

**GOVERNMENT OF THE DISTRICT OF COLUMBIA
OFFICE OF THE INSPECTOR GENERAL**

**Audit of the Department of
Health's Procurement of the
Biosafety Laboratory Level 3,
Modular Laboratory and
Learning Management System**



**CHARLES J. WILLOUGHBY
INSPECTOR GENERAL**

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General



July 24, 2008

Pierre N. D. Vigilance, MD, MPH
Director
District of Columbia Department of Health
825 North Capitol Street, N.E., Suite 4400
Washington, D.C. 20002

Dear Dr. Vigilance:

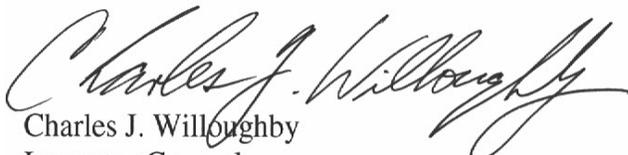
Enclosed is our final report summarizing the results of the Office of the Inspector General's (OIG) *Audit of the Department of Health's Procurement of the Biosafety Laboratory Level 3, Modular Laboratory and Learning Management System* (OIG No. 06-2-17MA).

Our report contains two recommendations for necessary action to correct the described deficiencies. We received responses to the draft report from the Department of Health (DOH) dated July 3, 2008, and July 11, 2008, respectively. DOH's actions taken and/or planned fully address the recommendations.

However, DOH did not provide target dates for completing the planned actions. Thus, we request that DOH provide our Office with the target dates for addressing the recommendations no later than August 22, 2008. The full texts of DOH's responses are included at Exhibit C and Exhibit D.

We appreciate the cooperation and courtesies extended to our staff during the audit. If you have questions, please contact William J. DiVello, Assistant Inspector General for Audits, at (202) 727-2540.

Sincerely,


Charles J. Willoughby
Inspector General

Enclosure

CJW/ws

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**AUDIT OF THE DEPARTMENT OF HEALTH'S PROCUREMENT OF
THE BIOSAFETY LABORATORY LEVEL 3, MODULAR
LABORATORY AND LEARNING MANAGEMENT SYSTEM**

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**AUDIT OF THE DEPARTMENT OF HEALTH'S PROCUREMENT OF
THE BIOSAFETY LABORATORY LEVEL 3, MODULAR
LABORATORY AND LEARNING MANAGEMENT SYSTEM**

ACRONYMS

BSL3	Biosafety Laboratory Level 3
BSL3 lab	Biosafety Laboratory Level 3, Modular Laboratory
BY	Budget Year
CDC	Centers for Disease Control and Prevention
DCMR	District of Columbia Municipal Regulations
DOH	Department of Health
EMS	Emergency Medical Services
HEPRA	Health Emergency Preparedness and Response Administration
HRSA	Health Resources and Services Administration
HSEMA	Homeland Security and Emergency Management Agency
HHS	U.S. Department of Health and Human Services
LMS	Learning Management System
MDLA	State of Maryland Department of Health and Mental Hygiene, Laboratory Administration
MOU	Memorandum of Understanding
OIG	Office of the Inspector General
OCP	Office of Contracting and Procurement
PHL	Public Health Laboratory
RFP	Request for Proposal
SOAR	System of Accounting and Reporting

EXECUTIVE DIGEST

OVERVIEW

The Office of the Inspector General (OIG) has completed an Audit of the Department of Health's Procurement of the Biosafety Laboratory Level 3, Modular Laboratory and Learning Management System. During the audit, the Department of Health (DOH) reorganized and combined the Emergency Health and Medical Services Administration with the DOH Public Health Laboratory (PHL)¹ to form the Health Emergency Preparedness and Response Administration (HEPRA). Our audit focused on DOH's acquisition of a \$6.8 million Biosafety Laboratory Level 3, Modular Laboratory (BSL3 lab) and a Learning Management System (LMS).²

According to its website, DOH's mission is to "promote and protect the health, safety, and quality of life of residents, visitors, and those doing business in the District of Columbia [District]."³ DOH's responsibilities include "identifying health risks; educating the public; preventing and controlling diseases, injuries and exposure to environmental hazards; promoting effective community collaborations; and optimizing equitable access to community resources."⁴ DOH officials consider disaster preparedness a core component of public health.

Preparedness for Bioterrorism. Preparedness for terrorist attacks and resultant injuries is an essential component of the U.S. public health surveillance and response system, which is designed to protect the population against any unusual public health emergency. Biological and chemical agents are numerous, and the public health infrastructure must be equipped to quickly respond to and resolve the crisis that would arise from a biological or chemical attack.

Early detection of and response to a bioterrorism attack are essential to saving lives and resources because biological agents can be difficult to detect. Some may not cause illness for several hours up to several days. A large-scale attack with bioterrorism agents could overwhelm the public health infrastructure. Early detection requires bioterrorism awareness among front-line healthcare providers, enhanced capabilities to investigate unexplained illnesses, and improved communication systems between those providers and public health officials. In 1998, Congress passed the Response to Weapons of Mass Destruction Act of 1997, which centered on emergency first-responders with training and equipment and targeted the nation's 120 largest cities, including the District of Columbia. In 1999, the

¹ The DOH PHL is a 63-year old facility with level 2 capabilities, working with agents of moderate risk, and plays a vital role in surveillance and testing of different biological and chemical agents (i.e., anthrax, sarin, plague, and tularemia). The PHL is slated to be part of the consolidated Bioterrorism and Forensics Laboratory.

² LMS is an online system that includes e-learning courses, online registration capabilities, automated course catalogs, competency management, assessment, resources management, tracking, and reporting. HEPRA obtained the LMS for the purpose of emergency preparedness training.

³ <http://www.doh.dc.gov> (go to "About DOH").

⁴ *Id.*

EXECUTIVE DIGEST

Centers for Disease Control and Prevention announced its intention to upgrade state and local health department preparedness and response capabilities relative to bioterrorism. An outgrowth of this expansion was the decision to construct a BSL3 lab and LMS. Pending construction of the BSL3 lab, the District and Maryland signed a Memorandum of Understanding to provide interim capabilities for testing BSL3 biological agents.

CONCLUSIONS

DOH incurred unnecessary delays in the procurement of a BSL3 lab capable of handling select biological agents. Although the project was initiated in May 1999, as of the date of this report, the BSL3 lab had not been completed. The delays occurred, in part because DOH and D.C. Office of Contracting and Procurement (OCP) officials did not develop a procurement plan that provided for coordination and continuity in the construction of a BSL3 lab from the initial stages to full operational capabilities. The lack of a procurement plan further contributed to delays with site identification and DOH's response to the turnover of agency staff responsible for the project. Procurement planning for construction and other contracted projects is required by the governing criteria of Title 27 of the District of Columbia Municipal Regulations. As a result, the District's response capabilities were negatively affected by the fact that laboratory samples had to be sent to Maryland and Virginia State Laboratories for sample analysis.

Also, OCP did not solicit competition in the procurement of the \$300,000 LMS. Instead, OCP issued a sole-source purchase order to obtain the LMS without adequate justification. Further, the contractor used a subcontractor to provide the LMS and related services. Without competition, there is no assurance that the District received the most reasonable price.

SUMMARY OF RECOMMENDATIONS

We directed two recommendations to the Acting Director of DOH. The recommendations focus on providing improved coordination between agencies by: (1) defining the authority and responsibilities of employees; and (2) developing and maintaining standard operating procedures. We are also providing a copy of the report to the Chief Procurement Officer because certain issues identified in this report are repetitive deficiencies relative to procurement and contract administration.

EXECUTIVE DIGEST

MANAGEMENT RESPONSES AND OIG COMMENTS

DOH provided written responses to our draft report dated July 3, 2008, and July 11, 2008, respectively. We consider the actions taken and/or planned by DOH to be responsive and to meet the intent of our recommendations. DOH's July 3, 2008, response to our draft report provided updated information and recommended certain changes relative to the report presentation. We considered DOH's comments and modified our report as appropriate. The full text of DOH's responses is included at Exhibit C and D.

INTRODUCTION

BACKGROUND

The Office of the Inspector General (OIG) has completed an Audit of the Department of Health's Procurement of the Biosafety Laboratory Level 3, Modular Laboratory (BSL3 lab) and Learning Management System (LMS). During the audit, the Department of Health (DOH) reorganized and combined the Emergency Health and Medical Services Administration with the DOH Public Health Lab (PHL)⁵ to form the Health Emergency Preparedness and Response Administration (HEPRA).

Health Emergency Preparedness and Response Administration. HEPRA is an administration within DOH and is an integral part of the department's strategic plan to prepare for, respond to, recover from, and mitigate the effects of emergencies and acts of terrorism in this region. DOH's strategic approach to achieve effectiveness is broken down into five major goals: (1) enhance the emergency health and medical preparedness of the Nation's Capital; (2) plan for the effective control and response to all public health emergencies; (3) establish and maintain plans and procedures for recovering from and improving the response to public health emergencies; (4) develop and maintain a robust emergency response communication and coordination capability; and (5) plan funding and other resources to meet requirements for public health emergency preparedness.

HEPRA is responsible for planning and coordinating the timely delivery of emergency medical health services and all-hazards responses to public health incidents for District residents, healthcare providers, visitors, and other stakeholders. HEPRA's fiscal years (FYs) 2006 and 2007 budgets were \$8.9 million and \$8.1 million, respectively. The FY 2008 budget is \$11.4 million. The administration's two major activities are providing emergency medical services (EMS) and operating the PHL. HEPRA is primarily funded by grant funds from the Health Resources and Services Administration (HRSA)⁶ and the Centers for Disease Control and Prevention (CDC), two agencies within the U.S. Department of Health and Human Services.

The Emergency Medical Services (EMS) Comfort Care Order (CCO) allows patients diagnosed with a specific medical or terminal condition to express their wishes regarding end of life resuscitation in the pre/post-hospital setting. The EMS CCO also allows EMS personnel to provide palliative care, as appropriate. The patient's attending physician must issue, certify and sign that the patient (adult or child) has a specific medical or terminal condition. EMS personnel responding to calls for either cardiac or respiratory

⁵ The DOH Public Health Lab has bioterrorism safety level 2 capabilities and is slated to be part of the consolidated forensics lab.

⁶ In FYs 2005 and 2006, HRSA awarded \$3.6 million in grants to HEPRA. HRSA provides funds to states and local health departments to upgrade and prepare hospitals and collaborating entities to respond to bioterrorism attacks under the Bioterrorism Hospital Preparedness Program. HRSA receives its funding from the federal government under the Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the United States Act of 2002 (Pub. L. No. 107-117).

INTRODUCTION

arrest related to the condition of a Comfort Care patient will not resuscitate the patient, unless the Order has been revoked.

PHL provides analytical and diagnostic support services such as operating free and non-profit clinics, conducting clinical tests and limited environmental tests and supporting emergency preparedness testing requirements. The PHL contains the following laboratories: immunology; microbiology; molecular biology and virology; medical diagnostics; and chemical terrorism.

HEPRA officials coordinate with the District Homeland Security and Emergency Management Agency (HSEMA)⁷ as well as other metropolitan-area disaster preparedness agencies. HEPRA also participates on at least 12 local, regional, and national disaster preparedness committees, such as The Critical Infrastructure Working Group, D.C. Hospital Association Emergency Preparedness Committee, BioEmergency Planners Group, Directors of Public Health Preparedness Committee, Pandemic Influenza Coordinating Committee, and the Essential Services Committee.

Bioterrorism Defined. The CDC defines a bioterrorism attack as the deliberate release of viruses, bacteria, or other germs and chemicals (bioterrorism agents) used to cause illness or death in people, animals, or plants. Typically found in nature, these agents can be changed to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to contaminate the environment. Bioterrorism agents can be spread via the air, water, or food. Depending on the severity of illness, or how easily they spread, bioterrorism agents can be grouped into three categories: A, B, or C, where Category A agents are considered the highest threat risk and Category C agents the lowest threat risk. See Exhibit B for a List of Bioterrorism Agents.

Bioterrorism Funding. In 1999, the CDC⁸ announced through “Program Announcement 99051, Notice of Availability of Funds” (Notice) the intent to upgrade state and local health departments preparedness and response capabilities relative to bioterrorism. In particular, the Notice discloses that in Focus Area C, Laboratory Capacity Biologic Agents,⁹ less than one-third of state public health laboratories operated a BSL3 lab (and those labs were primarily dedicated to work related to tuberculosis).

⁷ Mayor Adrian Fenty combined the D.C. Emergency Management Agency and the Office of Homeland Security to form HSEMA. HSEMA provides 24-hour emergency assistance to the public by mobilizing and deploying emergency services personnel and resources; updating emergency operation plans and strategies; training emergency personnel; managing special events; and informing the public of impending emergencies and disasters in order to save lives and protect property in the District of Columbia.

⁸ According to its website, the CDC is a federal government agency and responsible for promoting health and quality of life by preventing and controlling disease, injury, and disability. <http://www.cdc.gov/> (click on “ABOUT CDC”).

⁹ There are five focus areas delineated in the Notice. They are Preparedness Planning and Readiness Assessment; Surveillance and Epidemiology Capacity; Laboratory Capacity-Biologic Agents; Laboratory Capacity-Chemical Agents; and Health Alert Network/Training.

INTRODUCTION

However, the Notice also states that BSL3 facilities are recommended for testing of biological agents, but not required. On page 27, the Notice further states, “These State and local public health agency laboratories have the ability to rule in specific agents and to forward organisms or specimens to higher level laboratories.” In general, the Notice announced the availability of funds for state and local public health agencies to aid in the development of BSL3 testing capabilities.

The CDC provides funds to states and local health departments to improve their bioterrorism preparedness and response capabilities under the Public Health Preparedness and Response for Bioterrorism Program authorized under Sections 301(a), 317(k)(1)(2), and 319 of the Public Health Service Act of 1946 (42 U.S.C. §§ 241(a), 247b(k)(1)(2), and 247(d)). As of August 30, 2007, the CDC had awarded approximately \$55.2 million in grant funds to HEPRA over a 7 budget year (BY) period beginning in August 1999. Of this amount, approximately \$9.6 million was earmarked for Focus Area C Laboratory Capacity – Biologic Agents. HEPRA officials used funds from this focus area to develop and construct a BSL3 lab.

Table 1 illustrates the funds requested by DOH and awarded by the CDC for preparedness planning and readiness assessment; surveillance and epidemiology capacity; laboratory capacity – biologic agents; laboratory capacity – chemical agents; and health alert network/training.

Grant Budget Year¹⁰	Funds¹¹ Requested	Funds¹² Awarded	Direct¹³ Assistance
7	\$ 7,561,684	\$7,300,939	\$26,873
6	12,386,201	12,316,821	311,883
5	16,679,224	11,742,244	315,642
4	11,488,638	10,957,325	483,905
3	24,558,236	12,592,907	-0-
2	276,215	235,651	-0-
1	1,646,859	135,000	-0-
Total	\$74,597,057	\$55,332,456¹⁴	\$1,138,303

¹⁰ A grant BY runs from August to August.

¹¹ Source: line 15g, SF 424, Application for Federal Assistance submitted to Centers for Disease Control and Prevention.

¹² Source: line 11u, HHS 5152-1, Notice of Cooperative Agreement received from Centers for Disease Control and Prevention, less unobligated balance from prior budget period and cumulative prior awards for current budget period. This is an estimated amount.

¹³ Direct assistance in lieu of cash provided by the Public Health Service of the CDC.

¹⁴ Focus Area C awards: BY 5, \$5,565,301; BY 4, \$1,745,928; and BY, 3 \$2,280,361, respectively. We could not reconcile total funds awarded to financial status reports.

INTRODUCTION

Office of Contracting and Procurement. The mission of the Office of Contracting and Procurement (OCP) is to “provide contracting and procurement services and personal property management to District agencies so that they can have the quality goods and services that they need to accomplish their missions in a timely and cost effective manner.”¹⁵ OCP has five commodity buying groups: Building Renovation and Construction; IT Related Equipment and Services; Transportation and Specialty Equipment; Roads, Highways and Structures; and the D.C. Government Preparedness Contracting Office. OCP and DOH collaborated in the procurement of the BSL3 lab.

Bioterrorism Contract. On August 3, 2006, DOH, in conjunction with OCP, awarded a construction contract (POHC-2006-C-0006GM) to a private contractor in the amount of \$6.8 million. The scope of the contract required the design, manufacture, shipment, delivery, anchoring, finishing, and installation of a fully-equipped and furnished 5,285 square foot, non-combustible, prefabricated public health laboratory annex. DOH and OCP officials prepared a milestone chart on July 15, 2005, which was revised on April 3, 2006, for the construction, delivery, and installation of the BSL3 lab. The contract established the completion date for the project as August 30, 2007.

¹⁵ <http://www.ocp.dc.gov> (go to “About OCP”).

INTRODUCTION

OBJECTIVES, SCOPE, AND METHODOLOGY

Our audit objectives were to determine whether bioterrorism contracts were: (1) awarded in compliance with applicable laws, rules, regulations, policies, and procedures; and (2) monitored properly to ensure that the District received the services for which it paid.

To accomplish our objectives, we reviewed grant guidance and notices of grant awards issued by the CDC in order to obtain an understanding of the CDC grant process, and we held discussions with responsible staff of the CDC. We reviewed HEPRA grant applications, progress reviews, financial status reports, and HEPRA program files related to the BSL3 lab and the LMS. We also reviewed OCP contract files. We interviewed responsible officials of DOH, OCP, and the project manager (independent contractor) to obtain information related to the BSL3 project. Finally, on November 7, 2007, we conducted a site visit to observe the progress on the BSL3 lab located at D.C. Village.

We limited our audit to a review of contracts related to the procurement of the BSL3 lab and the LMS, both of which were funded by the CDC. Our audit focused only on funds provided to HEPRA by the CDC and excluded a review of the \$253 million Bioterrorism and Forensics Laboratory,¹⁶ which we considered outside the scope of this audit.

We relied on computer-processed data from the District's System of Accounting and Reporting (SOAR) to identify the universe of procurements funded by CDC and issued on behalf of HEPRA for FY 2005 and FY 2006. We did not perform a formal reliability assessment of these data because an independent certified public accounting firm assessed the reliability of SOAR data during the FY 2005 and FY 2006 Comprehensive Annual Financial Report audits.

The audit was conducted in accordance with generally accepted government auditing standards and included such tests as we considered necessary under the circumstances.

¹⁶ A state of the art facility that will house the Metropolitan Police Department Forensic Crime Laboratory, the Chief Medical Examiner, the DOH Public Health Laboratory, and the Pretrial Services Agency. The Bioterrorism and Forensic Laboratory is slated for development starting in 2007 and scheduled for completion by 2010.

FINDINGS AND RECOMMENDATIONS

FINDING 1: BIOSAFETY LABORATORY LEVEL 3 MODULAR LABORATORY

SYNOPSIS

DOH incurred unnecessary delays in the procurement of a BSL3 lab capable of handling select biological agents. Although the project was initiated in May 1999, as of the date of this report, the BSL3 lab had not been completed. The delays occurred, in part, because DOH and OCP officials did not develop a procurement plan that provided for coordination and continuity in the construction of a BSL3 lab from the initial stages to full operational capabilities. The lack of a procurement plan further contributed to delays with site identification and DOH's response to the turnover of agency staff responsible for the project. Procurement planning for construction and other contracted projects is required by the governing criteria of Title 27 of the District of Columbia Municipal Regulations. As a result, the District's response capabilities were negatively affected by the fact that laboratory samples had to be sent to Maryland and Virginia State Laboratories for sample analysis.

DISCUSSION

Procurement Planning. The District's governing criteria for planning a construction project is contained in Title 27 DCMR. Section 1210.3 states, "Procurement planning shall integrate the effort of all personnel responsible for significant aspects of the procurement." In addition, 27 DCMR §1210.5 provides the following:

Procurement planning shall begin as soon as the agency need is identified; preferably well in advance of the fiscal year in which the contract award is necessary. In developing the plan, the planner may form a team consisting of all those who will be responsible for significant aspects of the procurement, such as contracting, fiscal, legal, and technical personnel and, when applicable, the Minority Business Opportunity Commission.

Id. Some of the additional considerations required are the availability of funds and full and open competition. In our opinion, DOH did not properly plan for the development and construction of a BSL3 lab, because none of the procurement planning requirements cited above were achieved.

Further, we noted that there was no strategy developed by DOH and OCP officials to coordinate the procurement effort. We believe this lack of a coordinated procurement strategy further delayed the procurement of the BSL3 lab. Another issue that caused the procurement delay was whether the request for proposal (RFP) for the BSL3 lab was issued for construction or the purchase of goods and services. The issue needed to be resolved because it impacted the decision to apply Davis Bacon rates (as required for construction contracts) or service contract rates, or a combination of both. This issue took 9 months (from July 2005 to April 2006) to resolve.

FINDINGS AND RECOMMENDATIONS

Finally, there was a lack of an intra-agency coordinated procurement strategy among DOH officials.

DOH does not have internal guidance in the form of standard operating procedures covering the activities required by all parties involved in planning for a coordinated acquisition such as the BSL3 lab. We believe that developing and implementing a standard operating procedures manual that contains all pertinent information and processes for acquisitions would aid in ensuring coordination, continuity, and completion of future DOH procurements.

Project Management Planning. DOH officials could not provide us with a specific project management plan for the BSL3 lab. Effective project management planning requires long-range planning and a disciplined, decision-making process to achieve and manage performance goals and objectives with minimal risk, lowest life-cycle costs, and the greatest benefits to District agencies.

Project management planning consists of four phases including planning, budgeting, acquisition, and project management. Additional planning principles include a needs assessment and gap¹⁷ identification, an alternative evaluation, a review and approval framework (with established criteria for selection), and a long term capital investment plan. The development of a project management plan would assist in ensuring the quality of contract performance, reducing risk, and increasing cost effectiveness.

A review of DOH applications for federal assistance indicated that the District's BSL3 lab project was initiated in May 1999. However, the contract to construct the BSL3 lab was awarded in August 2006. The DOH grant application dated, May 13, 1999, identified a program director, who was to have the responsibility of administrative oversight for the BSL3 lab project. Due to the lack of testing capabilities, on August 26, 2005, a Memorandum of Understanding (MOU) between DOH and the State of Maryland Department of Health and Mental Hygiene Laboratories Administration was signed to provide laboratory testing services pending the construction of the District's BSL3 lab.

Contract for the BSL3 Laboratory. On August 3, 2006, DOH, in conjunction with OCP, awarded a construction contract (POHC-2006-C-0006GM) in the amount of \$6.8 million for the BSL3 lab. The scope of the contract required the design, manufacture, shipment, delivery, anchoring, finishing, and installation of a fully equipped and furnished 5,285 square foot, non-combustible, prefabricated BSL3 lab. A milestone chart was prepared on July 15, 2005, and revised on April 3, 2006, for the construction, delivery, and installation of the lab. The contract established the completion date as August 30, 2007. Subsequent to the issuance of our draft report, DOH informed us that the BSL3 lab was completed and keys accepted on May 29, 2008.

¹⁷ Interruption or break in contract administration or performance.

FINDINGS AND RECOMMENDATIONS

Site Identification. DOH officials identified at least four sites to develop, renovate, or construct a BSL3 lab. These sites included:

1. Department of Parks and Recreation, 1001 Virginia Avenue, N.W.
2. Department of Health/Air Monitoring Facility, 427 New Jersey Avenue, N.W.
3. D.C. Municipal Center, 301 C Street, N.W., 6th Floor.
4. D.C. General Hospital, 1900 Massachusetts Avenue, S.E., Building 9.
5. D.C. Village, 2-A Village Lane, S.W.

The aforementioned sites required renovations and offered limited space to house a BSL3 lab, considering the security and safety measures needed. The search for and identification of a viable BSL3 lab delayed the project. These sites were under consideration until a decision was made to build the BSL3 lab at D.C. Village, 2-A Village Lane, S.W. Picture 1 illustrates the initial delivery and setting of the BSL3 lab on June 27, 2007. Picture 2 illustrates the front left portion of the BSL3 lab as of February 2008 at the D.C. Village location.

Picture 1 – Initial Delivery/Set-up of BSL3 Lab



FINDINGS AND RECOMMENDATIONS

Picture 2 – BSL3 Lab (front left)



Department of Health Staff Turnover. We reviewed records obtained from DOH and CDC, which indicated that during the 8-year program grant cycle, from August 1999 to August 2007, four key positions (Director, Senior Deputy Director, Program Director, and Bioterrorism Coordinator) at DOH were occupied by at least 10 different individuals. In our opinion, staff turnover contributed to the delays in the procurement of the BSL3 lab.

BSL3 Laboratory Construction Finishing Work. In addition to site identification and staff turnover, as of February 2008, we were informed by HEPRA officials that at least 9 to 15 weeks of finishing work remained to be completed, including the installation of transformers (see Picture 3), commissioning,¹⁸ and required CDC inspections.

Picture 3 – Transformers to be installed



¹⁸ A commissioning agent is responsible for ensuring that the BSL3 lab systems are designed, installed, functionally tested, and capable of being operated and maintained to perform in accordance with the requirements of the CDC.

FINDINGS AND RECOMMENDATIONS

Maintenance of Records. During our review of DOH and OCP files relative to the BSL3 lab project, we discovered that a majority of the files that we needed to review – such as applications, notice of awards, and progress reports – were missing or incomplete. Therefore, we had to obtain the necessary records from the CDC. Project management planning established at the implementation or initial stage would promote effective collaboration between all responsible parties and aid in the maintenance of records. We discussed this issue with DOH officials who acknowledged that measures to improve records maintenance were needed.

Site Visit. On November 7, 2007, we conducted a site visit to observe the progress on the BSL3 lab. During our visit, we were accompanied by the Bioterrorism Coordinator and the construction manager. We observed a facility that lacked electrical power and internal work (such as furniture and fixtures in place) and incomplete safety and security measures.

Memorandum of Understanding - Interim Measure for Testing Biological Agents. The District did not have facilities capable of testing for BSL3 biological agents such as botulism, smallpox, and tularemia (see Exhibit B for a list of bioterrorism agent categories). In this regard, in February 2006, an MOU was executed between DOH and the State of Maryland Department of Health and Mental Hygiene, Laboratories Administration (MDLA).¹⁹ The purpose of the MOU is to provide the District with alternative measures for testing BSL3 biological agents. Services provided under the MOU include:

- pickup of specimens;
- delivery of supplies;
- delivery of reports of laboratory test results;
- specimen collection media;
- laboratory slips; and
- specimen labeling materials.

Summary. The need for a fully operational BSL3 lab is critical to ensure the health and safety of the citizens of the District of Columbia. Project management planning is essential in providing the framework in which to complete projects in a timely, efficient, and cost effective manner.

¹⁹ The maximum annual aggregate cost of the MOU is \$50,000 plus various fees for individual testing.

FINDINGS AND RECOMMENDATIONS

RECOMMENDATIONS:

We recommended that the Director, Department of Health:

1. Establish a process that requires development of project management plans and plan approval by the Director, DOH for all major acquisitions to ensure quality contract performance, reduce risk, and increase cost effectiveness.
2. Establish, maintain, and safeguard complete permanent files for all procurement projects to provide historical data and a frame of reference for future procurements.

DOH RESPONSE (Recommendation 1)

DOH concurred with the recommendation and stated that at the time the funding was approved and DOH was aware of the need to procure a laboratory, DOH did not have in place a process for developing project management plans. However, steps were taken to correct this deficiency, and a multidisciplinary team was developed and milestone plans were modified.

Further, DOH is in the process of establishing this method for managing all large-scale projects in the future.

OIG COMMENT

We consider DOH's actions to be responsive to this recommendation and we request that DOH provide an estimated completion date for the corrective action.

DOH RESPONSE (Recommendation 2)

DOH concurred with the recommendation and indicated that DOH has not yet fully implemented a system for establishing, maintaining, and safeguarding complete permanent files for all procurements. Elements of such a system are in place, but they need to be coordinated with the Office of Contracting and Procurement, as well as with the individual DOH program offices.

OIG COMMENT

We consider DOH's actions to be responsive to this recommendation. We request that DOH provide an estimated completion date for the corrective action.

FINDINGS AND RECOMMENDATIONS

FINDING 2: LEARNING MANAGEMENT SYSTEM

SYNOPSIS

OCP did not solicit competition in the procurement of the \$300,000 LMS. Instead, OCP issued a sole-source purchase order²⁰ to obtain the LMS, without adequate justification. Further, the contractor used a subcontractor to provide the LMS and related services. Without competition, there is no assurance that the District received the most reasonable price.

DISCUSSION

Learning Management System. The LMS is an online training program that includes e-learning courses, online registration capabilities, automated course catalogs, competency management, assessment, resources management, tracking, and reporting. The system was developed with an emphasis on bioterrorism, emergency medical services, and emergency preparedness training for the DOH. OCP issued a sole-source purchase order for the LMS without adequate justification.

Sole-Source Procurement Regulations. The governing criteria for sole-source procurements can be found in 27 DCMR §1710.1, which specifically states that a sole-source procurement may be made under emergency conditions. Section 1702.2 further allows the use of noncompetitive negotiation procedure for single available source procurements as long as the contracting officer makes a determination and finding that there is only one source available for the desired good or service. Specifically, the regulations provide as follows:

When determining whether there is only one (1) source for the requirement, the contracting officer (and, for procurements over twenty-five thousand dollars (\$25,000), the Director) shall consider whether there is a reasonable basis to conclude that the District's minimum needs can only be satisfied by the supplies, services, or construction proposed to be procured, and whether the proposed sole source contractor is the only source capable of providing the required supplies, services, or construction.

Id. OCP prepared a written Determination and Findings (D&F) to support a sole-source procurement, stating that the contractor selected was the only available source to provide the service. However, the D&F identified two contractors who also could provide an online LMS training program for bioterrorism. Therefore, the primary contractor was not the only available source capable of providing the service.

²⁰ The purchase order was issued in September 2004.

FINDINGS AND RECOMMENDATIONS

Further, the primary contractor was a management consulting firm (which billed and was paid by the District \$300,000 for the LMS) that did not directly provide the service. Instead, the primary contractor used a subcontractor to provide the actual LMS service to HEPRAs.

In our opinion, the District likely could have saved money by contracting directly with the subcontractor. The identification of any cost savings could not be determined due to missing files (such as the cost proposal and related information of the subcontractor).

We did not direct any recommendations regarding the sole-source procurement because this condition has been the subject of numerous prior audit reports, OCP readily acknowledges the problem, and OCP is working on measures to prevent unjustified sole-source procurements.

**EXHIBIT A: SUMMARY OF POTENTIAL BENEFITS
RESULTING FROM AUDIT**

Recommendations	Description of Benefit	Amount and Type of Benefit	Agency Reported Estimated Completion Date	Status²¹
1	Internal Controls and Compliance. Establishes a system to ensure agency staff follows procurement regulations and develops project management plans for major acquisitions to ensure quality contract performance, reduce risk, and increase cost effectiveness.	Non-Monetary		Open
2	Internal Controls. Create, maintain, and safeguard complete permanent files for all procurement projects to provide historical data and a frame of reference for future procurements.	Non-Monetary		Open

²¹This column provides the status of a recommendation as of the report date. For final reports, “Open” means management and the OIG are in agreement on the action to be taken, but action is not complete. “Closed” means management has advised that the action necessary to correct the condition is complete. If a completion date was not provided, the date of management’s response is used. “Unresolved” means that management has neither agreed to take the recommended action nor proposed satisfactory alternative actions to correct the condition.

EXHIBIT B: LIST OF BIOTERRORISM AGENTS

Bioterrorism agents can be grouped into three categories (shown below).²² Depending on the severity of illness or resulting death that they can cause and how easily they can be spread.

Category A

Included in this group are the organisms or toxins that pose the highest risk to the public and national security because they:

- can be easily spread or transmitted from person to person;
- result in high death rates and have the potential for major public health impact;
- might cause public panic and social disruption; and
- require special action for public health preparedness.

Category A agents/diseases include Smallpox, Anthrax, Plague, Botulism, Tularemia, Ebola hemorrhagic fever, Marburg hemorrhagic fever, Lassa fever, Junin (Argentine hemorrhagic fever), and related viruses.

Category B

Category B agents are the second highest priority because they:

- are moderately easy to spread;
- result in moderate illness rates and low death rates; and
- require specific enhancements of CDC's laboratory capacity and enhanced disease monitoring.

Category B agents/diseases include Q fever, Brucellosis, Glanders, Venezuelan encephalomyelitis, Eastern and western equine encephalomyelitis, Caster Beans, Epsilon toxin of *Clostridium perfringens*, and Staphylococcal enterotoxin B.

A subset of Category B agents include pathogens that are food or waterborne. These pathogens include but are not limited to *Salmonella* species, *Shigella dysenteriae*, *Escherichia coli* O157:H7, *Vibrio cholerae* (cholera), and *Cryptosporidium parvum*.

²² <http://emergency.cdc.gov/agent/agentlist-category.asp> (last visited May 21, 2008).

EXHIBIT B: LIST OF BIOTERRORISM AGENTS

Category C

These agents, which are the lowest risk, are considered emerging threats for disease because pathogens can be engineered to cause mass illness or death in the future. These agents:

- are easily available;
- are easily produced and spread; and
- have potential for high morbidity and mortality rates, and have a major health impact.

Category C agents/diseases include Nipah virus, Hantaviruses, tickborne hemorrhagic fever viruses, tickborne encephalitis viruses, yellow fever, and multidrug-resistant tuberculosis.

EXHIBIT C: MANAGEMENT RESPONSE DATED JULY 11, 2008

**GOVERNMENT OF THE DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH**

Office of the Director



July 11, 2008

Charles J. Willoughby, Inspector General
Office of the Inspector General
717 14th Street, NW
Washington, DC 20005

Subj: OIG No. 06-2-17

Dear Mr. Willoughby:

This letter is provided in response to your letter dated May 28, 2008, with the Control Number noted above.

On July 3, 2008, we provided comments on the text of the draft report summarizing the results of the Office of the Inspector General *Audit of the Department of Health's Procurement of the Biosafety Laboratory Level 3, Modular Laboratory and Learning Management System*. As your staff requested, this letter follows up on that earlier letter and provides specific responses to the two recommendations made in the draft report. They are as follow.

Recommendation #1: Establish a process that requires development of project management plans and plan approval by the Director, DOH, for all major acquisitions to ensure quality contract performance, reduce risk, and increase cost effectiveness.

Department of Health Response: At the time the funding was approved and DOH was aware of the need to procure a laboratory, DOH did not have in place a process for developing project management plans for approval by the Director. However, steps were taken to correct this deficiency, and a multidisciplinary team was developed and milestone plans were established, as required by DCMR 27, 1210.5. The team met weekly, and the milestone plans were modified as necessary until the contract was awarded.

DOH is in the process of establishing this method for managing all large-scale projects in the future and is committed to completing this process.

825 North Capitol Street, NE, Washington, DC 20002 202.442.5955

EXHIBIT C: MANAGEMENT RESPONSE DATED JULY 11, 2008

2

Recommendation #2: Establish, maintain, and safeguard complete permanent files for all procurement projects to provide historical data and a frame of reference for future procurements.

Department of Health Response: DOH has not yet fully implemented a system for establishing, maintaining, and safeguarding complete permanent files for all procurements. Elements of such a system are in place, but they need to be coordinated with the Office of Contracting and Procurement, as well as with the individual DOH program offices. DOH is committed to completing this process.

Please let me know if I can provide any additional information.

Sincerely,



Pierre N. D. Vigilance, M.D., M.P.H.
Director

cc:



EXHIBIT D: MANAGEMENT RESPONSE DATED JULY 3, 2008

GOVERNMENT OF THE DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH



Office of the Director

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July 3, 2008

Charles J. Willoughby, Inspector General
Office of the Inspector General
717 14th Street, NW
Washington, DC 20005

Subj: Comments on OIG No. 06-2-17MA

This letter is provided in response to your letter dated May 28, 2008, with the Control Number noted above.

In your letter you refer to a draft report summarizing the results of the Office of the Inspector General *Audit of the Department of Health's Procurement of the Biosafety Laboratory Level 3, Modular Laboratory and Learning Management System*.

We have reviewed the draft report, and our comments are provided in the attachment. As discussed with your staff, we ask that you extend the time allowed for our response to July 3, 2008.

Please let me know if I can provide any additional information.

Sincerely,

Pierre N. D. Vigilance, M.D., M.P.H.
Director

Attachment

cc:

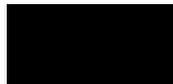


EXHIBIT D: MANAGEMENT RESPONSE DATED JULY 3, 2008

Department of Health Comments on

Office of the Inspector General Audit of the Department of Health's
Procurement of the Biosafety Laboratory Level 3, Modular Laboratory and
Learning Management System
June 30, 2008

1) In the Executive Digest, Conclusions, page ii, the paragraph shown below cites that the District response capabilities were degraded as a result of not having a BSL3 Laboratory. This is not true because the District had a contract with the Maryland and Virginia state laboratories to do this testing.

DOH incurred unnecessary delays in the procurement of a BSL3 lab capable of handling select biological agents. Although the project was initiated in May 1999, as of the date of this report, the BSL3 lab had not been completed. The delays occurred, in part because DOH and D.C. Office of Contracting and Procurement (OCP) officials did not develop a procurement plan that provided for coordination and continuity in the construction of a BSL3 lab from the initial stages to full operational capabilities. The lack of a procurement plan further contributed to delays with site identification and DOH's response to the turnover of agency staff responsible for the project. Procurement planning for construction and other contracted projects is required by the governing criteria of Title 27 of the District of Columbia Municipal Regulations. As a result, the District's response capabilities relative to bioterrorism were degraded.

This sentence should be changed to read "As a result, the District's response capabilities were somewhat negatively affected by the fact that laboratory samples had to be sent to Maryland and Virginia State Laboratories for sample analysis."

2) In the Introduction, Background, page 1, the paragraph shown below insufficiently discusses the Comfort Care Program.

HEPRA certifies and regulates all emergency medical service activities in the city. As part of the regulatory functions, an EMS officer is responsible for providing, regulating and monitoring EMS training centers and issuing guidelines for training centers to follow. In addition, the "Comfort Care Program" is designed to provide EMS personnel with the skills necessary to provide palliative care to terminally ill patients. Patients who pre-

registered are validated by their primary physician through the DOH and are identified by a bracelet.

The sentences should be edited to read "The Emergency Medical Services (EMS) Comfort Care Order (CCO) allows patients diagnosed with a specific medical or terminal condition to express their wishes regarding end of life resuscitation in the pre/post-hospital setting. The EMS Comfort Care Order also allows EMS personnel to provide palliative care, as appropriate. The patient's attending physician must issue, certify and sign that the patient (adult or child) has a specific medical or terminal condition. EMS personnel responding to calls for either cardiac or respiratory

EXHIBIT D: MANAGEMENT RESPONSE DATED JULY 3, 2008

arrest related to the condition of a Comfort Care patient will not resuscitate the patient, unless the Order has been revoked."

3) In Findings, Synopsis, page 6, the paragraph shown below should be changed to read as shown below for the same reason as cited in paragraph 1) above.

DOH incurred unnecessary delays in the procurement of a BSL3 lab capable of handling select biological agents. Although the project was initiated in May 1999, as of the date of this report, the BSL3 lab had not been completed. The delays occurred, in part, because DOH and OCP officials did not develop a procurement plan that provided for coordination and continuity in the construction of a BSL3 lab from the initial stages to full operational capabilities. The lack of a procurement plan further contributed to delays with site identification and DOH's response to the turnover of agency staff responsible for the project. Procurement planning for construction and other contracted projects is required by the governing criteria of Title 27 of the District of Columbia Municipal Regulations. As a result, the District's response capabilities relative to bioterrorism were degraded.

This sentence should be changed to read "As a result, the District's response capabilities were somewhat negatively affected by the fact that laboratory samples had to be sent to Maryland and Virginia State Laboratories for sample analysis."

4) In Findings and Recommendations, page 7, the paragraph shown below should be changed to read as shown below.

Contract for the BSL3 Laboratory. On August 3, 2006, DOH, in conjunction with OCP, awarded a construction contract (POHC-2006-C-0006GM) in the amount of \$6.8 million for the BSL3 lab. The scope of the contract required the design, manufacture, shipment, delivery, anchoring, finishing, and installation of a fully equipped and furnished 5,285 square foot, non-combustible, prefabricated BSL3 lab. A milestone chart was prepared on July 15, 2005, and revised on April 3, 2006, for the construction, delivery, and installation of the lab. The contract established the completion date as August 30, 2007. As of the date of this report, the BSL3 lab has not been completed.

"The BSL3 Lab was completed and keys accepted on May 29, 2008."