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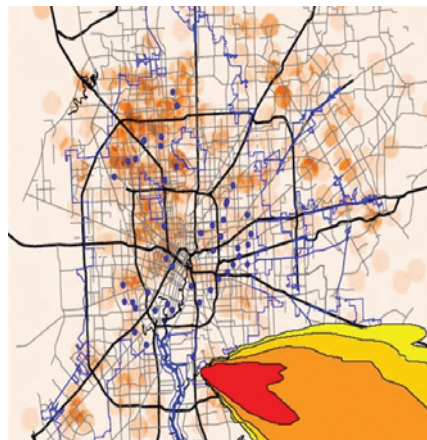
Catalyst for Improving the Environment

Evaluation Report

EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program

Report No. 2005-P-00012

March 23, 2005



Report Contributors:

Anne Emory
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Abbreviations

CDC	Centers for Disease Control and Prevention
DFU	Dry Filter Unit
DHS	Department of Homeland Security
DOD	Department of Defense
DOE	Department of Energy
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
GAO	Government Accountability Office
OIG	Office of Inspector General
PCR	Polymerase Chain Reaction
PSU	Portable Sampling Unit

Cover photos: From left: a BioWatch monitor (courtesy Environmental Protection Agency); a map demonstrating a hypothetical biological agent plume (courtesy Houston Department of Health and Human Services); and a gas mask worn during a demonstration (courtesy Department of Homeland Security).



At a Glance

Catalyst for Improving the Environment

Why We Did This Review

The Environmental Protection Agency (EPA) is an important partner in the BioWatch program and has a major role in sampling operations. We sought to answer the following questions:

- What are EPA's designated responsibilities in the BioWatch program?
- How well is EPA implementing its designated responsibilities in the BioWatch program?

Background

BioWatch is an early-warning system designed to detect the release of biological agents in the air through a comprehensive protocol of monitoring and laboratory analysis. BioWatch is a "detect to treat" network intended to detect biological agents within 36 hours of release, so that there is time for Federal, State, and local officials to determine emergency response, medical care, and consequence management needs.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:

www.epa.gov/oig/reports/2005/20050323-2005-P-00012.pdf

EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program

What We Found

The Department of Homeland Security (DHS) funds and oversees the BioWatch program while relying on the assistance and expertise of EPA and other agencies. DHS uses EPA to award and manage cooperative agreements to State and local air monitoring agencies to collect filter samples.

EPA's designated responsibilities include a crucial part of the BioWatch program – the sampling operations. These operations include monitor deployment, site security, oversight, and assessing monitor technology. However, we found that EPA did not provide adequate oversight of the sampling operations to ensure quality assurance guidance was adhered to, potentially affecting the quality of the samples taken. EPA completed a technology assessment of the existing BioWatch monitors, but also needs to be involved in assessing technologies that are more reliable and timely, and reduce costs. A lack of consequence management planning was highlighted when a biological agent was detected in Houston in 2003. After this incident, EPA collaborated with DHS and the Centers for Disease Control and Prevention on the development of consequence management plan guidance, but at the time of our review State and local consequence management planning was incomplete.

What We Recommend

EPA's Assistant Administrator for Air and Radiation should ensure that EPA fulfills all of the BioWatch-designated responsibilities, including ensuring quality assurance guidance is adhered to. Further, although not a responsibility specifically designated to EPA as part of the BioWatch program, we suggest that the Assistant Administrator for Air and Radiation have EPA work closely with the BioWatch partners to:

- use its air monitoring experience to assist DHS in identifying and testing alternative technologies that are more reliable, timely, and efficient for detecting biological agents; and
- ensure the Agency is adequately prepared to assist with consequence management plans in the event of a biological agent release.

The Agency agreed with our report and stated it has begun working with EPA regions to address many of the issues that we identified.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

March 23, 2005

MEMORANDUM

SUBJECT: EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program
Report No. 2005-P-00012

FROM: Jeffrey K. Harris /s/
Director for Program Evaluation, Cross-Media Issues

TO: Jeffrey R. Holmstead
Assistant Administrator, Office of Air and Radiation

This is the final report on our evaluation of the Environmental Protection Agency's (EPA's) role in the BioWatch program. The report contains findings that describe problems we identified and corrective actions we recommend. This report represents the opinion of the Office of Inspector General (OIG) and the findings in this report do not necessarily represent the final EPA position. Final determinations on matters in the report will be made by EPA managers in accordance with established procedures.

Our final report acknowledges and includes your February 8, 2005, response to our draft report. We commend the Office of Air and Radiation for taking actions to address the concerns of the report, as well as the actions planned. We included EPA's response in Appendix C. We also met with Department of Homeland Security (DHS) officials on March 8, 2005, based on EPA's concern about releasing sensitive information. DHS officials stated that our report does not release any sensitive information.

Action Required

In accordance with EPA Directive 2750, as the action official, you are required to provide this Office with a written response within 90 days of the final report date. The response should address all recommendations. For the corrective actions planned but not completed by the response date, please describe the actions that are ongoing and provide a timetable for completion. We appreciate the efforts of EPA officials and staff in working with us to develop this report. For your convenience, this report will be available at <http://www.epa.gov/oig>.

If you or your staff have any questions regarding this report, please contact me at (202) 566-0831 or Fredrick Light at (913) 551-7528.

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Chapter 1

BioWatch Is Designed to Detect the Release of Ambient Biological Agents

Purpose

BioWatch is an early-warning system designed to detect the release of biological agents in the air through a comprehensive protocol of monitoring and laboratory analysis. BioWatch is a “detect to treat” network intended to detect a biological agent within 36 hours of release so that there is time for Federal, State, and local officials to determine emergency response, medical care, and consequence management needs. BioWatch is intended to provide coverage for 80 percent of the population in select cities.

The Department of Homeland Security (DHS) funds and oversees the program while relying on the assistance and expertise of EPA, Department of Energy (DOE), Department of Defense (DOD), the Centers for Disease Control and Prevention (CDC), and State and local agencies for sampling, detection equipment, lab analysis, and response.

Our evaluation questions were:

- ▶ What are EPA’s designated responsibilities in the BioWatch program?
- ▶ How well is EPA implementing its designated responsibilities in the BioWatch program?

Background

BioWatch was created by DHS because of concern that terrorists could aerosolize a biological agent, potentially causing thousands of casualties. Without early detection, the magnitude of the problem might only be revealed as people arrived at hospitals with symptoms. The BioWatch network was designed to detect biological agents in select cities. BioWatch was introduced in early 2003 as part of an evolving nationwide bio-surveillance system that looks for early indicators of the exposure of people, animals, and plants to biological agents; and uses environmental monitoring networks in selected cities that can detect the agent directly. Three other initiatives complement BioWatch: BioSense, BioShield, and the National Biosurveillance Integration System. The BioSense program examines pre-diagnostic indicators of disease in the population through

syndromic surveillance.¹ The BioShield program develops, purchases, and stockpiles vaccines and facilitates the rapid development of new vaccines for biological agents. The National Biosurveillance Integration System integrates Federal, State, local, and private industry biosurveillance and monitoring information to identify and characterize potential biological attacks on the nation.

The BioWatch program has three components:

- ▶ Sampling for detection of biological agents
- ▶ Analysis of samples
- ▶ Response for positive biological agent detection

EPA maintains the sampling portion of the BioWatch program because of the Agency's experience in air monitoring and ability to provide grants to State and local air monitoring agencies conducting daily monitoring activities. EPA's Office of Air Quality Planning and Standards in the Office of Air and Radiation coordinates the air sampling component. This sampling component involves aerosol monitors mounted on pre-existing EPA air quality stations to detect biological pathogens that might be intentionally released by terrorists. The aerosol monitors draw in air and pass it through filters, which are manually collected at 24-hour intervals, 7 days a week, 365 days a year.² BioWatch uses three types of monitors for air sampling.

- ▶ Portable Sampling Unit (PSU)
- ▶ Dry Filter Unit (DFU)
- ▶ Distributed Sampling Unit

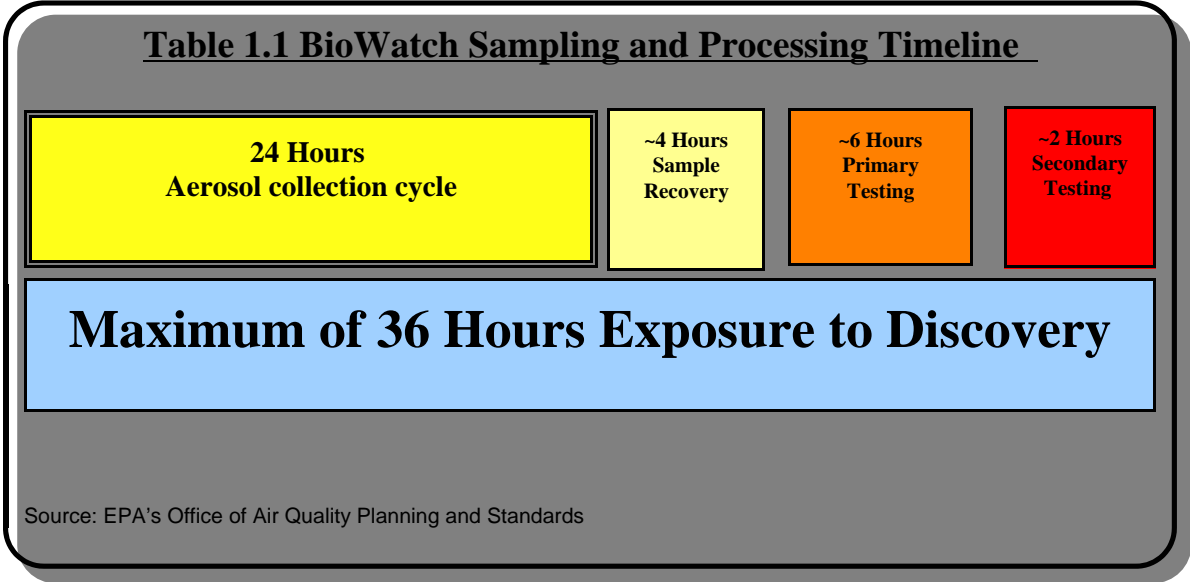
CDC is responsible for coordinating the laboratory analysis of the filters. State and local monitoring agencies deliver filters daily to CDC-operated BioWatch facilities located within Federal, State, or local public health laboratories for analyses. The filters are analyzed during a primary test for potential biological weapon pathogens using polymerase chain reaction (PCR) techniques.³ If a biological agent is detected, lab analysts perform a secondary test. A positive secondary test is considered a PCR-verified positive and indicates the existence of a biological material in the air due to either an intentional release or a natural occurrence.

¹ Syndromic surveillance is the monitoring of the population for disease outbreaks by categorizing early signs and symptoms of disease (the disease "prodrome") into syndromes that relate to the clinical manifestations of certain diseases.

² According to DHS officials, some BioWatch sites increase sample collection to every 8 or 12 hours during high threat alerts, or immediately following special events. Threat alerts are based on DHS intelligence and a color-coded threat system is used: Red (Severe); Orange (High); Yellow (Elevated); Blue (Guarded); and Green (Low).

³ The PCR technique is used to reveal the DNA sequence of biological material. Laboratory technicians use PCR to amplify a particular segment of DNA by repeated cycles of polymerization, to identify whether the DNA matches any of the biological agents that the BioWatch program monitors.

The sampling and analysis portion of the program is designed to detect and confirm the presence of biological agents within 36 hours of a release as shown in Table 1.1.⁴ Once a positive sample is PCR-verified, confirmational sampling determines the geographic extent of the biological agent release and whether it is an intentional terrorist activity or naturally occurring.



If a biological agent is confirmed by the laboratory, notification procedures are determined at the local level and typically involve contacting local health authorities, law enforcement including the Federal Bureau of Investigation (FBI), and DHS. The FBI is designated as the lead agency for the law enforcement response if a bio-terrorism act is confirmed.

A model of the BioWatch program is provided in Appendix A.

Scope and Methodology

To assess whether EPA has effectively fulfilled the Agency's responsibilities for the BioWatch program, we reviewed EPA documents and numerous BioWatch reports, and interviewed key stakeholders. We reviewed the BioWatch cooperative agreements administered by EPA and observed operations of several field collection agencies and health laboratory facilities. We also attended several conferences related to biological agent detection. Preliminary research and field work was conducted while collaborating with the Inspector General offices for DHS and the Department of Health and Human Services (which oversees CDC operations). Our methodology does not allow our observations to be projected to

⁴Our review did not determine whether 36 hours was an appropriate amount of time to detect a biological agent release to provide time for Federal, State, and local officials to determine emergency response, medical care, and consequence management needs.

all cities served by the BioWatch Program. However, we believe the problems in any location, be they systemic or not, are noteworthy and require corrective action.

We conducted this evaluation in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. Our field work was conducted from July 2004 to November 2004. For more details, see Appendix B.

Chapter 2

EPA Supports BioWatch Program

EPA plays a major role in the BioWatch program. DHS uses EPA to award and manage cooperative agreements to State and local air monitoring agencies that collect the filters. Some State and local agencies use contractors to collect the filter samples. EPA is responsible for: establishing, deploying, operating, and maintaining the BioWatch network and the filter collection process, including policy oversight and assessing technology. A number of documents outline EPA’s responsibilities, including: *The BioWatch Fact Sheet*; *the Memorandum of Agreement* among DHS, EPA, and CDC; and the *Quality Assurance Project Plan for Field Sampling Activities of the BioWatch Program*, as shown in Table 2.1.

Table 2.1: EPA’s BioWatch Responsibilities

<p>Establish, deploy, operate, and maintain the BioWatch network and filter collection process</p> <ul style="list-style-type: none"> • Administer cooperative agreements to fund the BioWatch sampling activities. • Develop cost estimates and budgets. • Procure field equipment beyond those procured by DOE, DOD, and DHS. • Assist with site evaluation and selection. • Work with the EPA regions and State and local organizations to determine the best sampling locations and the logistics for sampler deployment and filter transport to laboratories. • Assist with sampler set-up and initial operation. • Act as a liaison to groups working on the program and serve as primary liaison to State and local environmental agencies. • Implement a field communications network. • Implement and coordinate the sampling network and training with State and local environmental monitoring agencies. • Coordinate activities with CDC. • Develop quality assurance protocols and training. • Evaluate for re-siting and/or additional samplers.
<p>Provide policy oversight</p> <ul style="list-style-type: none"> • Coordinate and/or perform technical systems audits of the field data collection activities. • Provide quarterly reports. • Monitor network operations and reliability.
<p>Assess technologies</p> <ul style="list-style-type: none"> • Evaluate the performance of the BioWatch monitors. • Pursue newer, more advanced instrumentation.
<p><i>Source: OIG</i></p>

Federal laws, presidential directives, and strategic plans also justify EPA’s involvement with the BioWatch program, as shown in Table 2.2.

Table 2.2: Support for EPA's Involvement

Homeland Security Presidential Directives 5, 8, and 10

EPA will support and develop the preparedness of State, local, and tribal governments, and private industry, to respond to, recover from, and continue operations after a terrorist attack.

Clean Air Act

EPA cites the Clean Air Act (Section 103) as the Statutory Authority for the Agency's involvement in the sampling component of the BioWatch program. The Clean Air Act provides the principal framework for national, State, and local efforts to protect ambient (outdoor) air quality and designates EPA to set health-based standards, which control pollutants harmful to people and the environment.

Comprehensive Environmental Response, Compensation and Liability Act, Section 104

EPA responds to releases of hazardous substances, pollutants, and contaminants. A response is coordinated under the National Contingency Plan, which is the implementing regulation for EPA's Superfund program and provides guidelines and procedures for responding.

EPA Homeland Security Strategy

EPA's Homeland Security Strategy, dated October 2004, specifies that EPA will work with States, tribes, and other Federal agencies to develop and implement BioWatch.

National Response Plan

EPA has the authority to designate a Federal On-Scene Coordinator to direct response efforts at the scene of a discharge or release of oil, hazardous substances, pollutants, or contaminants, depending on the substance and the location and source of release.

Source: OIG

The capital costs for installation in each city were approximately \$1 million, and the annual budgeted operational costs were \$1 million per city. Details on costs are in Table 2.3. The fiscal year 2005 budget included a \$65 million increase to enhance current monitoring activities. DHS plans to enhance the number of monitors from 10-15 to up to 50 monitors in some cities to ensure coverage of 80 percent of the population within a city. The enhancement is expected to go beyond EPA's existing monitoring networks to cover subways and other facilities.

Table 2.3 BioWatch Costs (millions)

Fiscal Year	Approximate Sampling Costs	Approximate Total Costs
2003	\$12	\$40
2004	\$13	\$38
2005	\$15 ^a	\$129

Source: OIG

^a Does not include funding to support the enhancements planned for 2005.

Chapter 3

EPA Has Not Completely Fulfilled Its Program Responsibilities

EPA did not provide adequate oversight for the sampling component of the BioWatch program, including monitoring State and local agencies and any contractors used for filter collection, potentially affecting the quality of the samples taken. EPA completed a technology assessment of the existing BioWatch monitors, but needs to continue to be involved in assessing technologies that are more reliable and timely and reduce costs. The lack of consequence management planning was highlighted when a biological agent was detected in Houston in 2003. As a result of this incident, EPA collaborated with DHS and CDC on the development of consequence management planning guidance, but at the time of our review State and local consequence management planning was incomplete. The BioWatch program depends upon the successful implementation of each component. The failure of EPA to completely fulfill its responsibilities raises uncertainty about the ability of the BioWatch program to detect a biological attack.

EPA Did Not Ensure that BioWatch Network Was Deployed and Maintained Adequately

EPA helped to quickly establish the BioWatch network by administering cooperative agreements, procuring monitors, and working with State and local organizations to set up the filter collection system in 2003. EPA, however, did not provide adequate oversight to ensure that quality standards for BioWatch were met. Specifically, EPA did not ensure that BioWatch monitors were optimally deployed and secure.

Some Monitors Not Optimally Deployed

EPA did not provide adequate oversight of monitor deployment, potentially affecting the ability of the monitors to detect biological agents. For example, several BioWatch monitors were not installed according to EPA guidelines. Guidance required monitors to take air samples between the height of 5 and about 50 feet and be free of obstructions to air flows. We observed monitors sampling air below 5 feet, and a monitor on a building rooftop sampling air above 50 feet. We also found monitors located next to equipment trailers that obstructed air flow.

The Los Alamos National Laboratory is designated as the primary agency responsible for siting issues, but EPA officials acknowledged that they provide technical assistance for resiting activities. EPA's Quality Assurance Project Plan

also states that EPA will work with regions, States, and local organizations to determine the best sampling locations. Most of the BioWatch monitors were initially placed into existing EPA air monitoring sites because of DHS's concern to get the network operating rapidly. All 10 EPA regions indicated that monitors were resited after deployment for a variety of reasons, including access issues, wind patterns not taken into account during modeling, and construction. For example, the modeling used for site selection did not consistently take into account certain parameters, such as topography and seasonal wind pattern changes, and assumed the biological agent would be released from a stationary point rather than from a moving source.⁵

BioWatch monitors are located many miles apart, although a Congressional Research Service report (*The BioWatch Program: Detection of Bioterrorism*, November 2003) found that an outdoor biological warning system would require the placement of monitors as closely spaced as 300-500 meters.⁶ State and local agencies expressed concern because the monitors are distributed too widely and there are gaps in the coverage. For example, one locality requested and received an additional monitor to cover a perceived gap in the downtown area. Another locality installed an additional monitor to improve sampling to account for seasonal weather variations. These actions indicate that the existing monitors are not optimally located, potentially limiting the detection capability. DHS plans to enhance the BioWatch network in 2005 by adding additional monitors.

Security Inconsistent at Monitoring Sites

EPA did not ensure that monitors are consistently placed in secure locations. We found monitors placed next to a fence and out in the open, vulnerable to tampering and vandalism. One monitor, located outside a fire station, was easily accessible during the day through an open gate. Another monitor station had graffiti on the equipment trailer. Also, we observed one site where the equipment was not locked because the filter collector experienced trouble with the padlock.⁷

DHS considers information about the BioWatch program to be sensitive. For example, at a BioWatch training session in Atlanta in February 2003, DHS stressed that the program is so sensitive that employees should not discuss it with family members. According to EPA officials, DHS only requires that filter collectors be U.S. citizens. Background checks, however, are determined by State or local hiring practices, and some State and local agencies do not require

⁵EPA plans to revise its quality assurance guidance by April 30, 2005 (see Agency comments in Appendix C, page 21, of this report).

⁶DHS officials stated that this closeness of monitors may be greater than necessary, depending on the level of detection of the method used for the specific agent under consideration and the acceptable probability of detection for the population under surveillance against a reasonably expected agent release.

⁷EPA plans to conduct security analysis of the BioWatch monitors (see Agency comments in Appendix C, page 21, of this report).

background checks on employees or the contracted filter collectors. DHS is strengthening the language for this requirement, according to EPA officials.

EPA Provided Limited Oversight and Quality Assurance

EPA did not provide adequate oversight to ensure that quality assurance activities were consistently conducted, potentially affecting sample integrity. EPA developed the Standard Operating Procedures for the BioWatch sampling activities to ensure that field operators collect samples in a manner that does not compromise sample integrity and chain of custody, but did not consistently provide the guidance to the State and local agencies collecting the samples. For example, one EPA region did not provide quality assurance documents to six localities for almost a year.

Required Equipment Checks Not Conducted

EPA did not ensure that required equipment checks were consistently conducted. The PSU monitors require quarterly flow rate and leak checks, and weekly timer checks, which should alert field personnel of possible equipment problems and the need to recalibrate the equipment. We found that one locality had completed its first flow rate check a few weeks prior to our visit and several of the monitors were not calibrated correctly. A local agency official said they had just completed the calibration test because they did not receive guidance on performing these tests until 2 weeks prior to our visit. In addition, the DFU, a lower-cost and easier-to-use monitor, was used in 29 percent of the cities EPA supports. However, a DFU does not have a timer, flow indicator, or leak check device to determine whether the monitor is working properly, creating uncertainty in the ability to detect a biological agent release. In the absence of these data, EPA needs to ensure that quality assurance requirements are being completed, particularly in light of DHS's plans to enhance the BioWatch network with additional monitors.

Required Progress Reports Not Completed

EPA has not consistently assured that required progress reports have been completed or provided performance information to DHS. The terms and conditions of agreements stipulate that EPA assist with many of the details critical to the sampling collection, including progress reports to ensure field collections are conducted according to the quality assurance protocols. EPA recognized that the reports could be used as a troubleshooting tool to identify problems encountered and propose resolutions. During our grant file review, however, 4 out of 10 EPA regional offices could not initially provide us with required quarterly progress reports. In addition, one local agency had not completed the required quarterly reports because they were not aware of the requirement and the EPA region had not requested the report. The local agency had not submitted any

quarterly reports since the inception of the BioWatch program, a period of 1 year.⁸

EPA's Quality Assurance Project Plan tasks the Agency with developing Standard Operating Procedures for sampling, and coordinating and/or performing technical systems audits of the field data collection activities. According to EPA officials, DHS contracted with an audit firm to conduct the technical systems audits, and only asked EPA to supervise the creation of the audit template and coordinate the contractor schedule with regional, State, and local officials. Even though the audits were completed, our review determined that quality assurance protocols were still not being followed. For example, our observations about monitor siting, security, and equipment checks took place after the DHS contractor had audited the same locations.

Technological Assessment Needed to Improve BioWatch Capability

EPA has completed a technology assessment of the existing BioWatch monitors, but needs to continue to be involved in assessing technologies that are more reliable, timely, and efficient. The BioWatch sample collection program is labor intensive. The collection of filters from the monitors, processing of filters, and laboratory analysis require daily human intervention. Some State and local air monitoring agencies have expressed concern about the labor involved with BioWatch, particularly during high threat alerts when 8- to 12-hour sampling is requested by DHS. Two local agencies stated that they could not participate in 12-hour sampling due to limited staffing. Therefore, EPA needs to continue to be involved in assessing technologies that could reduce the labor involved in the sampling process.

EPA has evaluated monitor performance and recommended that the PSU monitor be used to enhance the BioWatch network. The Agency's efforts include the technical review of instrumentation specifications provided by DHS; aiding in the set-up of live agent testing performed by the Los Alamos National Laboratory at Dugway Proving Ground, Utah; and aiding in the investigation of new data management methods and peripheral data collection methods, such as meteorological measurements. However, EPA could help assess technologies that are more reliable and timely, and reduce costs. According to the November 2003 Congressional Research Service report, *The BioWatch Program: Detection of Bioterrorism*, technological assessment and improvement is needed to provide detection of more pathogens. For example, DOE is working on a project, called the Autonomous Pathogen Detection System, that is to provide automated continuous monitoring for many potential biological agents. The U.S. Postal Service also uses the BioHazard Detection System to monitor pieces of mail and

⁸EPA plans to consistently collect progress reports (see Agency comments in Appendix C, page 22, of this report).

detect whether there are particles of a specific pathogen coming off those pieces of mail.⁹

Consequence Management Planning Incomplete

If a biological agent is detected, a consequence management plan is needed to guide the local jurisdiction's response during the first 24 to 48 hours. EPA collaborated with DHS and CDC on the development of consequence management plan guidance but at the time of our review State and local consequence management planning was incomplete. The lack of consequence management planning was highlighted in October 2003 when tularemia was detected by BioWatch monitors in Houston, Texas. The Houston Department of Health and Human Services officials did not have a BioWatch consequence management plan to follow during the event.

A consequence management plan provides for the rapid collection of information used to assess the risk to public health and identify an appropriate response. The plan should be in place prior to a biological event to guide the local jurisdiction. The plan should include: identification of roles and responsibilities, a decision making process, and a notification protocol.¹⁰ Information gathered should include:

- Collecting confirmational samples.
- Performing laboratory analysis to determine agent viability and concentration levels.
- Conducting public health surveillance and epidemiologic investigations, including veterinary surveillance.
- Performing computer modeling and incident reconstruction.
- Conducting intelligence analysis and investigation.
- Comparing analysis of known pathogens endemic to the region and seasonal trends, including the history of reported human or animal cases not related to bioterrorism.

Because Houston did not have a consequence management plan, the following problems were encountered:

- Houston officials believed that the local hazardous materials response team would take over routine sampling collection if a positive biological agent was detected. The hazardous materials response team was not trained in the BioWatch sample collection process, however, so regular filter collectors continued to collect the filters.

⁹EPA plans to assist DHS in investigating and testing new technologies (see Agency comments in Appendix C, page 22, of this report).

¹⁰*Draft BioWatch Preparedness and Response Guidance*, dated February 5, 2004.

- Local officials had to collect and discuss information about the characteristic of tularemia after it was detected rather than having it readily available.
- The Los Alamos National Laboratory and the National Institute for Occupational Safety and Health sent in staff to assist with confirmatory sampling. The Houston Bureau of Epidemiology, however, received contradictory reports from various sources regarding what monitoring sites had presumptive positive results and how many of those had confirmatory results.
- The Bureau of Epidemiology alerted all sentinel hospitals to obtain reports of syndrome numbers and suspected tularemia cases. The symptoms supplied in the alert were common to many patients, so hospitals either reported a large number of cases daily or did not report at all.
- Local officials did not have procedures for decontaminating the monitors after a biological agent was detected.

After 3 weeks of testing and field investigations, the Houston lab determined that the tularemia reflected naturally occurring environmental background levels and did not require action. Officials at the Houston lab stated that because tularemia is a naturally occurring agent, DHS determined that it is acceptable in Houston to increase the concentration of tularemia necessary for the activation of notification protocols. According to EPA officials, both DHS and EPA recognized the lack of consequence management planning during deployment, but the Houston event prompted DHS to revisit and address the lack of Federal guidance.

After the Houston incident, EPA participated in the development of consequence management response templates with DHS, CDC, FBI, and the national labs to provide guidance for consequence management planning. The templates address the first steps covering the initial 24 to 48 hours of a response, and were made available to each BioWatch city in February 2004. At a BioWatch workshop in February 2004, DHS stressed that the response templates were only “guidance” that States and locals could use for strategic planning. During our review, State and local agencies consequence management plans were incomplete. According to a February 2004 Government Accountability Office report,¹¹ no State is fully prepared to respond to a major public health threat. States have improved their disease surveillance systems, laboratory capacity, communication capacity, and workforce needed to respond to public health threats, but gaps in each remain. EPA officials said DHS recognizes the need to continue to develop full consequence management plan guidance, and intends to focus resources in this area in 2005.¹²

¹¹ *PUBLIC HEALTH PREPAREDNESS: Response Capacity Improving, but Much Remains to Be Accomplished* (GAO-04-458T), dated February 12, 2004.

¹² EPA plans to provide consequence management assistance to local governments if they request it (see Agency comments in Appendix C, page 22, of this report).

Conclusion

EPA's lack of oversight and quality assurance for the BioWatch program raises concerns about the capability of the program and makes it difficult for EPA and partnering agencies to ensure that program results are accomplished. A comprehensive assessment of the BioWatch program is needed.

Recommendations

EPA's Assistant Administrator for Air and Radiation should ensure that:

- 3-1 EPA fulfill all BioWatch-designated responsibilities, including such oversight responsibilities as ensuring quality assurance guidance is adhered to.

Further, although not a responsibility specifically designated to EPA as part of the BioWatch program, we suggest that the Assistant Administrator for Air and Radiation have EPA work closely with the BioWatch partners to:

- use its air monitoring experience to assist DHS in identifying and testing alternative technologies that are more reliable, timely, and efficient for detecting biological agents.
- ensure the Agency is adequately prepared to assist with consequence management plans in the event of a biological agent release.

Agency Comments and OIG Evaluation

The Agency agreed with our report and stated that it has begun working with EPA regions to address many of the issues that we identified. EPA made detailed technical comments on our draft report and, where appropriate, we made revisions. The Agency response is in Appendix C. We did not include a portion of the EPA response in part because it included potentially sensitive information.

EPA expressed concerns about the sensitivity of the information in the report. We met with DHS officials, who stated that our report does not release any sensitive information. DHS also made technical comments on our draft report and, where appropriate, we made revisions.

Additional Work

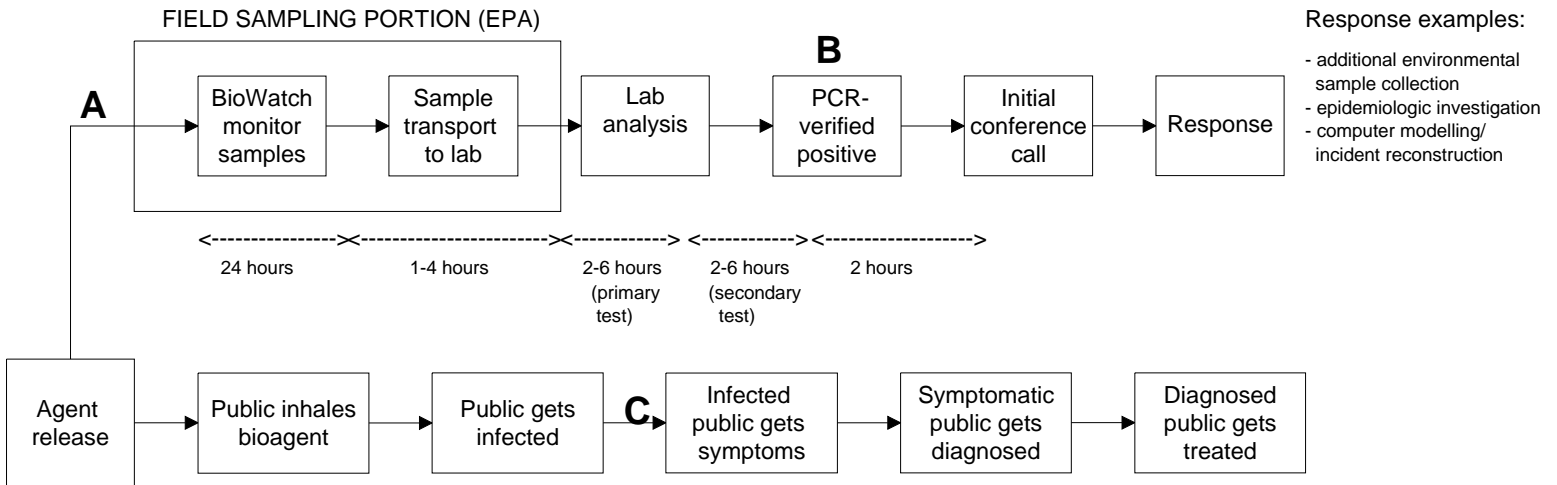
The success of the BioWatch program is dependent upon the successful implementation of each major component – sampling, analysis, and response. The effectiveness of the program requires that:

- any terrorist release of biological agents into the air of a major city area be detected,
- the presence of a bioagent can be confirmed and identified,
- the appropriate decision makers are informed in a timely manner, and
- the designated responders are able to execute an emergency response plan that mitigates the effects of the attack on the populace to the greatest extent possible.

No one agency has the capability to conduct all of the functions required by BioWatch. As we noted previously, DHS funds and oversees the program while relying on the assistance and expertise of EPA, CDC, DOE, DOD, and State and local agencies for sampling, detection equipment, lab analysis, and response. Therefore, to fully assess the ability of BioWatch to respond to a terrorist attack, the Inspectors General of Health and Human Services and DHS have initiated complementary reviews to specifically address their respective components of the BioWatch Program.

BioWatch Program Model

As shown below, the BioWatch program has three components: sampling (A), analysis (B), and response (C).



Source: OIG

Details on Scope and Methodology

We conducted this evaluation in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. Preliminary research and field work was carried out in collaboration with the OIGs from DHS and the Department of Health and Human Services. Field work was conducted from July 2004 to November 2004.

We limited the scope of our review to EPA's designated responsibilities for the BioWatch program. For example, we did not determine whether 36 hours was an appropriate amount of time to detect a biological agent release, or whether the agents being tested for are supported by credible threat information. Our methodology does not allow our observations to be projected to all cities served by the BioWatch Program. However, we believe the problems in any location, be they systemic or not, are noteworthy and require corrective action.

We reviewed the BioWatch cooperative agreements administered through EPA and grant files maintained by EPA Regions for the sampling portion of the program for 12 elements including:

- Sample collection issues
- Type and number of monitors used
- Equipment and supply problems
- Monitor siting issues
- Progress reports
- Labor issues
- Consequence management issues

To assess EPA involvement in the BioWatch Program and whether the Agency has effectively fulfilled its role, we reviewed numerous reports about air monitoring, bioterrorism, and threat and risk assessments, including the following:

- *BioWatch Fact Sheet*
- *Memorandum of Agreement* among DHS, EPA, and CDC
- *The Quality Assurance Project Plan for Field Sampling Activities of the BioWatch Program*
- *Standard Operating Procedures for the BioWatch Program*
- *EPA's Homeland Security Strategy*
- *Draft BioWatch Preparedness and Response Guidance*
- *BioWatch Program: Detection of Bioterrorism*, Congressional Research Service
- *Homeland Security: Effective Intergovernmental Coordination Is Key to Success* (GAO-02-1013T)
- *Public Health Preparedness: Response Capacity Improving, but Much Remains to Be Accomplished* (GAO-04-458T)
- *Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks* (GAO/NSIAD-99-163)

We interviewed key stakeholders involved in the BioWatch program, including:

- EPA's Office of Air Quality Planning and Standards
- EPA's Regional contacts for BioWatch
- DHS Director of Science and Technology
- CDC Chief of the Laboratory Response Branch Bioterrorism Preparedness and Response Program
- State and local monitoring agencies
- Academia (a professor of Environmental and Occupational Health Sciences)

We attended several conferences related to biological agent detection, including:

- The National BioWatch Workshop, in February 2004
- EPA's 2003 Science Forum

As the implementers of the BioWatch network, State and local air pollution control agencies are critical to the success of the network. To understand how the BioWatch monitors are operated and maintained, and how and what type of information is collected, we observed several field collection operations in different parts of the country. We discussed the issues and challenges associated with the network and EPA's involvement. To understand the health laboratory and analytical processes, we observed the laboratories responsible for analyzing BioWatch filters.

Agency Comments

MEMORANDUM

SUBJECT: Response to the Draft Report No. 2004-00313 "EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program"

FROM: Jeffrey R. Holmstead
Assistant Administrator

TO: Jeffrey K. Harris
Director for Program Evaluation, Cross-Media Issues

The purpose of this memorandum is to respond to the recommendations in the draft report, "EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program, Assignment No. 2004-00313."

Thank you for providing us the opportunity to respond to the draft report from the Office of Inspector General (OIG) issued January 7, 2005. We appreciate the recommendations to help strengthen the BioWatch program, and OAR has already begun working with the Regions to address many of the issues identified (e.g., reporting, security, quality assurance) in the draft evaluation. As has been discussed, OAR, the states, and local agencies responded very quickly to the request by the Department of Homeland Security (DHS) to help them establish their BioWatch program. With our collective experience managing the program, we now have the data and understanding of the program to review and, in some cases, revise procedures and guidance.

We have attached three documents. The first document (Attachment A) responds to the recommendations outlined in the draft evaluation. The second (Attachment B) provides general comments on the text of the draft evaluation. The third (Attachment C) identifies information that OAR believes may be sensitive and not previously available in the public domain.

If you have additional questions or require clarifications, please contact Peter Tsirigotis at (919) 541-9411.

Attachments

cc: Fredrick Light, Office of Inspector General
Tom Dunn, Acting Assistant Administrator for Solid Waste and Emergency Response
Elizabeth Craig, Deputy Assistant Administrator, Office of Air and Radiation
Steve Page, Director, Office of Air Quality Planning and Standards, OAR
Debbie Dietrich, Director, Office of Emergency Management, OSWER
Thomas Curran, Assistant Director for Information & Program Assessment, OAQPS
Peter Tsirigotis, Director, Emissions, Monitoring and Analysis Division, OAQPS

Kay Holt, Director, Planning, Resources, and Regional Management Staff, OAQPS
Laurie Trinca, OAQPS Audit Coordinator

Attachment A

Responses to the Recommendations for EPA's Assistant Administrator for Air and Radiation

3-1 ... *fulfill all BioWatch-designated responsibilities, including such oversight responsibilities as ensuring quality assurance guidance is adhered to.*

OAR agrees with the OIG recommendation that we fulfill all of our designated BioWatch responsibilities which include: monitor deployment, site security, oversight, and assessment of monitor technology.

The BioWatch program is the first of its kind. We worked with DHS and the state and local agencies to deploy monitors on an extremely tight schedule because of rising security concerns. Now that the network has been successfully established, we agree that it is an opportune time to review the network internally, and with our federal, state and local partners, revise our guidance and procedures, where necessary.

OAR agrees that there is a need for increased oversight of the programmatic requirements identified in the grants and Quality Assurance (QA) guidance. OAR issued Quality Assurance Project Plan (QAPP) guidance and Standard Operating Procedure (SOP) documentation that was based upon deployment of an ambient air monitoring network (the fine Particulate Matter monitoring network). The fine Particulate Matter guidance served as a basis for deploying the network quickly and with good quality control. Based upon the subsequent experience with the BioWatch network, OAR now believes that the guidance should be updated for siting and QA.

Particular sites were chosen for specific attributes (in priority order of) latitudinal and longitudinal location, 24/7/365 access, security, and other site attributes. OAR gave top priority to have a monitor operating in some capacity in a given area around a certain latitude/longitude, as prescribed by modeling by Los Alamos National Laboratory, in order to properly protect selected population areas. In some cases, BioWatch monitors were sited in less than perfect conditions, which may not meet the QAPP guidance, but which provided proper area coverage. An example in the report references monitors being above QAPP height requirements. This situation was in some cases impossible to avoid due to the priority to be near a certain latitude and longitude. OAR plans to work with the Regions to revise the QAPP and SOP by April 30th to properly reflect monitor siting criteria priorities more specific to BioWatch, while still striving to meet the best possible balance between location and physical siting.

With regard to securing BioWatch monitors, field operators are required to maintain the site and ensure that the monitor is physically locked at a minimum, and when possible, secure from tampering. OAR has asked the EPA regions to work with the states and locals to monitor the sites for security problems and correct, as needed. OAR will ensure that our grantees make their best efforts to maintain security at BioWatch sites, including the safekeeping of the monitors themselves. Eight of the ten Regions have completed their security analysis by the date of this memorandum.

With regard to oversight and quality assurance, OAR agrees that this area merits additional attention and efforts are already underway to collect past due QA reports and to consistently

gather quarterly and annual reports to be reviewed by the regions. OAR plans to clearly define the role of Headquarters and Regional staff with respect to performing Technical Systems Audits, which will be reflected in the revised guidance. OAR will create a standardized format for the QA reports during the process of revising the QAPP and SOP to properly reflect the vital information that must be reported, such as sample collection completeness, equipment operability, staffing issues (including background checks), and consumable inventory status.

OAR also plans to review the existing grant language used in the BioWatch grants to ensure that the issues raised in the draft evaluation are addressed in the grants.

3-1a Further, although not a responsibility specifically designated to EPA as part of the BioWatch program, we suggest that the Assistant Administrator for Air and Radiation have EPA work closely with the BioWatch partners to:

a) Use its air monitoring experience to assist DHS in identifying and testing alternative technologies that are more reliable, timely, and efficient for detecting biological agents.

OAR is actively involved and will continue to assist DHS and LANL in the investigation and testing of prospective new technologies for the BioWatch program. Activities include:

- Participation in the LANL sponsored test-bed called BioNet that is field testing four prototype biological agent monitors.
- Participating in test planning with LANL for the live agent testing of BioWatch prototypes at Dugway Proving Grounds.
- Reviewing vendor solicitations for prototype BioWatch monitors and modifications to existing BioWatch monitoring hardware.
- Reviewing and advising on alterations being made to existing BioWatch data acquisition and data management hardware and software.

b) Ensure the Agency is adequately prepared to assist with consequence management plans in the event of a biological agent release.

BioWatch is an evolving program, and consequence management planning is proceeding as quickly as possible given the competing demands that other Homeland Security issues are making on local, state and federal agencies. EPA is aware that BioWatch consequence management planning is incomplete and we will continue to provide assistance to local governments in developing these plans if they so request. This assistance will be provided by Regional emergency response staff, and the Assistant Administrator for Solid Waste and Emergency Response is the National Program Manager for that effort.

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