SPECIAL FOCUS

SAVING SISYPHUS

ADVANCED BIODETECTION FOR THE 21ST CENTURY

A REPORT BY THE
BIPARTISAN COMMISSION ON BIODEFENSE

October 2021

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The Bipartisan Commission on Biodefense appreciates the efforts of the many officials who have endeavored since 2003 to emplace and operate a functional biodetection system for the Nation and thanks them for their willingness to share their original vision and current assessment. The Commission recognizes the enormous burden state and local officials bear in hosting federal biodetection systems, and thanks them for sharing their perspectives on the cost of state and local response and how that cost balances against federal investments. We thank the companies, academic institutions, national laboratories, and federal science and technology agencies that provided the Commission with their viewpoints as they continue to work diligently to develop technology that can detect evolving biological threats. We greatly appreciate the evaluation and assessment of current biodetection needs, requirements, and performance by Dr. George Poste, Dr. William Karesh, Ms. Rachel Levinson, and our other *ex officio* members. The Commission expresses its gratitude for the financial support our donors provide and thanks Hudson Institute for serving as our fiscal sponsor.

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TARGETED, AEROSOLIZED RELEASES OF ANTHRAX IN BIOWATCH LOCATIONS

Federal inaction on national biodetection systems jeopardizes the Nation

June 2026: As the World Cup Tournament, a joint U.S.-Canada-Mexico effort, begins to wind down, media reports from around the United States of simultaneous surges of patients presenting flu-like symptoms in all 11 U.S. cities hosting matches have marred events and festivities. A clinician in a Cincinnati, Ohio-based hospital notices worsening symptoms in several patients and suspects that they may have been exposed to anthrax. CT scans and blood tests confirm the diagnosis of inhalational anthrax just as a patient dies in New York City with the same symptoms. As the Ohio Health Department reports their findings to the Centers for Disease Control and Prevention (CDC), local hospitals discover additional cases in Seattle and Atlanta. Boston, Dallas, Kansas City, and Miami also soon report suspected and confirmed anthrax cases. CDC issues guidance to impacted states and localities, but more people die before they can get medical treatment.

A Federal Bureau of Investigation (FBI) field office alerts their headquarters to the presence of anthrax in Denver, Colorado. FBI personnel out of Quantico, Virginia and Washington, DC believe that the number and geographic spread of cases mean that the Nation has been attacked with a biological weapon. The FBI opens an investigation and notifies the White House, Department of Defense (DOD), Department of Health and Human Services (HHS), Department of Homeland Security (DHS), and Department of Justice. The origin and spread of the attack remain unknown during the following week without new information regarding the perpetrators and attack locations. Investigators begin to suspect that attackers released weaponized anthrax in stadiums crowded with World Cup fans. Unfortunately, the biodetection equipment provided to each stadium by DHS to help protect these National Security Special Events fails to provide any data.

During a news conference regarding six anthrax-related deaths in the City of Brotherly Love, the Mayor of Philadelphia, Pennsylvania, expresses anger and frustration with the biodetection equipment newly acquired by DHS through its Biodetection in the 21st Century (BD21) program and installed the previous year in 2025. Considering the daily nuisance false alarms the city had been experiencing for months, local responders were not surprised that the BD21 equipment failed to protect Philadelphia's citizens. A filter from the legacy BioWatch biodetection system near the Lincoln Financial Field football stadium tests positive for the presence of anthrax, but authorities cannot specifically determine when the attack took place, as the filter from the system is collected only once every 24 hours. Because BioWatch filters are destroyed during the testing process,

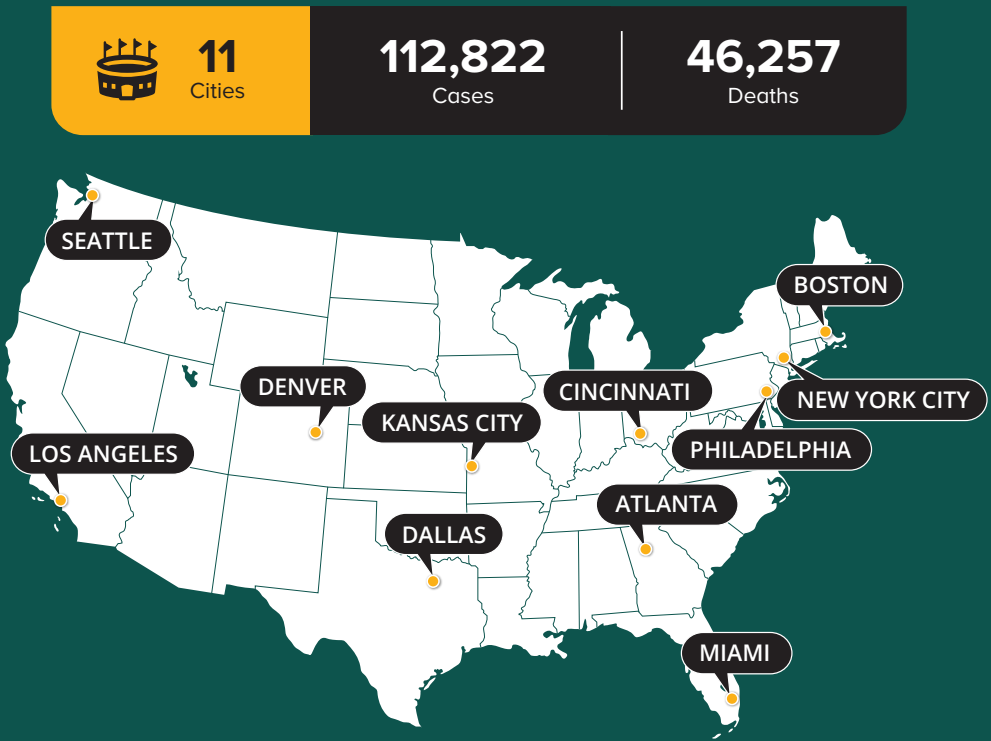
no evidence is provided from BioWatch to FBI investigators to help determine how these anthrax attacks came about, who is responsible, why they occurred, where the biological agent came from, or where it was weaponized.

Two weeks after the first attacks, the Los Angeles County Department of Public Health acknowledges that they have made little progress in characterizing the anthrax attack on SoFi Stadium, home of the National Foot League teams the Los Angeles Chargers and the Los Angeles Rams. BD21 and BioWatch detectors failed to provide the county with any useful data, despite heavy investment in these programs by DHS and substantial commitment of resources by the BioWatch local jurisdictions themselves.

The families hold funerals for the victims, now numbering 46,257 deaths caused by the attack at U.S. stadiums.

We can prevent much of the suffering described in the fictional scenario above by taking the following actions now to create a functional biodetection system to replace current BioWatch technology.

Figure 1: Locations of Anthrax Attacks in Scenario



EXECUTIVE SUMMARY

The George W. Bush Administration established a national biodetection program in 2003 at DHS, dubbing it BioWatch. DHS spends nearly $80 million a year on this program but has never been able to consistently demonstrate its operational capability in the field. The system detects a small number of organisms with questionable accuracy and produces results up to 36 hours after a pathogen may have been present near a detector, long after responders would need to act. It is far more likely that sick people seeking treatment at hospitals will make public health and safety officials aware of a biological event well before BioWatch results are available.

The BioWatch mission is unclear and return on investment is minimal. BioWatch technology was inadequate from the outset and has not improved over the past two decades. Federal and local responses to erroneous results indicating the presence of biological agents (i.e., false positives) are also expensive and further compound the problem. It is as unreasonable to force localities hosting BioWatch systems to respond continuously to numerous false positives as it is to force DHS to sustain a deeply flawed program.

Our Commission recommended in its 2015 foundational report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, that the Secretary of Homeland Security shut down BioWatch unless new technology producing valid and reliable results could replace current equipment and procedures. Congress does not want to shut down the problematic program until a replacement program is ready. Without congressional approval or elimination of dedicated appropriations for BioWatch, DHS has no choice but to continue spending tens of millions of dollars to maintain and try to improve upon a system that does not adequately safeguard the Nation.

Since the inception of the system in 2003, DHS has attempted and failed to acquire better performing technology to replace BioWatch. The Department has not experienced success in refreshing BioWatch through their current biodetection acquisition program, BD21. Early efforts underscore the need to take a different direction to acquire needed biodetection technology. Better technology and approaches to biodetection exist. Current performance specifications, biodetection technology, and the ability to integrate with other sources of data should change to meet the biological threat that has evolved greatly over the past 18 years.

Immediate Action Plan for National Biodetection

DHS can execute this plan without additional authorization from Congress. However, congressional direction would hasten replacement of current BioWatch technology, enable national biodetection far more quickly, and ensure the success of a program that has failed for almost 20 years to deliver. Congress should seize this opportunity to do more than mention BioWatch in legislation and should instead mandate requirements that appropriators and the Office of Management and Budget (OMB) can use to support at least the near term success of the program.

Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Homeland Security to:

- Obtain current intelligence and information about the biological threat, redefine the mission of the BioWatch program taking today's biological threats into consideration, and characterize the environment in which BioWatch detectors will operate *within 30 days of enactment*.
- Develop (with state, local, tribal, territorial, and federal stakeholders, and assistance from knowledgeable national laboratories and academic institutions) new BioWatch program requirements for national biodetection, new technical requirements for biodetection technologies to replace existing BioWatch technology, and new requirements to share results obtained by BioWatch directly with the governors of, and public health departments in, jurisdictions that host the system *within 60 days*.
- Identify BioWatch replacement technologies and determine where to emplace detectors and other equipment throughout the Nation *within 90 days*.
- Acquire at least three technologies that can–either individually or together– meet BioWatch mission requirements and the needs of newly identified BioWatch jurisdictions *within 180 days*.
- Procure and send this newly acquired biodetection technology to BioWatch jurisdictions, test new equipment and laboratory protocols, exercise use, and end old and establish new agreements with public health laboratories in BioWatch jurisdictions to conduct tests and provide other laboratory support *within one year*.
- Replace old BioWatch—and piloted newer BD21—equipment, end contracts for laboratory testing, and remove government contractors from public health laboratory facilities *within 18 months*.

Research and Development Plan for National Biodetection

DHS has tried since 2003 to acquire new biodetection technology for BioWatch. The inability of the Department to identify sufficient requirements for, and industry to provide, needed technology point clearly to the need for DHS to engage in basic research for biodetection. Basic research at DHS falls under the purview of the Science and Technology Directorate. DHS needs a multi-year, comprehensive biodetection research and development program that leverages broad public and private sector knowledge to develop a system that meets current and future biodetection requirements.

Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Homeland Security to:

- Produce and implement a long-term research and development plan for BioWatch that includes collaboration with the HHS Biomedical Advanced Research and Development Authority, DOD Defense Advanced Research Projects Agency (DARPA) and National Aeronautics and Space Administration (NASA), and input from industry, academia, and the national laboratories, *within 30 days of enactment*.
- Engage the National Academies of Sciences and industry to conduct periodic external evaluations (as they did for the Pentagon's biodetection system) to identify gaps and potential failure points, and recommend contingency requirements in the event prospective technology does not perform as expected or intended, *within one year and annually thereafter*.
- Develop a robust testing protocol for biodetection prototypes with support and evaluation from collaborating federal departments and agencies and industry, test prototypes in the environments in which BioWatch detectors will or could be deployed, involve officials from these jurisdictions in this prototype testing, and obtain an external evaluation of prototypes to help identify the most promising technologies to achieve the BioWatch mission *within 120 days*.
- Determine how best to deploy replacement technologies strategically and most effectively throughout the Nation on an annual basis with input from the DOD, national laboratories, and National Academies of Sciences *within one year and annually thereafter*.
- Deploy replacement biodetection technology to participating areas following a successful final evaluation conducted with the jurisdictions and collaborating federal departments and agencies *within one year and continuously thereafter.*
- Continue regular development and prototyping of biodetection technology in this manner.

BIOWATCH FITS AND STARTS

Timeline

2001

As letters containing anthrax arrived in various locations throughout the Nation shortly after the terrorist events of September 11, 2001, authorities lacked immediately available, actionable information to respond. In the aftermath of these events, the Bush Administration understood the need to quickly detect and contain future biological attacks. The federal government subsequently engaged in efforts to deploy an environmental biodetection system throughout the Nation.

2003

During his 2003 State of the Union address, President George W. Bush announced that the federal government would be "deploying the Nation's first early warning network of sensors to detect biological attack."[1] The goal was to emplace technology that could detect a catastrophic biological attack (defined by the federal government as an event large enough to cause at least 10,000 casualties).[2] Deployed later that year, the system (known as the BioWatch Program or BioWatch) utilized air samplers in tandem with polymerase chain reaction (PCR) laboratory testing.[3] The filters from the samplers were routinely and usually sent to public health laboratories for testing by government contractors occupying space there. The technology underpinning the BioWatch system was derived from the Biological Aerosol Sentry and Information System (BASIS), developed by the Lawrence Livermore National Laboratory and Los Alamos National Laboratory in 1999.[4] The Bush Administration and Congress made DHS responsible for funding, deploying, and overseeing the program.

Only 35 metropolitan jurisdictions received BioWatch detectors[5] and the program has yet to achieve comprehensive national biodetection coverage. The list of BioWatch participant localities is not publicly available, although the media reports biodetectors in Atlanta, Boston, Chicago, Houston, Los Angeles, New York City, Philadelphia, Saint Louis, San Diego, San Francisco, and Washington DC. Some detectors in the program are visible (e.g., in subway stations). The federal government did not permanently deploy BioWatch technology to other locations in

the country. Instead, DHS brings BioWatch detectors in for limited periods of time to support mass gatherings (e.g., the Super Bowl, presidential national conventions).

The system suffers from high numbers of false positives and expensive responses based on those inaccurate results. Additionally, the system requires personnel to visit every detector once a day to collect and bring filters back to a laboratory for testing. This virtually guarantees that the system will not identify a biological threat in less than 24 hours. Because false positives occur so frequently, all positive PCR laboratory test results from BioWatch air sampler filters require additional discussion and analysis to determine whether the results can be considered BioWatch Actionable Results (BARs). Even if the technology worked as intended, the information offered by a BAR is insufficient by itself for any BioWatch jurisdiction to determine whether the result is indicative of a biological attack. States and localities would never decide to evacuate public venues, shut down airports, or otherwise act, based solely on this data.

The system is designed to only detect five or six known pathogens at a time, informed by federal threat assessments focused on the biological agents that adversaries have already weaponized or would most likely use in an attack. BioWatch was not designed to track naturally occurring, emerging infectious diseases. Biodetection technology does exist, however, that could have detected diseases like the 2019 novel coronavirus disease (COVID-19) in the environment.

The ease of altering and synthesizing genetic material and the ever-increasing number of emerging infectious diseases that threaten human and animal populations have substantially amplified the biological threat. Modern technology has the potential to allow the Nation's enemies to weaponize (or further weaponize) any pathogen. The system or systems we rely on to detect these threats must have broad capabilities to address a wider range of pathogens than was required 20 years ago. Continued reliance on PCR-based technologies to confirm the presence of only a small, previously specified number of pathogens is also insufficient to meet the evolving biological threat.

> ***Ideally, biodetection systems should be able to identify biological attacks (including those using genetically engineered organisms), naturally occurring outbreaks, and accidental pathogen releases caused by an enormous variety of pathogens. A collateral benefit provided by such systems would be widespread routine monitoring for infectious diseases and toxins wherever the equipment is deployed.***

2014

For more than a decade, DHS has discussed upgrading BioWatch biodetection technology to better address a broader range of biological agents; provide real-time data across the homeland security enterprise; and improve biodetection information-sharing among federal, state, and local officials. An acquisition effort to replace BioWatch with next generation biodetection technology (known as Generation 3) terminated in 2014 following cost and accuracy concerns raised about the program within DHS, and by the Government Accountability Office (GAO)[6] and Congress. GAO recommended at the time that any replacement effort would require further evaluation of mission needs and a cost-benefit approach to identify technology solutions. Acknowledging the continued problems with the technology currently used by the program, DHS leadership tasked the DHS Science and Technology Directorate (DHS S&T) with working on a BioWatch replacement following cancellation of the Generation 3 program in 2014. DHS S&T conducted some technology evaluations but did not identify a suitable replacement at that time.

2015

In recognition of the technological, logistical, and programmatic issues plaguing the program, the Commission recommended the development of a 21st Century-worthy environmental detection system in its 2015 *National Blueprint for Biodefense*. The Commission urged: (a) Congress to fund the development of an advanced system to replace BioWatch; and (b) the Secretary of Homeland Security to replace BioWatch detectors with this newly developed technology by 2020 and remove the old detectors from service.[7]

2016

The U.S. House of Representatives Committee on Homeland Security convened an industry roundtable in 2016 to address DHS engagement with the private sector to develop next generation biodetection solutions. The Committee found that some companies declined to work with DHS on biodetection because they were frustrated with the engagement processes. In keeping with the Commission's findings and recommendations regarding the dire need for additional congressional oversight, the Committee also received a briefing from DHS and DOD on each department's biodetection activities and efforts to collaborate with one another.[8]

2018

DHS began testing several new biodetection technologies in 2018 as part of its BD21 program to acquire and eventually replace existing BioWatch detectors by 2025.[9] The DHS Office of Countering Weapons of Mass Destruction (CWMD) tested technology candidates (among them biodetection technologies previously rejected by DOD) at 12 sites nationwide.[10] DHS CWMD intended to use this testing to identify requirements for the replacement system, and acquire, procure, and deploy new biodetectors by 2025 (10 years after the release of the Commission's recommendation and 22 years after the BioWatch program's initial deployment in 2003). Contrary to this seemingly reinvigorated effort, DHS CWMD ceased conducting routine full-scale exercises with BioWatch jurisdictions this year.[11]

> ***Appropriations of more than $80 million per year from FY2008 through FY2021 for the BioWatch program have resulted in only the ineffectual status quo, inexplicably supporting legacy technology that has long outlived its utility. The technology used initially to implement BioWatch in 2003 was never intended to be permanent. Replacing BioWatch in 2025 means BioWatch will have been left in place virtually unchanged and poorly performing for 22 years at a cost of more than $1.5 billion to the taxpayer.***

DHS officials also announced that BD21 would acquire a system to replace BioWatch and that could rapidly alert first responders to potential biological threats, well before laboratory confirmation. When it initiated BD21, however, DHS CWMD engaged only federal partners (e.g., DOD, HHS, DHS S&T).

2019

BD21 squandered a year during which DHS CWMD tested technology without any mission requirements or needs defined by state or local personnel who would have to respond to results generated by the new system. DHS CWMD eventually hosted a concept-of-operations working group in 2019, providing non-federal stakeholders with the opportunity to provide their perspectives on biodetection requirements. In October 2019, DHS CWMD temporarily halted the BD21 program in order to further engage non-federal governmental and private sector biodetection experts. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (P.L. 116-22) passed that same year required HHS to work with DHS and DOD to identify, exchange, and make recommendations about biodetection technology.

2021

After additional delays (due to the COVID-19 pandemic), DHS CWMD resumed testing potential BD21 technology at two sites in New York and New Jersey. Development continued for the algorithm proof-of-concept algorithm that would govern the BD21 system. In September 2021, DHS issued an a Request for Information to industry for biosensor technology that could meet the needs of the BD21 program.[12]

Arguments Remaining to Keep BioWatch in Operation

Considering the widely acknowledged problems with BioWatch, only two possible arguments remain for continuing to operate the system. Its presence: (1) deters the use of biological weapons against the United States; and (2) strengthens partnerships with public health and other state and local officials that support the program.

The first argument—that the BioWatch system serves as a deterrent—finds no support, given the very public failures and criticisms of the program by Congress, federal watchdogs, the media, and this Commission. No adversary can possibly fear at this point that BioWatch would hinder their plans to release a deadly pathogen in the United States.

The second argument—that BioWatch strengthens partnerships with public health and other state and local officials—has some merit. Working with the public health community to achieve early detection of biological threats can be beneficial to localities. Additionally, adjudication of a BAR forces federal departments and agencies to discuss results and potential responses to a seemingly positive test with state and local officials. However, some BioWatch jurisdictions find hosting the technology to be costly to their own budgets. Additionally, the impact of a BAR varies across jurisdictions, inconveniencing some and majorly disrupting others. Responding frequently to false positive results draws human and other resources away from areas in need, could shut down transportation hubs and other public venues, and reduces confidence in test results.

Federal watchdog agencies continue to identify problems with both the current BioWatch program and the BD21 initiative. In March 2021, the DHS Office of the Inspector General (OIG) found that unplugged equipment and security breaches disrupted biodetection activities in 34 of 35 BioWatch jurisdictions.[13] GAO reported in May 2021 that while BD21 was still in the early stages of its acquisition life cycle, the program faced technical challenges from applying technology in unproven ways, and its documentation lacked the detail necessary for successful acquisition.[14] Current BD21 concepts assume the continued use of PCR testing for confirmation, which GAO assessed would continue to prevent the system from being able to detect new and evolving biological threats quickly (as is also the case with the current BioWatch program). GAO went on to say that the scope of BD21 is largely focused on acquiring more advanced detectors with triggers utilizing a singular algorithm (yet to be developed and proven) and that DHS CWMD does not have a fallback option for improving or replacing BioWatch technology if this effort fails.

TECHNOLOGY PITFALLS AND PROMISES

The Bush Administration intended to expand the number of locations covered by BioWatch and improve the technology upon which the program depends. Nearly 20 years later, however, the system has seen no significant technology upgrade and struggles to achieve its mission. Biological threats to the Nation have evolved but BioWatch has not. The United States can certainly use and develop technology to detect the next biological threat but the government must make this a priority and learn from previous attempts to improve or replace BioWatch in order to do so successfully.

Settling for Less

As with the failed Generation 3 replacement effort, BD21 focuses on short-term acquisition of commercial-off-the-shelf technology to detect a limited set of biological agents. BD21 program officials are also preparing to acquire currently available biodetection technology that uses PCR for confirmation (the same technology utilized for laboratory testing of BioWatch samples), yet still only detects a small range of predetermined pathogens. Preliminary acquisitions by BD21 would also only address indoor environments.

The cornerstone of the BD21 replacement system for BioWatch will be an anomaly detection algorithm (still in development) supported by a suite of technologies (yet-to-be identified) deployed on-site. The algorithm would ideally trigger when on-site equipment reports the presence of pathogenic biological material above an established baseline. In development by the Massachusetts Institute of Technology (MIT) Lincoln Laboratory, the algorithm is still in the proof-of-concept phase. Even if the algorithm does work as intended, the final algorithm will likely allow for one false alarm per day, per location. The BioWatch program compares this to once-a-day filter collection from existing BioWatch detectors, but the human and other resources needed to respond to false alarms far exceed those needed to collect and test filters every day. Localities may be unwilling or unable to respond to daily false alarms.

DHS officials have not yet determined which technology or technologies BD21 will acquire to inform/enable the algorithm, making any assessment of the ultimate capability of BD21 difficult. It is unclear why BD21 has made so little progress over the last three years to identify suitable biodetection technology for acquisition, when other public and private sector entities already utilize far better technology. The BioWatch program has clearly communicated its goal to reduce the algorithm's false positive rate. However, they need to elicit, analyze, and validate at least their own needs, expectations, constraints, and interfaces to establish requirements that reflect their clear understanding of what will enhance national security and satisfy localities that host or will host the new system; and

clearly articulate performance requirements (other than the goal of reducing the algorithm's false positive rate). The program should draw upon the acquisition expertise of its own staff and that resident in the DHS Management Directorate to develop these requirements and ensure BioWatch will be able to use currently available or future technology.

Upon initial deployment, technology acquired by BD21 will only operate in indoor environments.[15] BioWatch equipment used in outdoor environments will remain unchanged and in place. Before it can replace old BioWatch equipment used outdoors, DHS will need to: (1) engage in another, longer-term acquisition effort or further modify technology previously acquired by BD21; and (2) obtain more funding for procurement. This means the legacy BioWatch system will remain in place outdoors, even as new equipment acquired by BD21 is emplaced indoors, placing additional demands on already strained local resources to support and respond to two different systems.

While DHS aspires to create and emplace a functioning, sensitive national biodetection system, their statements regarding their goals for BD21 specifically, and environmental biodetection more broadly, have failed to convey a clear vision for what they want the next generation biodetection system to accomplish. DHS OIG, Congress, GAO, and the science and technology community do not fully understand what outcomes will constitute success. They also do not understand how much it will cost or how long it will take to develop, acquire, and procure biodetection technology, because DHS estimates have proven incorrect thus far.[16] For its part, the BioWatch program could better understand the universe of current biodetection technology if they greatly increased their engagement with industry, academia, and the national laboratories.

Raising the Bar

Biodetection technologies (both PCR- and non-PCR-based) have progressed greatly since the BioWatch program began in 2003.[17, 18] Since then, DHS has taken advantage of advances in PCR technology to evaluate replacements for BioWatch and plans for BD21. The BioWatch program may decide to utilize some combination of cameras, particle counters, and other currently available detection equipment to provide data for the BD21 algorithm. However, other technologies (many of which are described in the Commission's 2021 report, *The Apollo Program for Biodefense*) could revolutionize biodetection. Ubiquitous sequencing, minimally- and non-invasive infection detection, and massively multiplexed diagnostics all broaden the realm of possibility in detecting biological threats.[19] Academic research and development has led to promising new technologies for biodetection, including open-air sequencing,[20] portable real-time sequencing,[21] and advanced trigger technology.[22] Commercial clinical laboratories have developed and now offer multiplex profiling and differentiation of host responses to bacterial and viral infections. The BioWatch program should consider these advances, explore deployment and information gathering configurations beyond that used by the current system, and investigate technologies other than PCR.

The BioWatch program should also look within its own department to DHS S&T, and to other federal departments and agencies, for assistance in identifying the technology it needs. The Department of Agriculture, DOD, Department of Energy, HHS, Environmental Protection Agency, NASA, National Science Foundation, and DHS S&T are all actively engaged in research, development, and (in some cases) deployment of new and viable biodetection technologies.[23]

NASA is developing biodetection technology based on canine mechanisms used to detect pathogens like COVID-19, called the E-Nose.[24] Originally developed to detect airborne contaminants in crew cabins during spaceflights, E-nose was the first nanotechnology-based device in space in 2007. DHS CWMD knew of this effort and was so impressed that they asked NASA in 2012 to modify this technology to detect chemical leaks or attacks. The technology's sensor module was smaller than a cell phone at the time, connected to a mobile application (i.e., a computer program designed to run on a mobile communications device), and could transmit data via a cloud system to emergency operations centers. In 2018 and 2019, NASA worked with the Lawrence Livermore National Laboratory to modify the technology again for other purposes, including monitoring in deep space, protecting soldiers on the battlefield, and checking personal health. In 2020, NASA received funding from HHS to modify the technology again to detect COVID-19. If it so chose, the BioWatch program could pursue further development of the E-Nose or other industry initiatives to detect numerous pathogens in various environments.

Like some currently available commercial solutions, Los Alamos National Laboratory is conducting research to mimic host recognition of biomarkers (pathogen traits that are recognized by a host's immune system) for early environmental biodetection (i.e., recognizing a biological agent in the environment without prior knowledge of the organism). The technology is already capable of differentiating between bacterial and viral signatures and could allow the system to detect biological agents from a distance. Such a capability could be useful for a BioWatch replacement program.

DOD also continues to conduct extensive biodetection research and development and field its own biodetection systems, in addition to the department's long investment in biodetectors for use on the battlefield. For example, in 2004, the Pentagon Force Protection Agency successfully emplaced an effective biodetection system throughout the Pentagon. The system uses a tiered suite of technologies. Tier 1 technologies are low-cost particle counters. These particle counters continuously collect and store data and will trigger an alarm if they detect abnormalities in the air, automatically initiating a secondary phase of detection with Tier 2 technologies. The Tier 2 technologies (developed by MIT Lincoln Laboratory) can detect small amounts of organisms in the air within five minutes.[25] Using genetically engineered cells that react to certain pathogens (about the same number of pathogens as BioWatch PCR technology), Tier 2 can alert operators after a bioluminescent reaction occurs almost immediately upon contact. An on-site laboratory

constitutes Tier 3 and conducts confirmatory testing. DOD also successfully operationalized light detection and ranging (LIDAR) technology for biodetection in 2004, but felt utilizing it would be too costly for this purpose. Considering the BD21 determination to only provide indoor biodetection, the program should at the very least utilize the same commercial biodetection technology used by the Pentagon over the last 17 years, technology that is far superior to currently deployed BioWatch technology. The BioWatch program should also consider utilizing LIDAR, since the technology has advanced significantly since 2004, and costs have decreased in recent years.

DARPA is also working on environmental biodetection technologies that leverage techniques (e.g., Raman spectroscopy) designed to detect a broad range of pathogens. These systems (i.e., SIGMA+, SenSARS) leverage numerous different technologies and algorithms in unison to increase reliability of resulting data, minimize false positives, and improve the chance of true detection.[26, 27] DARPA also intends to see whether they can incorporate next-generation sequencing technology to achieve pathogen-agnostic biodetection, enabling recognition of agents specifically engineered to elude traditional means. In 2019, DARPA successfully demonstrated SIGMA+ maturity and reliability at the Indianapolis 500.[28] Having co-located with DARPA at this race to test some BD21 technologies, the BioWatch program is aware of this new biodetection technology and could use the same or similar technology in outdoor environments addressed by BioWatch.

DHS should keep common characteristics of successful biodetection in mind. We likely will not know what the next biological threat is before it arrives, so any next generation biodetection system should be pathogen-agnostic. The technology should be able to rapidly detect organisms (as close to real-time as is feasible) before people become ill and seek treatment. The program should also leverage sequencing technologies alongside machine learning to differentiate naturally occurring pathogens from those created in a laboratory.

Characteristics of Successful Biodetection Technology

- PATHOGEN-AGNOSTIC
- QUICK
- ACCURATE
- ABLE TO PROVIDE INFORMATION FOR ATTRIBUTION
- ADAPTABLE AND FLEXIBLE
- USER-FRIENDLY

Responders and decisionmakers require accurate results so they can make decisions based on data and not expend resources unnecessarily to deal with false positives. The technology should be able to provide evidence reliably for attribution and law enforcement purposes, thereby finally enabling BioWatch to serve as an effective deterrent. In order to evolve as the biological threat evolves, the system should be adaptable and flexible (with performance criteria for both) regarding the ease with which underlying technology can be replaced and the ability to operate effectively in both small and large environments. Finally, the technology should be user-friendly, at a minimum reducing sample collection needs and requiring little technical expertise to operate. DHS should not move forward with any acquisition without clearly articulating performance requirements for these critical functions and their contribution to the biodetection architecture.

Table 1. Examples of Biodetection Technologies by Success Characteristics.[29,30]

BIODETECTION TECHNOLOGIES	PATHOGEN-AGNOSTIC	QUICK	ACCURATE	USEFUL FOR ATTRIBUTION	ADAPTABLE	USER-FRIENDLY
NASA E-Nose		●	●		●	●
LANL Biosensor[31]	●		●		●	●
Pentagon System		●	●	●		
DARPA SIGMA+; SenSARS	●	●	●	●	●	
Sequencing	●		●	●	●	
Trained Canines[32]		●	●			●
BD21						
BioWatch						

Note: this categorization does not serve as a conclusive assessment of the technologies.

REPLACING AND ADVANCING BIOWATCH

In its 2021 report, *Biodefense in Crisis: Immediate Action Needed to Address National Vulnerabilities*, the Commission made the following recommendation to redirect BioWatch funding into more viable technologies:

> **Considering the continued inability of DHS to identify, test, acquire, procure, and deploy replacement biodetection technology, OMB, in coordination with the National Security Council, should eliminate the BioWatch program from all future Presidential Budget Requests.** Instead, OMB should increase the budget for a directed funding request for research and development…to produce biodetection technology that can be used in national biodetection systems. Congressional appropriators should deny further funding for BioWatch activities until proven replacement technology is identified and confirmed to meet the needs of the program.

Our Commission recommended in its 2015 *National Blueprint for Biodefense*, that the Secretary of Homeland Security shut down BioWatch unless new technology producing valid and reliable results could replace current equipment and procedures. Congress does not want to shut down the flawed program until a replacement program is ready. Without congressional approval or elimination of dedicated appropriations for BioWatch, DHS has no choice but to continue spending tens of millions of dollars to maintain and try to improve upon a system that does not adequately safeguard the Nation. Instead, Congress should now require the development of next-generation technologies as part of a comprehensive biodetection system that marries functional technologies with updated mission needs, performance requirements, and a realistic concept of operations developed in concert with state, local, tribal, and territorial officials in jurisdictions that host or will host the system.

Immediate Action Plan for Biodetection

Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Homeland Security to:

- Obtain current intelligence and information about the biological threat, redefine the mission of the BioWatch program taking today's biological threats into consideration, and characterize the environment in which BioWatch detectors will operate *within 30 days of enactment.*
- Develop (with state, local, tribal, territorial, and federal stakeholders, and assistance from knowledgeable national laboratories and academic institutions) new BioWatch program requirements for national biodetection, new technical requirements for biodetection technologies to replace existing BioWatch technology, and new requirements to share results obtained by BioWatch directly with the governors of, and public health departments in, jurisdictions that host the system *within 60 days.*
- Identify BioWatch replacement technologies and determine where to emplace detectors and other equipment throughout the Nation *within 90 days.*
- Acquire at least three technologies that can—either individually or together—meet BioWatch mission requirements and the needs of newly identified BioWatch jurisdictions *within 180 days.*
- Procure and send this newly acquired biodetection technology to BioWatch jurisdictions, test new equipment and laboratory protocols, exercise use, and end old and establish new agreements with public health laboratories in BioWatch jurisdictions to conduct tests and provide other laboratory support *within one year.*
- Replace old BioWatch—and piloted newer BD21—equipment, end contracts for laboratory testing, and remove government contractors from public health laboratory facilities *within 18 months.*

While the BioWatch program obtains some biological intelligence and information, it should not have to do so on their own. Congress should direct the DHS Under Secretary of Intelligence and Analysis to obtain current biological intelligence from the Intelligence Community and provide additional analysis to inform BioWatch research and development, setting of requirements, and emplacement of equipment throughout the Nation.

Engaging state, local, tribal, territorial, and federal stakeholders, national laboratories, academic institutions, and industry is a large endeavor in and of itself. Congress should direct the DHS Office of Partnership and Engagement and the BioWatch program to work with these stakeholders and organizations to develop new requirements. This effort is too large for the

BioWatch program to handle on its own, especially considering previous decisions to minimize engagement in an effort to increase efficiency in communications and management.

Considering the difficulties the BioWatch program continues to experience in replacing old technology and acquiring new technology with BD21, Congress should terminate BD21 and direct DHS S&T to lead the research and development effort for biodetection. DHS S&T originally operated BioWatch until 2007, when the department transitioned the program to the Office of Health Affairs.[33] Congress has previously supported the development of a replacement system by DHS S&T, to the point that in 2016, Senate appropriators proposed transferring $12 million from BioWatch to DHS S&T to develop new, functional biodetection technology.[34] DHS S&T also already possesses the necessary acquisition authority. Since Congress has empowered the Directorate to develop needed science and technology to meet homeland security needs, it should direct DHS S&T to develop the biodetection technology BioWatch needs.

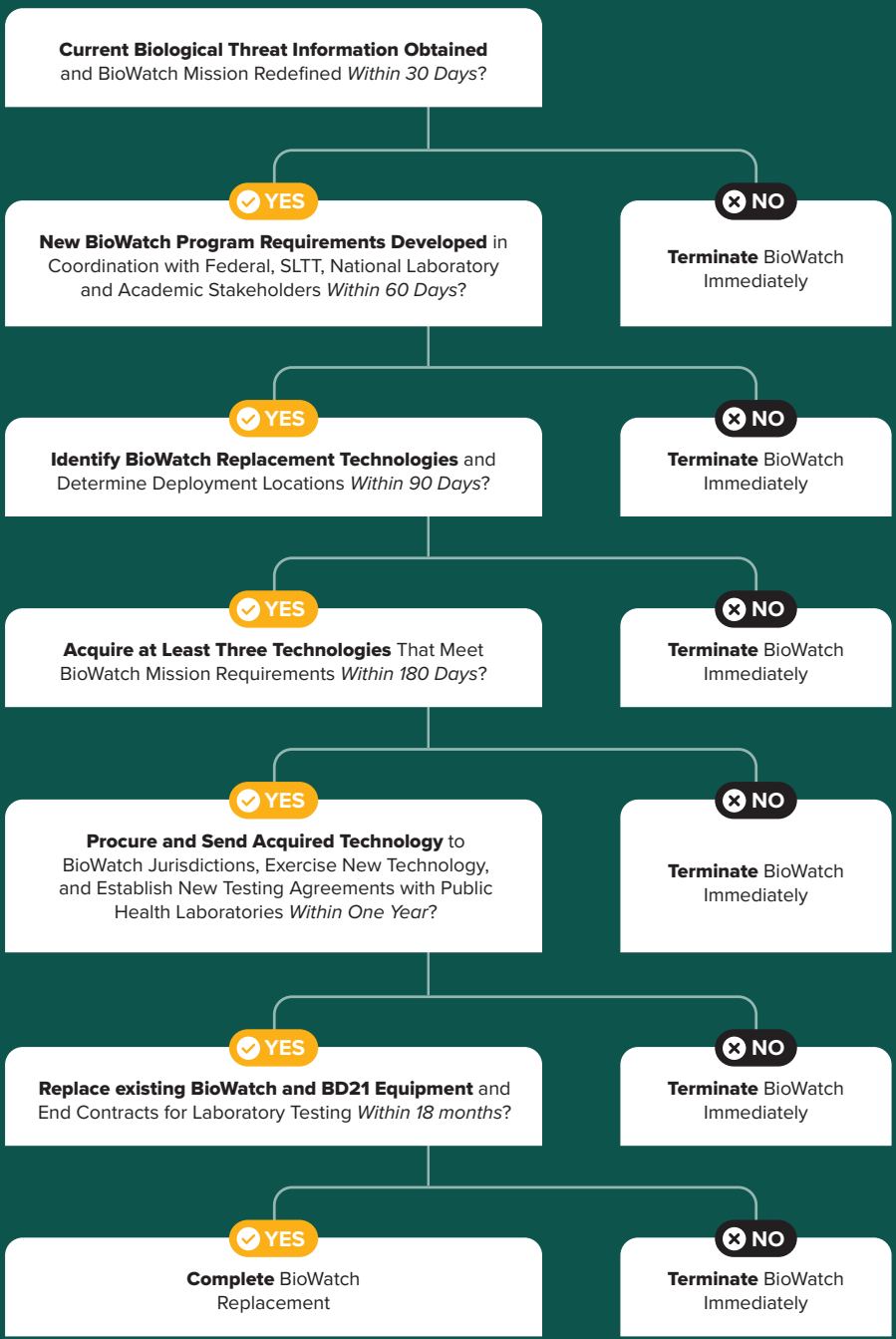
BioWatch will not be able to procure needed technology with their current or projected budgets. If Congress does not want to provide that funding, then it will, in effect, prevent BioWatch from ever achieving success. BD21 exists to acquire new biodetection technology, not procure it.

DHS currently utilizes government contractors to test BioWatch filters. DHS borrows space to conduct this testing from public health laboratories in or near jurisdictions that host BioWatch equipment. For the most part, states, localities, and the CDC provide funding needed for building and laboratory operations, but DHS does not reimburse jurisdictions or the CDC for using this space. While laudatory when BioWatch was initially implemented in exigent circumstances, this arrangement is not fiscally acceptable. As a BioWatch pilot program already demonstrated in Minnesota, there is no need for DHS to employ contractors to test BioWatch filters when public health laboratories employ scientists who are perfectly capable of doing the testing themselves. The BioWatch program should pay the public health laboratories to conduct needed tests and limit or eliminate the use of contractors for this purpose.

DHS can take and complete these actions in 18 months or less. Understanding the challenge that developing and acquiring comprehensive, next generation technology in a short timeframe presents, the Commission recommends utilizing currently available biodetection technologies to replace BioWatch. Some may not confirm the presence of a specific pathogen but would still provide useful information to public health and other authorities to track the spread of biological agents. Technology currently exists that can detect specific biological agents more effectively than BioWatch, and easily be adapted to detect naturally occurring infectious diseases like influenza.[35] BioWatch would greatly benefit from replacing its obsolete equipment with functioning technology, even if it must utilize an array of equipment that produces different types of data. This would also finally provide BioWatch's sister program, the National Biosurveillance Integration System, with DHS-owned data to incorporate and analyze.

The courses of action are clear:

Figure 2. BioWatch Replacement Decision Tree



If DHS is unable or unwilling to execute ANY of the steps in the process described above, Congress should terminate the BioWatch program and redirect biodetection funding to long-term biodetection research and development.

Research and Development Plan for National Biodetection

Congress should amend the Homeland Security Act of 2002 (P.L. 107-296) to direct the Secretary of Homeland Security to:

- Produce and implement a long-term research and development plan for BioWatch that includes collaboration with the HHS Biomedical Advanced Research and Development Authority, DARPA and NASA, and input from industry, academia, and the national laboratories, *within 30 days of enactment.*
- Engage the National Academies of Sciences and industry to conduct periodic external evaluations (as they did for the Pentagon's biodetection system) to identify gaps and potential failure points, and recommend contingency requirements in the event prospective technology does not perform as expected or intended, *within one year and annually thereafter.*
- Develop a robust testing protocol for biodetection prototypes with support and evaluation from collaborating federal departments and agencies and industry, test prototypes in the environments in which BioWatch detectors will or could be deployed, involve officials from these jurisdictions in this prototype testing, and obtain an external evaluation of prototypes to help identify the most promising technologies to achieve the BioWatch mission *within 120 days.*
- Determine how best to deploy replacement technologies strategically and most effectively throughout the Nation on an annual basis with input from the DOD, national laboratories, and National Academies of Sciences *within one year and annually thereafter.*
- Deploy replacement biodetection technology to participating areas following a successful final evaluation conducted with the jurisdictions and collaborating federal departments and agencies *within one year and continuously thereafter.*
- Continue regular development and prototyping of biodetection technology in this manner.

There is no need to wait to engage in this longer-term research and development effort to replace current BioWatch technology. This program is not just "one and done." Since the biological threat evolves unceasingly, so should DHS engage in continuous research and development to replace obsolete ineffective technology.

Developing a proper plan for research and development is crucial. Performance requirements should not solely focus on matching or exceeding current standards for today's BioWatch system. Instead, research and development should address key gaps in the current BioWatch system, including the extremely limited list of pathogens that equipment and tests are designed to identify, and the overlong time between an event and the results of testing.

The research and development phase should involve close collaboration with external stakeholders (e.g., host jurisdictions, FBI) and experts (e.g., DARPA, NASA, National Academies of Science) who can provide feedback and identify problems and solutions. DHS S&T should leverage these relationships to test prototypes and components in field environments consistently to keep the process moving. External collaboration and evaluation should occur throughout the prototype testing phase as well, and should help to determine the most promising candidates.

Once these candidates are identified, the Federal Emergency Management Agency and DHS S&T should assist the BioWatch program in conducting exercises that test the technologies in intended environments in conjunction with participating jurisdictions. Exercises should inform all needed modifications before widespread deployment of the replacement system.

Final deployment will require its own strategy to ensure effective placement across the Nation. The geographic footprint of the new system should be substantially larger than that of today's BioWatch system, utilizing current threat analysis to help determine which jurisdictions are at highest risk and where detectors should be deployed. DHS should establish a biodetection development cycle to revisit the mission and technology regularly, ensuring that national biodetection capabilities keep up with evolving biological threats (See Figure 3).

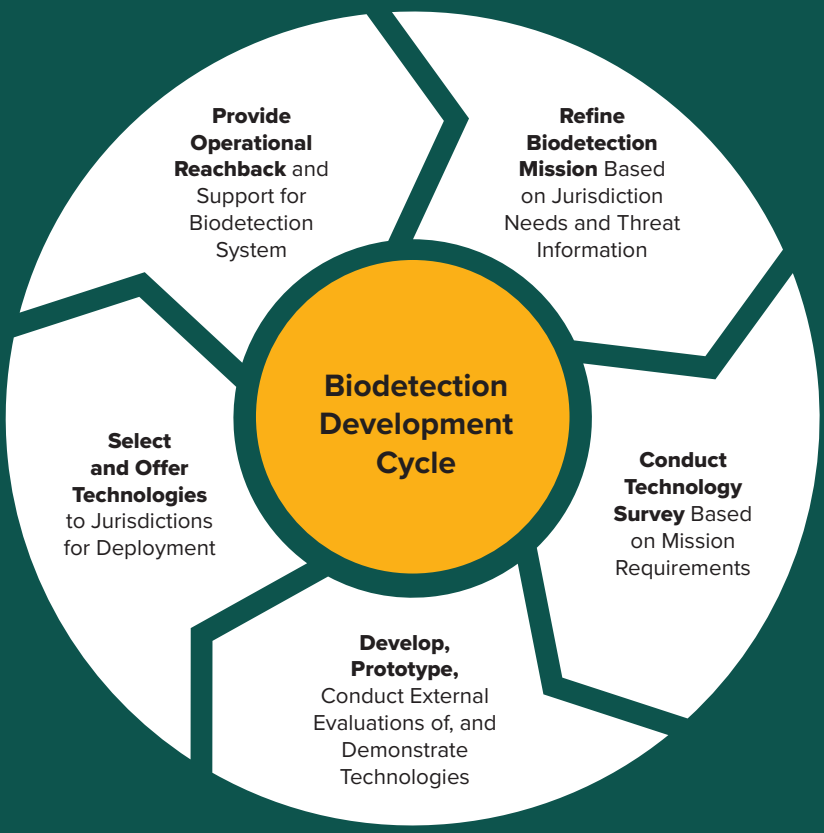


Figure 3. Biodetection Development Cycle

CONCLUSION

On September 6, 2001, six days before the attacks on September 11, and two weeks before letters containing weaponized anthrax were mailed throughout the United States (including to two U.S. Senate offices, the Department of State, and four media outlets), the Senate Committee on Foreign Relations held a hearing to examine the biological threat to the Nation. Then Chairman Joseph R. Biden Jr. opened the hearing with a frank and accurate assessment of the implications and likelihood of a biological event:

> *"If, God forbid, America should ever be attacked by biological weapons, it will be the scientists and public health professionals on the front lines, not just our men and women in uniform…as well as state and local governments and public servants, who will have to be fully prepared to engage the enemy, whoever it is and whatever it is… The truth is that such an attack is more likely today than it ever has been in the past, and that the comparable natural epidemic is all too possible in the decades to come…In my view, the threat from anonymously delivered biological weapons and from emerging infectious diseases simply dwarf the threat that we will be attacked by a third world ICBM with a return address."*[36]

The U.S. government established the BioWatch program in part due to the devastating and tumultuous events of 2001. The officials who founded the system did so with good intentions and an admirable goal, informed by current intelligence and the available technology of the day. However, nearly two decades later, no objective analysis of the program's performance has determined that the technology actually works. Despite the evolution of the biological threat, DHS never revisited the BioWatch mission, including where and how it should be deployed to provide maximum information and assistance to local jurisdictions. Even if it had been able to realign the BioWatch mission to address more current biological threats, DHS cannot expand the system to cover more of the United States with current and projected resources.

Congress cannot continue to invest $80 million a year in a BioWatch program that does not demonstrate value. Similarly, the BD21 acquisition effort has yet to demonstrate that it is adequately factoring mission needs and effective new biodetection technologies into its acquisition process. DHS should replace BioWatch technology with other better performing and currently available technologies. DHS should also pursue continuous improvement of BioWatch through dedicated long-term research and development.

The Department of State and others in the Intelligence Community currently assess that nation states and terrorist organizations are actively pursuing and developing biological weapons (some having already stated their determination to use biological weapons to gain asymmetric advantage over the United States). DHS now finds itself in the unenviable position of endlessly doing the same things over and over without achieving the comprehensive biodetection the Nation needs. It is time to save Sisyphus and either replace BioWatch or put an end to it.

ACRONYMS

BAR	BioWatch Actionable Result
BASIS	Biological Aerosol Sentry and Information System
BD21	Biodetection in the 21st Century
CDC	Centers for Disease Control and Prevention
COVID-19	novel coronavirus disease 2019
DARPA	DOD Defense Advanced Research Projects Agency
DHS	Department of Homeland Security
DHS CWMD	DHS Countering Weapons of Mass Destruction Office
DHS S&T	DHS Science and Technology Directorate
DOD	Department of Defense
FBI	Federal Bureau of Investigation
GAO	Government Accountability Office
HHS	Department of Health and Human Services
LIDAR	Light Detection and Ranging
MIT	Massachusetts Institute of Technology
NASA	National Aeronautics and Space Administration
OIG	Office of the Inspector General
OMB	Office of Management and Budget
PCR	Polymerase Chain Reaction

ENDNOTES

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[7] **"Recommendation 31: Develop a 21st Century-worthy environmental detection system. The Nation continues to lack a rapid and reliable environmental detection system for known and unknown biological threats, a situation that must be rectified. ACTION ITEMS: a. Fund the development of advanced environmental detection systems to replace BioWatch.** Congress, through its appropriations to DHS and DOD, should fund an advanced environmental detection system capable of rapid agent characterization and confirmation. The system should be capable of recovering live agents from collection devices, determining geographical distribution, determining environmental persistence, and providing advanced molecular diagnostics at the laboratories that will support operational activities. The Vice President of the United States should call for a formal process between DHS, DOD, and all other federal agencies utilizing or developing biodetectors to share information regarding their biodetection successes and failures, up to and including a mandate to procure another agency's technology if it fits requirements. For domestic biodetection, DHS must work with end-users in states, localities, tribes, and territories at the earliest stages of requirement development. DHS must also develop a standardized integration strategy and training requirements based on these discussions. **b. Replace BioWatch Generation 1 and 2 detectors.** The Secretary of Homeland Security must replace these detectors within five years with the systems developed per action item 31a. If they cannot be replaced within that timeframe, the Secretary of Homeland Security should remove them from service."

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