of updated bioinformatics platform in the field including efforts in the ROK. Initiate investigations to mature chemical and/or NTA diagnostic assays for use in forward field settings or at point-of-need. Initiate efforts to integrate or converge platform technologies to detect antimicrobial resistance/multidrug resistant (AMR/MDR) microbes at the single molecular level. Initiate incorporation of stability and pre-clinical studies for diagnostic assays in development to further support pre-EUA submissions. FY 2018 to FY 2019 Increase/Decrease Statement: | 16.099 | 25.878 | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | Date: February 2018 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | Project (Number/Name) TM3 / <i>TECHBASE MED DEFENSE (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 | FY 2019 |
| Program/project funding transferred to another funding line. | | | | |
| Title: 2) Bacterial Therapeutics Description: Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents. FY 2018 Plans: Initiate multiple efforts to advance candidate therapeutics, with a focus on non-traditional candidates, through preclinical evaluation toward IND and phase I clinical studies. Establish optimal dosing regimen of novel orally-delivered therapeutic in models of B. pseudomallei infection. Continue strategy to engage industry in the development of therapeutics for BWA indications through the evaluation of late development and/or FDA approved compounds for efficacy in pivotal Good Laboratory Practices Non-Human Primate (GLP NHP) models against aerosolized challenge of Yersinia pestis, Bacillus anthracis, or Francisella tularensis in support of submission of a supplemental New Drug Application (sNDA) under the Animal Rule. FY 2019 Plans: Continue multiple efforts to advance candidate therapeutics, with a focus on non-traditional candidates, through preclinical evaluation toward IND and phase I clinical studies. Complete optimization of dosing regimen and formulation of a novel orally-delivered therapeutic in models of B. pseudomallei infection. Continue strategy to engage industry in the development of therapeutics for Biowarfare agent indications through the evaluation of late development and/or FDA approved compounds for efficacy in pivotal Good Laboratory Practices Non-Human Primate (GLP NHP) models against aerosolized challenge of Yersinia pestis, Bacillus anthracis, or Francisella tularensis in support of submission of a supplemental New Drug Application (sNDA) under the Animal Rule. FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments. | | 10.913 | 19.386 | 21.286 |
| Title: 3) Bacterial/Toxin Vaccines Description: Evaluate the best single agent bacterial and toxin vaccines and pretreatments for effectiveness against aerosol challenge in large animal models. FY 2018 Plans: Complete initial T cell and B cell antigen discovery for Q Fever vaccine design and testing. Continue evaluation of live attenuated Tularemia vaccine candidates. Evaluate efficacy of mucosal delivery of ricin monoclonal antibody against ricin toxin in relevant animal model. Evaluate efficacy of next generation anthrax vaccine in combination with Protective-antigen (PA)-based vaccine in relevant animal models. Identify mechanism of immunity of next generation anthrax vaccine. Continue evaluation and manufacturing development of Burkholderia Outer Membrane Vesicle (OMV) vaccine. Complete botulinum toxin mAb | | 15.378 | 17.724 | 17.891 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | Date: February 2018 | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | Project (Number/Name) TM3 / <i>TECHBASE MED DEFENSE (ATD)</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 |
| <p>manufacturing development and release assay development. Manufacture product for clinical trials. Initiate new manufacturing and formulation studies and continue IND enabling preclinical animal modeling and GLP safety evaluation of bot mAb's.</p> <p>FY 2019 Plans: Complete validation of T cell and B cell epitopes and antigens for Q Fever vaccine design and testing. Complete down-selection of live attenuated Tularemia vaccine candidates for advancement into manufacturing and clinical development. Continue manufacturing development and investigative new drug (IND) enabling studies of Outer Membrane Vesicle (OMV) and other lead Burkholderia candidates based on results in animal models. Continue development of human monoclonal antibodies to ricin toxin selected from vaccinated volunteers. Continue evaluation of efficacy and conjugate production and formulation of capsule conjugate anthrax vaccine in combination with Protective-antigen (PA)-based vaccine. Define correlate of immunity of next generation CPS conjugate anthrax vaccine. Continue evaluation and manufacturing development of Burkholderia OMV vaccine. Continue animal-rule efficacy studies of multivalent monoclonal antibody cocktail for protection against A and B serotypes of botulinum neurotoxin in relevant animal models. Complete botulinum toxin mAb manufacturing and formulation development and release assay qualification and validation including reference standards. Complete botulinum toxin mAb manufacture and prepare IND. Initiate formulation development and efficacy studies of pentavalent mAb product against botulinum intoxication targeting serotypes ABCDE.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | | |
| <p>Title: 4) Biosurveillance (BSV)</p> <p>Description: Integrate existing disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced warning systems, and leverage and enhance advanced epidemiological models and algorithms for disease prediction, forecasting, 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 disease modeling, medical resource estimation and decision support tools. This effort will be realigned in FY19 to CB3 (Chemical Biological Defense) Threat Surveillance.</p> <p>FY 2018 Plans: Devices will continue to be tested at the OCONUS sites and data will be submitted to the BSVE and DTRA for analysis.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement: Program/project funding transferred to another funding line.</p> | | 4.552 | 4.326 |
| Title: 5) Diagnostic Device Platforms | | 17.130 | 8.482 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | Date: February 2018 | | |
| 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 2017 | FY 2018 | FY 2019 |
| <p>Description: 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. This effort will be realigned in FY19 to TM3 (Techbase Med Defense) Medical Diagnostics.</p> <p>FY 2018 Plans: Continue developing point-of-need diagnostic platforms with host biomarker diagnostic assays and testing performance. Continue evaluating metrics of host-based diagnostics with pathogen detection approaches in analytical and/or clinical environments. Continue genomic-based and proteomic-based comprehensive identification and characterization platform development for field forward capabilities. Continue high sensitivity immunoassay and protein detection platforms for clinical samples.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement: Program/project funding transferred to another funding line.</p> | | | | |
| <p>Title: 6) Neurologic Therapeutics</p> <p>Description: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to CWA. This effort involves the development of neuroprotectants, anticonvulsants, and improved therapies for brain enzyme reactivation. Supports eventual FDA licensure of new compounds or to identify licensed products for use in the treatment of chemical warfare casualties.</p> <p>FY 2018 Plans: Continue optimizing real-time microdialysis system. Continue using proof-of-concept in vivo experiments to measure neuroprotective effects of known and novel compounds. Continue maintaining the ADMET CoE to ensure capability for development and supporting regulatory science to facilitate FDA licensure of chemical therapeutics.</p> <p>FY 2019 Plans: Employ optimized real-time microdialysis system to support therapeutic candidate analysis and development. Continue using proof-of-concept in vivo experiments to measure neuroprotective effects of known and novel compounds. Continue maintaining the ADMET CoE to ensure capability for development and supporting regulatory science to facilitate FDA licensure of chemical therapeutics. Initiate advanced development of lead therapeutic candidates.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | 0.350 | 0.397 | 1.884 |
| Title: 7) Vaccine Platforms and Research Tools | | 7.610 | 2.948 | 2.976 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | Date: February 2018 | | |
| Appropriation/Budget Activity 0400 / 3 | | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | | Project (Number/Name) TM3 / <i>TECHBASE MED DEFENSE (ATD)</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | | FY 2017 | FY 2018 | FY 2019 |
| <p>Description: 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>FY 2018 Plans: Continue identification of bio-physiologic markers of alphavirus infection in NHPs. Continue development of OMV and nanoparticle vaccine platforms targeting Burkholderia and Francisella. Initiate development of native conformation membrane protein expression and presentation system. Select Venezuelan equine encephalitis virus (VEEV) and Eastern equine encephalitis virus (EEEV) formulations for advancement to next round of clinical studies.</p> <p>FY 2019 Plans: Continue development of methods for evaluation of non-lethal symptomology and biomarkers of alphavirus infection in NHPs. Continue development of OMV and nanoparticle vaccine platforms targeting Burkholderia, Francisella and Yersinia. Continue development of native conformation membrane protein expression and presentation system. Continue advancement of manufacturing and formulation for Venezuelan equine encephalitis virus (VEEV) and Eastern equine encephalitis virus (EEEV) for entry to clinical studies. Continue IND enabling studies with new formulation and delivery method for VEEV, EEV and WEEV vaccine.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | | | | |
| <p>Title: 8) Viral Therapeutics</p> <p>Description: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.</p> <p>FY 2018 Plans: Initiate small molecule and monoclonal antibody selection and evaluation in large NHP models for pan-ebola/ pan-filovirus and alphaviral therapeutic applications. Test efficacy of hemofiltration for treatment of cytokine-induced shock from filoviral infection. Continue monoclonal antibody development for broad spectrum capabilities.</p> <p>FY 2019 Plans: Continue small molecule and monoclonal antibody selection and evaluation in NHP models for pan-ebola/pan-filovirus and alphaviral therapeutic applications. Continue monoclonal antibody development for broad spectrum capabilities.</p> <p>FY 2018 to FY 2019 Increase/Decrease Statement:</p> | | | 11.097 | 7.495 | 5.350 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | Date: February 2018 | | |
| Appropriation/Budget Activity 0400 / 3 | | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | | Project (Number/Name) TM3 / <i>TECHBASE MED DEFENSE (ATD)</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | | FY 2017 | FY 2018 | FY 2019 |
| Decrease due to fact of life change in the program/project. | | | | | |
| Title: 9) Viral Vaccines | | | 5.500 | 6.210 | 6.269 |
| Description: Evaluates the best vaccine candidates for Alphaviruses and Filoviruses for effectiveness and duration of protective immune response against aerosol challenge in large animal models. Animal models will be developed to support FDA licensure of mature vaccine candidates. | | | | | |
| FY 2018 Plans: Continue manufacturing and formulation development for Alphavirus (WEVEE) vaccines. Continue assay development for Western, Eastern, and Venezuelan Equine Encephalitis Virus vaccines. Finalize manufacturing and assay development for vesicular stomatitis virus (VSV) trivalent Filovirus vaccine. Continue nonclinical and clinical safety development of trivalent filovirus vaccine covering Zaire Ebolavirus, Sudan Ebolavirus and Marburg Marburgvirus. Finalize animal model validation for filovirus vaccine licensure. | | | | | |
| FY 2019 Plans: Continue manufacturing and formulation development and initiate efficacy and safety studies for advanced Alphavirus (WEVEE) vaccines. Continue manufacturing and assay development for vesicular stomatitis virus (VSV) trivalent Filovirus vaccine with new manufacturer. Complete licensure development of Zaire ebolavirus vaccine. Continue development of an rVSV vaccine for Marburgvirus. Advance correlate of immunity validation for filovirus vaccines. Begin evaluation of candidate vaccines against arenavirus infection. Evaluate ability of candidates to elicit sterilizing immunity in the mucosa. | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Minor change due to routine program adjustments. | | | | | |
| Title: 10) Medical Diagnostics | | | - | - | 32.532 |
| Description: Make medical diagnostics ubiquitous and comprehensive against chemical and biological threats (including NTAs, pharmaceutical-based agents, and toxins) by advancing diagnostic innovations; investigating emerging technologies; ensuring medical diagnostics rapid adaptation to emerging threats; harvesting and synergizing the immense volume of diagnostic data; and aligning medical diagnostics capabilities with the Food and Drug Administration (FDA) pipeline and larger commercial supply chain. This effort will be realigned in FY19 from TM3 (Techbase Med Defense) Assays and Reagents and TM3 (Techbase Med Defense) Diagnostic Device Platforms. | | | | | |
| FY 2019 Plans: Complete high sensitivity immunoassay and protein detection platforms for clinical samples. Continue the development of assays and technologies for biological and chemical agent detection and characterization. Continue verification and testing performance of biomarker assays and reagents for point-of-need diagnostic platforms. Continue to optimize pipelines to improve unbiased | | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 0400 / 3 | | | | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | | | | Project (Number/Name) TM3 / <i>TECHBASE MED DEFENSE (ATD)</i> | | | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | | | | | | | | | FY 2017 | FY 2018 | FY 2019 |
| <p>pathogen discovery and/or detection in clinical samples. Complete efforts and studies on host response biomarker classifiers (viral versus bacterial). Continue the development of a chemical diagnostic platform to diagnose exposure to chemical agents for use in forward field settings or at the point-of-need. Continue incorporation of stability and pre-clinical studies for diagnostic assays in development to further support FDA pre-Emergency Use Authorization submissions. Initiate independent verification of sequencing protocols. Continue incorporation of stability and pre-clinical studies for diagnostic assays in development to further support pre-Emergency Use Authorization (EUA) submissions. Continue multi-echelon diagnostic testing and assessments of novel point of need medical diagnostics in low resource settings and austere environments. Initiate efforts to integrate or converge platform technologies to detect antimicrobial resistance/multidrug resistance. Initiate the investigation for designing biomarker verification/validation methods and activities. Initiate efforts to investigate the use of machine learning to develop diagnostic assays and/or predict assay erosion.</p> <p><i>FY 2018 to FY 2019 Increase/Decrease Statement:</i> Program/project funding transferred from another funding line.</p> | | | | | | | | | | | | |
| Accomplishments/Planned Programs Subtotals | | | | | | | | | | 88.629 | 92.846 | 88.188 |
| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | | |
| Line Item | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost | |
| • MB4: <i>MEDICAL BIOLOGICAL DEFENSE (ACD&P)</i> | 58.800 | 83.999 | 73.090 | - | 73.090 | 35.432 | 26.460 | 13.317 | 6.506 | Continuing | Continuing | |
| • MC4: <i>MEDICAL CHEMICAL DEFENSE (ACD&P)</i> | 4.816 | 5.165 | 2.790 | - | 2.790 | 4.675 | 3.975 | 7.098 | 7.098 | Continuing | Continuing | |
| • MB5: <i>MEDICAL BIOLOGICAL DEFENSE (EMD)</i> | 92.313 | 136.553 | 107.815 | - | 107.815 | 141.385 | 170.160 | 154.262 | 153.288 | Continuing | Continuing | |
| • MC5: <i>MEDICAL CHEMICAL DEFENSE (EMD)</i> | 51.903 | 47.388 | 62.092 | - | 62.092 | 38.576 | 40.607 | 31.746 | 25.740 | Continuing | Continuing | |
| • MB7: <i>MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)</i> | 6.999 | 11.950 | 9.850 | - | 9.850 | 3.728 | 6.060 | 6.532 | 2.969 | Continuing | Continuing | |
| Remarks | | | | | | | | | | | | |
| D. Acquisition Strategy | | | | | | | | | | | | |
| N/A | | | | | | | | | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | Date: February 2018 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | Project (Number/Name) TM3 / <i>TECHBASE MED DEFENSE (ATD)</i> |
| <u>E. Performance Metrics</u> N/A | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | | | | | | | | | Date: February 2018 | | |
|--|-------------|---------|---------|--------------|---|---------------|---------|---------|---|---------------------|------------------|------------|
| 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 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| TT3: TECHBASE TECHNOLOGY TRANSITION | - | 6.765 | 10.765 | 10.191 | - | 10.191 | 11.003 | 11.033 | 11.031 | 11.031 | Continuing | Continuing |

A. Mission Description and Budget Item Justification

Project TT3 validates high-risk/high-payoff technologies, concepts-of-operations, and a Joint Combat Developer 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. Upon conclusion of the technical and operational demonstrations, the user or sponsor provides a determination of the military utility and operational impact of the technology and capability demonstrated. Successfully demonstrated technologies with proven military utility can remain in place for future extended user evaluations, accepted into the advanced stages of the formal acquisition process, proceed directly into limited or full-scale production or be returned to the technical base for further development. This project addresses four family of products areas: Biological Resiliency, to include Biosurveillance; Integrated Early Warning, to include Remote Detection; Chemical and Biological Warfare Agent Destruction and Disablement; and Hazard Mitigation. Biological resiliency efforts are targeted to reduce biological threats. Integrated Early Warning is conducted through a coordinated program approach focused on layering Chemical and Biological Detection technologies and integrating CB threat indicators with rapid response actions. WMD Disablement and Destruction 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.

B. Accomplishments/Planned Programs (\$ in Millions)

| | FY 2017 | FY 2018 | FY 2019 |
|---|----------------|----------------|----------------|
| Title: 1) Experiment & Technology Demonstrations | 6.765 | 10.765 | 10.191 |
| Description: Project TT3 validates high-risk/high-payoff technologies and concepts-of-operations through the use of the Advanced Technology Demonstration (ATD), Rapid Military Utility Assessment (RMUA) processes and Demonstration Concept Development and Experimentation on initiative. Advanced Technology Demonstrations (ATDs) are Chemical Biological Defense Program (CBDP) efforts designed to demonstrate the maturity and potential of advanced technologies across the Sense/Shape/Shield/Sustain spectrum for enhanced military operational capability or cost effectiveness. The RMUA is a formal development and experimentation process with the Maneuver Support Center of Excellence (MSCOE) and the Joint Combat Developer that enables both material and non-material solutions through the identification and integration of innovative CB technologies. These new capabilities are demonstrated via an agile, short-timeline (6-12 month) to enable transition of mature technologies to Advanced Component Development and Prototype programs. The Demonstration Concept Development and Experimentation effort validates technology requirements and scopes future ATD programs with Warfighter stakeholders, including Combat Developers and Service representatives. This project addresses enterprise priority areas of Early Warning and Integrated & Layered Defense. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Chemical and Biological Defense Program | | Date: February 2018 | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i> | Project (Number/Name) TT3 / <i>TECHBASE TECHNOLOGY TRANSITION</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 |
| <p><i>FY 2018 Plans:</i> Initiate situational understanding at the tactical level for the comprehensive early warning ATD. Continue S&T integration activities for CB sensor technologies onto mobile platforms as part of the second phase of the comprehensive early warning ATD. Begin integration of wearable sensors as Phase 3 of the comprehensive early warning ATD. Continue transition activities with JPEO early warning ECD. Continue to conduct rapid military utility assessments and field experiments to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer. Initiate Warfighter Integration activities through baseline demonstrations and assessments in support of Integrated & Layered Defense.</p> <p><i>FY 2019 Plans:</i> Continue situational understanding at the tactical level and initiate situational understanding at the operational level for the comprehensive IEW ATD. Continue S&T integration activities for CB sensor technologies onto mobile platforms as part of the second phase of the comprehensive early warning ATD. Demonstrate integration of wearable sensors as part of the comprehensive early warning ATD. Demonstrate prototype end-to-end early warning capability at an OCONUS area of responsibility. Continue transition activities with advanced development and associated JPM program efforts supporting the CBDP IEW focus area. Continue to conduct RMUAs and field experiments to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer. Continue Demonstration Concept Development and Experimentation activities in support of Early Warning and Integrated & Layered Defense.</p> <p><i>FY 2018 to FY 2019 Increase/Decrease Statement:</i> Minor change due to routine program adjustments.</p> | | | |
| Accomplishments/Planned Programs Subtotals | | 6.765 | 10.765 |
| C. Other Program Funding Summary (\$ in Millions) | | | |
| N/A | | | |
| Remarks | | | |
| D. Acquisition Strategy | | | |
| N/A | | | |
| E. Performance Metrics | | | |
| N/A | | | |