



DHS Biosurveillance Systems

September 28, 2020

Fiscal Year 2020 Report to Congress



**Homeland
Security**

*Science and Technology Directorate and
Countering Weapons of Mass Destruction
Office*

Joint Message from the Senior Official Performing the Duties of the Under Secretary for Science and Technology and the Assistant Secretary for the Countering Weapons of Mass Destruction Office

September 28, 2020



William N. Bryan



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We are pleased to submit the following report, “DHS Biosurveillance Systems,” which has been prepared by the Science and Technology Directorate (S&T) and the Countering Weapons of Mass Destruction Office (CWMD).

The report has been compiled pursuant to direction in House Report 116-180, which accompanies the Fiscal Year 2020 Department of Homeland Security Appropriations Act (P.L. 116-93). The report provides information on the development of a successor program to BioWatch and on the collaboration between S&T and CWMD within the biodetection mission space

Pursuant to congressional requirements, this report is being provided to the following Members of Congress:

The Honorable Lucille Roybal-Allard
Chairwoman, House Appropriations Subcommittee on Homeland Security

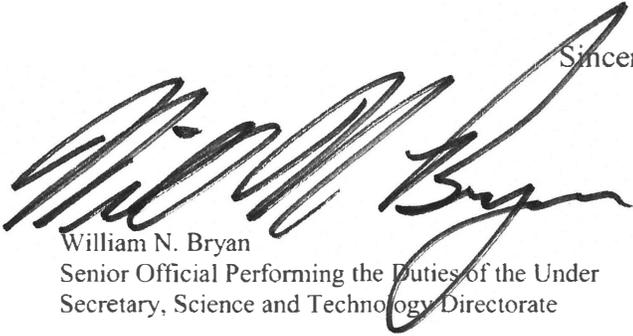
The Honorable Chuck Fleischmann
Ranking Member, House Appropriations Subcommittee on Homeland Security

The Honorable Shelley Moore Capito
Chairman, Senate Appropriations Subcommittee on Homeland Security

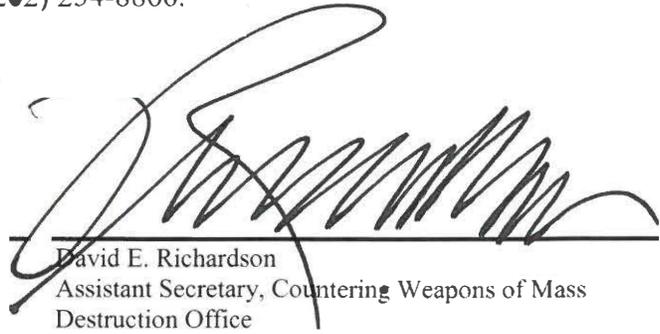
The Honorable Jon Tester
Ranking Member, Senate Appropriations Subcommittee on Homeland Security

We would be pleased to respond to any questions that you may have. Please do not hesitate to contact S&T at (202) 254-8392 or CWMD at (202) 254-8866.

Sincerely,



William N. Bryan
Senior Official Performing the Duties of the Under
Secretary, Science and Technology Directorate



David E. Richardson
Assistant Secretary, Countering Weapons of Mass
Destruction Office

Executive Summary

S&T and CWMD are working together to develop capabilities based on state-of-the-art technologies to detect and alert rapidly on the presence of a biological threat in both outdoor and indoor environments to guide execution of effective response strategies. S&T delivers this report in partnership with CWMD in response to the Appropriations Committee's request for a status update on the development of a successor program to BioWatch and on the collaboration between the two organizations within the biodetection mission space.

CWMD is executing the Biological Detection for the 21st Century acquisition program (BD21) potentially to close the capability gaps of BioWatch, the current operational biosurveillance capability for airborne biological threat agents installed in more than 30 major metropolitan areas. Although BioWatch is trusted and proven, it has a lengthy detection timeline of 12 to 36 hours. BD21 aims to address goals one and two of the 2018 National Biodefense Strategy regarding surveillance and detection and is necessary to inform decision-making at the operational level, to respond rapidly, and to reduce the impacts of biological incidents. BD21 is early in the acquisition process, focused on analyzing alternative solution concepts, conducting experimental technology demonstrations, gathering data and partner feedback, and establishing operational requirements.

BD21 presents a paradigm shift for biodetection operations employing anomaly detection sensors and data analytics for continuous monitoring as well as on-site field screening equipment. BD21 will provide timely notification of an airborne biological release to authorities. BD21's goal is to improve the detection timeline to enable an earlier response and to provide a common operating picture to federal, state, and local stakeholders.

CWMD's BD21 team is in close coordination with S&T through integrated product teams (IPT) and CWMD Alliance (a collaborative partnership between S&T, CWMD, and the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense). S&T is conducting several projects aligned with the CWMD Strategic Plan to fill knowledge gaps in the bio-threat space. S&T and CWMD are creating a CWMD Research and Development Coordination IPT to coordinate DHS research and development efforts and investments.



DHS Biosurveillance Systems

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I. Legislative Language

This document was compiled pursuant to direction in House Report 116-180, which accompanies the Fiscal Year (FY) 2020 Department of Homeland Security (DHS) Appropriations Act (P.L. 116-93).

House Report 116-180 states:

The Committee directs S&T and the Countering Weapons of Mass Destruction Office (CWMD) to provide a joint report to the Committee, within 60 days of the date of enactment of this Act, on the status of developing and testing a successor bio-threat detection system, along with plans to complete development and field the new capability. The report shall also describe planned changes to biodetection operations to improve upon the legacy program and how CWMD and S&T will coordinate their respective biodetection roles and activities.

II. Background

The mission of DHS's Science and Technology Directorate (S&T) is to enable effective, efficient, and secure operations across all homeland security missions by applying scientific, engineering, analytic, and innovative approaches to deliver timely solutions and to support Departmental acquisitions.

S&T's mission is accomplished through four Strategic Goals:

1. Build trusted relationships with customers that support the delivery and adoption of mission-critical solutions.
2. Excel at a set of core offerings and capabilities that are aligned to customer mission needs.
3. Strengthen external partnerships to advance homeland security mission priorities.
4. Create a unified and dynamic organizational infrastructure and culture.

CWMD's mission is to enable operational partners to prevent weapons of mass destruction (WMD) use against the Homeland and to promote readiness for chemical, biological, radiological, nuclear, and health security threats.

CWMD's mission is accomplished through four Strategic Goals:

1. Anticipate, identify, and assess current and emerging WMD threats.
2. Strengthen detection and disruption of chemical, biological, radiological, and nuclear (CBRN) threats to the homeland.
3. Synchronize homeland counter-WMD and health security planning and execution.
4. Mature and strengthen CWMD as an operational support Component.

S&T and CWMD have a shared responsibility to address biological threats and advanced technology to improve biological defense for our Nation. CWMD has primary responsibility for providing a surveillance and detection capability that gives near real-time warning of a bioterrorism incident that involves airborne biological particulates in order to minimize or prevent casualties. This mission forms the basis for the Biological Detection for the 21st Century (BD21) acquisition. Well prior to the establishment of CWMD, S&T conducted research and development (R&D) activities in support of detection and mitigation of biological threats as well as recovery from a biological attack or event. S&T continues to execute several projects specifically aligned with the CWMD Strategic Plan to fill technological and knowledge gaps in the bio-threat space.

CWMD currently executes the BioWatch Program, established in 2003 by DHS, to provide surveillance of a bioterrorist attack by providing air-monitoring, analysis, notification procedures, and risk assessment to more than 30 major metropolitan areas. In 2013, the legacy Office of Health Affairs (OHA) managed BioWatch and recognized the need to improve the timeliness of detection. OHA initiated an analysis of alternatives that assessed several potential approaches including environmental detection combined with manual sample retrieval and laboratory analysis, autonomous identification, designated populations wearing sentinel collection systems with manual laboratory analysis, and clinical diagnosis. Cost and

performance factors resulted in OHA's decision to continue operating BioWatch as-is. In 2017 and 2018, DHS OHA, and then CWMD, built on the analysis of alternatives and other analyses, market surveys, and several workshops conducted with state and local decision-makers to initiate the Biodetection Technology Enhancement (BTE) effort. BTE began with the development of an independent mission needs statement that focused on improved timeliness, increased population and environment coverage, and flexible agent detection. Several modeling and cost analyses, combined with technology demonstration testing, indicated that probability of detection and the potential for false positives, among other effectiveness and performance factors, posed significant challenges for deployment. Based on the biodetection system capability challenges identified in the BTE effort, CWMD leadership initiated the BD21 program in November 2018 with a stated goal to increase sensor density over what was proposed for BTE and to incorporate an independent concept of applying machine learning and data analytics for enhanced system operation, specifically to reduce the impact of excessive false positive reports by available commercial-off-the-shelf trigger devices.

CWMD is pursuing BD21 as a next-generation biodetection capability to close BioWatch's gaps in consultation with S&T but will continue to support BioWatch as the Nation's operational system to detect aerosolized biological threat agents until a proven solution is fielded.

III. Discussion

A. Developing and testing a successor bio-threat detection system.

CWMD initiated BD21 as an acquisition program in November 2018, pursuing a next-generation capability to close BioWatch's capability gaps. CWMD is aiming to alleviate critical capability gaps in our Nation's ability to detect the presence of biological threat agents intentionally released into the air. The most significant gap is timeliness, with a lengthy detection timeline of 12 to 36 hours. The BD21 concept includes continuous monitoring for intentional releases of airborne and aerosolized biological agent using anomaly detection sensors and data analytics. BD21 completed the Needs Phase of the DHS Acquisition Lifecycle Framework on June 7, 2019, and is now in the Analyze/Select Phase. To date, CWMD completed the Biodetection Mission Needs Statement, BD21 Capabilities Development Plan, BD21 Threat Basis Study, and BD21 Alternatives Analysis Study Plan. BD21 remains early in the acquisition process, focused on analyzing alternative solution concepts, conducting experimental technology demonstrations, gathering data and partner feedback, and establishing operational requirements.

Concurrently, CWMD is executing the BD21 Technology Demonstration, which is an experimental, nonoperational project to collect data for anomaly detection algorithm development, to evaluate anomaly detection sensors (triggers), and to provide a learning environment for concepts of operations development. The BD21 Technology Demonstration will continue to support BD21 through the current acquisition phase.

B. Plans to complete development and field the new capability.

BD21 plans to achieve the Acquisition Decision Event 2A (ADE-2A) in the third quarter of FY 2021. During ADE-2A, the Under Secretary for Management, as the Acquisition Decision Authority, approves the acquisition program and initiates the next phase in the acquisition process. At ADE-2A, the Acquisition Decision Authority approves the recommendation from the program for the overall best capability alternative that provides the required performance at acceptable cost, schedule, and risk. The initial operating capability timeline is not determined until ADE-2A.

CWMD is investigating potential operating environments and numbers of systems to deploy through technology demonstrations and maturity assessments. Factors to be considered include the technology's limits of detection, the technology's suitability for specific environments, and input from jurisdictions. CWMD also is comparing the BioWatch modeling assumptions to those in the BD21 Threat Basis. An initial deployment strategy will begin to take shape at the end of the current acquisition phase.

C. Planned changes to biodetection operations to improve upon the legacy program.

BioWatch typically operates on a once-per-day scheduled collection by field operators. The cycle from filter retrieval to lab verification takes approximately 12 hours. Therefore, the BioWatch timeline can take 12-36 hours from attack to verification (of the presence of a biological threat agent).

BD21 presents a paradigm shift for biodetection operations. The BD21 concept includes: (1) continuous monitoring for airborne releases of a biological agent using anomaly detection sensors and data analytics; and (2) timely notification (within minutes) of a potential threat to authorities in addition to onsite field screening with portable equipment. BD21 will enable (1) first responders and other local officials to take immediate actions that minimize the impact of a biological release; and (2) earlier delivery of biological samples to laboratories for confirmatory analysis that supports additional response actions and deployment of medical countermeasures. Primary users will include state and local public health officials, emergency managers, and response personnel. Figure 1 depicts the BD21 Operational Concept and provides a timeline comparison to BioWatch.

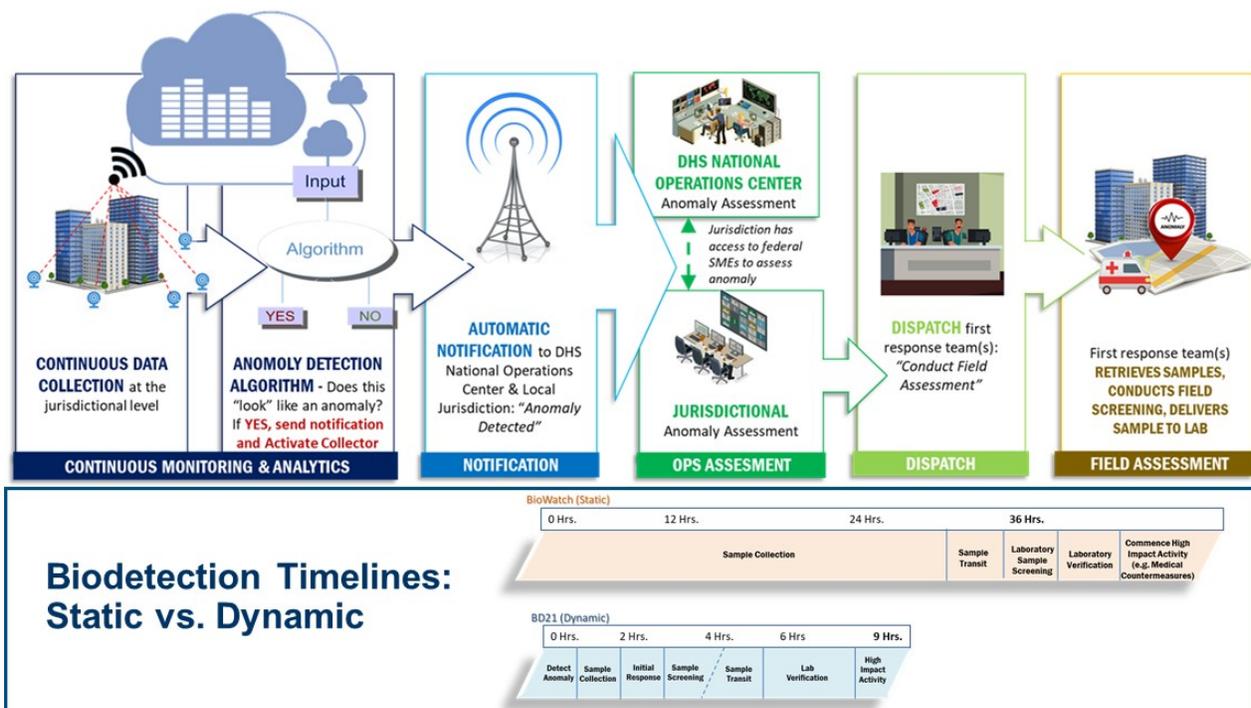


Figure 1. BD21 Operational Concept

D. CWMD and S&T biodetection coordination.

S&T and CWMD maintain close coordination through the BD21 Steering Committee, BD21 integrated product teams (IPT) and the CWMD Alliance. In addition to these reoccurring working groups, S&T is conducting several R&D projects in support of the CWMD BD21 Program.

S&T's Hazard Awareness and Characterization Technology Center, using historical data from the Biological Terrorism Risk Assessment Program, informed the CWMD BD21 Program, which completed version 1 of the Threat Basis in December 2019. The living Threat Basis document will continue to inform program requirements and analysis of potential fielding strategies.

S&T's National Environmental Biothreat Detection Architecture (NEBDA) activity provided a series of support to BioWatch, BTE, and the subsequent BD21 Program at CWMD. Both the BioWatch Program team, as well as the BD21 Program team, provided direct inputs regarding Component needs that defined the overall functionality of the architecture. Furthermore, both BioWatch and BD21 attended the NEBDA technical interchange meetings during which near-term to far-term use cases were reviewed to shape the NEBDA architecture further. Additionally, NEBDA, under a tasking to provide direct acquisition program document support to Components, has developed a series of products for the BD21 Program. NEBDA developed an initial scoping statement for BD21, and further assisted in the development of the BD21 Lexicon, by which terms pertinent to the BD21 Program and how they are defined in terms of the program scope are outlined. Also, NEBDA assisted the BD21 Program in defining the program milestones outlined under the DHS acquisition process and developed state-of-the-market analyses, both of which were included in the Capability Development Plan developed by CWMD prior to the passage of the ADE-1 gate. Finally, NEBDA developed an Operational Parameters Study in support of BD21, which provided CWMD with a preliminary set of Measures of Effectiveness, Measures of Performance, Measures of Suitability, and system selection criteria.

S&T's NEBDA Project fully intends to continue its coordination and support to the BD21 Program and other biological detection programs such as BioWatch throughout DHS. The NEBDA Project team is also in close discussions with CWMD with large to expand support to DHS Component biodetection technology acquisitions in support of the CWMD Office Strategy, to plan focus technology evaluations to conduct final refinements of Component inputs to technology needs outlined in the NEBDA biodetection architecture jointly with CWMD, and to further a NEBDA biological event risk basis tied to the NEBDA architecture that will be developed jointly in conjunction with CWMD and S&T's Probabilistic Analysis for National Threats Hazards and Risks Program.

S&T is engaged in several activities with New York City stakeholders. S&T's Urban Threat Dispersion Project is coordinating with BD21 technology demonstrations positioned in New York City to participate in an urban release of a biological agent simulant in Fall 2021.

S&T's SenseNet Project is coordinated and aligned closely with BD21. SenseNet, like BD21, is designed as a continuous environmental monitoring system with triggers to alert on a potential

threat within 10 minutes, followed by steps to identify presumptively a biothreat within 60 minutes. This timeline is significantly shorter than the current 12-to-36-hour BioWatch timeframe and is consistent with BD21 goals. Although both programs are addressing the indoor biological aerosol release, SenseNet continues to focus on cleaner, smaller environments like office buildings, while BD21 is evaluating more varied environments with higher concentrations of people.

Fundamentally, SenseNet is investigating the use of low-cost sensors to determine if an affordable system can be developed to meet the performance needs of an indoor biodetection system. The low-cost constraint and multiple sensor approach have resulted naturally in the selection of different sensors and simpler data analytics than the more robust instruments and adaptive algorithms that are needed for successful BD21 deployment. SenseNet uses simple particle counters and change-detection analytics to trigger an alert, followed by a presumptive identification step. S&T currently is funding the development of an automated sample collection and polymerase chain reaction capability, as well as a mass spectrometer for SenseNet presumptive identification purposes. Comparatively, BD21 is expected to employ a suite of sensors to collect information that includes particle size, concentration, and fluorescence. Data collected from the multiple sensors are analyzed using data fusion techniques and machine learning algorithms to discriminate biological material from ambient background particles and to determine whether any of the material represents a biohazard. The complementary systems being developed by SenseNet and BD21 are part of a layered biothreat protection approach that DHS is pursuing to address National Biodefense Strategy objectives for detecting and rapidly responding to bioincidents.

Additionally, SenseNet is creating a sensor-agnostic, open platform to lower the barrier to entry and to enable plug-and-play interoperability to ensure that the system can continue to evolve over time, creating a security system that provides an increasing level of safety against not only aerosolized biothreats, but also other threats of interest including chemical, explosive, radiological, nuclear, and active shooter. SenseNet also is designed to integrate with building management systems and to take automated, pre-authorized actions such as changing fan speeds; closing heating, ventilation, and air conditioning dampers; and notifying building supervisors to reduce losses of life, injury, and damage.

When deployed, SenseNet will include a display to provide alerts, threat status, and automated building response actions being taken. This information can be transmitted and conveyed to appropriate internal building personnel and external organizations to facilitate and coordinate response activities. In this model, SenseNet can serve as a point detector as part of the broader BD21 sensor constellation.

CWMD and S&T have embraced the concept of One DHS in support of Component customers and the first responder community in the bio-threat space by the following: (1) Formalizing agreements (memoranda of agreement, IPT charters, letters of intent) are developed between CWMD and S&T to address overlapping authorities in the chemical-biological space and to validate mutually beneficial activities; (2) Aligning the S&T IPT process with the CWMD WMD Requirements Operational Council to address methodically biothreat issues driven by capability gaps and requirements to meet mission needs, supported through technical analysis and vetted by

appropriate organizational resources, built on cross-organizational collaboration to include active participation in significant programmatic reviews, and characterized by clear transition plans and tracking of operational impact; (3) Coordinating R&D investments for DHS Components and first responders, and (4) Leveraging project activities for multi-purpose application (e.g., Urban Threat Dispersion test event in New York City to collect information about chemical-biological aerosol dispersion and to exercise BD21 technologies).

IV. Conclusion/DHS Action Plan

Biological threats are persistent as separately, nation-states and terrorist groups have found value in pursuing biological weapons, and there can be no confidence that will change in the future. CWMD's BD21 major acquisition program is addressing the goals of the 2018 National Biodefense Strategy and is attempting to alleviate BioWatch's critical capability gaps in our Nation's ability to detect intentional releases of biological threat agents. The BD21 value proposition includes the following: (1) Identify threats in a timely manner; (2) Enable initial response sooner; (3) Inform decisions for the U.S. Department of Health and Human Services and other senior government officials to mobilize medical countermeasures sooner; (4) Enable more effective post-attack Federal Bureau of Investigation investigations; and (5) Provide a common operating picture to federal, state, and local stakeholders. Expertise within CWMD and S&T is being utilized to understand the maturity of the BD21 concept. S&T not only is leveraging previous R&D discoveries but presently is conducting several projects aligned with the CWMD Strategic Plan to fill knowledge gaps in the bio-threat space. S&T and CWMD are pursuing formal agreements (memoranda of agreement, IPT charters, letters of intent) to address overlapping authorities in the chemical-biological space and to validate mutually beneficial activities.

Appendix: Abbreviations

Abbreviation	Definition
ADE-2A	Acquisition Decision Event 2A
BD21	Biological Detection for the 21st Century
BTE	Biodetection Technology Enhancement
CBRN	Chemical, Biological, Radiological, and Nuclear
CWMD	Countering Weapons of Mass Destruction Office
DHS	Department of Homeland Security
FY	Fiscal Year
IPT	Integrated Product Team
NEBDA	National Environmental Biothreat Detection Architecture
OHA	Office of Health Affairs
R&D	Research and Development
S&T	Science and Technology Directorate
WMD	Weapons of Mass Destruction