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Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Chemical and Biological Defense Program **Date:** May 2021

Appropriation/Budget Activity 0400: <i>Research, Development, Test & Evaluation, Defense-Wide / BA 3: Advanced Technology Development (ATD)</i>	R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
Total Program Element	-	209.552	191.001	197.824	-	197.824	-	-	-	-	-	-
CB3: <i>Chemical Biological Defense (ATD)</i>	-	26.426	27.448	27.146	-	27.146	-	-	-	-	-	-
ET3: <i>Emerging Threats (ATD)</i>	-	0.000	0.000	6.000	-	6.000	-	-	-	-	-	-
NT3: <i>Non-Traditional Agents Defense (ATD)</i>	-	28.344	15.308	18.396	-	18.396	-	-	-	-	-	-
TM3: <i>Techbase Medical Defense (ATD)</i>	-	142.123	137.829	137.495	-	137.495	-	-	-	-	-	-
TT3: <i>Technology Transition (ATD)</i>	-	12.659	10.416	8.787	-	8.787	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

The projects in this program element (PE) demonstrate technologies supporting transition to advanced component development for 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 early warning 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.

Individual projects include:

- Chemical Biological Defense (CB3): demonstrations of CB physical science defense technologies including biological detection, chemical detection, digital battlespace management, protection, and decontamination.

- Emerging Threats (ET3): identify and develop scientific solutions, or to modernize capabilities, that allow for a more rapid response to emerging threats.

- Non-Traditional Agents (NTA) Defense (NT3): supports all efforts (both medical and non-medical) including chemical diagnostics, medical pretreatments, therapeutics, detection, and protection and hazard mitigation. Starting in FY21, a portion of the NTA lines have been merged into RDT&E Projects CB3, Chemical Biological Defense, and TM3, Techbase Medical Defense. The administrative change is intended to improve S&T budget agility and transition efficiency.

- Techbase Medical Defense (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.

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- Technology Transition (TT3): validates high-risk/high-payoff technologies, concepts-of-operations, and a Joint Combat Developer concept development and experimentation process to significantly improve Warfighter capabilities in preparation for transition of mature chemical and biological (CB) defense technologies to advanced development programs.

The CBDP S&T Advanced Technology Development stakeholders: The U.S. Army Combat Capabilities Development Command Chemical Biological Center (DEVCOM CBC), 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.

Work conducted under this PE will transition to and will provide risk reduction for Advanced Component Development and Prototypes (PE 0603884BP) and System Development and Demonstration (PE 0604384BP) activities.

B. Program Change Summary (\$ in Millions)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total
Previous President's Budget	175.486	188.001	188.479	-	188.479
Current President's Budget	209.552	191.001	197.824	-	197.824
Total Adjustments	34.066	3.000	9.345	-	9.345
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.000	3.000			
• Congressional Directed Transfers	0.000	-			
• Reprogrammings	35.165	-			
• SBIR/STTR Transfer	-1.099	-			
• Other Adjustments	0.000	-	9.345	-	9.345

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: CB3: *Chemical Biological Defense (ATD)*

Congressional Add: *High Air Flow ChemBio Filtration System Enhancement*

	FY 2020	FY 2021
	-	3.000
Congressional Add Subtotals for Project: CB3	-	3.000
Congressional Add Totals for all Projects	-	3.000

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Appropriation/Budget Activity
0400: *Research, Development, Test & Evaluation, Defense-Wide / BA 3: Advanced Technology Development (ATD)*

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

Change Summary Explanation

Funding: FY20 (+\$35.163 Million): Internal Reprogramming (FY20-31 IR) for the Coronavirus Aid, Relief, and Economic Security (CARES) Act (+\$26.300 Million); below threshold reprogramming increase for COVID-19 SARS CoV-2 vaccine development project (+\$5.404 Million), and medical defense pretreatments efforts (+\$3.459 Million).

FY20 (-\$1.099 Million): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts.

FY21 (+\$3.000 Million): Congressional Add for High Air Flow Chemical Biological (CB) Filtration System Enhancement.

FY22 (+\$9.345 Million): Increase for 1) Emerging Threat Rapid Response Capabilities, 2) COVID-19 SARS-CoV-2 vaccine development, and 3) to accelerate efforts to develop and deliver nerve agent medical countermeasures (+\$12.111 Million). Departmental inflation/travel adjustments (-\$2.766 Million).

Schedule: N/A

Technical: N/A

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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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
CB3: <i>Chemical Biological Defense (ATD)</i>	-	26.426	27.448	27.146	-	27.146	-	-	-	-	-	-
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Project CB3 develops technology advancements for joint service application in the areas of digital battlespace management technologies, protection/ hazard mitigation and detection. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. A portion of Project NT3, Techbase Non-Traditional Agents Defense, will merge into this Project starting in FY21.

Individual efforts in this project include:

- Digital battlespace management focuses on situational awareness and threat agent applications, analytic applications platform for operational situational awareness, non-traditional detection sciences, tactical decision aids, and advanced computational methods.
- 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.
- Non-Traditional Agent (NTA) Defense includes chemical diagnostics, medical pretreatments, therapeutics, detection, and protection and hazard mitigation.

FY20-22 reorganizes, renames legacy Bullet titles and introduces new Bullets (Thrust Areas). These new "Thrust" titles are in line with the CBDP Core Capability Areas and intended to provide more detail and traceability from the S&T program to advanced development.

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

	FY 2020	FY 2021	FY 2022
Title: 1) CARES Act - Dial A Threat	0.495	-	-
Description: This effort will add additional tasks to provide a COVID detection/diagnostic assay, optimize sample preparation methods for SARS CoV-2, and evaluate the performance of CRISPR based assays for SARS CoV-2.			
Title: 2) CARES Act - EpiGrid, Advanced Capabilities for Human Health Effects Modeling, Interior Modeling	1.000	-	-
Description: Expand and enhance epidemiological modeling capabilities to allow for modeling of COVID-19 in populations. Enhance hazard prediction capabilities for use in COVID-19 scenarios.			
Title: 3) CARES Act - Rapid Detection and Identification of Biological Events Testing	0.081	-	-

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Description: Further evaluate Zeteo Tech BioFlyte prototype which is a MALDI-TOF MS instrument and supplement the library build with SARS CoV-2 in order to benchmark the prototype instrument compared to other MS technologies for desired DoD and Defense applications.</p>			
<p>Title: 4) CARES Act - RATE Operationalization</p> <p>Description: Rapidly enhance non-invasive physiological detection algorithms for pre-symptomatic prediction of COVID-19 infection. Conduct multiple, large cohort studies to include warfighters across the Services and other DoD personnel to collect, analyze and interpret data to improve early detection algorithms.</p>	6.490	-	-
<p>Title: 5) Expeditionary Collective Protection</p> <p>Description: Develop new technologies for soldiers to determine the remaining chemical vapor service life of their chemical warfare agent (CWA) filters. This effort is transitioning to the Air Purification Enhancements thrust area starting in FY21.</p>	0.639	-	-
<p>Title: 6) Air Purification Enhancements</p> <p>Description: This effort supports the Expeditionary Collective Protection (CP) Core Capability Area. Existing CP systems have high life cycle costs driven by maintenance and limited service life. Science & Technology efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Complete field-testing and sampling Residual Life Indicator (RLI) filters at fixed sites and provide final report. - Transition Residual Life Indicator (RLI) filters to the Collective Protection Modernization Program of Record. - Continue to scale up manufacture of novel filter bed materials and integrate into filters for testing against threat agents of interest. Initiate materials testing for effectiveness against novel threats for Next Generation Filtration systems. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue materials testing for effectiveness against novel threats for Next Generation Filtration systems. - Incorporate novel materials into Collective Protection (ColPro) systems that increase the performance against agents delivered in all states of matter (vapor, aerosol, and liquid) in operationally relevant environments. - Engineer novel filter bed materials for chemical agent destruction, integrate them into next generation filters, and develop methods to assess filter performance in an operationally-relevant environment. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>	-	0.237	0.287
<p>Title: 7) Respiratory and Ocular Protection</p>	3.683	-	-

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>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). This effort is being separated into two thrust areas starting in FY21: All-Hazards & Respiratory Protection and Multifunction Materials for Protection.</p>			
<p>Title: 8) All-Hazards & Respiratory Protection</p> <p>Description: This effort supports the Respiratory and Ocular Protection Core Capability Area. Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit Self-Contained Breathing Apparatus.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue to explore trade space for next generation general purpose mask. - Continue development of systems that provide chemical biological respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system. - Complete system testing and transition cooling garment systems to Uniform Integrated Protection Ensemble Family of Systems Program of Record. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Transition lightweight protective garment for all hazards environments to Uniform Integrated Protection Ensemble Family of Systems Program of Record - Complete development of systems that provide chemical biological respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system. - Develop next generation respiratory protection technology in the form of a low-burden, non-contact powered respirator with novel filter designs that integrates with Warfighter technologies and reduces encumbrance. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p>	-	1.718	0.814
<p>Title: 9) Multifunction Materials for Protection</p> <p>Description: This effort supports the Respiratory and Ocular Protection, Percutaneous Protection, Expeditionary Collective Protection, Materiel Contamination Mitigation, and Personnel Contamination Mitigation Core Capability Areas. Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual</p>	-	1.260	1.105

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents.				
<p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to feed air purification enhancement. - Continue to integrate engineered reactive/catalytic nano-structure materials (derived from BA2 efforts) into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to feed air purification enhancement. - Continue to integrate engineered reactive/catalytic nano-structure materials (derived from BA2 efforts) into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. - Test and transition self-decontaminating, reusable protective garments (derived from BA2 efforts) of composite textiles with a reactive barrier, improved protection, and reduced thermal burden/life-cycle costs for insertion into the Uniform Integrated Protection Ensemble Family of Systems Program of Record. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>				
<p>Title: 10) Warning and Reporting</p> <p>Description: Develop a framework for integrating and correlating timely, relevant information sources. Investigate new approaches and methodologies such as machine learning, artificial intelligence, and advanced data analysis to accelerate analytical processes and provide early warning of chemical and biological threats. This effort is transitioning to the CBRN Battlespace Surveillance, Alerting & Response thrust area starting in FY21.</p>		1.021	-	-
<p>Title: 11) CBRN Battlespace Surveillance, Alerting & Response</p> <p>Description: To improve upon the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. JSTO will expand on developing predictive CB exposure algorithms based on non-invasively collected human biomarkers. Current predictive algorithms in development by JSTO are based on large in-hospital datasets from patients with comorbidities. Improving on the applicability and efficacy of these algorithms will focus on large, real-time human data collects of chemical and biological agent / agent proxy exposures. Additionally, studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. This capability will enable early implementation</p>		-	2.160	4.848

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>of countermeasures such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. The maturation of algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity.</p> <p>FY 2021 Plans: - Improve algorithms development that leverage non-invasive physiological monitoring devices to provide earlier warning of chemical and biological agent exposure.</p> <p>FY 2022 Plans: - Continue the improvement of algorithms that leverage non-invasive physiological monitoring devices to provide earlier warning of chemical and biological threats and/or exposure. - Continue the advancement of standoff physiological monitoring capabilities. - Continue to develop predictive algorithms and analytic tools utilizing Artificial Intelligence (AI) and ML techniques to allow for rapid response to Emerging Threats.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p>				
<p>Title: 12) Decision Analysis and Management</p> <p>Description: Enable the prediction of chemical and biological hazards, exposures, casualties, and infections along with providing timely and accurate warnings and recommended courses of action. Develop methods to utilize non-traditional detection methods to provide indications of Chemical and Biological exposure risk. This effort is being separated into two thrust areas starting in FY21: CBRN Decision Aids and CBRN Situational Awareness.</p>		5.424	-	-
<p>Title: 13) CBRN Decision Aids</p> <p>Description: In order to unencumber the warfighter at the tactical edge, continue to develop and field CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Capabilities will focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. During this time period, a focus will be put on developing a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards.</p> <p>Another area of focus will be the development of Autonomous Asset Guidance. This capability will be used in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize the use of Autonomous Assets and reduce the burden incurred by the warfighter in order to operate them. This capability will also aim to incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.</p>		-	1.150	1.400

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue the development and porting of decision support plug-ins for integration with Tactical Assault Kit (TAK), including the Android, web, Windows OS, and Virtual Reality (VR) and Augmented Reality (AR) versions to further leverage the TAK infrastructure and cross-community tools. - Initiate use of Graphics Processing Units (GPUs) for faster than real-time high resolution hazard prediction modeling capabilities and initiate user testing. - Continue development of approaches to translate raw sensor data and publish to a common standard. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue the improvement of decision support plug-ins for integration with TAK, including the Android, web, Windows OS, and virtual and augmented reality versions to further leverage the TAK infrastructure and cross-community tools. - Further develop the use of GPUs for faster than real-time high resolution hazard prediction modeling capabilities and initiate user testing. - Finalize the development of approaches to translate raw sensor data and publish to a common standard. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>			
<p>Title: 14) CBRN Situational Awareness</p> <p>Description: To enhance CB Situational Awareness, JSTO will expand the types of threats that can be modeled with hazard assessment capabilities to include fixed-wing and rotary-wing drones of interests. These capabilities will allow for single drones and swarms to be modeled.</p> <p>Virtual Reality (VR) and Augmented Reality (AR) technologies will be leveraged to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Virtual training environments will be developed to implement, visualize and account for hazard source terms and plumes generated by transport and dispersion (T&D) models. Augmented Reality applications will also be explored for tactical use to maximize warfighter CB situational awareness on the battlefield.</p> <p>JSTO will modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems to operationalize Reachback support. JSTO will further enhance hazard modeling by creating a seamless indoor-to-outdoor T&D modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. New state-of-the-art computational fluid dynamics modeling techniques and their exploitation of the latest computing resources will be leveraged to increase both speed and accuracy.</p>	-	4.948	5.016

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>JSTO will develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Epidemiological models will be developed that quantify and visualize mission operational impacts from exposure to, and spread of, infectious biological threat agents to DoD relevant populations. Additionally, JSTO will leverage Threat Agent Science (TAS) data to enhance capabilities for modeling health effects and host pathogen interactions from exposures to traditional and non-traditional CB agents. This will provide the warfighter with more accurate casualty estimates accounting for human health effects.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue configuration management of science and technology prototype for transition of upgraded capabilities. - Continue performance enhancements for T&D models, particularly for urban environments. - Further develop a comprehensive infectious disease epidemiological modeling applications for disease prediction, forecasting, medical planning and treatment. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue configuration management of science and technology prototype for transition of upgraded capabilities. - Continue improvement of performance enhancements for T&D models, particularly for urban environments. - Continue the development of comprehensive infectious disease epidemiological modeling applications for disease prediction, forecasting, medical planning and treatment. - Continue to enhance CB situational awareness capabilities for integration into Head up Display (HUD) technologies for tactical use. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p>			
<p>Title: 15) Detection</p> <p>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 includes 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. This effort is being separated into five thrust areas in FY21: Distributed CB Reconnaissance, Enhanced/Emerging Biothreat Sensing, Expeditionary Analytical Toolkit (ExAnT), Unattended Perimeter Monitoring, Unconventional Detection Modality.</p>	5.356	-	-
<p>Title: 16) Distributed CB Reconnaissance</p>	-	3.216	2.079

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Description: Develop distributed chemical and biological reconnaissance tools to enhance early warning and situation awareness of chemical and biological threats to include low cost point sensor and sensing/collection systems for manned and unmanned platforms.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue refinement and testing of sensors to achieve a more robust system that can decipher between threats and non-threats. - Examine potential solutions for augmenting and replacing current paper-based technologies. - Develop relevant capabilities to address current and emerging threats. - Development of Artificial Intelligence and Machine Learning capabilities to support integrated early warning, sensor networking, and autonomous sensing. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Incorporate sensors into maneuver autonomy to enhance biological threat reduction. - Develop innovative sensor solutions to increase situational awareness and provide operational advantage. - Sensor development will include integration of technologies such as photonics and Waveguide-Enhanced Raman Spectroscopy (WERS) into detectors as sensor arrays. - Develop low-cost, low-burden detection technologies to support tactical and dismounted site assessment missions. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Program/project funding transferred from another funding line.</p>			
<p>Title: 17) Enhanced/Emerging Biothreat Sensing</p> <p>Description: Establish robust capability to assess emerging and enhanced biological threats to rapidly develop biosensors for detecting emerging or enhanced biological threats. Quickly develop adaptable, analyte-agnostic laboratory and field-forward detection capabilities to provide a spectrum of improved detection assets for novel threats. This thrust area leverages multi-omics data science or the combining multiple measurements to inform rational and rapid design and development of biodetection solutions. Synthetic biological concepts will be thoroughly evaluated and exploited for the development of biosensing solutions and refinement of laboratory methods.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue development of detection capabilities for identifying genomic editing events and rapid assessment and detection of emerging biological threats. - Continue development of algorithms and laboratory workflows to identify threats in unknown samples. - Continue development of far-forward pathogen agnostic sensing toolkit. - Continue development of ruggedized, scalable sensor with adaptable design. 	-	1.768	2.848

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>- Continue development of sample stabilization methods.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of detection capabilities focused on addressing emerging biological threats. - Continue development of algorithms and laboratory workflows to identify threats in unknown samples. - Continue development of far-forward pathogen agnostic sensing toolkit. - Continue development of in-silico design to expedite assay development. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>				
<p>Title: 18) Expeditionary Analytical Toolkit (ExAnT)</p> <p>Description: Develop a suite of expeditionary chemical sensors to provide the warfighter with modernized detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue development of chemical vapor sensor utilizing dielectric excitation with focus on attaining sensitivity - Continue development of sensors based on semiconductor thin films coated with plasmonic metal and metal oxide nanoparticles <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of chemical vapor sensor utilizing dielectric excitation with focus prototype delivery and validation. - Continue development of sensors based on semiconductor thin films coated with plasmonic metal and metal oxide nanoparticles; focus on validation and testing systems. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>		-	3.083	3.333
<p>Title: 19) Unattended Perimeter Monitoring</p> <p>Description: Automated technologies to improve detection of aerosolized hazards while minimizing or removing user intervention to enable a reliable detect-to-warn capability, providing a capability for unattended monitoring of perimeters for temporary defense positioning, including base camps, to enable early indication of threats. This thrust area will evaluate current and novel technologies to provide improved chemical threat detection and automated biological detection capabilities.</p> <p>FY 2021 Plans:</p>		-	0.931	1.094

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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)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>- Continue development of fully-automated biosurveillance system capable of air sample collection, sample preparation, and analysis for both chemical and biological threats.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Evaluate technology for next generation UAV-borne and wearable approaches - Integrate automated technologies to improve stand-off detection of vapor, aerosol, solid and liquid hazards for chemical detection. - Integrate refined trigger, collector, and detector/identifier technologies for bioaerosol detection. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>				
<p>Title: 20) Unconventional Detection Modalities</p> <p>Description: Utilize a targeted set of programs pushing the boundaries of sensor development by pulling technologies developed from academia and basic research to be integrated into early detection prototypes. These technologies focus on keeping the warfighter ahead of the chemical and biological threats with portable, low SWaP detectors that will protect the general forces and enhance operations on the battlefield by providing warning and field analytics.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue and validate chemical detection modalities utilizing Waveguide Enhanced Raman Spectroscopy (WERS) and Refractive Index sensing. - Continue to synthesize and further assess SIC materials by coating various surface coupons. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue model development for machine learning algorithms. - Continue development of detection of emerging biothreats using cell-free platforms onto an integrated prototype. - Conduct detection sensing validation for detection by utilizing nanoparticles and voltammetry electrochemistry. - Conduct model testing and validation of machine learning algorithms for chemical detection sensors. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>		-	1.142	0.781
<p>Title: 21) 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. This effort is being separated into two thrust areas in FY22: Lightweight Protective Garments and Dynamic Multifunction Materials for Second Skin.</p>		0.285	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021		
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)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>Title: 22) Lightweight Protective Garments</p> <p>Description: This effort supports the Percutaneous Protection Core Capability Area. Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data on test garments.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - No BA3 efforts planned for FY20 and FY21. - Transition improved protective garment test methodologies (derived from BA2 efforts) that provide greater validation of CB protection, are repeatable and support testing under relevant conditions to the Uniform Integrated Protection Ensemble Family of Systems Program of Record. - Continue assessment for antimicrobial fabrics (derived from BA2 efforts) to be used as inner layer/liner in protective uniforms to prevent excessive growth of microbes associated with hygiene/extended wear and reduce the need for laundering. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments. This effort was funded under Percutaneous Protection.</p>		-	-	0.144
<p>Title: 23) Dynamic Multifunction Materials for Second Skin</p> <p>Description: This effort supports the Percutaneous Protection Core Capability Area. Efforts will utilize responsive technologies to provide CB protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Increase molecular selectivity of responsive interpenetrating polymers (derived from BA2 efforts) towards nerve and blister agents. - Demonstrate and scale carbon nanotube membrane responsive textiles (derived from BA2 efforts) efforts into garments that increase protection levels in response to chemical weapons agents while preserving moisture vapor transport rate. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Program/project transitioned to Advanced Technology Development</p>		-	-	1.379
Title: 24) Material Contamination Mitigation		1.952	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
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)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>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. This effort is being separated into three thrust areas starting in FY21: Enhanced Survivability Coatings, Equipment Decontamination, and Personnel Decontamination.</p>			
<p>Title: 25) Enhanced Survivability Coatings</p> <p>Description: This effort supports the Materiel Contamination Mitigation Core Capability Area. Military equipment coatings are challenging and logistically intensive to decontaminate. Efforts within this thrust seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military equipment to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return equipment to mission operations level.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Demonstrate temporary coatings (derived from BA2 efforts) to improve vehicle decontaminability in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record. - Perform industry coating materials survey to identify candidate temporary chemical/biological agent resistant coatings. - Improve success of decontamination through the evaluation and incorporation of appliques (to include chemical transport studies current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats). - Improve equipment coatings through bio-inspired surface treatments to repel agents of interest from current military coatings. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Increase chemical agent resistance of current military coatings through development and testing of novel temporary coatings to reduce the spread of contamination and enable more facile decontamination of military assets. Improve success of decontamination through the evaluation and incorporation of appliques. - Characterize chemical transport in current military coatings, thin film overcoats, and strippable, reactive, and lock-down coats in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>	-	0.173	0.345
<p>Title: 26) Equipment Decontamination</p> <p>Description: This effort supports the Materiel Contamination Mitigation Core Capability Area. The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts within this thrust seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly</p>	-	1.737	0.649

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
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)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>return high-value equipment to normal use; and develop improved realistic test methods. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Complete biological hot air decontamination technology for bacterial spore decontamination of aircraft and sensitive equipment and transition process to the Joint Biological Agent Decontamination System (JBADS) Program of Record. - Publish laboratory test methods that measure impact of complex surfaces and real world factors on decontamination. - Complete Sprayable Decontaminant Slurry formulation and operational user assessment for tactical level equipment decontamination. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Begin integrating contamination mitigation technologies by advancing the proof of concept for hot-air CWA decontamination by validating the operational performance envelope. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements. - Transition Sprayable Decontaminant Slurry technology for immediate chemical warfare agent decontamination of equipment to the Service Equipment Decontamination System (SEDS) Program of Record. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p>			
<p>Title: 27) Personnel Decontamination</p> <p>Description: This effort supports the Personnel Contamination Mitigation Core Capability Area. Efforts will develop decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to warfighters for mass casualty decontamination. Decrease Warfighter burden in the event of a CWA exposure by identifying science and technology gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue to assess reactive sorbant assessment for individual and skin decontamination. - Begin investigations to optimize form factors for dry skin decontamination. - Continue personnel decontamination efforts to enhance current processes and support mass casualty personnel decontamination warfighter operations, including homeland defense mission, including efficacy data against representative nontraditional agents required to achieve FDA approval. <p>FY 2022 Plans:</p>	-	0.925	1.024

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
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)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
- Continue investigations to optimize form factors for dry skin decontamination. - Develop and assess physical removal technologies for potential replacement of RSDL. - Continue to integrate new dry decontamination into a mitt form factor and determine S&T challenges within process and procedure improvements. This includes development of methodologies and procedures for military working dog (MWG) decontamination.			
<i>FY 2021 to FY 2022 Increase/Decrease Statement:</i> Program/project funding transferred from another funding line.			
Accomplishments/Planned Programs Subtotals	26.426	24.448	27.146

	FY 2020	FY 2021
<i>Congressional Add:</i> High Air Flow ChemBio Filtration System Enhancement	-	3.000
<i>FY 2021 Plans:</i> Develop High Air Flow ChemBio Filtration System Enhancement for expeditionary and mobile collective protection systems through combination of filter elements, incorporation of new filter bed materials, and reduction of element size.		
Congressional Adds Subtotals	-	3.000

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

Line Item	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
• CA4: Contamination Avoidance (ACD&P)	18.806	10.326	32.923	-	32.923	-	-	-	-	-	-
• DE4: Decontamination (ACD&P)	7.009	6.286	18.385	-	18.385	-	-	-	-	-	-
• IS4: Information Systems (ACD&P)	0.517	4.661	0.000	-	0.000	-	-	-	-	-	-
• TE4: Test & Evaluation (ACD&P)	5.054	4.107	0.000	-	0.000	-	-	-	-	-	-
• TT4: Technology Transition (ACD&P)	0.000	0.577	0.866	-	0.866	-	-	-	-	-	-

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program **Date:** May 2021

Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) ET3 / Emerging Threats (ATD)
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
ET3: <i>Emerging Threats (ATD)</i>	-	0.000	0.000	6.000	-	6.000	-	-	-	-	-	-
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

Project ET3 aims to identify and develop scientific solutions, or to modernize capabilities, that allow for a more rapid response to emerging threats. This project supports the development of defense capabilities, collaborating across the DoD and specific interagency partners for doctrine, equipment, and training for the Warfighter and civilian population for defense against emerging threats. Additionally, this project supports advanced development of defensive science and technology capabilities aimed at proactive characterization of threats and potentially disruptive technologies.

Individual efforts in this project include:

- Developing new science and technology capabilities that allow for the rapid characterization of emerging threats to support operational decision making and requirements setting. Support an integrated approach to developing new or enhanced countermeasures against emerging threats through innovative science and technology 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 emerging threats.

The Chemical and Biological Defense Emerging Threat Innovation Fund challenges DoD Labs and innovation cells to deliver transformational technologies against emerging threats that enables the force to compete, deter, and win in strategic environments described in the National Defense Strategy.

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

	FY 2020	FY 2021	FY 2022
Title: 1) Emerging Threat Innovation	-	-	6.000
Description: The Chemical and Biological Defense Emerging Threat Innovation Fund challenges DoD Labs and innovation cells to deliver transformational technologies against emerging threats that enables the force to compete, deter, and win in strategic environments described in the National Defense Strategy.			
FY 2022 Plans: Initiate enhanced capability to more rapidly characterize, and the development of medical countermeasures against, emerging chemical and biological threats through investment in high throughput technologies.			
FY 2021 to FY 2022 Increase/Decrease Statement: Program/project is new start effort in FY 2022.			
Accomplishments/Planned Programs Subtotals	-	-	6.000

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program **Date:** May 2021

Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) ET3 / Emerging Threats (ATD)
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2020</u>	<u>FY 2021</u>	<u>FY 2022</u> <u>Base</u>	<u>FY 2022</u> <u>OCO</u>	<u>FY 2022</u> <u>Total</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• CA4: Contamination Avoidance (ACD&P)	18.806	10.326	32.923	-	32.923	-	-	-	-	-	-
• DE4: Decontamination (ACD&P)	7.009	6.286	18.385	-	18.385	-	-	-	-	-	-
• IP4: Individual Protection (ACD&P)	1.997	2.483	3.968	-	3.968	-	-	-	-	-	-
• TE4: Test & Evaluation (ACD&P)	5.054	4.107	0.000	-	0.000	-	-	-	-	-	-

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program										Date: May 2021		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) NT3 / Non-Traditional Agents Defense (ATD)			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
NT3: Non-Traditional Agents Defense (ATD)	-	28.344	15.308	18.396	-	18.396	-	-	-	-	-	-
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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. 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 transitioning to advance development.

Individual efforts in this project include:

- 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.

Starting in FY21, a portion of the NTA lines have been merged into RDT&E Projects CB3, Chemical Biological Defense, and TM3, Techbase Medical Defense. The administrative change is intended to improve S&T budget agility and transition efficiency.

FY20-22 reorganizes, renames legacy Bullet titles and introduces new Bullets (Thrust Areas). These new "Thrust" titles are in line with the CBDP Core Capability Areas and intended to provide more detail and traceability from the S&T program to advanced development.

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

	FY 2020	FY 2021	FY 2022
Title: 1) Material Contamination Mitigation	0.520	-	-
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.			
Title: 2) Modeling & Simulation	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			

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) NT3 / Non-Traditional Agents Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
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.			
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.	0.488	-	-
Title: 4) 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.	0.408	-	-
Title: 5) Respiratory and Ocular Protection 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.	0.501	-	-
Title: 6) Test & Evaluation Description: Develop test and evaluation technologies and processes in support of NTA activities.	0.785	-	-
Title: 7) 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.	3.008	-	-
Title: 8) Pretreatments and Prophylactics - 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).	11.184	-	-
Title: 9) Detection Description: Focuses on technologies to provide NTA detection capabilities. This effort is being separated into three thrust areas in FY21: Distributed CB Reconnaissance, Expeditionary Analytical Toolkit (ExAnT), and Unconventional Detection Modalities.	11.214	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) NT3 / Non-Traditional Agents Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Title: 10) Distributed CB Reconnaissance</p> <p>Description: Develop distributed chemical reconnaissance tools to enhance early warning and situation awareness of non-traditional chemical and biological threats to include low cost point sensor and sensing/collection systems for manned and unmanned platforms.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue to develop low size, weight, power, and cost sensors capable of real-time classification or detection of low volatility chemical threats - Continue to evaluate passive biomimetic sensor capability to discriminate between targets and background and integrate sensor on unmanned platforms. - Refine and continue more rigid testing of miniature aerosol sensors that selectively detect presence of airborne particles. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Validate testing of miniature aerosol sensors that selectively detect presence of airborne particles. - Model the response of passive biomimetic sensor capability to detect chemical threat simulants and interferents for identification. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>	-	1.500	2.407
<p>Title: 11) Expeditionary Analytical Toolkit (ExAnT)</p> <p>Description: Focuses on technologies to provide non-traditional threat detection capabilities.</p> <p>Project NT3, Techbase Non-Traditional Agents Defense (Test & Evaluation), will merge into this program starting in FY21.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue the development of sensor technologies against non-traditional threats of concern. - Initiate the development of non-traditional chemical sensor platforms for ground and aerial systems for hazard awareness and assessment. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue the development of sensor technologies against non-traditional threats of concern to develop class-based detection and reduce reliance on known threat libraries. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>	-	12.410	14.166
<p>Title: 12) Unconventional Detection Modalities</p>	-	1.398	1.823

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) NT3 / Non-Traditional Agents Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Description: Utilize a targeted set of programs pushing the boundaries of sensor development by pulling technologies developed from academia and basic research to be integrated into early detection prototypes. These technologies focus on keeping the warfighter ahead of nontraditional chemical threats with portable, low SWaP detectors that will protect the general forces and enhance operations on the battlefield by providing warning and field analytics.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue development of integrated photonics sensors. - Initiate application of miniaturized Raman spectrometers. - Initiate application of machine learning to disparate sensor feeds. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development and refinement of integrated photonics. - Continue development and refinement of miniaturized Raman spectrometers. - Continue development and refinement of machine learning algorithms for integrating disparate sensor feeds. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>			
Accomplishments/Planned Programs Subtotals	28.344	15.308	18.396

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
• CA4: Contamination Avoidance (ACD&P)	18.806	10.326	32.923	-	32.923	-	-	-	-	-	-
• DE4: Decontamination (ACD&P)	7.009	6.286	18.385	-	18.385	-	-	-	-	-	-
• IP4: Individual Protection (ACD&P)	1.997	2.483	3.968	-	3.968	-	-	-	-	-	-
• TE4: Test & Evaluation (ACD&P)	5.054	4.107	0.000	-	0.000	-	-	-	-	-	-

Remarks

D. Acquisition Strategy
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program										Date: May 2021		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) TM3 / Techbase Medical Defense (ATD)			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
TM3: <i>Techbase Medical Defense (ATD)</i>	-	142.123	137.829	137.495	-	137.495	-	-	-	-	-	-
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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. A portion of Project NT3, Techbase Non-Traditional Agents Defense, will merge into this Project starting in FY21.

Individual efforts in this project include:

- Evaluating innovative biotechnology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents.
- 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.
- Non-Traditional Agent (NTA) Defense includes chemical diagnostics, medical pretreatments, therapeutics, detection, and protection and hazard mitigation.

FY20-22 reorganizes, renames legacy Bullet titles and introduces new Bullets (Thrust Areas). These new "Thrust" titles are in line with the CBDP Core Capability Areas and intended to provide more detail and traceability from the S&T program to advanced development.

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

	FY 2020	FY 2021	FY 2022
Title: 1) CARES Act - A Highly Multiplexed Point-of-Care Digital Protein Assay Platform with Digital Molecular Capability Description: Potential COVID-19 Related Options to Expand Effort. Tests will independently verify and validate results.	1.934	-	-
Title: 2) CARES Act - Host Response (Organs-on-chips) Description: Initiated characterization of the pathogenesis of the SARS CoV-2 virus in vitro through the use of various organs-on-chips systems	4.000	-	-
Title: 3) CARES Act - SARS COV-2 VSV vaccine Description: Initiate non-clinical development to determine efficacy of a SARS CoV-2 Vesicular Stomatitis (VSV) vaccine.	12.300	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
Title: 4) Internal COVID - New Horizons Diagnostics Corporation - Serology Description: Create COVID-19 peptide array to monitor antigen drift in subsequent waves.		1.473	-	-
Title: 5) Internal COVID - Serology Development and IV&V Testing Description: National Strategic Research Institute (NSRI) - Spiral Development of Prototypes to Support the COVID-19 Pandemic Response. Independent evaluation of tests developed by New Horizons Diagnostics.		3.300	-	-
Title: 6) Internal COVID - Systems Approach to Medical Countermeasures Development Description: Assess and integrate emerging technologies to inform screening and down selection of potential MCM candidates.		0.250	-	-
Title: 7) Internal COVID - Systems Approach to Medical Countermeasures Development Description: Prototype a systems approach for rapid MCM development via screening and design of adaptive platform, assess efficacy of candidate compounds, and architect a future integrated systems-of-systems for rapid MCM development platform.		4.700	-	-
Title: 8) Internal COVID - VSV SARS CoV-2 vaccine Description: Provide the Warfighter with protection against COVID-19 through the development of a SARS CoV-2 VSV vaccine. FY 2022 Plans: Complete pre-clinical development of the Vesicular Stomatitis Virus - delta G (VSVdeltaG) SARS CoV-2 vaccine. FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to accelerated development effort. Supports COVID-19/pandemic response efforts.		5.404	-	5.100
Title: 9) Medical Diagnostics Description: Investigate medical diagnostics that are agnostic 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; develop prototypes and tools that advance medical diagnostics towards FDA approval. This effort is being separated into four thrust areas starting in FY21: Battlefield Readiness, Chemical Diagnostics, Clinical Evaluation, and Emerging Threats.		19.583	-	-
Title: 10) Battlefield Readiness Description: Develop field forward medical diagnostics that provide multiplexed detection of biological and toxin threats to facilitate triage and diagnosis at lower roles of care.		-	9.386	7.774

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Complete and transition to advanced developer data the development of rapid, low cost, consumable tests that can detect biological threats that cause Plague and Melioidosis, reducing discovery-to-decision times. - Continue to develop a portable, ultrasensitive immunological diagnostic platform that enables rapid identification and diagnosis of a broader range of threats across the continuum of care, post symptom onset. - Continue the development and evaluation of a customizable, lightweight, comfortable, in ear wearable device (EWD) and algorithms to detect disease onset by monitoring a Warfighter's health state. - Complete and transition the generation of POC diagnostics assays and devices that detect a panoply of different species and variants of Old World Hantavirus across the Korean peninsula. - Continue the development of vertical flow assay technologies that are rapid, capable of multiplexing, portable, and may result in a faster sample to answer and more sensitive detection level than traditional lateral flow diagnostics. - Initiate a program to identify biological indicators that predict disease severity, which will lead to the development of a diagnostic that alerts medical personnel that a patient's condition may worsen or require immediate intensive care. - Initiate the development of a POC diagnostic platform that can provide the Warfighter pre-symptomatic diagnosis of infection, irrespective of whether the underlying pathogens are viral, bacterial, or parasitic. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Complete the development a portable, ultrasensitive immunological diagnostic platform that enables rapid identification and diagnosis of a broader range of threats across the continuum of care, post symptom onset. - Complete the development and evaluation of a customizable, lightweight, comfortable, in EWD and algorithms to detect disease onset by monitoring a Warfighter's health state. - Continue the development of vertical flow assay technologies that are rapid, capable of multiplexing, portable, and may result in a faster sample to answer and more sensitive detection level than traditional lateral flow diagnostics. - Continue program to identify biological indicators that predict disease severity, which will lead to the development of a diagnostic that alerts medical personnel that a patient's condition may worsen or require immediate intensive care. - Continue the development of a POC diagnostic platform that can provide the Warfighter pre-symptomatic diagnosis of infection, irrespective of whether the underlying pathogens are viral, bacterial, or parasitic - Initiate the development of a non-invasive prototype platform capable of diagnosing infectious diseases through collection and analysis of an individual's breath. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>			
Title: 11) Battlefield Readiness	-	3.784	4.400

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Description: Provide capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care through development of field forward medical diagnostics that provide multiplexed detection of biological and toxin threats.</p> <p>FY 2021 Plans: - Initiate development of a portable, ultrasensitive immunological diagnostic platform that enables rapid identification and diagnosis of a broader range of threats across the continuum of care, post symptom onset.</p> <p>FY 2022 Plans: - Complete the development a portable, ultrasensitive immunological diagnostic platform that enables rapid identification and diagnosis of a broader range of threats across the continuum of care, post symptom onset. - Initiate the development of additional panels for infectious disease diagnostic tests on the immunological diagnostic platform.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>			
<p>Title: 12) Chemical Diagnostics</p> <p>Description: Develop diagnostics for exposure to traditional and nontraditional chemical warfare agents (CWAs) and pharmaceutical based agents (PBAs). Early identification and diagnosis is key to appropriate medical countermeasure (MCM) treatment and enhances force protection and lethality.</p> <p>FY 2021 Plans: - Continue the research and development of a wearable device that is a continuous sensing platform for detecting indicators of chemical exposure (DICE), capable of alerting the Warfighter to potential exposure to traditional and nontraditional CWAs.</p> <p>FY 2022 Plans: - Complete the research and development of a wearable device that is a continuous sensing platform for DICE, capable of alerting the Warfighter to potential exposure to traditional and nontraditional CWAs. - Initiate efforts that expand the capability of wearable devices from an alert to an FDA-approved diagnostic platform that can detect a chemical threat and allow a physician to diagnose and determine a treatment strategy for exposure to traditional/ nontraditional chemical agents.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>	-	3.429	3.710
<p>Title: 13) Chemical Diagnostics</p>	-	1.973	-

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>Description: Develop diagnostics for exposure to traditional and nontraditional CWAs and PBAs. Early identification and diagnosis is key to appropriate MCM treatment and enhances force protection and lethality.</p> <p>FY 2021 Plans: - Initiate and complete an effort to build a dedicated, sustainable, and robust diagnostic capability at the United States Army Medical Research Institute for Chemical Defense (USAMRICD) to serve as an integral component of force protection that provides timely responses to global CWA threats.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Program/project is entering completion and all activities will be closed.</p>				
<p>Title: 14) Clinical Evaluation</p> <p>Description: This thrust area optimizes the diagnostic development pathway by incorporating independent testing and evaluation for more informed prototype transition to advanced development. This area maintains access to research sites that offer native populations exposed to diseases of interest that would affect the Warfighter in battlefield settings and provides the ability to acquire novel technologies and provide analytical testing, evaluation, and reach back support for technologies already fielded.</p> <p>FY 2021 Plans: - Continue to maintain the capability to access clinical samples for infectious diseases of interest, and collaborate with sites around the world where diseases of concern are circulating. - Initiate test plans for bacterial versus viral prototypes to include the Cepheid Omni instrument for Next Generation Diagnostics System (NGDS) 2 Man Portable Diagnostic System (MPDS) and the MeMed Diagnostics Immuno POC protein-based platform.</p> <p>FY 2022 Plans: - Continue to maintain the capability to access clinical samples for infectious diseases of interest, and collaborate with sites around the world where diseases of concern are circulating. - Complete third party testing for bacterial versus viral prototypes. - Initiate test plans for a prototype capable of single molecule-based pathogen identification and assessment of pathogen susceptibility to antimicrobial agents. - Initiate test plans for a wearable sensor capable of detecting exposure to chemical warfare agents.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>		-	5.040	3.210
<p>Title: 15) Emerging Threats</p>		-	3.227	6.324

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Description: The Emerging Threats thrust area pushes beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise by leveraging novel approaches to classify a threat from an unknown sample.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Initiate work on POC diagnostics to identify antimicrobial resistant (AMR) microorganisms and perform antimicrobial susceptibility testing (AST) in less than one hour. - Complete the development of the Cepheid Bacterial vs. Viral Host Response Biomarker Cartridge and transition to the Joint Product Executive Office (JPEO) Program of Record (POR) for inclusion in the Next Generation Diagnostics System (NGDS) 2 Man Portable Diagnostic System (MPDS). - Complete data report for diagnostic meta-analysis on existing viral and bacterial biomarker infection data to elucidate a host biomarker panel for viral/bacterial differentiation. - Continue work on POC diagnostics to identify antibiotic resistant microorganisms and perform AST in less than one hour. - Initiate the development of a universal blood sample preparation platform to be compatible with several diagnostic systems. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Complete work on POC diagnostics to identify AMR microorganisms and perform AST in less than one hour. - Initiate efforts that explore the proteomic expression profiles of bacterial pathogens when they are challenged with antibiotics to characterize regulatory mechanisms of antibiotic resistance. - Complete work on POC diagnostics to identify Antimicrobial Resistance (AMR) microorganisms and perform AST in less than one hour. - Continue the development of a universal blood sample preparation platform to be compatible with several diagnostic systems. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Program/project funding transferred from another funding line.</p>			
<p>Title: 16) Diagnostic Building Blocks</p> <p>Description: The Diagnostic Building Blocks thrust area lays a foundation for the entire diagnostics portfolio by exploiting areas such as machine learning (ML), synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Initiate efforts that support the advancement of genomics capabilities at the United States Army Medical Research Institute for Infectious Disease (USAMRIID). - Complete data transitions of S&T efforts that monitor and incorporate new genomics data on pathogens to continuously validate and revise our collection of molecular diagnostic assays, which will allow rapid response to current and emerging infectious diseases by predicting accurate PCR assays designs. - Complete data transitions for the development of complementary diagnostic assays that can be used to support vaccine and countermeasure development efforts. 	11.461	10.179	7.701

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>- Continue the development of protocols for generating SYMBAs that are sensitive and specific and can be applied to various diagnostic platforms, supporting open-architecture capabilities.</p> <p>- Initiate the research and development of Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR) based solutions for field diagnostics that will provide an ultra-sensitive, cost-effective, and accurate medical diagnostic solution for the Warfighter against unknown biological threats.</p> <p>FY 2022 Plans:</p> <p>- Continue efforts that support the advancement of genomics capabilities at USAMRIID.</p> <p>- Initiate novel efforts in artificial intelligence (AI) and ML for designing broader and more specialized assay panels for Chemical and Biological (CB) threats. - Complete the development of protocols for generating SYMBAs that are sensitive and specific and can be applied to various diagnostic platforms, supporting open-architecture capabilities.</p> <p>- Continue the research and development of CRISPR based solutions for field diagnostics that will provide an ultra-sensitive, cost-effective, and accurate medical diagnostic solution for the Warfighter against unknown biological threats.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p>				
Title: 17) Vaccine Platforms and Research Tools		1.498	-	-
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.				
Title: 18) Viral Vaccines		4.541	-	-
Description: Evaluate 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. This effort is transitioning to the Bacterial, Viral and Toxin Prophylaxis thrust area starting in FY21.				
Title: 19) Bacterial/Toxin Vaccines		14.518	-	-
Description: Evaluate the best single agent bacterial and toxin vaccines and pretreatments for effectiveness against aerosol challenge in large animal models. This effort is transitioning to the Bacterial, Viral and Toxin Prophylaxis thrust area starting in FY21.				
Title: 20) Bacterial, Viral and Toxin Prophylaxis		-	36.229	34.160

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Description: Provide the warfighter protection against biothreat agents through the pre-exposure administration of prophylaxis against known bacterial, viral and toxin threats of interest as well as emerging infectious threats.</p> <p>FY 2021 Plans:</p> <p>Bacterial:</p> <ul style="list-style-type: none"> - Complete preclinical studies of Burkholderia outer membrane vesicle (OMV) vaccine and subunit vaccine for initiation of a Phase 1 clinical trial. - Continue IND enabling development of live-attenuated tularemia vaccine. - Initiate manufacturing of capsule conjugate manufacturing process development and formulation for next generation anthrax vaccine in combination with Protective-antigen (PA) based vaccine. - Complete correlates of immunity and down selection of next generation capsular polysaccharides (CPS) conjugate anthrax vaccine. - Complete assay qualification for OMV vaccine studies for use in upcoming Phase 1 clinical trial. - Continue manufacturing and nonclinical development of next generation plague and tularemia monoclonal antibody cocktail. - Continue manufacturing development of OMV and nanoparticle vaccine platforms targeting Francisella, Yersinia and Q Fever. - Continue seroprevalence studies in support of potential clinical trials, reagent generation and biomarker discovery. <p>Viral:</p> <ul style="list-style-type: none"> - Continue assay qualification and validation for Ebola virus, Marburg virus, and alphavirus vaccines. - Continued development of alphavirus animal models to support animal rule licensure of alphavirus vaccines - Continue evaluation of rVSV Ebola vaccine duration of protection assessment. - Continue evaluation and mitigation studies of Filovirus aerosol pathology. <p>Toxins:</p> <ul style="list-style-type: none"> - Complete IND enabling efforts and filings in support of human clinical trials for animal-rule licensure of the multivalent monoclonal antibody cocktail for protection against A and B serotypes of botulinum neurotoxin. - Complete Phase 1 clinical trial for multivalent monoclonal antibody cocktail for transition to advanced development BoNT mAb program. <p>FY 2022 Plans:</p> <p>Bacterial:</p> <ul style="list-style-type: none"> - Complete non-clinical safety and efficacy studies for Tularemia prophylaxis with the ClpB vaccine for advancement to clinical Phase 1. - Complete non-clinical safety and efficacy studies with the Tularemia Fn-IgID vaccine for advancement to clinical Phase 1. 			

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<ul style="list-style-type: none"> - Continue manufacturing and nonclinical development of next generation plague and tularemia monoclonal antibody cocktail. - Complete non-clinical safety and efficacy studies on a live attenuated plague vaccine candidate for advancement to clinical Phase 1. - Complete the proof of efficacy animal testing for the anthrax CPS conjugate vaccine candidate for advancement to clinical Phase 1. - Complete Q Fever human seroprevalence study to determine what percentage of Warfighter would be eligible to receive QVax vaccine. Results will be transitioned to advanced development to support their evaluation of QVax for further advanced development. <p>Viral:</p> <ul style="list-style-type: none"> - Continue assay qualification and validation for Ebola virus, Marburg virus, and alphavirus vaccines. - Continued development of alphavirus animal models to support animal rule licensure of alphavirus vaccines - Complete evaluation of rVSV Ebola vaccine duration of protection assessment to support CONOPs development for Ebola Vaccine use by the Services. - Continue evaluation and mitigation studies of Filovirus aerosol pathology. - Initiate animal efficacy testing against panel of respiratory viruses of broad spectrum epithelial nanosponge technology. <p>Toxins:</p> <ul style="list-style-type: none"> - Complete transition of the multivalent monoclonal antibody cocktail for protection against A and B serotypes of botulinum neurotoxin to advanced development BoNT mAb program at JPEO-CBRND following the completion of the Phase 1 clinical trial. - Initiate large animal efficacy testing of mAb cocktail for protection against Palytoxin. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>				
<p>Title: 21) Chemical Therapeutics</p> <p>Description: Focuses on pretreatment and post treatment strategies to effectively minimize injuries resulting from exposure to CWAs. 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. This effort is being separated into four thrust areas starting in FY21: Nerve Agent Prophylaxis/Pretreatments, Pharmaceutical Based Agents (PBAs), and Reactivators of AChE as Therapeutics (ReACT).</p>		1.883	-	-
<p>Title: 22) Nerve Agent Prophylaxis/Pretreatments</p>		-	9.918	6.857

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>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).</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue efforts to develop organophosphorus nerve agents (OPNA) catalytic scavenger enzymes in support of investigational new drug (IND) submission to the FDA. - Complete non-Good Laboratory Practices (GLP) pharmacokinetics, immunogenicity and efficacy of catalytic scavenger enzyme candidates in small animals and choose two lead candidate enzymes for development. - Continue formulation efforts. - Initiate enzyme non-current Good Manufacturing Practice (cGMP) manufacturing scale-up. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue efforts to develop OPNA catalytic scavenger enzymes in support of investigational new drug (IND) submission to the FDA. - Initiate GLP pharmacokinetics, immunogenicity and efficacy of catalytic scavenger enzyme lead candidates in small animals. - Initiate enzyme cGMP manufacturing scale-up. - Hold pre-IND Meeting with FDA to obtain guidance on the regulatory path. - Continue formulation efforts. - Continue enzyme non-cGMP manufacturing scale-up. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p>			
<p>Title: 23) Pharmaceutical Based Agents (PBAs)</p> <p>Description: Focuses on therapeutic and proactive strategies to effectively minimize injuries resulting from exposure to Pharmaceutical Based Agents (PBAs). This effort involves the evaluation FDA approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the Warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment and pretreatment against chemical warfare injury.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue development of ROCS higher concentration Naloxone formulation for use in a multiuse vial format through New Drug Approval (NDA) by FDA. - Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure. 	-	2.019	4.065

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<ul style="list-style-type: none"> - Assess operational feasibility of employing FDA approved opioid antagonist MCM to provide extended duration of protection. - Develop novel therapeutic products to mitigate Opioid Induced Respiratory Depression (OIRD) to reduce lethality in CWA exposed Warfighters. - Continue studies to assess safety, efficacy, and tolerance of COTS products and dosages for opioid based PBA exposure. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of Rapid Opioid Countermeasure System (ROCS) higher concentration Naloxone formulation for use in a multiuse vial format through NDA by FDA. - Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure. - Assess operational feasibility of employing FDA approved opioid antagonist MCM to provide extended duration of protection. - Continue development of novel therapeutic products to mitigate OIRD to reduce lethality in CWA exposed Warfighters. - Continue studies to assess safety, efficacy, and tolerance of COTS products and dosages for opioid based PBA exposure. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p>			
<p>Title: 24) Reactivators of AChE as Therapeutics (ReACT)</p> <p>Description: Focuses on therapeutic strategies to effectively minimize injuries resulting from exposure to CWAs. This effort involves the development of improved therapies for enzyme reactivation. Efforts in this area are designed to develop potential candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue to advance pre-clinical development of lead therapeutic candidates - Continue investigating technologies for delivering therapeutics to the brain. - Continue formulation efforts for lead therapeutic candidates. - Continue in vivo screening for lead therapeutic candidates. - Continue pre-clinical studies of lead reactivators to support future investigational new drug (IND) filing. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to advance pre-clinical development of lead therapeutic candidates. - Continue investigating technologies for delivering therapeutics to the brain. - Continue formulation efforts for lead therapeutic candidates. - Continue in vivo screening for lead therapeutic candidates. 	-	3.904	6.649

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
- Continue pre-clinical studies of lead reactivators to support future IND filing.				
FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to change in program/project technical parameters.				
Title: 25) Bacterial Therapeutics		12.058	17.800	12.846
Description: Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents.				
FY 2021 Plans:				
- Continue multiple efforts to identify and advance candidate therapeutics, with a focus on non-traditional candidates, through preclinical evaluation toward investigational new drug (IND) and Phase 1 clinical studies. Preclinical candidate selection for small molecule broad-spectrum antibacterial targeting <i>B. pseudomallei</i> and initiate IND enabling toxicology studies.				
- Expand layered defense against bacterial threats that evaluates the combination of vaccination with antibiotic therapy, as well as promising monoclonal antibodies and nontraditional therapeutics.				
- Utilizing flexible and agile acquisition vehicles, continue to partner with interagency, international and industry partners to develop nonclinical biodefense efficacy packages for therapeutic assets in advanced development.				
- Complete small animal proof of concept efficacy studies on two (nontraditional) immunomodulatory drugs.				
- Deliver non-human primate pharmacokinetic study package to interagency joint development programs.				
FY 2022 Plans:				
- Continue multiple efforts to identify and advance candidate therapeutics, with a focus on non-traditional candidates, through preclinical evaluation toward IND and Phase 1 clinical studies.				
- Utilizing flexible and agile acquisition vehicles, continue to partner with interagency, international, and industry partners to develop nonclinical biodefense efficacy packages for therapeutic assets in advanced development.				
- Complete non-human primate studies to demonstrate efficacy at humanized doses against anthrax or melioidosis and transition to HHS BARDA.				
- Complete non-human primate pharmacokinetics studies for one immunomodulatory drug readying the candidate for transition to advanced development and transition to Health & Human Services (HHS) Biomedical Advance Research and Development Authority (BARDA).				
- Continue to deliver proof of concept and humanized nonhuman primate efficacy biodefense data packages to interagency joint development programs for transition to HHS BARDA.				
- File INDs for novel orally-delivered and IV therapeutic for treatment of <i>B. pseudomallei</i> infection. This will support planned Phase I clinical trial.				
FY 2021 to FY 2022 Increase/Decrease Statement:				

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
Decrease due to change in program/project technical parameters.				
Title: 26) Viral Therapeutics		17.293	9.417	12.847
Description: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.				
FY 2021 Plans: - Continue broad-spectrum, small molecule and monoclonal antibody selection and evaluation in NHP models for multiple anti-viral therapeutic applications. - Continue joint development of pan-Marburg monoclonal antibody development with interagency partners. - Begin studies on adjunct therapies that decrease morbidity after viral exposure.				
FY 2022 Plans: - Continue broad-spectrum, small molecule and monoclonal antibody selection and evaluation in NHP models for multi therapeutic applications. - Transition lead Alphavirus Therapeutics small-molecule candidate to advanced development.				
FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to change in program/project technical parameters.				
Title: 27) Toxin Therapeutics		-	0.243	0.250
Description: Discover and develop therapeutic countermeasures to protect the warfighter against biotoxin threats.				
FY 2021 Plans: - Initiate evaluation of the efficacy of repurposed drug for treatment of botulinum neurotoxin (BoNT) A intoxication in non-human primate animal model.				
FY 2022 Plans: - Continue evaluation of efficacy of repurposed drug for treatment of botulinum neurotoxin (BoNT) B, E or F intoxication in non-human primate animal model.				
FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.				
Title: 28) Medical Countermeasures Initiative		15.900	21.281	21.602
Description: Platform development Chem Bio Incident Preparedness and Response-Medical Countermeasures Initiative (CBIPR-MCMI):				

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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 Medical Defense (ATD)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>The MCMI will integrate the regulatory science and manufacturing technologies and processes developed into the Advanced Development and Manufacturing Facility (MCM-ADM) to support establishment of platform capabilities as enablers of the advanced development of CBDP medical countermeasure products. These initiatives will lead to the development of multi-use platforms that have the potential to accelerate medical product development and/or regulatory approval as well as reduce overall development costs.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue to fund monoclonal antibodies technologies to counter threat agents both prophylactically and therapeutically. - Continue to fund novel expression systems, including rapid manufacturing systems. - Continue expansion of outer membrane vesicle based bacterial expression platforms for bacterial vaccine candidates. - Continue to fund novel platform technologies to support rapid medical countermeasure candidate development, including prospective candidate DNA banking, additional cell line development. - Continue the advancement of the conjugate polysaccharide based vaccine platform, live attenuated bacteria, subunit vaccines and the DNA vaccine platform. - Fund technologies that support regulatory science. - Continue to fund animal model development to support, test, and evaluate MCMs and the capability to respond to emerging threats. - Support manufacturing advancements for biologics. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Conduct Phase 1 clinical trial for Venezuelan Equine Encephalitis (VEE) DNA vaccine. - Continue to invest in novel expression systems and expand outer membrane vesicle based bacterial expression platforms for bacterial vaccine candidates. - Invest in novel platform technologies to support rapid medical countermeasure candidate development, including prospective candidate DNA banking, additional cell line development. - Invest in novel expression systems, including rapid manufacturing systems. - Continue to invest in technologies that support regulatory science. - Continue to invest in animal model development to support, test, and evaluate MCMs and the capability to respond to emerging threats. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>				
Title: 29) Laboratory Operations & Support		10.027	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
Description: Support for laboratory operations, facilities sustainment, and regulatory compliance for critical chemical biological defense activities at USAMRIID and USAMRICD.			
Accomplishments/Planned Programs Subtotals	142.123	137.829	137.495

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
• MB4: Medical Biological Defense (ACD&P)	41.997	47.727	47.351	-	47.351	-	-	-	-	-	-
• MB5: Medical Biological Defense (SDD)	170.345	117.956	137.348	-	137.348	-	-	-	-	-	-
• MC5: Medical Chemical Defense (SDD)	55.269	54.392	50.362	-	50.362	-	-	-	-	-	-
• MB7: Medical Biological Defense (Op Sys Dev)	2.663	2.308	3.833	-	3.833	-	-	-	-	-	-
• MC7: Medical Chemical Defense (Op Sys Dev)	1.222	1.817	1.336	-	1.336	-	-	-	-	-	-

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program										Date: May 2021		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) TT3 / Technology Transition (ATD)			
COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
TT3: Technology Transition (ATD)	-	12.659	10.416	8.787	-	8.787	-	-	-	-	-	-
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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 to significantly improve Warfighter capabilities in preparation for transition of mature chemical and biological (CB) defense technologies to advanced development programs. This project addresses the three primary chemical and biological defense thrust areas of Assess, Protect, and Mitigate with an emphasis on Integrated Early Warning (IEW) and Integrated Layered Defense (ILD). IEW is conducted through a coordinated program approach focused on layering chemical and biological detection technologies and integrating CB threat indicators, providing a combination of awareness and understanding that facilitates effective decision making so the force can continue military operations and achieve mission success in a CBRN environment. The ILD achieves solutions for capability gaps across medical and non-medical commodity areas to enable warfighter survival and rapid recovery in a CBRN environment.

Individual efforts in this project include:

- Programs that offer the opportunity to identify and efficiently mature emerging technologies, reduce risks, and finalize engineering and integration efforts.
- Programs that 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.

FY20-22 reorganizes, renames legacy Bullet titles and introduces new Bullets (Thrust Areas). These new "Thrust" titles are in line with the CBDP Core Capability Areas and intended to provide more detail and traceability from the S&T program to advanced development.

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

	FY 2020	FY 2021	FY 2022
Title: 1) Experiment & Technology Demonstrations	12.659	-	-
Description: Utilize Technology Concepts, Early User Assessments, and Advanced Technology Demonstrations (ATDs) to demonstrate the maturity and potential of advanced technologies across the Assess, Protect, and Mitigate spectrum for enhanced military operational capability and technology transition effectiveness. This effort is being separated into three thrust areas starting in FY21: Advanced Technology Demonstration, Technology Concept, and User Assessment.			
Title: 2) Advanced Technology Demonstration	-	5.724	5.640

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021	
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TT3 / Technology Transition (ATD)	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021
<p>Description: ATDs enable the effective transition of cutting edge CBRN S&T Technologies to the Warfighter by providing them an opportunity to engage with these new technologies in a mission oriented demonstration. Feedback from the Warfighters ensures that these technologies are operationally relevant, value added, and can be matured and transitioned in a timely and effective manner to end users for employment.</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue CMWD Integrated Tactical Information Recon System (CITRIS): integrate a remote sensing capability into the tactical mobile application system. - Continue Integrated Threat Response Advanced Technology Demonstration (ITR ATD) Demonstrate whole of force (IEW and ILD) Warfighter operations in a CBRN Environment. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue CITRIS: heads up display CWMD Common Tactical Picture to support end user CWMD tactical situational awareness. - Continue Integrated Threat Response Advanced Technology Demonstration (ITR ATD) Demonstrate whole of force (IEW and ILD) Warfighter operations in a CBRN Environment. <p>FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>			
<p>Title: 3) Technology Concept</p> <p>Description: Initiatives to validate technology requirements and scope future S&T programs with Warfighter stakeholders, including Combat Developers and Service representatives. Technology Concept efforts utilize Table Top Exercises (TTXs), Limited Objective Experiments (LOEs), and User workshops to inform emerging capabilities and concepts of employment (CONEMPs).</p> <p>FY 2021 Plans:</p> <ul style="list-style-type: none"> - Continue seven concept studies: Layered and Integrated Medical Intervention Technologies (LMIT), Limited-use Medical Countermeasures Operational Capability (LMOC), Genedrive, CBRN Hazard Prediction, Leave and Forget Sensor, Temporary Coatings, Decon Slurry. - Initiate Throw-away CBRN Sensor Concept and Respiratory Concept Focus Groups. <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Conduct three to five concept studies including LMIT, LMOC, Leave and Forget Sensor Concept. <p>FY 2021 to FY 2022 Increase/Decrease Statement:</p>		-	2.292
		1.296	

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TT3 / Technology Transition (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
Decrease due to change in program/project technical parameters.			
Title: 4) User Assessment	-	2.400	1.851
Description: User Assessments examine maturing technologies and provide opportunities for early Warfighter input into the form, fit, and function of maturing S&T prototypes and technologies; and as appropriate, assess them within a simulated operational environment.			
FY 2021 Plans: - Continue three assessment events including the annual CB Operational Analysis (CBOA), Decon Slurry, and LMOC Field Assessment.			
FY 2022 Plans: - Continue the annual CBOA event.			
FY 2021 to FY 2022 Increase/Decrease Statement: Minor change due to routine program adjustments.			
Accomplishments/Planned Programs Subtotals	12.659	10.416	8.787

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2020</u>	<u>FY 2021</u>	<u>FY 2022</u> <u>Base</u>	<u>FY 2022</u> <u>OCO</u>	<u>FY 2022</u> <u>Total</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• TT4: Technology Transition (ACD&P)	0.000	0.577	0.866	-	0.866	-	-	-	-	-	-

Remarks

D. Acquisition Strategy

N/A