



DHS Biosurveillance Systems

February 6, 2023

Fiscal Year 2022 Report to Congress

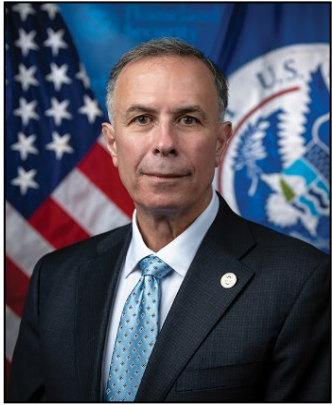


**Homeland
Security**

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

Joint Message from the Under Secretary for Science and Technology and the Acting Assistant Secretary for the Countering Weapons of Mass Destruction Office

February 6, 2023



Dimitri Kusnezov



Gary C. Rasicot

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

The report was compiled pursuant to direction in House Report 117-87, which accompanies the Fiscal Year (FY) 2022 Department of Homeland Security (DHS) Appropriations Act (P.L. 117-103). The report provides information on:

- The status of developing and testing a biothreat detection system to succeed BioWatch, along with plans to complete development and fielding of that new capability,
- 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, and
- DHS S&T progress in developing novel prototype sensors for real-time detection of aerosolized biological threat agents using newer technologies, such as matrix-assisted laser desorption ionization-time of flight mass spectrometry.

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

The Honorable Dave Joyce
Chairman, House Appropriations Subcommittee on Homeland Security

The Honorable Henry Cuellar
Ranking Member, House Appropriations Subcommittee on Homeland Security

Chair, Senate Appropriations Subcommittee on Homeland Security

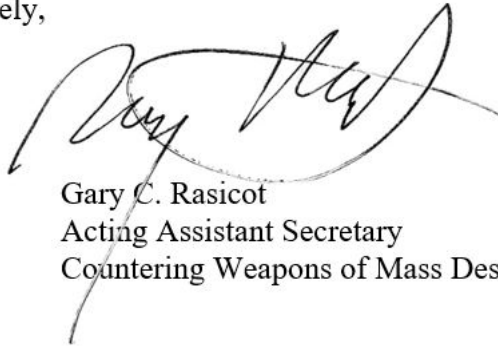
Ranking Member, Senate Appropriations Subcommittee on Homeland Security

We would be pleased to respond to any questions that you may have. Please do not hesitate to contact the Office of Legislative Affairs at (202) 447-5890.

Sincerely,



Dimitri Kusnezov
Under Secretary
Science and Technology



Gary C. Rasicot
Acting Assistant Secretary
Countering Weapons of Mass Destruction

Executive Summary

CWMD's BioWatch Program operates in more than 30 major metropolitan areas across the United States and is designed to warn of an aerosol-based bioterrorism attack in time to save lives. S&T and CWMD work together to develop state-of-the-art technologies and capabilities to enhance the ability of BioWatch and any successor programs to detect and alert the presence of biological threat agents rapidly in both outdoor and indoor environments. CWMD and S&T coordinate closely on research and development activities to avoid duplication of effort and to ensure that technologies under development will meet DHS's mission needs.

In the first quarter of FY 2022, CWMD leadership reviewed all of CWMD's environmental biodetection programs; this activity included risk-informed discussions across CWMD. In January 2022, the Acting Assistant Secretary for CWMD issued interim strategic guidance to drive modernization efforts in environmental biodetection to:

- (1) Accelerate treatment decisions (also known as "detect to treat");
- (2) Improve warnings to public health officials; and
- (3) Inform state, local, tribal, and territorial response better.

Upon review, CWMD senior leaders determined that both short-term and long-term gaps remain in CWMD's biodetection programs. Therefore, CWMD initiated the process of recalibrating its biodetection programs:

- For the near-term, CWMD formed a BioWatch Integrated Product Team comprising subject matter experts from across the homeland security enterprise—including our federal, state, and local partners—to assess how BioWatch's time-to-agent detection and breadth of agent coverage immediately can be improved.
- For long-term gap closure, CWMD is conducting an environmental biodetection capabilities-based assessment (CBA) to assess the biological risks facing the United States and to assess which emergent or technologically plausible systems could serve to mitigate these risks. The CBA will be independent of the current environmental monitoring posture and programs. Once completed, the CBA will enable CWMD to assess better if and how the current DHS biodetection programs dovetail with DHS's risk mitigation goals and to provide a roadmap either to adjust current programs or to develop new technologies, as necessary.

CWMD continues to support BioWatch as the Nation's operational program of record to detect aerosolized biological threat agents and will continue to do so until a proven solution is fielded.



DHS Biosurveillance Systems

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I. Legislative Language

This document was compiled pursuant to direction in House Report 117-87, which accompanies the Fiscal Year 2022 Department of Homeland Security (DHS) Appropriations Act (P.L. 117-103).

House Report 117-87 states:

Biosurveillance Systems.—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 to BioWatch, along with plans to complete development and field the new capability. The report shall describe planned changes to bio-detection operations that improve upon the legacy program and how CWMD and S&T will coordinate their respective bio-detection roles and activities.

The report should also include information on the progress of the Homeland Security Advanced Research Projects Agency Chemical and Biological Defense Division [S&T] in developing novel prototype sensors for real-time detection of aerosolized biological threat agents, using newer technologies such as matrix-assisted laser desorption ionization-time of flight mass spectrometry.

II. Background

Overview of Current Biodetection Efforts

The Science and Technology Directorate (S&T) and CWMD have a shared responsibility to address biological threats and to advance technologies that improve the biological defense posture of the Nation. Within the biodetection mission space, CWMD has the primary responsibility for providing operational surveillance and detection capabilities for aerosol-based bioterrorism attacks in the United States. The goal is to prevent or minimize casualties. Both CWMD and S&T manage robust biodetection research and development (R&D) portfolios with the overarching goal of enabling our federal and state, local, tribal, and territorial (SLTT) operational partners to detect a biological attack efficiently and effectively. S&T executes several projects specifically aligned with the CWMD strategic plan to fill technological and knowledge gaps within the biothreat landscape.

S&T and CWMD coordinate closely on R&D activities to avoid duplication and to ensure that the technology under development will meet the DHS mission needs. Formal coordination mechanisms include the CWMD R&D Coordination Integrated Product Team (IPT) and the CWMD Alliance, a collaborative partnership between S&T, CWMD, and the Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense and Defense Threat Research Agency.

BioWatch

- As the Nation's primary environmental biodetection capability, CWMD's BioWatch Program warns of aerosol-based bioterrorist attacks in more than 30 major metropolitan areas across the United States. In each of the 30+ BioWatch jurisdictions, automated collectors draw air through filters to capture particles. Field technicians then retrieve those filters and transport them to laboratories, where scientists process and analyze the samples for evidence of biological threat agents. In the event that a threat agent is identified, BioWatch then would alert federal, state, and local subject matter experts and decision makers using a robust notification system.
- Throughout the entire cycle, a rigorous quality assurance program ensures that the results of the BioWatch program are accurate and reliable. This allows decision makers to respond with confidence in the event of a positive test result.
- While centrally managed by the CWMD Office, the program is operated locally by a network of scientists, laboratory technicians, emergency managers, law enforcement officials, and public health officials. BioWatch preparedness programs support coordination of federal, state, and local responders across disciplines and municipal, city, and state boundaries.

- The combination of detection, rapid notification, preparedness, and planning helps federal, state, and local decision makers to take steps to mitigate the consequences of an aerosol release of a biological agent—most importantly, to prevent the loss of life. The BioWatch program’s coordinated response planning across organizational boundaries broadly benefits all-hazards response planning.
- Though labor-intensive, the BioWatch technology uses sensitive polymerase chain reaction technology with highly specific assays and has proven reliable for certain biological agents, including the bacterium that causes anthrax. DHS modeling has shown that a BioWatch warning can reduce casualties by 75 percent if antibiotic prophylaxis and vaccinations are administered 2 days after an anthrax attack relative to implementing these measures 5 days after an attack.

Biological Detection for the 21st Century (BD21)

- Since 2018, CWMD has undertaken technology development efforts as part of BD21. The goal has been to design, develop, and deploy networked detection systems that continuously monitor the air, collect real-time data, and employ data analytics to detect anomalies that may indicate the presence of biological agents. The faster that anomalies are detected, the faster that first responders can address potential threats.
- Progression of the BD21 acquisition program has continued to mature technologies to meet mission needs; however, BD21 has faced challenges similar to those encountered by previous attempts to replace BioWatch, including technology readiness and scalability.
- After an initial review of the BD21 program’s progress and its alignment with new CWMD strategic guidance on environmental biodetection (i.e., released in 2022 and described in section III.A.), our acquisition milestones for BD21 are on hold until CWMD completes its strategic-level gap assessment (described in section III.B.). However, the BD21 program office continues its technology maturation activities.

III. Discussion

A. Environmental Biodetection Strategic Guidance

In January 2022, the Acting Assistant Secretary for CWMD issued interim strategic guidance based upon an in-depth review of CWMD's environmental detection programs and risk-informed discussions across CWMD. The guidance highlighted three main priorities:

1. Modernization in environmental biodetection is imperative. Modernization will help to accelerate treatment decisions, to improve warnings to public health officials, and to inform SLTT response efforts better. As much as possible, environmental biodetection should help to prepare communities to respond, to deter adversaries, and to facilitate public warning, while aiding in attribution.
2. Current and future programs not only should address known agents on select agent lists, but also should address a broader range of biological threats. If possible, biodetection should move from detecting only a specific list of agents, to characterizing elements in a more general manner within a timeframe appropriate to advise treatment, to warn officials, and to inform a response.
3. CWMD environmental biodetection efforts should continue to identify ways to reduce the timeline for detection of aerosolized agents to identify what may be accomplished, within reason, in the near-, mid-, and long-term.

B. Planned Actions to Improve Environmental BioDetection

After reviewing CWMD's existing biodetection efforts against the new strategic guidance, CWMD senior leaders determined that both short-term and long-term gaps remain in CWMD's biodetection programs. As such, CWMD initiated the process of recalibrating its biodetection programs:

- For the short-term gap closure, CWMD formed a BioWatch IPT, comprising subject matter experts from across the DHS enterprise, including federal, state, and local partners, to assess how BioWatch's time-to-agent-detection and breadth of agent coverage immediately can be improved.
- For long-term gap closure, CWMD is conducting an environmental biodetection capabilities-based assessment (CBA) to assess the biological risks facing the United States and to assess which existing, emergent, or technologically plausible systems could serve to mitigate these risks. The CBA remains independent of the current environmental monitoring posture and programs. Once completed, the CBA will enable CWMD to assess better if and how the current DHS biodetection programs dovetail with DHS's risk mitigation goals and to provide a roadmap either to adjust current programs or to develop new technologies, as necessary.

Near-Term Enhancements to BioWatch

DHS is focused on identifying and implementing cost-effective improvements to the BioWatch program as the Nation's frontline aerosol-based bioterrorism detection capability. The BioWatch IPT is focused on:

- Re-evaluating the most appropriate pathogens for surveillance and if expansion of the current list is appropriate and feasible;
- Reducing the time to detection through various strategies;
- Increasing the efficiency or reducing the cost of the laboratory analysis protocols; and
- Exploring the incorporation of other particulate threats, such as biological toxins.

Additionally, the BioWatch program office is:

- Moderating the BioWatch Enhancement and Expansion Working Group (BEEW). The BEEW is a stakeholder working group of 30 state and local partners representing approximately 25 BioWatch cities and 2 cities that fall outside of the program. The BEEW convenes to ensure CWMD's awareness of potential impacts to jurisdictions if BioWatch is altered. The BEEW met monthly between June and December 2022.
- Analyzing the deployment of BioWatch sampling units to inform decisions on optimizing coverage on the basis of the most recent population data.
- Conducting R&D on a data package for air sampling units to provide real-time information on the health and operating status of each unit.
- Enhancing the biological threat exercise programs beyond a more narrowly defined exercise of BioWatch detection protocols to incorporate additional elements, such as intelligence information, preventive operations, and post-event evidence collection for attribution.

CWMD also established a formal outreach to state and local BioWatch partners. The Stakeholder Environmental Biodetection Effort (SEBE) connects CWMD leadership with state and local decision makers in BioWatch jurisdictions to improve biodetection readiness and response. The SEBE meets quarterly, and 12 senior BioWatch stakeholders participate on a rotating basis.

Long-Term Outlook

The strategic guidance issued in January 2022 revealed a need for broader gap analysis. Therefore, CWMD is working with a federally funded R&D center to undertake a CBA to inform an objective strategic-level gap analysis of the environmental biodetection mission space.

Further, CWMD has initiated, through the Deputy Secretary of Homeland Security, a Biodefense Strategic Review—similar to the recent DOD Biodefense Posture Review—to evaluate all DHS biodetection-related programs. Through this review, DHS will be poised better to understand what gaps and redundancies exist within and among Department-level activities and to understand how DHS programs fit within the broader biodefense architecture of the U.S. Federal

Government. Identifying and codifying remaining gaps will help DHS to adjust its current environmental biosurveillance programs and to direct the scope of future programs.

Continued R&D Cooperation between S&T and CWMD

As CWMD charts the course for its evolving and future biodetection programs, the S&T Office of Mission and Capability Support (MCS) and CWMD continue collaborating to develop, test, and deploy new technologies to decrease the time required to detect a biological incident. S&T plans to develop and transition technologies to CWMD's operational biodetection programs that:

- Decrease the time to detection of biological agents, and
- Have the capacity to expand to accommodate new biological agents as they emerge and/or become operationally relevant.

Coordination with Biodefense Experts beyond DHS

DHS is not proceeding down this path on its own. The Department is part of an interagency effort to prepare for and respond to biological threats. DHS works closely with federal partners, including the Department of Health and Human Services and DOD, on environmental biodetection efforts.

In addition to its federal partners, DHS collaborates and contracts with university-affiliated research centers, the Johns Hopkins University Applied Physics Laboratory, and federally funded R&D centers such as the Massachusetts Institute of Technology Lincoln Laboratory, the RAND Corporation, and the Institute for Defense Analyses. DHS also leverages the Department of Energy National Laboratories, including Argonne, Sandia, Lawrence Livermore, and Los Alamos.

C. S&T Progress in Developing Novel Prototype Sensors

S&T is developing digital matrix-assisted laser desorption/ionization time-of-flight (digitalMALDI) mass spectrometry for aerosol biodetection. This comprises a novel prototype sensor technology that enables real-time detection of aerosolized bacteria, viruses, and toxins. The prototype sensor will be a unification of two component technologies—a trigger and a detector. By combining these technologies, this novel sensor offers the potential for continuous air monitoring, with the ability to identify quickly and efficaciously biological particles that indicate that a bioterrorism event occurred. Also, limited human intervention is required for sample collection and analysis.

digitalMALDI Accomplishments

- DHS captured ambient aerosol background samples and particle concentration data from two mass transit facilities. For this effort, S&T leveraged CWMD's BD21 Technology Demonstration Program and S&T's Chem-Biodefense Advanced Capability Testbed operational test and evaluation (OT&E) sites. DHS used these samples and data to create mock aerosols in a laboratory setting. This enabled DHS to demonstrate prototype mass

spectrometer performance and synthetic data processing and analysis techniques in lieu of the planned deployment for OT&E.

- digitalMALDI prototype instruments have been designed, fabricated, integrated, and refined. The first-generation Triggered Mass Spectrometer prototype instrument was deployed to a mass transit facility and a large event venue for OT&E.
 - To date, DHS has captured more than 5 million single particle spectra during these deployments at the mass transit facility—leveraging a BD21 Technology Demonstration Program site for extended OT&E.
 - The instrument collected background environmental measurements over several months to satisfy operational testing requirements.
 - The digitalMALDI prototype deployment to the large event venue leveraged a testbed established by the Sensors and Platforms Technology Center in S&T’s Office of Science and Engineering. This represents one of several successful matrix partnerships that the S&T MCS team established during the span of the effort.
 - Future R&D to design and fabricate a refined prototype (digitalMALDI Generation 2) will address size, weight, and power constraints. The next-generation prototype will have a reduced volume and footprint and will be the template for additional development, testing, and evaluation with the objective of producing a technology for transition to BD21.
 - Resulting OT&E data sets have been analyzed by S&T’s Chemical Security Analysis Center and have been shared with BD21 stakeholders.

S&T has undertaken a technology readiness assessment (TRA) of the digitalMALDI prototype during option year 4 of the period of performance. The S&T Systems Engineering and Standards Division conducted the TRA and assessed the digitalMALDI prototype at a technology readiness level of 5. CWMD provided relevant data from both phase I and phase II of its Multiplexed Biothreat Detection with Fieldable Mass Spectrometry project to assist with the TRA. The TRA report will be shared with CWMD BD21 and R&D staff as a knowledge product, informing subsequent scope requirements to mature the technology in preparation for transition to the BD21 Program for advanced development, fielding, and sustainment.

IV. Conclusion

Expertise within CWMD and S&T is used to understand environmental biodetection capabilities, gaps, and opportunities more fully. S&T leverages R&D discoveries and current projects aligned with the CWMD strategic plan to fill knowledge gaps in the biothreat space.

Attacks with biological agents remain a significant risk. This strategic approach to environmental surveillance and agent detection/identification will ensure that efforts by CWMD and S&T are focused in areas that will provide the greatest risk-mitigation impacts for DHS and its SLTT partners now and into the future.

V. Appendix: Abbreviations

Abbreviation	Definition
BD21	Biological Detection for the 21st Century (Program)
BEEW	BioWatch Enhancement and Expansion Working Group
CBA	Capabilities-Based Assessment
CWMD	Countering Weapons of Mass Destruction Office
DHS	Department of Homeland Security
digitalMALDI	Digital Matrix-Assisted Laser Desorption/Ionization Time-of-Flight
DOD	Department of Defense
FY	Fiscal Year
IPT	Integrated Product Team
MCS	S&T Office of Mission and Capability Support
OT&E	Operational Test and Evaluation
R&D	Research and Development
S&T	Science and Technology Directorate
SEBE	Stakeholder Environmental Biodetection Effort
SLTT	State, Local, Tribal, and Territorial
TRA	Technology Readiness Assessment