DEPARTMENT OF HOMELAND SECURITY
Office of Inspector General

DHS' Management of BioWatch Program

OIG-07-22

January 2007

Office of Inspector General

U.S. Department of Homeland Security
Washington, DC 20528

January 11, 2007

Preface

The Department of Homeland Security (DHS) Office of Inspector General (OIG) was established by the Homeland Security Act of 2002 (*Public Law 107-296*) by amendment to the Inspector General Act of 1978. This is one of a series of audit, inspection, and special reports prepared as part of our oversight responsibilities to promote economy, efficiency, and effectiveness within the department.

This report addresses DHS' management of the BioWatch program. It is based on interviews with employees and officials of relevant agencies and institutions, direct observations, and a review of applicable documents.

The recommendations herein have been developed to the best knowledge available to our office, and have been discussed in draft with those responsible for implementation. It is our hope that this report will result in more effective, efficient, and economical operations. We express our appreciation to all of those who contributed to the preparation of this report.

Richard L. Skinner
Inspector General

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Appendices

Abbreviations

BWEEP	BioWatch Exercise and Evaluation Program
BioWatch	BioWatch Program
CDC	Centers for Disease Control and Prevention
CoC	Chain-of-Custody
DGI	Defense Group, Inc.
DOE	Department of Energy
DHS	Department of Homeland Security
Economy Act	Economy Act of 1932, as amended, 31 USC § 1535
EPA	Environmental Protection Agency
GAO	Government Accountability Office
HHS	Department of Health and Human Services
LRN	Laboratory Response Network
MOA	Memorandum of Agreement
OIG	Office of Inspector General
S&T	Science and Technology Directorate
SETA	Systems Engineering and Technical Assistance
SMS	Sample Management System

Executive Summary

DHS, through the Science and Technology (S&T) Directorate, provides management oversight to the BioWatch program (BioWatch), an early warning system designed to detect the release of biological agents in the air through a comprehensive protocol of monitoring and laboratory analysis. We conducted a review of BioWatch to determine the extent BioWatch program management implemented proper controls for coordinating responsibilities and funding with its partner agencies.

The program operates in various cities, but DHS still needs to design and implement management controls to follow-up on deficiencies in field and laboratory operations. Further, DHS has not properly enforced or monitored partner agency reporting needed to coordinate BioWatch. The need to enhance management controls over BioWatch exposes the program to possible mismanagement of funds and could jeopardize DHS' ability to detect biological agents and protect the populace of the United States.

We recommended that the Under Secretary for Science and Technology:

- Address and rectify after-action and previous field operation findings;
- Enforce federal partners' requirements, including monthly and quarterly reporting requirements; and
- Closely review and monitor required reports submitted by its federal partners to determine and resolve discrepancies.

The Under Secretary has taken action to resolve the issues. Based on management's description of actions taken, we consider the recommendations resolved and closed. We have incorporated the Under Secretary's comments, dated November 2, 2006, into the body of this report and made changes where appropriate. Appendix B contains the full text of management's comments in its entirety.

Background

DHS, through the S&T Directorate, provides management oversight to BioWatch, an early warning system designed to detect the release of biological agents in the air through a comprehensive protocol of monitoring and laboratory analysis. The program was designed to demonstrate the effectiveness of new technology in protecting public health.

The goals of BioWatch are to:

- Provide early warning of a biological attack by expeditiously identifying the bio-agent, thereby minimizing casualties in an affected area;
- Assist in establishing forensic evidence on the source, nature, and extent of biological attack to aid law enforcement agents in identifying the perpetrators; and
- Determine a preliminary spatial distribution of biological contamination, including what populations may have been exposed.

DHS manages the program in cooperation with its federal partners, the Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC), a Department of Health and Human Services (HHS) agency. The parties coordinate and manage their respective responsibilities for BioWatch through a Memorandum of Agreement (MOA) (see Appendix C) and interagency agreements under the Economy Act of 1932, as amended, 31 USC § 1535 (Economy Act). The MOA and interagency agreements are the vehicles by which the S&T Directorate obtains services to carry out the BioWatch program. The MOA requires EPA to provide services and technical expertise to BioWatch including, but not limited to, the following:

- Establishing, deploying, operating, and maintaining a network of collectors in BioWatch cities;
- Establishing, operating, and maintaining a filter collection process for such a network;
- Coordinating the monitoring activities of the network with state and local environmental monitoring agencies; and
- Coordinating activities with CDC.

The MOA requires CDC and its Laboratory Response Network (LRN) to provide technical expertise and services to BioWatch including, but not limited to, the following:

- Providing laboratory analysis services;
- Developing and implementing specific protocols for each laboratory that makes up the LRN and is designated as a laboratory responsible for BioWatch filter testing;
- Coordinating laboratory analyses with state health departments and state public health laboratories;
- Coordinating activities with EPA;
- Tasking the U.S. Department of Energy (DOE) National Laboratories to provide external filter analysis and consulting services on a contingency basis; and
- Providing leadership and technical assistance to state and local health departments regarding the management of public health emergencies resulting from BioWatch's detection of biological pathogens.

At the program's inception, DHS did not have a formal BioWatch organizational structure to enable proper management of the program. In December 2004, DHS joined with three contractors to form Systems Engineering and Technical Assistance (SETA). Each of the three contracts contained the same Statement of Work, which included supporting DHS in (1) coordinating, managing, and improving existing BioWatch program operations; (2) providing financial management and analysis; and (3) facilitating interagency cooperation in the areas of program policies, plans, needs, and other such items of mutual interest. The three SETA contractors are:

- The Tauri Group, which serves as team lead, provides strategic planning, and is the focal point for financial management and analysis, and interagency cooperation;
- Logistics Management Institute, which provides logistics and quality management; and
- SRS Technologies, which provides engineering and surge support.

Results of Audit

DHS operates the program in various cities. DHS identified areas for improvement in the operation of the program, but did not follow-up on these areas. Further, DHS did not enforce the required submission of monthly and quarterly status reports from EPA and CDC, which would have enabled it to properly monitor its federal partners.

DHS Follow-up on Previously Identified Issues

From March 2004 through June 2004, Defense Group Inc. (DGI), a DHS contractor, conducted the BioWatch Exercise and Evaluation Program (BWEEP), a full-scale evaluation of all aspects of BioWatch that included field and laboratory site visits and written reports of day-to-day activities. The purpose of the BWEEP was to ensure that BioWatch was functioning according to DHS procedures and protocols. The BWEEP discovered areas of noncompliance in field and laboratory operations. Between September 2005 and December 2005, SETA conducted a second round of BWEEP site visits. In comparison to the first round, the second round resulted in slightly lower average grades even though three laboratories and seven field operations improved their grades from the first round. According to BioWatch program management, the lower average grades in the second round may have been partially due to a shorter advance notice given to field and laboratory representatives, from a number of days to 24 hours.

In addition, several noncompliance issues identified in the first round of BWEEP site visits were identified again in the second round, including issues in field collection, transport of filters, and laboratory operations, any of which could potentially cause cross-contamination of samples. As a result, uncorrected issues could jeopardize DHS' ability to protect the populace of the United States or to prosecute suspected perpetrators.

BioWatch was rolled out in just under 80 days from late January 2003 to mid-April 2003. During this roll-out, DHS maintained after-action reports for each city that identified areas of concern or problems encountered. According to the summary report of the first round of BWEEP site visits, dated July 20, 2004, BioWatch was "functioning well" and "is in good standing." However, a chart of the BWEEP results in this summary report indicated that 16 percent of the laboratories and 3 percent of the field operation units required remedial training and follow-up evaluation.

The summary report of the first round of BWEEP site visits also identified procedural deficiencies in field collection, transport of filters, and laboratory operations that needed to be addressed to ensure the effectiveness of BioWatch. Examples of high error rates (rounded) in the summary report included the following:

- Improper transfer of exposed filters. At 84 percent of the laboratories, the exposed filters were not transferred properly from the field to the laboratory personnel.
- Improper decontamination of the Chain-of-Custody bags, inner bags, and holders. At 74 percent of the laboratories, Chain-of-Custody bags or holders were not wiped down properly with bleach prior to filter cutting.
- Procedural errors made in the handoff from the field personnel to the laboratory personnel. At 65 percent of the cities evaluated, procedural errors were made, including the improper transfer of exposed filters.
- Improper quality control. In 53 percent of the laboratories evaluated, critical reagents[1] received improper quality control prior to the first use.
- Improper storage of exposed filters during transport. At 42 percent of the cities evaluated, field personnel improperly stored or transported the exposed filters in containers that could not be easily decontaminated.
- Improperly conducted Sample Management System (SMS) functions. At 32 percent of the laboratories evaluated, field personnel conducted SMS functions in the same room as laboratory filter intake increasing the risk of cross-contamination.

Several of the areas in field collection, transport of filters, and laboratory operations reported as requiring improvement in the first round of BWEEP site visits were also reported in the second round. The summary report of the second round included the following suggestions from DHS for operational and laboratory improvement:

- Establish separate areas for sample receipt, SMS functions (when performed at the laboratory), new filter holder assembly, and sample processing.
- Perform thorough decontamination of sample transport container prior to transport to laboratory processing areas.
- Perform proper decontamination of Chain-of-Custody bags, inner bags, and holders prior to filter cutting and transfer, as well as scissors, cassette openers, and hood between samples.

[1] Reagents are substances used in detecting or measuring a component because of their chemical or biological activity.

- Decontaminate bags (containing holders, cassettes Chain-of-Custody bags, and inner bags), DNA extract tubes, and any other materials with bleach prior to removing from the biological safety cabinet and hood.
- Implement quality assurance and quality control on reagents, including plates, strips, and verification panels, upon arrival; and analyze environmental laboratory swipes and swabs weekly.
- Separate new filter holders from exposed holders during sample collection by transporting them in separate coolers or containers that can be easily decontaminated.

The addition of the SETA contracts should assist DHS management in implementing corrective action on BWEEP recommendations to reduce the number of repeat findings.

DHS Enforcement of Federal Partners' Reporting Requirements

Through interagency transfers of funds, DHS provided $26.8 million to EPA and $28.5 million to CDC during fiscal years 2004 and 2005 for operation of the BioWatch program. According to the Statements of Work, SETA was required to develop and maintain a financial management database to track and account for all BioWatch program funding, including all program funds going to program participants. However, neither DHS nor SETA enforced the monthly and quarterly reporting due from EPA and CDC, as required by the MOA.

The MOA required monthly status reports from EPA and CDC to provide DHS managers with operations and expense information, including staffing; recurring costs; travel; administration; information technology support; a numeric breakdown of monthly laboratory costs; and a numeric breakdown of monthly costs on a per BioWatch city basis. Handwritten revisions from EPA (see Appendix C) to the MOA changed its monthly reporting requirement for operations and expense information quarterly. The MOA also required EPA and CDC to provide the following categories of reports to DHS on a quarterly basis: problem and problem resolution reports, EPA Performance Standards reports, CDC Performance Standards reports, and such other reports as may be reasonably requested by DHS.

EPA did not submit any reports to DHS. CDC did not consistently submit monthly reports and did not submit any quarterly reports to DHS. The DHS Financial Resource Manager assigned to BioWatch, a contractor, was unaware the MOA required such quarterly reports. Further, it appears DHS did not closely review the monthly reports submitted by CDC because there were

inconsistencies in the financial information and no evidence of review to detect or resolve the inconsistencies.

BioWatch program management said that DHS has recently begun issuing grants directly to state and local air monitoring agencies. To date, BioWatch program management reported that it has awarded grants to approximately 33 percent of the state and local agencies and anticipates completing this process by the end of September 2006. Although DHS has recently begun issuing grants directly, it still has not received any reports from EPA or grantees, and thus it does not know how the grants are being spent. In its March 23, 2005, Evaluation Report, No. 2005-P-0012, "EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program," EPA OIG also identified instances where EPA did not consistently complete or provide performance information to DHS.

DHS and SETA had not implemented proper controls over funding to its federal partners. Although BioWatch partners are federal agencies, DHS is responsible for monitoring DHS-funded projects. Not obtaining or properly monitoring monthly and quarterly reports limits DHS' oversight of its federal partners and could lead to loss of controls or mismanagement of funds.

Recommendations

We recommend that the Under Secretary for Science and Technology:

Recommendation #1:

Address and rectify after-action and previous field operation findings.

Recommendation #2:

Enforce federal partners' requirements, including monthly and quarterly reporting requirements.

Recommendation #3:

Closely review and monitor required reports submitted by its federal partners to determine and resolve discrepancies.

Management Comments and OIG Analysis

Management Comments to Recommendation #1

The Under Secretary for S&T noted that major changes had been implemented in the BioWatch program in FY05 and FY06 to address the issues noted in this report. We consider their actions, described below, as responsive to our recommendations.

Although the second round of BWEEP site visits resulted in slightly lower average grades in comparison to the first round, DHS stated that year-to-year comparisons of the scores are not, in and of themselves, indicative of changes in operational competence, particularly given that the FY05 was more thorough, including additional collector sites, field operations, and laboratories. DHS also stated that the department continues to improve the BWEEP process in order to provide a more comprehensive assessment of operational status and to identify areas where the department can better assist the jurisdictions. In addition, the department developed and implemented a protocol to reduce those deficiencies identified in both the first and second rounds of BWEEP site visits and procedures to ensure that the jurisdictions promptly correct identified deficiencies, including developing a corrective action plan within 30 days of the BWEEP report.

Management Comments to Recommendation #2

DHS stated that the department has developed and implemented a system of cooperative agreements directly with state and local agencies to streamline the process of funding field operations. Also, DHS developed and implemented an approach to staff laboratory positions through a contract vehicle under direct control of DHS. DHS stated that these modifications should facilitate monthly and quarterly reporting requirements being met.

Management Comments to Recommendation #3

DHS agreed that the department had not closely reviewed and monitored the required reports submitted by its federal partners and has instituted new processes and standards to address this issue. DHS stated that, beginning in fiscal year 2006, the department is thoroughly reviewing all reports on a monthly basis to evaluate expenditures, levels of effort and progress towards milestones.

OIG Comments and Analysis

We consider all recommendations resolved and closed.

Our objectives were to determine the extent BioWatch program management implemented proper controls for coordinating responsibilities and funding with its partner agencies.

Our fieldwork included interviews, site visits, information and documentation review, and data analysis necessary to achieve our objectives. Specifically, we obtained and reviewed the MOA, interagency agreements, partner agency reports, BWEEP reports, after-action reports, Government Accountability Office (GAO) reports, and a Congressional Research Report. We relied on the data provided by S&T Directorate, but we did not test the validity of the information. We also interviewed BioWatch program managers and officials, and reviewed the Economy Act.

During the preliminary phase of the review, we observed field and laboratory operations and interviewed field and laboratory representatives at two sites: Washington, DC, in June 2004 and Houston, Texas, in September 2004. We conducted the Houston, Texas site visit in conjunction with the EPA OIG and the HHS OIG.

The period of our review was from March 1, 2003, through February 28, 2005. To fully test management controls, we extended our testing of partner agency reports through May 12, 2006 and reviewed the results of the second round of BWEEP site visits, which occurred between September and December 2005. We performed fieldwork at BioWatch offices of the S&T Directorate in Washington, DC.

We conducted our review between March 2005 and August 2006 under the authority of the Inspector General Act of 1978, as amended, and according to generally accepted government auditing standards.

We would like to extend our appreciation to S&T for the cooperation and courtesies extended to our staff during the review.

Appendix B
Management's Response to the Draft Report

U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

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MEMORANDUM FOR: David M. Zavada
Assistant Inspector General for Audit

FROM: Jay M. Cohen 11/2/06
Under Secretary for Science and Technology

SUBJECT: *DHS' Management of BioWatch Program*
FOR OFFICIAL USE ONLY (FOUO)

Thank you for the opportunity to review and comment on the draft report, *DHS' Management of BioWatch program.*

S&T is responding to your memorandum dated October 3, 2006 which requests S&T to advise your office within 30 days of the progress of implementing the recommendations. Please refer to the attached document "S&T's Response to the OIG Report; *DHS' Management of BioWatch program*" document which addresses the recommendations in your draft report.

If you have any further questions regarding these comments or corrective actions, please feel free to contact Cindy Christian, Administrative Officer, 202-254-5357.

Attachment

S&T's Response to the OIG Report

DHS' Management of BioWatch Program

The Office of the Inspector General (OIG) of DHS undertook a review of the BioWatch program and issued a report, ***DHS' Management of BioWatch Program*** (herein referred to as "Draft Report"), which makes the following recommendations to the Under Secretary for Science and Technology regarding management of the BioWatch Program:

1. Address and rectify after-action and previous field operation findings;
2. Enforce federal partners' requirements, including monthly and quarterly reporting requirements; and
3. Closely review and monitor required reports submitted by its federal partners to determine and resolve discrepancies.

The OIG requests comments and specific responses to each recommendation.

General Comments

The stated period of review for the Draft Report was from March 1, 2003, through February 28, 2005. However, some of the issues raised in the Draft Report address program elements that occurred outside of that period, e.g., the FY05 BWEEP process.

Perhaps more importantly, the Draft Report does not reflect major changes that were implemented by the BioWatch Program in FY05 and FY06 specifically to address many of the issues that were noted. These changes were discussed during meetings with the OIG staff.

Recommendation 1: Address and rectify after-action and previous field operation findings

Under the BioWatch Exercise and Evaluation Program (BWEEP), all jurisdictions undergo a yearly assessment of operational proficiency. As part of this process, each jurisdiction is assigned a numerical score that represents an average of the ratings for a wide range of operational factors. The initial evaluation was conducted in FY04. The Draft Report notes that the second round of BWEEP site visits in FY05 resulted in slightly lower average scores and that some of the deficiencies identified in FY04 were found again in FY05.

A) Comparison of FY04 and FY05 BWEEP Methodology

The FY04 BWEEP was designed to provide the program an initial assessment of the general operational readiness of the BioWatch network, which at that point

had been operating for about one year, and to provide immediate training or advice to the jurisdictions as needed.

The results of the FY04 evaluation were used to refine the goals, objectives and methodology of the FY05 BWEEP, and significant changes were made. Among those changes was an improved grade scale that made the numerical scores more exact. In addition, the FY05 BWEEP was significantly more thorough. For example, in FY04 sample exchange operations were not observed at all collector locations, whereas in FY05 all collectors were visited. These differences were noted in the FY05 BWEEP report itself, which states:

> "In comparison to the first BWEEP evaluations, the average grades were slightly lower for the second installment of BWEEP ..., however, three laboratories and seven field operations improved their grades from last year. The field operations evaluations differed from the first BWEEP in that all collector sites were visited, enabling the evaluators to observe possible inconsistencies between collector site locations. Evaluations for both the field and laboratory operations were more thorough and detailed in an attempt to ensure system-wide compliance in the midst of challenging enhancement activities. In addition, four laboratories and two field operations were evaluated for the first time, since they were not operational during the 2004 BWEEP."

The BioWatch program continues to improve the BWEEP program in order to provide a more comprehensive assessment of operational status and to identify areas where DHS can better assist the jurisdictions. To achieve this goal, additional changes were made to the FY06 BWEEP process, and more are contemplated for FY07. For these reasons, year to year comparisons of the scores are not, in and of themselves, indicative of changes in operational competence.

2) Implementing New Protocols to Reduce Reoccurring Deficiencies

During the FY05 BWEEP effort the BioWatch program noted that some of the deficiencies found in FY04 had reoccurred. This was also noted in the Draft Report.

Most of the repeated deficiencies related to handling of the samples in the field or in the laboratory. To reduce the occurrence of repeated deficiencies, the BioWatch Sample Exchange Protocol was developed. The new protocol provides jurisdictions with more detailed instructions regarding correct sample handling

procedures.[1] It was implemented in March of 2006, and the jurisdictions are being evaluated on their adherence to the protocol as part of the FY06 BWEEP.

The new protocol has been successful, and a significant improvement in sample handling operations has been observed. (The FY06 BWEEP is not yet complete.)[2]

3) Following-up on Identified Deficiencies

After the FY05 BWEEP, the BioWatch program determined new procedures were needed to ensure that jurisdictions promptly correct deficiencies. The BioWatch Corrective Action Plan was developed and implemented as part of the FY06 BWEEP. The jurisdictions are now required to submit, within thirty days, a plan to address each "Area of Improvement" identified during the BWEEP process. If warranted, the BWEEP team will return to the jurisdiction to verify that the corrections have been made.

Recommendation 2: Enforce federal partners' requirements, including monthly and quarterly reporting requirements

1) EPA Responsibilities Modified

The Draft Report notes that the BioWatch program did not receive the required monthly reports from the EPA. This problem was also note by the OIG of the EPA.

Prior to late FY06, jurisdictional funding for field operations was provided as a grant handled through the EPA. This element of the program accounted for almost all the BioWatch funds given to the EPA, and the EPA was responsible for reports on this activity. The BioWatch program found the process to be cumbersome and switched to a system of cooperative agreements handled through the DHS Grants and Training Office. The new system streamlines the process of

[1] Specifically, the Sample Exchange Protocol was implemented to address several of the issues mentioned on pages 5 and 6 of the Draft Report including: Improper transfer of exposed filters; Improper decontamination of Chain-of-Custody Bags; Procedural errors made in the handoff from the field personnel to the laboratory personnel; Improper storage of exposed filters during transport; Improperly conducted Sample Management System (SMS) functions; Establishment of separate areas for sample receipt, SMS functions, new filter holder assembly, and sample processing; Performing thorough decontamination of sample transport container prior to transport to laboratory processing areas; Separating new filter holders from exposed holders during sample collection by transporting them in separate coolers or containers that can be easily decontaminated.

[2] The Draft Report (page 5) cites as a deficiency the BWEEP observation that over half the labs had "below average processing time for filters." In fact, the labs that have below average processing time are demonstrating proficiency in that they were able to complete the filter analysis process sooner than had been anticipated.

funding jurisdictions, ensures quick turnaround of funds and avoids the prior report problems. The agreements were awarded during May and June of 2006, and the required reports come directly from the Grants and Training Office. Currently, the BioWatch Program is working with the EPA to determine the support and tasks that will be provided in FY07. The Program will endeavor to ensure there is a clear understanding regarding status reports for any future work.

2) CDC Responsibility Modified

The Draft Report notes that the CDC did not provide the BioWatch program with all the required reports.

In FY04 and FY05, the laboratory staff required for BioWatch operations was filled by personnel hired by the CDC, and the CDC was responsible for regular reports on the funds used for that purpose. In FY06 the CDC and the BioWatch program agreed to change the approach to laboratory staffing, and beginning that year all the lab staff positions are filled through a contract vehicle under direct DHS control. BioWatch receives monthly reports on this component of the program through the prime contractor, and the CDC is no longer responsible for the monthly and quarterly reports on that element of the program.

The CDC continues to receive some BioWatch funding, and the BioWatch program has worked with CDC management to correct reporting requirements. Monthly reports are now being received and reviewed by the BioWatch Systems Program Office.

Recommendation 3: Closely review and monitor required reports submitted by its federal partners to determine and resolve discrepancies

BioWatch Reviews of Status Reports

All the BioWatch partners (including federal agencies) who receive program funds are required to submit monthly reports, and the Program recognizes the importance of regular reviews of these reports. In the past, reports provided by several partner organizations have fallen short of these requirements. The BioWatch program has since worked with those organizations to ensure the submittals are on-time and provide the information needed to effectively manage the program. The compliance with reporting requirements is now generally good.

In FY06 the BioWatch program instituted new processes and standards for reviewing status reports. *All* reports are thoroughly reviewed on a monthly basis to evaluate expenditures, levels of effort and progress towards milestones. The

partner agencies are contacted immediately if inconsistencies are noted or additional information is required.

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MEMORANDUM OF AGREEMENT
AMONG
THE DEPARTMENT OF HOMELAND SECURITY
THE CENTERS FOR DISEASE CONTROL AND PREVENTION
AND
THE ENVIRONMENTAL PROTECTION AGENCY

THIS MEMORANDUM OF AGREEMENT ("MOA") is hereby entered into on March 5, 2004 (the "Effective Date") among the Department of Homeland Security ("DHS"), the Centers for Disease Control and Prevention ("CDC"), and the Environmental Protection Agency ("EPA"), hereinafter jointly referred to as the "Parties" and individually as a "Party".

1. BACKGROUND AND PURPOSE

1.1 BACKGROUND. The DHS Directorate of Science and Technology has established a Chemical, Biological, Radiological, and Nuclear Countermeasures program to prepare for and respond to a wide range of terrorist threats involving weapons of mass destruction. As part of this effort, DHS is partnering with CDC and EPA to implement and administer a program involving the deployment of a network of sensors to detect and report the release of bioterrorist pathogens in densely populated areas ("BioWatch"). BioWatch is an early warning system that is designed to detect trace amounts of biological materials in the air rapidly, whether they result from intentional release or constitute minute quantities that might occur naturally in the environment. BioWatch will assist public health experts in determining the presence and geographic extent of a biological agent release, allowing Federal, state, and local officials to determine emergency response, medical care, and consequence management needs more quickly.

1.2. PURPOSE. The purpose of this MOA is to set forth the terms and conditions by which: (a) CDC and EPA will provide services and technical expertise to BioWatch; (b) the Parties will coordinate and manage their respective responsibilities for BioWatch; and (c) DHS will provide DHS Funds (as defined in Section 4 below) and management oversight to CDC and EPA. The Parties agree that they will review this MOA if the BioWatch program expands or otherwise changes significantly as compared with its configuration as of the Effective Date and, if necessary, effect appropriate amendments hereto.

2. AUTHORITY

This MOA is entered into pursuant to the Economy Act of 1932, as amended (31 U.S.C. 1535), Sections 302(2), (4), (5)(B), and (13) of the Homeland Security Act of 2002 (Public Law 107-296), and Section 103(b)(2) of the Clean Air Act, as amended (42 U.S.C. 7401 et seq.). In accordance with FAR 17.503, the following Determination and

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Findings ("D&F") have been made: (a) use of an interagency acquisition for services is in the best interest of the Government; (b) the supplies and services rendered by CDC and EPA pursuant to this MOA cannot be obtained by DHS as conveniently or economically by contracting directly with a private source; and (c) in CDC's and EPA's capacity as servicing agencies under this MOA, CDC and EPA are authorized by law to purchase supplies or services on behalf of DHS if such purchases are necessary to fulfill their obligations under this MOA and the attached interagency agreement. (cc EPA)

3. SERVICES

3.1. DESCRIPTION OF SERVICES.

3.1.1 SERVICES PROVIDED BY CDC. CDC and its Laboratory Response Network ("LRN") will provide technical expertise and services to BioWatch, including but not limited to: (a) laboratory analysis services; (b) developing and implementing specific protocols for each laboratory comprising the LRN and designated as a laboratory responsible for BioWatch filter testing; (c) coordinating laboratory analyses with state health departments and state public health laboratories; (d) coordinating activities with EPA; (e) tasking DOE National Laboratories (through DHS) to provide external filter analysis and consulting services on a contingency basis; (f) providing leadership and technical assistance to state and local health departments regarding the management of public health emergencies resulting from the BioWatch program's detection of biological pathogens; (g) preparing and issuing situation reports as necessary; and (h) such other services as are directed by DHS in connection with BioWatch and described in a funds transfer document issued pursuant to Section 5 below (collectively, "CDC Services"). CDC will only use DHS Funds for CDC Services. For clarification, CDC may also use DHS Funds for the following activities, materials, supplies, and personnel related to BioWatch: laboratory staffing; recurring supplies; diagnostic hardware; critical and specialty reagents; training; testing; travel directly related to the BioWatch program; and personnel evaluation. CDC may only utilize DHS Funds for other purposes (even if such purposes are related to BioWatch) upon the written authorization of the DHS BioWatch Program Manager.

3.1.2 SERVICES PROVIDED BY EPA. EPA will provide services and technical expertise to BioWatch including but not limited to: (a) establishing, deploying, operating, and maintaining a network of sensors (the "BioWatch Sampling Network") in the BioWatch Cities (as defined in Section 3.2 below); (b) establishing, operating, and maintaining a filter collection process (in accordance with mutually agreed EPA Performance Standards as described below) for such BioWatch Sampling Network; (c) coordinating the monitoring activities of the BioWatch Sampling Network with state and local environmental monitoring agencies; (d) coordinating activities with CDC; and (e) such other services as are directed by DHS in connection with BioWatch and described in a funds transfer document issued pursuant to Section 5 below (collectively, "EPA Services"). EPA will only use DHS Funds for EPA Services. For clarification, EPA may use DHS Funds for the following activities, materials, supplies, and personnel related to BioWatch: program staffing; recurring supplies and equipment; hardware and software

used to track samples, site monitors, or complete programs directly related to BioWatch; training; testing; travel directly related to the BioWatch program; and personnel evaluation. EPA may only utilize DHS Funds for other purposes (even if such purposes are related to BioWatch) upon the written authorization of the DHS BioWatch Program Manager.

3.2 BIOWATCH CITIES. As of the Effective Date of this MOA, DHS has provided to EPA and CDC a list of cities which will be monitored as part of BioWatch ("BioWatch Cities"). The designation of cities as BioWatch Cities is sensitive but unclassified information which may not be disclosed to the public. The Parties agree that during the course of this MOA and upon written notice to CDC and EPA, DHS may designate additional cities, different cities, or fewer cities as BioWatch Cities.

3.3 PERFORMANCE STANDARDS.

3.3.1 CDC PERFORMANCE STANDARDS. CDC will perform the CDC Services in accordance with the following performance standards: (a) adhering to CDC-established criteria for public health reference laboratories; (b) adhering to all BioWatch standard operating procedures and protocols contained in the "Standard Operating Procedure Manual" developed by the Parties; and (c) adhering to such other standards as may be mutually agreed by the Parties (collectively, the "CDC Performance Standards").

3.3.2 EPA PERFORMANCE STANDARDS. EPA will perform the EPA Services in accordance with the following performance standards: (a) adhering to all BioWatch standard operating procedures and protocols contained in the "Standard Operating Procedure Manual" developed by the Parties; (b) coordinating with CDC to ensure that each filter within the BioWatch Sampling Network arrives at the designated LRN facility or alternate facility (i.e. LLNL or alternate site) in a timely manner in order to facilitate timely analysis of the filters by CDC in partnership with state public health laboratories; and (c) adhering to such other standards as may be mutually agreed by the Parties (collectively, the "EPA Performance Standards").

4. DHS RESPONSIBILITIES

DHS will provide funding to CDC and EPA in accordance with DHS's appropriations and available funds ("DHS Funds") and in accordance with the number of BioWatch Cities. DHS will also provide strategic management oversight to CDC and EPA for the services and technical expertise CDC and EPA will provide to BioWatch. DHS will provide a full-time BioWatch Program Manager to provide overall leadership for BioWatch, including budgeting and assigning tasks to CDC and EPA. The BioWatch Program Manager will also brief CDC and EPA periodically on upcoming changes to the BioWatch program (e.g., expansion of the program's scope). DHS will also provide an Operations Director who will oversee and direct day-to-day DHS operations of BioWatch. As of the date of this MOA, the BioWatch Program Manager is to be determined by DHS, and the Operations Director is Mr. Brian M. Hayes. DHS may

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replace such designees at any time upon notice to CDC and EPA. If there is a national emergency or elevation of the national threat level, DHS may provide EPA and CDC with verbal instructions for operational changes (e.g., monitoring additional cities or increasing the frequency of testing filters from the BioWatch Sampling Network) and, at a later date, provide written notice of such operational changes.

Certain Department of Energy ("DOE") National Laboratories, particularly Los Alamos and Lawrence Livermore National Laboratories, will provide technical expertise in biological sampling systems and training assistance to state and local agencies as determined by DHS in accordance with its arrangements with DOE.

5. FUNDING

5.1 PAYMENT OF FUNDS.

5.1.1 PAYMENT OF FUNDS TO CDC. DHS will provide, through interagency funds transfers, DHS Funds to CDC for the CDC Services. DHS Funds will be allocated by CDC for laboratory staffing, recurring costs (e.g., reagents and expendables), travel, administration, and information technology support for the then-current fiscal year. If the number of BioWatch Cities is expanded, DHS will allocate additional DHS Funds (if available) to CDC for the additional CDC Services.

5.1.2 PAYMENT OF FUNDS TO THE EPA. DHS will provide, through an interagency funds transfer, DHS Funds to EPA for the EPA Services. DHS Funds will be allocated by EPA for program staffing, recurring costs (e.g., supplies and equipment), travel, administration, and information technology support for the then-current fiscal year. If the number of BioWatch Cities is expanded, DHS will allocate additional DHS Funds (if available) to EPA for the additional EPA Services.

5.2 REMBURSEMENT OF EXCESS COSTS AND EXPENSES. From time to time, DHS may increase the National Alert Status based on threats to national security. When DHS increases the National Alert Status, both CDC and EPA will create situational reports that identify the total number of personnel hours and amount of materials used in connection with the CDC Services and the EPA Services beyond normal operating parameters and submit such reports to DHS upon the lowering of the National Alert Status or upon DHS's request. DHS will subsequently provide additional DHS Funds to EPA and CDC as reasonably necessary to reimburse EPA and CDC for additional CDC Services and EPA Services beyond normal operating parameters.

5.3 REIMBURSEMENT OF EXCESS PAYMENTS TO DHS. EPA and CDC will carry over unobligated DHS Funds into the new fiscal year and subtract the balance from their budget requests for additional DHS Funds. Upon termination of BioWatch, EPA and CDC will promptly return all unobligated DHS Funds to DHS.

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6. REPORTS AND MEETINGS

6.1 REPORTS.

6.1.1 CDC REPORTS. CDC will provide an operations and expense report for each laboratory within the LRN where CDC Services are performed (with each report containing the following cost categories: laboratory staffing; recurring costs (e.g., reagents and expendables); travel; administration; information technology support; and a numeric breakdown of monthly laboratory costs as a factor of per filter analysis). CDC will provide such operations and expense reports to DHS on a monthly basis by the fifth day of each month containing information pertaining to the preceding month. CDC will also provide the following categories of reports to DHS on a quarterly basis by the fifth day of each quarter containing information related to the previous quarter so that DHS may monitor the performance of the CDC Services: (a) problem and problem resolution reports (e.g., problems encountered with the CDC Services, root cause analysis, and problem resolution efforts); (b) CDC Performance Standards reports (meeting of CDC Performance Standards and failure to meet CDC Performance Standards); and (c) such other reports as may be reasonably requested by DHS.

6.1.2 EPA REPORTS. EPA will provide an operations and expense report for the BioWatch Sampling Network (with each report containing the following cost categories: staffing; recurring costs (e.g., supplies and equipment); travel; administration; information technology support; and a numeric breakdown of monthly costs on a per BioWatch City basis). EPA will provide such operations and expense reports to DHS on a ~~monthly~~ quarterly basis by the fifth day of each month containing information pertaining to the preceding month. EPA will also provide the following categories of reports to DHS on a quarterly basis by the fifth day of each quarter containing information related to the previous quarter so that DHS may monitor the performance of the EPA Services: (a) problem and problem resolution reports (e.g., problems encountered with the EPA Services, root cause analysis, and problem resolution efforts); (b) EPA Performance Standards reports (meeting of EPA Performance Standards and failure to meet EPA Performance Standards); and (c) such other reports as may be reasonably requested by DHS.

6.2 MEETINGS.

6.2.1 MEETINGS WITH CDC. Meetings among CDC, associated public health partners, and DHS will be held at either Party's request and upon reasonable notice.

6.2.2 MEETINGS WITH EPA. Meetings between EPA and DHS will be held at either Party's request and upon reasonable notice.

6.2.3 STEERING COMMITTEE MEETINGS. DHS will conduct bi-weekly steering committee meetings among DHS, EPA, and CDC representatives to manage coordination of BioWatch. Steering committee members will include operational leads from EPA, CDC, and DHS. The steering committee will be chaired by the DHS

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BioWatch Program Manager. In the meetings, committee members will give status reports, discuss operational issues, and discuss any potential future changes to the BioWatch program. Minutes from the steering committee meetings will be available for each Party's review. Steering committee meetings may be held more frequently upon DHS's request.

7. PROJECT MANAGEMENT

7.1 POINTS OF CONTACT.

7.1.1 DHS POINTS OF CONTACT. The primary point of contact at DHS with regard to issues related to BioWatch (other than day-to-day operations) will be the DHS-designated BioWatch Program Manager. The Operations Director, Mr. Brian M. Hayes of DHS will be the point of contact for day-to-day operations of BioWatch.

Operations Director:
Mr. Brian M. Hayes
Directorate of Science and Technology
Department of Homeland Security
Washington, DC 20528
Phone: 202-772-9706
Fax: 202-772-9715
Mobile: 202-360-3165

7.1.2 CDC POINTS OF CONTACT.

Strategic Lead:

Dr. William Raub
Principal Deputy Assistant Secretary
Office of the Assistant Secretary for Public Health Emergency Preparedness
Department of Health and Human Services
Phone: 202-205-2882

Charles A. Schable
Director
Office of Terrorism Preparedness & Emergency Response
Centers for Disease Control and Prevention
404-639-7405

Day-to-Day management:
Dr. Michael Miller
Bioterrorism Preparedness and Response Program
National Center of Infectious Diseases
Centers for Disease Control and Prevention
Phone: 404-639-3029

Charles Schable
Bioterrorism Preparedness and Response Program
National Center of Infectious Diseases
Centers for Disease Control and Prevention
Phone: 404-639-3996

7.1.3 EPA POINTS OF CONTACT.

Mr. Nealson Watkins
U.S. EPA, Office of Air Quality Planning and Standards
Monitoring & Quality Assurance Group (C339-02)
Research Triangle Park, NC 27711
Phone: 919-541-5522
E-mail: Watkins.nealson@epa.gov
Fax: 919-541-1903

7.2 INTERAGENCY COORDINATION. The BioWatch Program Manager will coordinate with EPA and CDC representatives to track daily activities associated with BioWatch. EPA and CDC will execute daily operations and tasks associated with BioWatch to maintain functionality of the EPA Services and CDC Services to ensure continued and uninterrupted BioWatch operations. EPA and CDC will promptly report known, anticipated, or recurring problems with BioWatch operations to the BioWatch Program Manager to ensure continuity of BioWatch operations.

7.3 DISPUTE RESOLUTION. The BioWatch Program Manager will coordinate dispute resolution activities among the Parties. If the dispute is at the operational level, the DHS Operations Director will intervene and resolve as appropriate.

7.4 RECORD RETENTION. Records related to the CDC Services and EPA Services will be retained by CDC and EPA, respectively, as directed by the BioWatch Program Manager in writing (e.g., record type and length of time to be held). EPA will retain field sampling records from the BioWatch Sampling Network for one (1) year, unless otherwise directed by the BioWatch Program Manager..

8. SECURITY POLICIES

Except documentation cleared for public release through DHS public affairs, the Parties will label all documentation related to BioWatch "For Official Use Only" and such documentation will be subject to release and destruction requirements associated with such labeling, which shall be provided to CDC and EPA by the BioWatch Program Manager in writing.

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9. AMENDMENT

The terms of this MOA may be modified in writing upon the mutual agreement of the Parties.

10. TERM AND TERMINATION

10.1 TERM. The term of this MOA shall begin on the Effective Date and shall expire one (1) year after the Effective Date (the "Initial Term"). The Initial Term shall automatically renew for successive one-year renewal terms, unless DHS provides written notice to EPA and CDC at least sixty (60) days prior to the expiration date of the then-current one-year term of its intent not to renew this MOA, in which case this MOA will terminate as of the expiration of then then-current term.

10.2 TERMINATION. Each Party may terminate this MOA for convenience and without cause at any time by giving the other Parties at least sixty (60) days prior written notice (with copies to the General Counsel's Office of each Party) designating the termination date.

APPROVED and AGREED BY:

Department of Homeland Security
Name: [signature]
Title: ASSISTANT SECRETARY SCIENCE AND TECHNOLOGY DEPARTMENT OF HOMELAND SECURITY
Date: MARCH 5, 2008

Centers for Disease Control and Prevention
Name: William F Carr
Title: Principal Deputy Assistant Secretary for Public Health Emergency Preparedness
Date: 02 August 2004

Environmental Protection Agency
Name: for Elizabeth Craig Jeffrey Holmstead
Title: Assistant Admin. for Air and Radiation
Date: Aug. 5, 2004

DHS Warranted Contracting Officer
Name: _____
Title: _____
Date: _____

Appendix D
Major Contributors to this Report

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Edward Jeye, Auditor-in-Charge
Brian Lynch, Auditor
David DeHaven, Auditor

Appendix E
Report Distribution

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