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BIOSURVEILLANCE

**Preliminary Observations
on Department of
Homeland Security's
Biosurveillance Initiatives**

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Director Homeland Security and Justice Issues





Highlights of [GAO-08-960T](#), a testimony before the Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives

Why GAO Did This Study

The United States faces potentially dangerous biological threats that occur naturally or may be the result of a terrorist attack. The Department of Homeland Security (DHS) is developing two major initiatives to provide early detection and warning of biological threats: the National Biosurveillance Integration Center (NBIC), a center for integrating and coordinating information on biological events of national significance, and the BioWatch program that operates systems used to test the air for biological agents. The Implementing Recommendations of the 9/11 Commission Act of 2007 requires DHS to establish a fully operational NBIC by September 30, 2008. This statement discusses the status of DHS's efforts to (1) make NBIC fully operational by the mandated deadline, and (2) improve the BioWatch program's technology. GAO's preliminary observations of these two programs are based on our ongoing work mandated by the Implementing Recommendations of the 9/11 Commission Act of 2007 to review U.S. biosurveillance efforts. To conduct this work, GAO reviewed related statutes; federal directives; and DHS planning, development, and implementation documents on these two initiatives. We also interviewed DHS program officials to obtain additional information about NBIC and BioWatch.

DHS reviewed a draft of this testimony and provided technical comments, which were incorporated as appropriate.

To view the full product, including the scope and methodology, click on [GAO-08-960T](#). For more information, contact William O. Jenkins, Jr. at (202) 512-8777 or jenkinswo@gao.gov.

BIOSURVEILLANCE

Preliminary Observations on the Department of Homeland Security's Biosurveillance Initiatives

What GAO Found

DHS has made progress making NBIC fully operational by September 30, 2008, as required by the Implementing Recommendations of the 9/11 Commission Act of 2007, but it is unclear what operations the center will be capable of carrying out at that point. DHS has acquired facilities and hired staff for the center but has not yet defined what capabilities the center will have in order to be considered fully operational. DHS has also started to coordinate biosurveillance efforts with other agencies, but DHS has not yet formalized some key agreements to fulfill NBIC's integration mission. For example, DHS has signed memoranda of understanding with 6 of 11 agencies DHS identified to support the operations of NBIC. However, DHS has not yet completed other key agreements to, for example, facilitate the technical exchange of information, such as data on human health, between NBIC and the agencies. In addition, a contractor DHS hired to enhance NBIC's information technology system delivered an upgrade to the system on April 1, 2008, intended to enhance data integration capabilities. However, before this upgrade can be used effectively, DHS officials said that NBIC will need to train its employees to use the system and negotiate interagency agreements to define the data that the agencies using the system will provide. DHS officials expect that NBIC will complete the training in early 2009.

DHS has two ongoing efforts to improve the detection technology used by the BioWatch program, which deploys detectors to collect data that are then analyzed to detect the presence of specific biological agents. First, the Directorate for Science and Technology (S&T) within DHS is developing next-generation detectors for the BioWatch program. DHS plans for this new technology to collect air samples and automatically test the samples for a broader range of biological agents than the current technology. Under the current system, samples are manually collected and taken to a laboratory for analysis. DHS plans to operationally test and evaluate the new automatic technology in April 2009 and to begin replacing its existing detection technology in 2010. Operational testing and evaluation of the new technology is planned to take place in April 2009, about 1 year later than DHS initially planned, because S&T officials received revised requirements for the new system about 4 months before S&T was scheduled to complete development of the system. Second, while S&T is completing its work on the new detection technology, DHS is developing an interim solution, managed by the Office of Health Affairs, to enhance its current detection technology. This interim solution is intended to automatically analyze air samples for the same number of biological agents currently monitored by the BioWatch program. Contingent on successful operational testing and evaluation that is to start in November 2008, DHS plans to decide whether to acquire over 100 of these enhanced detectors.

Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to be here today to discuss some issues associated with the Department of Homeland Security's (DHS) biosurveillance initiatives, specifically the National Biosurveillance Integration Center (NBIC) and the BioWatch program. The United States faces potentially dangerous biological threats that occur naturally or may be the result of a terrorist attack. New diseases, such as Avian Influenza, West Nile virus, and severe acute respiratory syndrome (SARS) have emerged in recent years. Infectious diseases have the potential to develop into widespread outbreaks and could have significant consequences, such as causing hundreds of thousands of casualties, disrupting and weakening our economy, damaging public morale and confidence, and threatening our national security. In addition to naturally occurring infectious disease outbreaks, the United States faces the possibility that terrorists will use biological agents as weapons of mass destruction. Threats of bioterrorism, such as anthrax attacks and high-profile disease outbreaks, have drawn attention to the need for systems that provide early detection and warning about biological threats, known as biosurveillance systems. DHS, in cooperation with various other federal agencies, is developing two major initiatives to provide early detection and warning about biological threats: NBIC, a center for integrating information on biological events of national significance, which the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act) mandated DHS to establish and make fully operational by September 30, 2008¹, and the BioWatch program, which operates systems to test the air for specific biological threats.

My remarks today will focus on the status of DHS's efforts to (1) make NBIC fully operational by the statutorily mandated deadline and (2) improve the technology used by the BioWatch program. Our preliminary observations of these two DHS programs are based on our ongoing review of U.S. biosurveillance efforts, as required by the 9/11 Commission Act.² The law mandates that GAO review U.S. biosurveillance efforts at the federal, state, local, and tribal levels of government. Our preliminary observations on NBIC and the BioWatch program are based on reviews of DHS planning, development, and implementation documents concerning these initiatives; related statutes and federal directives; and interviews

¹ Pub. L. No. 110-53, § 1101, 121 Stat. 266, 375-79 (2007).

² *Id.* at § 1102, 121 Stat. at 379.

with DHS officials. We interviewed officials from the Office of Health Affairs (OHA) responsible for establishing NBIC and managing the BioWatch program. We also interviewed officials from DHS's Directorate for Science and Technology (S&T), the primary research and development office responsible for developing next-generation detection technology for BioWatch. We conducted our work from February 2008 to July 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Summary

DHS has made progress making NBIC fully operational by September 30, 2008; however, it is unclear what operations the center will be capable of carrying out at that point. DHS has faced difficulties completing some key tasks, such as defining what capabilities the center will provide once fully operational, formalizing agreements to obtain interagency coordination, and completing work related to the new information technology (IT) system. For example, NBIC has made some progress in developing its capabilities to be fully operational by September 30, 2008, as mandated by the 9/11 Commission Act, but NBIC has not yet defined the capabilities the center will have in order to be considered fully operational. DHS, through NBIC, has also started to coordinate interagency biosurveillance efforts and finalized some, but not all, key interagency coordination documents. For example, DHS has yet to finalize interagency agreements with relevant agencies that describe programmatic, financial, and staffing arrangements between NBIC and these agencies. In addition, a contractor DHS hired to enhance NBIC's IT system delivered an upgrade to the system on April 1, 2008; however, NBIC officials stated that they need to complete additional work before granting other agencies full access to the new system. For example, NBIC is still in the process of training employees to use the system and negotiating agreement on the data that agencies will provide to NBIS.

DHS has two ongoing efforts to improve the detection technology used by the BioWatch program. First, S&T within DHS is developing new detectors for the BioWatch program, a program that deploys detectors to collect data that are then analyzed to detect the presence of specific biological agents. These new detectors, known as Generation 3.0, are intended to provide additional capabilities and replace the existing detection technology beginning in 2010. The new detector technology is designed to

both collect and automatically test air samples for biological agents, unlike the current system in which samples must be manually collected and taken to a laboratory for analysis. DHS officials anticipate that the new technology will reduce the elapsed time between air sampling and detection of a biological threat by at least 4 hours and possibly as much as 30 hours. Additionally, the new technology is designed to detect more biological agents than the existing technology. Operational testing and evaluation of this technology is scheduled for April 2009, about a year later than initially planned because OHA provided S&T with revised requirements about 4 months before S&T was scheduled to complete the development of the new prototype detector. Second, while S&T completes its work on the new detection technology, OHA is developing an interim solution to enhance the existing detection technology so that it can automatically analyze air samples. Contingent on successful operational testing and evaluation that is to begin in November 2008, DHS plans to acquire over 100 of the enhanced detectors.

Background

Since the attacks of September 11, 2001, there has been concern that another terrorist attack on U.S. soil could occur involving biological, chemical, radiological, or nuclear weapons. Concerns like these have prompted increased federal attention to and investment in national emergency preparedness—that is, the nation’s ability to prevent, protect against, respond to, and recover from large-scale emergency events. Effective preparation for, detection of, and response to a major biological event requires effective pre- and postdisaster coordination and cooperation among different federal agencies, levels of government, nongovernmental organizations, and the private sector. In the case of biological threats, detection of biological agents is a first step in an effective response to a natural, accidental, or intentional outbreak of a biologically caused disease.

In August 2007, the 9/11 Commission Act required DHS to establish NBIC to detect, as early as possible, a biological event of national concern that presents a risk to the United States, or the infrastructure or key assets of the United States. The 9/11 Commission Act provides that the mission of NBIC is to enhance the capability of the federal government to:

- rapidly identify, characterize, localize, and track a biological event of national concern;
- integrate and analyze data relating to human health, animal, plant, food, and environmental monitoring systems; and

-
- disseminate alerts to member agencies, and state, local, and tribal governments.³

The 9/11 Commission Act also requires NBIC to be fully operational by September 30, 2008.

Prior to the passage of the 9/11 Commission Act, two presidential directives charged federal agencies to coordinate federal efforts and create a new biological threat awareness capacity to enhance detection and characterization of a biological attack.⁴ In response to these presidential directives, DHS began the National Biosurveillance Integration System (NBIS) program in 2004 as a means of integrating information across government agencies regarding biological events. The NBIS program developed an IT system, also known as NBIS, to bring together various data used for human, animal, and plant health surveillance; environmental monitoring data; and intelligence and threat analysis. Subsequently, the 9/11 Commission Act established NBIC as the entity responsible for, among other things, developing and running the IT system, still known as NBIS. Since it was created in March 2007, OHA has overseen NBIS and now the NBIC program office.

DHS, in cooperation with other federal agencies, created the BioWatch program in 2003 to detect the release of airborne biological agents. The BioWatch program deploys detectors which collect data that, when analyzed, can be used to identify biological agents on the BioWatch threat list.⁵ Current BioWatch detection technology contains filters that collect

³ According to the 9/11 Commission Act, the term ‘member agency’ means any federal department or agency that, at the discretion of the head of that department or agency, has entered a memorandum of understanding regarding participation in the NBIC. DHS is working with 11 other federal agencies to establish NBIC: Department of Defense, U.S. Department of Agriculture, Department of Health and Human Services, Department of the Interior, Department of State, Veteran’s Affairs, Department of Transportation, the Environmental Protection Agency, U.S. Postal Service, Department of Commerce, and Department of Justice.

⁴ Homeland Security Presidential Directive (HSPD) 9, *Defense of United States Agriculture and Food* (Jan. 30, 2004), charges federal agencies to create a new biological threat awareness capacity. Additionally, HSPD 10, *Biodefense for the 21st Century* (Apr. 28, 2004), calls for an integrated and comprehensive attack warning system that will assist in recognizing and responding to biological attacks on humans, animals, food, water, agriculture, and environmental resources.

⁵ DHS has identified a list of specific biological agents that could pose a health threat if aerosolized and released to the environment.

air samples, but the filters must be collected manually, and testing of the samples is carried out in state and local public health laboratories. Using this manual process, results are usually obtained within 10 to 34 hours of an agent's detection. BioWatch detectors are currently deployed in 30 cities, and local jurisdictions are responsible for the public health response to positive findings in the BioWatch program. OHA has responsibility for managing the operations of the BioWatch program. S&T, which is the primary research and development arm of DHS, is responsible for developing detectors for the BioWatch program.

DHS Has Made Progress in Making NBIC Fully Operational by the Mandated September Deadline, but Faces Difficulties Completing Key Tasks

DHS has made progress making NBIC fully operational by September 30, 2008, as required by the 9/11 Commission Act, but has faced difficulties completing some key tasks, such as defining what capabilities the center will provide once fully operational, formalizing agreements to obtain interagency coordination, and fully implementing its IT system. NBIC has not yet defined what capabilities the center should have in place in order to be fully operational. According to NBIC officials, NBIC has drafted, but not finalized, planning documents to define these capabilities. In addition, NBIC has initiated coordination with member agencies through memoranda of understanding (MOUs) and interagency working groups. NBIC is working to establish additional coordination efforts to enhance NBIC's integration capabilities. Further, a contractor DHS hired to enhance NBIC's IT system delivered an upgrade to the system on April 1, 2008, but more work remains to be done. For example, member agencies will not have full access to the IT system until NBIC employees have been trained to use the system. Additionally, NBIC reports that it continues to negotiate agreements with member agencies on the data they are to provide for the IT system.

Progress Has Been Made, but It Is Unclear What Capabilities NBIC Will Have by the September 30, 2008, Deadline

DHS has made progress making NBIC fully operational by the mandated September 30, 2008, deadline; however, it is unclear what operations the center will be capable of carrying out at that point. NBIC has acquired a facility that accommodates office space, a 24-hour watch center, as well as secure areas to handle classified materials. Additionally, in January 2008 NBIC hired a permanent Director to oversee NBIC operations. As of July 2008, NBIC has also filled 26 of 37, or 70 percent, of NBIC's available staff positions, and according to NBIC officials, NBIC is in the process of hiring four additional staff members, including a Deputy Director. NBIC officials are planning to use contractors to fill the remaining 7 positions. Furthermore, NBIC has also acquired one detailee from a member agency, the Department of Health and Human Services, and is working to acquire

additional detailees. NBIC has drafted a concept of operations; a finalized version is pending comments from NBIC's member agencies. Officials have also drafted, but not finalized, standard operating procedures. In fiscal year 2008, \$8 million were available to NBIC officials to establish the center; officials told us that they recently requested an additional \$4.2 million in a reprogramming that DHS has not yet approved.

NBIC has not yet defined the capabilities the center should have in order to be considered fully operational. The 9/11 Commission Act does not define fully operational or what capabilities NBIC needs to have in place by the statutorily mandated September 30, 2008, deadline. NBIC officials told us that they are currently trying to define "fully operational" and are drafting detailed plans for the final 90 days of planning before the deadline. Officials told us that these documents describe the details of NBIC's expected operational capabilities and functions, such as the state of their IT system, personnel expectations, analytic capabilities, and include specific goals, objectives, milestones, and cost estimates. DHS did not provide us with these planning documents because the documents are in draft form.

NBIC Has Taken Steps to Coordinate with Federal Agencies, but Has Not Formalized Agreements to Obtain Their Cooperation

NBIC has initiated coordination efforts with 11 federal agencies but faces difficulties completing formal agreements to obtain their cooperation. Since the new NBIC Director started in January 2008, NBIC has organized interagency working groups and has finalized MOUs with 6 of the 11 agencies that NBIC identified as important to the operational needs of the center. NBIC has an interagency working group consisting of these 11 agencies, in addition to DHS, that first met under the direction of the new Director in March 2008. As part of the interagency working group, DHS officials stated, NBIC has created a sub-working group that meets on a weekly basis to discuss issues such as the daily operations of NBIC, reporting requirements, and data-sharing issues. NBIC also organized an interagency oversight council, which includes representatives from member agencies, private-sector organizations, and academia, to provide technical oversight and guidance in the development and implementation of NBIC's operations. The oversight council plans to meet for the first time in August 2008. NBIC has begun facilitating interagency coordination while continuing to implement additional elements of the program. For example, NBIC officials told us that they helped coordinate the federal government's efforts to deal with the recent national salmonella outbreak, while simultaneously continuing to work on making NBIC fully operational to meet the September 30, 2008, deadline.

As part of its efforts to establish interagency coordination, NBIC is seeking to formalize its relationship with federal agencies through three types of documents: MOUs, interagency security agreements (ISAs), and interagency agreements (IAAs). First, DHS is asking federal agencies to sign MOUs to confirm the agency or department's initial agreement to participate in NBIC as a member agency. Second, DHS is asking agencies to sign ISAs that formalize the technical exchange of information, such as data on human health, between NBIC and these agencies. Finally, DHS is asking agencies to sign IAAs that define programmatic, financial, and staffing arrangements between NBIC and these agencies. As part of the IAAs, agencies are to agree to provide detailees to work at NBIC. These detailees will provide subject-matter expertise and facilitate NBIC coordination with their respective home department or agency.

To date, NBIC and potential member agencies have finalized 6 of 11 MOUs; however, they have not finalized any ISAs or IAAs. DHS has signed MOUs with the Departments of Defense, Agriculture, Health and Human Services, Interior, State, and Transportation. DHS is still working to finalize MOUs with another 5 agencies to formalize their membership in NBIC.⁶ NBIC does not have ISAs or IAAs in place with any of its current and potential member agencies. According to NBIC officials, one difficulty in finalizing the ISAs is due, in part, to defining the data-sharing arrangements with member agencies given the constraints on arrangements for sharing data imposed by the traditional roles of these agencies. For example, interagency coordination for the purposes of characterizing a biological event may require data that NBIC member agencies have not previously shared with other agencies. In addition, DHS faces difficulty finalizing IAAs, the formal mechanisms through which NBIC obtains detailees from federal agencies. In the absence of IAAs, according to NBIC's draft concept of operations, the center cannot effectively perform its integration and analytical mission without the subject-matter knowledge from interagency detailees. As of July 2008, NBIC has been able to secure one detailee from a member agency. Officials were unable to predict how many additional MOUs, ISAs, IAAs, or detailees NBIC will have in place by September 30, 2008.

⁶ The five departments and agencies with pending MOUs include the Department of Commerce, the Environmental Protection Agency, Department of Justice, United States Postal Service, and Department of Veterans Affairs.

NBIC Recently Upgraded Its IT System, but Additional Work Remains

A contractor DHS hired to enhance NBIC's IT system delivered an upgrade to the system in April 2008; however, NBIC officials stated that they need to complete additional work before granting member agencies full access to the system. The system, known as NBIS, provides tools to enhance NBIC's data integration capabilities and collaboration with member agencies. Such tools include a worldwide geographical map displaying emergent and ongoing adverse health events, an assessment of the homeland security implications of those events, a library of all referenced data, and general disease and situational reports. NBIC officials told us that additional work needs to be done before giving member agencies full access to the system. For example, NBIC does not have interagency security agreements in place with member agencies that specify the data that agencies will share with the system. In addition, as NBIC officials work with the NBIS system, they are identifying additional improvements that need to be made to the system. Furthermore, while member agencies will have access to some of the individual tools that are a part of NBIS, until NBIC analysts have been trained to use NBIS, member agencies will not have full access to all of the system's interagency collaboration functions. Officials estimate that training will not be completed until at least early 2009.

DHS Has Two Ongoing Efforts to Improve the BioWatch Technology, Which May Decrease Detection Time or Increase the Number of Agents That Can Be Identified

DHS has two ongoing efforts to improve the detection technology used by the BioWatch program. S&T is developing a new technology. OHA is developing an interim solution to enhance the detectors currently in use.

S&T is developing new detection technology known as Generation 3.0 which would replace the existing technology used by the BioWatch program. This new technology is to provide a fully automated detector which not only collects air samples but also analyzes them for threats. The current technology collects air samples which are periodically manually removed from the equipment and taken to a laboratory for analysis, a process that could take 10 to 34 hours. Officials stated that automating analysis of air samples could reduce the elapsed time between air sampling and testing it for threats from the current 10 to 34 hours to 4 to 6 hours, reducing detection time by at least 4 hours and possibly as much as 30 hours. In addition to the automated detection capability, Generation 3.0 is to detect a broader range of identified biological agents to eventually cover all the biological agents on the BioWatch threat list—a list of specific biological agents that could pose a health threat if aerosolized and released to the environment. The estimated cost for acquiring these detectors is \$80,000 to \$90,000 per unit, with yearly operation and maintenance costs of \$12,000 to \$41,000 per unit.

Operational testing and evaluation of this technology is scheduled for April 2009, about a year later than initially planned because OHA provided S&T with revised functional requirements about 4 months before S&T was scheduled to complete the Generation 3.0 prototype detector. S&T developed the original requirements for the Generation 3.0 technology, which required the automatic detectors to, among other things, operate continuously, detect more biological threats, be less expensive to operate, and be deployed in both indoor and outdoor environments. S&T planned to complete the development of the hardware and software and conduct field tests of its prototype Generation 3.0 detectors by April 2008, at which point OHA was to take responsibility for final operational testing and evaluation of the detectors. However, OHA provided S&T with new requirements for the Generation 3.0 detector in January 2008, which delayed operational testing and evaluation by 1 year, from April 2008 to April 2009. The new requirements included additional requirements and provided additional details for some of the original requirements. For example, OHA's new requirements contain restrictions for the size and weight of the Generation 3.0 detector which were not specified in the original requirements. As a result of the 1-year delay, S&T also designed an additional field test for the Generation 3.0 prototypes, scheduled to begin in the first quarter of fiscal year 2009, which will occur in an urban environment and allow for the prototypes to be tested in real-world conditions. According to S&T and OHA officials, the Generation 3.0 detector will ultimately replace all current BioWatch detectors by 2013, with initial deployment beginning in 2010.

While S&T is completing its work on the Generation 3.0 detectors, OHA is developing an interim solution to enhance the detectors currently in use by adding the capability to automatically analyze air samples for some biological agents. OHA's interim technology, known as Generation 2.5, is intended to add the capability to automatically analyze air samples for the same number of biological agents currently monitored by the existing BioWatch detector technology. However, the enhanced detectors will not have the capability to identify additional biological agents listed on the BioWatch threat list. According to OHA officials, Generation 2.5 detectors will, like Generation 3.0 detectors, reduce the elapsed time between sampling the air and detecting a biological agent by at least 4 hours and possibly as much as 30 hours. Further, OHA officials stated that they plan to operationally test and evaluate new prototype detectors beginning in November 2008 and to acquire over 100 of these new detectors, contingent on successful completion of operational testing and evaluation. The estimated cost for acquiring and testing these detectors is \$120,000 per unit, with yearly maintenance costs of \$65,000 to \$72,000 per unit.

According to DHS officials, OHA plans to deploy these new detectors both indoors and outdoors; however, no procedural guidance exists for responding to positive results from detectors placed indoors. According to OHA officials, they plan to develop this guidance by October 2008 and apply it to all future BioWatch detectors deployed indoors.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Committee may have at this time.

Contact and Acknowledgments

For further information regarding this testimony, please contact me or E. Anne Laffoon, Assistant Director, at (202) 512-4199. Michelle Cooper, Jessica Gerrard-Gough, Tracey King, Amanda Krause, Juan Tapia-Videla, John Vocino, and Sally Williamson made key contributions to this testimony.

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