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.
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.

<table>
<thead>
<tr>
<th>B. Program Change Summary ($ in Millions)</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018 Base</th>
<th>FY 2018 OCO</th>
<th>FY 2018 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous President's Budget</td>
<td>140.094</td>
<td>127.941</td>
<td>142.815</td>
<td>-</td>
<td>142.815</td>
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<td>Current President's Budget</td>
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<tr>
<td>Total Adjustments</td>
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<td>0.000</td>
<td>2.544</td>
<td>-</td>
<td>2.544</td>
</tr>
<tr>
<td>• Congressional General Reductions</td>
<td>-</td>
<td>-</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>• Congressional Directed Reductions</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>• Congressional Rescissions</td>
<td>-</td>
<td>-</td>
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<td>-</td>
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<tr>
<td>• Congressional Adds</td>
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<td>-</td>
<td></td>
<td>-</td>
<td>-</td>
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<tr>
<td>• Congressional Directed Transfers</td>
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<td>-</td>
<td></td>
<td>-</td>
<td>-</td>
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<tr>
<td>• Reprogrammings</td>
<td>-6.024</td>
<td>-</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>• SBIR/STTR Transfer</td>
<td>0.000</td>
<td>-</td>
<td></td>
<td>-</td>
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<tr>
<td>• Other Adjustments</td>
<td>0.000</td>
<td>-</td>
<td>2.544</td>
<td>-</td>
<td>2.544</td>
</tr>
</tbody>
</table>

**Change Summary Explanation**

Funding: N/A

Schedule: N/A

Technical: N/A
UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: FY 2018 Chemical and Biological Defense Program

Date: May 2017

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)

<table>
<thead>
<tr>
<th>Prior Years</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018 Base</th>
<th>FY 2018 OCO</th>
<th>FY 2018 Total</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022 Cost To Complete</th>
<th>Total Cost</th>
</tr>
</thead>
</table>

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)

**Title:** 1) Expeditionary Collective Protection

**Description:** Develop new technologies for soldiers to determine the remaining chemical vapor service life of their chemical warfare agent (CWA) filters.

**FY 2016 Accomplishments:**
Continued Residual Life Indicator (RLI) satellite filter cartridge system integration and surveillance of prototype RLI filters.

**FY 2017 Plans:**
Assess performance of optimized RLI satellite filter cartridge. Verify the RLI performance is correlated to that of the carbon bed in a CBRN collective protection filter. Establish the filter bed performance is effectively correlated with the RLI and extended with Guard Bed.

**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.

**Title:** 2) Material Contamination Mitigation

**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 2016 Accomplishments:**

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)

Chemical and Biological Defense Program

UNCLASSIFIED

Page 3 of 27

R-1 Line #43
B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th></th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed Point-of-Use Formulation (previously named Dial a Decon) effort and transitioned data to the program of record Joint Service General Purpose Decontaminant - Hardened Military Equipment (JSGPD-HME). Initiated laboratory scale development and testing for hot air biological decontamination effort to address sensitive equipment, platform interior, and aircraft decontamination needs, focusing on viral and vegetative bacterial efficacy and using a germinant to reduce the time needed to kill bacterial spores. Initiated laboratory scale development and test for responsive and resistant coatings efforts to enhance decontaminability as part of the systems approach to achieving efficacy goals.</td>
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<tr>
<td><strong>FY 2017 Plans:</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Transition sorbent decontaminant formulation effort to advanced development for immediate decontamination, focusing on efficacy testing and final formulation compatibility testing. Initiate room temperature ionic liquid decontaminant effort to address sensitive equipment decontaminant need (enzyme and catalytic) projects, specifically focusing on efficacy testing and formulation. Continue application of data gathered from surface science investigations to inform design to initiate development of the next generation of hazard mitigation technologies that include integration of multiple systems to achieve efficacy goals. Continue enhanced CB survivability and responsive coatings projects to enhance decontaminability as part of the systems approach to achieving efficacy goals. Demonstrate the wide-area decontamination hazard mitigation effort, which focuses on biological spore decontamination in a representative outdoor environment.</td>
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</tr>
<tr>
<td><strong>FY 2018 Plans:</strong></td>
<td></td>
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</tr>
<tr>
<td>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.</td>
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</tbody>
</table>

**Title:** 3) 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.

**FY 2016 Accomplishments:**
Continued efforts to engineer and manufacture system integration of multifunctional materials. Developed system integration approaches for incorporation of those materials in protective garments. Continued development of the Integrated Protective Fabric System (IPFS) lightweight ensembles with composite materials and omniphobic coatings optimized for lower thermal burden.

**FY 2017 Plans:**

<table>
<thead>
<tr>
<th></th>
<th>2.699</th>
<th>0.453</th>
<th>0.687</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)</td>
<td></td>
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</tbody>
</table>

Chemical and Biological Defense Program
## B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop and demonstrate fully integrated ensembles for full-spectrum hazards that support tactical operations for all services. Develop ensembles that include novel garment designs that integrate with body armor, helmet, cooling systems, breathing apparatuses, and combat loads that are scalable to mission demands which will fill a broad set of existing capability gaps for many diverse DoD units.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2018 Plans:</strong></td>
<td>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.</td>
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</tr>
<tr>
<td><strong>Title:</strong> 4) Personnel Contamination Mitigation</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Description:</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2017 Plans:</strong></td>
<td>Continue to develop new technologies to alleviate 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 to support warfighter operations, including the homeland defense mission. This effort also leverages the related BA2 development effort started in FY16.</td>
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</tr>
<tr>
<td><strong>Title:</strong> 5) Respiratory and Ocular Protection</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Description:</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2016 Accomplishments:</strong></td>
<td>Continued efforts to develop, fabricate, and evaluate hybrid system respirator technology prototypes. Transitioned a synthetic nano-structured material focused on toxic industrial chemical removal to the Joint Service General Purpose Mask (JS-GPM).</td>
<td></td>
</tr>
<tr>
<td><strong>FY 2017 Plans:</strong></td>
<td>Continue integration of respirator component technologies into a full-spectrum protection system which provides scalable protection. Research and development efforts will include nanotechnologies, anti-fogging materials, dynamic response breathing, oxygen storage and CO2 scrubbing.</td>
<td></td>
</tr>
<tr>
<td><strong>FY 2018 Plans:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>Title: 6) Biosurveillance (BSV)</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>-</td>
<td>2.643</td>
<td>2.532</td>
</tr>
</tbody>
</table>

**FY 2017 Plans:**
Continue biosurveillance analytic evaluations and various analytic capability development, including sequence data sharing, disease reemergence analytics, and pathogen spread visualizations in support of the Joint Program Management Office - Information Systems (JPM-IS). These efforts were developed in FY16 under BA3 TM3 Biological Diagnostics.

**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 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.

<table>
<thead>
<tr>
<th>Title: 7) Detection</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>4.159</td>
<td>4.066</td>
<td>3.235</td>
</tr>
</tbody>
</table>

**FY 2016 Accomplishments:**
Continued sequence based comprehensive identification and characterization platform development for field forward capability.

**FY 2017 Plans:**
Continue handheld sequencer based platforms for comprehensive identification and characterization for field forward capabilities.

**FY 2018 Plans:**
<table>
<thead>
<tr>
<th>Exhibit R-2A, RDT&amp;E Project Justification: FY 2018 Chemical and Biological Defense Program</th>
<th>Date: May 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriation/Budget Activity</td>
<td>PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)</td>
</tr>
<tr>
<td>R-1 Program Element (Number/Name)</td>
<td>Project (Number/Name)</td>
</tr>
<tr>
<td>0400 / 3</td>
<td>CB3 / CHEMICAL BIOLOGICAL DEFENSE (ATD)</td>
</tr>
</tbody>
</table>

B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>FY 2016 Accomplishments:</th>
<th>FY 2017 Plans:</th>
<th>FY 2018 Plans:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete the development of genomic sequencing based platforms protocols for comprehensive identification and characterization for field forward capabilities.</td>
<td>Continued implementation of new numerical schemes and performance optimization for transport and dispersion models. Continued enhancement of high-fidelity urban transport and dispersion. Continued configuration management of science and technology prototype to establish upgraded capabilities listed as valid requirements for HPAC/Joint Effects Model (JEM). Continued validation studies for waterborne transport models.</td>
<td>Continued 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title: 8) Hazard Prediction</th>
<th>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 industrial materials.</th>
<th>3.713 3.006 3.551</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>FY 2017 Plans:</th>
<th>FY 2017 Plans:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigated potential methods for implementation of the CB-1.</td>
<td>Investigated potential methods for implementation of the CB-1.</td>
</tr>
</tbody>
</table>

| Title: 9) Data Analysis | Description: Develop chemical, biological, radiological and nuclear 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. | 0.208 0.313 0.029 |
B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continue to implement the Chemical and Biological Agent Effects Manual Number 1 (CB-1) on DTRIAC STARS. Provide CBRN defense community access to CB-1.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FY 2018 Plans:**
Continue to provide CBRN defense community access to CB-1.

**Title:** 10) 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 CBRN incidents on decision-making. Focus areas include consequence management, population modeling, and knowledge management.

**FY 2016 Accomplishments:**
Continued system performance model (SPM) integration and advanced development for program-wide exploitation for collective and individual protection and contamination avoidance. Continued operational effects research and analysis efforts to provide objective, quantitative analysis in support of science and technology initiatives, material developments, operational guidance, and requirements setting.

**FY 2017 Plans:**
Continue system performance model integration and advanced development for program-wide exploitation for collective and individual protection and contamination avoidance. 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.

**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 (JECP) program.

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<tr>
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<tbody>
<tr>
<td>• CA4: CONTAMINATION AVOIDANCE (ACD&amp;P)</td>
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<td>42.308</td>
<td>29.211</td>
<td>-</td>
<td>29.211</td>
<td>33.181</td>
<td>27.908</td>
<td>20.208</td>
<td>14.131</td>
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### Exhibit R-2A, RDT&E Project Justification:

**FY 2018 Chemical and Biological Defense Program**

**Date:** May 2017

<table>
<thead>
<tr>
<th>Appropriation/Budget Activity</th>
<th>R-1 Program Element (Number/Name)</th>
<th>Project (Number/Name)</th>
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<tbody>
<tr>
<td>0400 / 3</td>
<td>PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)</td>
<td>CB3 / CHEMICAL BIOLOGICAL DEFENSE (ATD)</td>
</tr>
</tbody>
</table>

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

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<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>• <strong>DE4</strong>: DECONTAMINATION SYSTEMS (ACD&amp;P)</td>
<td>2.753</td>
<td>0.500</td>
<td>9.900</td>
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<td>9.900</td>
<td>7.477</td>
<td>6.281</td>
<td>12.773</td>
<td>9.539</td>
<td>Continuing</td>
<td>Continuing</td>
</tr>
<tr>
<td>• <strong>IS4</strong>: INFORMATION SYSTEMS (ACD&amp;P)</td>
<td>7.224</td>
<td>5.928</td>
<td>5.941</td>
<td></td>
<td>5.941</td>
<td>0.854</td>
<td>0.291</td>
<td>0.075</td>
<td>0.071</td>
<td>Continuing</td>
<td>Continuing</td>
</tr>
</tbody>
</table>

#### Remarks

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

N/A
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)

<table>
<thead>
<tr>
<th>Title: 1) Diagnostics - Medical</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
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<tbody>
<tr>
<td>Description:</td>
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</tbody>
</table>

**FY 2016 Accomplishments:**
Continued development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. Continued transition method development for identification and validation of NTAs in clinical samples to the Laboratory Response Network. All efforts transition to TM3 (Techbase Med Defense)/Assays and Reagents in FY17.

<table>
<thead>
<tr>
<th>Title: 2) Material Contamination Mitigation</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
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</table>

**FY 2016 Accomplishments:**
Completed Point-of-Use Formulation (previously named Dial a Decon) effort and transitioned data, including NTA efficacy data to the Joint General Purpose Decontaminant - Hardened Military Equipment program of record. Initiated laboratory scale...
### B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>3) Personnel Contamination Mitigation</td>
<td>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.</td>
<td>-</td>
<td>0.623</td>
<td>0.807</td>
</tr>
</tbody>
</table>

**FY 2017 Plans:**
Continue exploring combinations of complementary technologies to reduce the NTA contamination hazard faster with less outside support and develop revolutionary prototype systems that sense, respond, and signal contamination to support warfighter operations, including homeland defense mission; specifically, advancing formulation options and concepts of operations that include efficacy testing for multiple classes of NTAs.

**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.

| Title | 4) Respiratory and Ocular Protection | 0.693 | 0.226 | 0.357 |

**Title:** 3) Personnel Contamination Mitigation

**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 2017 Plans:**
Continue integration of a Government owned decontaminant formulation system, specifically addressing other classes of emerging threats. Integrate NTAs into the continuing responsive coatings projects to enhance decontaminability as part of the systems approach to achieving efficacy goals. Complete NTA efficacy testing for primary and other emerging threat NTAs to support the transition of the sorbent decontamination formulation effort. Examine room temperature ionic liquid decontaminant efficacy against representative agents from three categories of NTAs.

**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.

### Development and testing for zirconium hydroxide (Zr(OH)₄) to meet warfighter immediate and operational NTA decontamination needs.

Integrated NTAs, including newly identified emerging threats, into all material contamination mitigation projects.
### B. Accomplishments/Planned Programs ($ in Millions)

**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 2016 Accomplishments:**
Initiated efforts to investigate performance limitations of current and developmental respiratory protection systems against NTA challenges and investigate counter-measures to these specific limitations.

**FY 2017 Plans:**
Continued to investigate performance limitations current and development of respiratory protection systems against NTA challenges and investigate counter-measures to these specific limitations.

**FY 2018 Plans:**
Continue to develop closed circuit SCBA and novel respirator technologies against NTA challenges.

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>5) Pretreatments - Medical</td>
<td>Develop pretreatments and prophylactics that provide protection against NTAs and emerging chemical threats. Prophylactic bioscavengers should rapidly bind and detoxify a broad spectrum of compounds of interest (COIs).</td>
<td>6.649</td>
<td>2.129</td>
<td>5.164</td>
</tr>
<tr>
<td>6) Therapeutics - Medical</td>
<td>Efforts in this area support the confirmation of mechanisms of action for NTAs and emerging chemical threats by probable routes of field exposure and seek to refine standard experimental routes in order to identify/assess targets for</td>
<td>1.872</td>
<td>1.217</td>
<td>3.175</td>
</tr>
</tbody>
</table>
### FY 2016 Accomplishments:
Supported enabling technology to facilitate delivery of therapeutic regimen to the brain. Evaluated compounds in high-throughput in vitro screens for reactivation of cholinesterases in relevant species. Separated enantiomers of novel therapeutic and performed experiments to determine which isomer should be further developed as a medical countermeasure. Developed in vivo microdialysis assay to measure cholinesterase function in brain and effects of centrally active reactivators. Continued to refine and validate small animal models to support FDA licensure.

### FY 2017 Plans:
Continue support of enabling technology to facilitate delivery of therapeutics to the brain. Continue to validate small animal models to support FDA licensure of therapeutics used in the treatment of NTA exposures.

### FY 2018 Plans:

<table>
<thead>
<tr>
<th>Title: 7) Detection</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description: Detection NTA: Focuses on technologies to provide NTA detection capabilities.</td>
<td>8.569</td>
<td>10.351</td>
<td>11.840</td>
</tr>
</tbody>
</table>

**FY 2016 Accomplishments:**
Continued integration studies for Next Generation Chemical Detector (NGCD) Variant 1 based on Micro Electro-Mechanical Systems components for Gas Chromatography and Mass Spectrometry. Completed the development of test methodology to validate signatures for chemical aerosol threat materials, including traditional and non-traditional agents, and toxic industrial chemicals. Completed the transfer of validated signatures into the NGCD Variant 2.

**FY 2017 Plans:**
Complete integration studies and prototype delivery for transition to NGCD based on Micro Electro-Mechanical Systems components for Gas Chromatography and Mass Spectrometry.

**FY 2018 Plans:**

---

**Title:** 7) Detection

**Description:** Detection NTA: Focuses on technologies to provide NTA detection capabilities.
<table>
<thead>
<tr>
<th>B. Accomplishments/Planned Programs ($ in Millions)</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>0.204</td>
<td>0.240</td>
<td>0.238</td>
</tr>
<tr>
<td><strong>Title:</strong> 8) Modeling &amp; Simulation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Description:</strong> 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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2016 Accomplishments:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continued system performance model integration and development for program-wide exploitation for decontamination.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2017 Plans:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue sensitivity and validation studies on NTA source term models and update and expand NTA databases.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2018 Plans:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue system performance model integration and development for program-wide exploitation for decontamination.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Title:</strong> 9) Percutaneous Protection</td>
<td>0.650</td>
<td>-</td>
<td>0.157</td>
</tr>
<tr>
<td><strong>Description:</strong> 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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2016 Accomplishments:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed NTA evaluation and testing of IPFS lightweight ensembles.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2017 Plans:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Title:</strong> 10) Test &amp; Evaluation</td>
<td>0.676</td>
<td>0.802</td>
<td>0.802</td>
</tr>
<tr>
<td><strong>Description:</strong> Develops test and evaluation technologies and processes in support of NTA activities.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2016 Accomplishments:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed methodology and protocol development to support the evaluation of Next Generation Chemical Detector technologies.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2017 Plans:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### B. Accomplishments/Planned Programs ($ in Millions)

Initiate rapid prototyping and evaluation of chemical detection platforms.

**FY 2018 Plans:**
Continue rapid prototyping and evaluation of chemical detection platforms.

<table>
<thead>
<tr>
<th>Accomplishments/Planned Programs Subtotals</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20.633</td>
<td>17.173</td>
<td>23.655</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• CA4: CONTAMINATION AVOIDANCE (ACD&amp;P)</td>
<td>74.684</td>
<td>42.308</td>
<td>29.211</td>
<td>-</td>
<td>29.211</td>
<td>33.181</td>
<td>27.908</td>
<td>20.208</td>
<td>14.131</td>
<td>Continuing</td>
<td>Continuing</td>
</tr>
<tr>
<td> • IP4: INDIVIDUAL PROTECTION (ACD&amp;P)</td>
<td>5.473</td>
<td>3.235</td>
<td>5.145</td>
<td>-</td>
<td>5.145</td>
<td>2.000</td>
<td>1.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0</td>
<td>16.853</td>
</tr>
<tr>
<td>• MC4: MEDICAL CHEMICAL DEFENSE (ACD&amp;P)</td>
<td>1.060</td>
<td>5.681</td>
<td>5.165</td>
<td>-</td>
<td>5.165</td>
<td>2.790</td>
<td>4.675</td>
<td>3.975</td>
<td>7.098</td>
<td>Continuing</td>
<td>Continuing</td>
</tr>
</tbody>
</table>

**Remarks**

- **D. Acquisition Strategy**
  
  N/A

- **E. Performance Metrics**
  
  N/A
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.

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, and these efforts within science and technology (S&T) have been concentrated in advancing two areas: 1) regulatory science and 2) flexible manufacturing technologies and processes for MCMs. These MCMI efforts are enablers supporting the DoD Medical Countermeasures Advanced Development and Manufacturing (MCM-ADM) capability. The focus of these efforts is unchanged, but starting in FY17 all MCMI efforts under TM3 are transitioned into Bacterial Therapeutics to reduce budget management complexity and highlight the range of MCM efforts ongoing with the ADM.

B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>Title:</th>
<th>Assays and Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Development and verification of rapid, sensitive, and specific tests for the identification of 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.</td>
</tr>
<tr>
<td>FY 2016 Accomplishments:</td>
<td>Initiated efforts and studies on host response biomarker classifiers. Completed the development of 50 multi-plex assays utilizing the MAGPIX format (multiplexing platform capable of performing qualitative and quantitative analysis) for the detection of Burkholderia pseudomallei and its near neighbors. Completed process to extend Republic of Korea (ROK) Project Agreement to include a Phase II. Transitioned thirty-three molecular transition packages (MTP) to the Defense Biological Product Assurance Office (DBPAO). Transitioned 888 genomic sequences for Burkholderia pseudomallei and its near neighbors to Next Generation Diagnostics System, Increment 1 (NGDS Inc 1). Transitioned Nucleic Acid-Programmable Protein Array and clone library data for Vaccinia virus to DBPAO. Transitioned clinical laboratory improvement amendments (CLIA)-Waived protocols for the FilmArray Respiratory Panel to NGDS Inc 1. Transitioned genomic sequence data for Crimean -Congo hemorrhagic fever, Makona</td>
</tr>
<tr>
<td>FY 2016</td>
<td>11.335</td>
</tr>
<tr>
<td>FY 2017</td>
<td>16.488</td>
</tr>
<tr>
<td>FY 2018</td>
<td>25.878</td>
</tr>
<tr>
<td>FY 2016</td>
<td>FY 2017</td>
</tr>
<tr>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>0400 / 3</td>
<td>PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.698</td>
<td>16.033</td>
<td>19.386</td>
</tr>
</tbody>
</table>

**Exhibit R-2A, RDT&E Project Justification:** FY 2018 Chemical and Biological Defense Program  
**Date:** May 2017

**Appropriation/Budget Activity**

<table>
<thead>
<tr>
<th>Appropriation/Budget Activity</th>
<th>R-1 Program Element (Number/Name)</th>
<th>Project (Number/Name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0400 / 3</td>
<td>PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)</td>
<td>TM3 / TECHBASE MED DEFENSE (ATD)</td>
</tr>
</tbody>
</table>

**R-1 Line #43**

**Title:** 2) Bacterial Therapeutics

**Description:** Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents.

**FY 2016 Accomplishments:**

Conducted evaluation of an FDA approved compound for efficacy in pivotal GLP NHP studies against an aerosolized challenge of F. tularensis in support of submission of a supplemental new drug application (sNDA) under the Animal Rule. Down selected between novel ribosome inhibitors and a novel topoisomerase inhibitor as therapeutics for priority bacterial pathogens. Continued non-clinical research required to submit IND applications to the FDA for additional products. Continued supportive pivotal GLP studies to further the advancement of both novel and approved therapeutics for limited priority pathogen indications under the Animal Rule.

**FY 2017 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 informatics. Evaluate optimization and enhancement of updated bioinformatics platform in the field including efforts in the ROK.

**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 informatics. Continue evaluating optimization and enhancement of updated bioinformatics platform in the field including efforts in the ROK. Initiate investigations to maturate 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.
## Exhibit R-2A, RDT&E Project Justification: FY 2018 Chemical and Biological Defense Program

<table>
<thead>
<tr>
<th>Appropriation/Budget Activity</th>
<th>R-1 Program Element (Number/Name)</th>
<th>Project (Number/Name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0400 / 3</td>
<td>PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)</td>
<td>TM3 / TECHBASE MED DEFENSE (ATD)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expand evaluation of FDA approved compounds for efficacy in pivotal GLP non-human primate models against aerosolized challenge of Yersinia pestis, Bacillus anthracis, or Francisella tularensis in support of submission of a sNDA under the Animal Rule. Combinatorial testing of FDA approved drugs for efficacy and decreased development of resistance. Submission of an IND to the FDA for a small molecule inhibitor for the treatment of Burkholderia pseudomallei. Continue non-clinical research to advance additional therapeutic products with the goal of submission of an IND to the FDA. Work previously funded under TM3/MCMI to evaluate and develop platforms for enablers of the advanced development of medical countermeasures will be continued here.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FY 2018 Plans:</td>
<td>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 GLP NHP models against aerosolized challenge of Yersinia pestis, Bacillus anthracis, or Francisella tularensis in support of submission of a sNDA under the Animal Rule.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Title:</strong> 3) Bacterial/Toxin Vaccines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Description:</strong> Evaluate the best single agent bacterial and toxin vaccines for effectiveness against aerosol challenge in large animal models.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2017 Plans:</strong></td>
<td>Conduct feasibility studies to assess efficacy of lead type A Francisella tularensis (Tularemia) vaccine prototypes. Demonstrate feasibility and efficacy of combinations of vaccines designed with different antigens to protect against aerosolized, engineered pathogens in animal models. Assess feasibility of prototype oral Bacillus anthracis (anthrax) vaccines in small animal model. Complete tri-target and penta-target formulations of monoclonal antibody-based pretreatment against botulinum neurotoxin. Continue studies utilizing human monoclonal antibodies against ricin toxin in assay development and post-exposure prophylaxis models.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FY 2018 Plans:</strong></td>
<td>6.393</td>
<td>15.698</td>
<td>17.724</td>
</tr>
</tbody>
</table>
### B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
</table>

**Title:** 4) Biosurveillance

**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.

**FY 2016 Accomplishments:**
Completed the development and testing of a fieldable "smart trap" for long-term autonomous surveillance of arboviruses. Continued the development of the BSV Ecosystem to include analyst collaboration tools, advanced analytics, and analyst workbench. Continued the development of various biosurveillance analytic capabilities including a surveillance window app (SWAP), a suite of five epidemiological tools for integration into the BSV Ecosystem, and a BSV Ecosystem evaluation support capability. Completed OCONUS clinical testing of first set of devices initially established during the 24 Month Challenge and identified the second set of devices, including new platforms and assay, that will be deployed to the OCONUS sites for clinical testing.

**FY 2017 Plans:**
Complete the development of the BSV Ecosystem platform to include analyst collaboration tools, advanced analytics, and analyst workbench. Complete the development of various biosurveillance analytic capabilities including a SWAP, and a suite of epidemiological forecasting and prediction tools. Continue the field forward diagnostic evaluation capability to assess technical feasibility and limitations of deploying point of need diagnostics in austere environments.

**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.

<table>
<thead>
<tr>
<th>Title: 5) Chemical Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.342</td>
</tr>
<tr>
<td>-</td>
</tr>
<tr>
<td>-</td>
</tr>
</tbody>
</table>
### B. Accomplishments/Planned Programs ($ in Millions)

<table>
<thead>
<tr>
<th>Description</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6) Diagnostic Device Platforms</strong></td>
<td>19.149</td>
<td>16.354</td>
<td>8.482</td>
</tr>
</tbody>
</table>

**Description:** Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.

**FY 2016 Accomplishments:**
Continued the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs in clinical samples. All efforts transition to TM3 (Techbase Med Defense)/Assays and Reagents in FY17.

**FY 2017 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. Complete the development of candidate devices for potential transition to support the development of point of care diagnostic capabilities. Continue development of hardware solutions and assay formats to enable point of need diagnostic capabilities. Continue optimization and enhancement of updated bioinformatics platform to support genomic and clinical informatics.

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

<table>
<thead>
<tr>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.467</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Title:** 7) Medical Countermeasures Initiative

**Description:** 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.

**FY 2016 Accomplishments:**
Continued 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 to develop agile, flexible manufacturing processes that are amenable to the DoD Advanced Development and Manufacturing capability (ADMc). All efforts transitioned to TM3 (Techbase Med Defense)/Bacterial Therapeutics in FY17.

**FY 2018 Plans:**

| 1.064 | 0.405 | 0.397 |

**Title:** 8) Neurologic Therapeutics

**Description:** 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 therapies for brain enzyme reactivation. Supports eventual Food and Drug Administration (FDA) licensure of new compounds or to identify licensed products for use in the treatment of chemical warfare casualties.

**FY 2016 Accomplishments:**
Established high-throughput, in vitro assays to test known therapeutics for reactivation capability of cholinesterase inhibited by selected NTAs. Initiated development of real-time microdialysis system to monitor behavior of animal treated with reactivators. Initiated proof of concept, in vivo experiments to monitor neuroprotective properties of therapeutics. Maintained ADMET CoE to ensure capability for supporting regulatory science to facilitate FDA licensure.

**FY 2017 Plans:**
Maintain the ADMET CoE partnership and capability to ensure capability for development of and supporting regulatory science to facilitate FDA licensure of chemical therapeutics.

**FY 2018 Plans:**
**Title:** 9) Toxin Therapeutics

**Description:** Identify, optimize and evaluate potential therapeutic candidates effective against biological toxin threat agents.

**FY 2016 Accomplishments:**
Completed characterization and evaluation of humanized pentavalent antibody cocktail to prevent and/or treat BoNT intoxication, advancing to preclinical studies. Completed testing of novel small molecule inhibitors in NHP model of BoNT A intoxication for efficacy. Finalized preclinical studies to advance antibody based therapeutic for staphylococcal enterotoxin B intoxication into phase I clinical trials.

<table>
<thead>
<tr>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.961</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**FY 2017 Plans:**
Down-select target antigens based on immunogenicity for Yersinia pestis (plague), Coxiella (Q-fever) and other relevant indications for production in plant-based vaccine platform. Continue platform vaccine assessment activities: Explore antigen candidates for type A Francisella tularensis (Tularemia) using the RNAactive vaccine platform technology. (Moved from TM3 - MCMI.) Further evaluate and define the DNA-based and nanoparticle vaccine platforms and targeted vaccine delivery systems. (Transitioned from TM2 - Vaccine Platforms and Research Tools.)

**FY 2018 Plans:**
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.

<table>
<thead>
<tr>
<th>Title: 11) Viral Therapeutics</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.</td>
<td>6.870</td>
<td>6.198</td>
<td>7.495</td>
</tr>
</tbody>
</table>

**FY 2016 Accomplishments:**
Evaluated immunotherapies for alphaviruses in small animal and NHP models. Continued a repurposing screening program to determine the efficacy of FDA approved compounds against emerging infectious diseases. Continued 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.

**FY 2017 Plans:**
Continue to develop and evaluate broad spectrum therapies against various strains of alphaviruses. Evaluate human plasma from people exposed to the Sudan strain of Ebola to optimize a monoclonal or polyclonal cocktail for use as a prophylactic. Support diagnostic evaluation of clinical samples from West Africa to assess the efficacy of immune plasma from Ebola survivors as a potential treatment.

**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.

<table>
<thead>
<tr>
<th>Title: 12) Viral Vaccines</th>
<th>7.933</th>
<th>5.500</th>
<th>6.210</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
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</tr>
</tbody>
</table>

**FY 2016 Accomplishments:**
Continued to support Alphavirus and Filovirus vaccine candidates by determining correlates of protective immunity. Continued natural history studies for Alphaviruses (W/E/VEEV) to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure. Demonstrated proof-of-concept safety and immunogenicity with a monovalent Filovirus vaccine candidate. Developed and evaluated bridging strategies for interim fielding capability readiness.

**FY 2017 Plans:**
Exhibit R-2A, RDT&E Project Justification: FY 2018 Chemical and Biological Defense Program

Date: May 2017

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


**FY 2018 Plans:**

### FY 2018 Plans:

### Accomplishments/Planned Programs Subtotals

<table>
<thead>
<tr>
<th></th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

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

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>• MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&amp;P)</td>
<td>68.160</td>
<td>65.648</td>
<td>83.999</td>
<td>-</td>
<td>83.999</td>
<td>73.090</td>
<td>35.432</td>
<td>26.460</td>
<td>13.317</td>
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<tr>
<td>• MC4: MEDICAL CHEMICAL DEFENSE (ACD&amp;P)</td>
<td>1.060</td>
<td>5.681</td>
<td>5.165</td>
<td>-</td>
<td>5.165</td>
<td>2.790</td>
<td>4.675</td>
<td>3.975</td>
<td>7.098</td>
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<tr>
<td>• MB5: MEDICAL BIOLOGICAL DEFENSE (EMD)</td>
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<td>-</td>
<td>136.553</td>
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<tr>
<td>• MC5: MEDICAL CHEMICAL DEFENSE (EMD)</td>
<td>64.773</td>
<td>39.504</td>
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<td>47.388</td>
<td>62.092</td>
<td>38.576</td>
<td>40.607</td>
<td>31.746</td>
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### Remarks

D. Acquisition Strategy

N/A
**UNCLASSIFIED**

**Exhibit R-2A, RDT&E Project Justification: FY 2018 Chemical and Biological Defense Program**

<table>
<thead>
<tr>
<th>Appropriation/Budget Activity</th>
<th>R-1 Program Element (Number/Name)</th>
<th>Project (Number/Name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0400 / 3</td>
<td>PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)</td>
<td>TM3 / TECHBASE MED DEFENSE (ATD)</td>
</tr>
</tbody>
</table>

**E. Performance Metrics**

N/A
UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: FY 2018 Chemical and Biological Defense Program

Date: May 2017

Appropriation/Budget Activity
0400 / 3

R-1 Program Element (Number/Name)
PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)

Project (Number/Name)
TT3 / TECHBASE TECHNOLOGY TRANSITION

<table>
<thead>
<tr>
<th>COST ($ in Millions)</th>
<th>Prior Years</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018 Base</th>
<th>FY 2018 OCO</th>
<th>FY 2018 Total</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
<th>Cost To Complete</th>
<th>Total Cost</th>
</tr>
</thead>
</table>

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)

**Title:** 1) Experiment & Technology Demonstrations

**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 Warfighter Integration Demonstration, Joint Exercise and Transition initiative. 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. The Warfighter Integration initiative supports Combating WMD missions through the identification and integration of innovative technologies to demonstrate new capabilities via an agile, short-timeline (6-12 month) to enable transition of mature technologies to Advanced Component Development and Prototype programs. This project addresses enterprise priority areas of Early Warning and Integrated & Layered Defense.

**FY 2016 Accomplishments:**
Evaluated prototypes and existing technologies for disablement activities in support of key operational planning scenarios. For the DoD/DHS collaborative biosurveillance ATD, completed technology and CONOPS/TTP development and system integration of information systems for the whole of Government and demonstrated system operation. Continued to conduct rapid military utility...
B. Accomplishments/Planned Programs ($ in Millions)

Assessments and field experiments process to assess early technology capability contributions, in collaboration with the CBP joint Combat Developer and with outcomes to support warfighter requirements and capability development. Initiated risk reduction activities for a comprehensive early warning ATD in FY17. Began development of an architecture for the integration of sensor and mobile platforms along with methods of information sharing to enable early warning in forward deployed locations.

**FY 2017 Plans:**
Continue to develop and demonstrate prototypes and technologies for the WMD expeditionary disablement ATD which will address WMD rapid disablement and destruction program area in support of key operational planning scenarios. Initiate S&T integration activities for CB sensor technologies onto mobile platforms as part of the comprehensive early warning ATD. Conduct risk reduction activities for the development and integration of wearable sensors as part of the comprehensive early warning ATD. Continue to conduct rapid military utility assessments and field experiments to assess early technology capability contributions, in collaboration with the CBP joint Combat Developer. Continue risk reduction activities through baseline assessments in preparation for a mass casualty decontamination and medical support ATD.

**FY 2018 Plans:**
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 CBP joint Combat Developer. Initiate Warfighter Integration activities through baseline demonstrations and assessments in support of Integrated & Layered Defense.

<table>
<thead>
<tr>
<th></th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
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</thead>
<tbody>
<tr>
<td>Accomplishments/Planned Programs Subtotals</td>
<td>7.206</td>
<td>7.821</td>
<td>10.765</td>
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</table>

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A