

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PUBLIC HEALTH LABORATORY
TESTING TO DETECT AND
REPORT BIOLOGICAL THREATS**



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E X E C U T I V E S U M M A R Y

OBJECTIVE

To assess the extent to which State public health laboratories have made progress toward the Centers for Disease Control and Prevention's (CDC) requirements intended to decrease the time needed to detect and report biological public health threats.

BACKGROUND

Since 2002, the Department of Health and Human Services has made available more than \$7 billion in funding to increase State and local public health preparedness and emergency response capabilities. These funds were awarded through the Office of the Assistant Secretary for Preparedness and Response, CDC, and the Health Resources and Services Administration.

In 2006, through its Public Health Emergency Preparedness Cooperative Agreement (Cooperative Agreement), CDC allocated approximately \$766 million to 62 awardees to meet nine overarching preparedness goals. Preparedness Goal 3: Detect and Report is the only goal that focuses on public health laboratory testing and reporting of biological threats. This goal contains two required critical tasks, with a total of 11 requirements. Further, these requirements contain multiple elements that State public health laboratories must meet to decrease the time needed to detect and report biological public health threats. These critical tasks and requirements have remained unchanged since 2005 and should be completed in 5 years, ending in 2010.

To meet most of the Preparedness Goal 3 testing and reporting requirements, State public health laboratories must coordinate with private clinical laboratories that perform preliminary testing and ship specimens to the State. These are known as sentinel laboratories.

Sentinel laboratories perform diagnostic tests on specimens from patients to identify biological agents that cause illness. When sentinel laboratories cannot identify the biological agents in specimens, they ship specimens to a confirmatory laboratory, usually the State public health laboratory, for further testing.

We surveyed public health laboratory officials in all 50 States and three metropolitan areas (hereafter referred to as 53 States) about the extent to which they met 9 of the 11 testing and reporting requirements for

State public health laboratories specified by the Cooperative Agreement.

FINDING

All States reported meeting at least three of the CDC public health laboratory testing and reporting requirements that we reviewed, but no State met all nine. States reported meeting the nine public health laboratory testing and reporting requirements we reviewed to varying degrees. At least 87 percent of States reported meeting all elements in four of nine requirements:

- All States reported the availability of a Biosafety Level-3 (BSL-3) testing facility or had an agreement to use the BSL-3 testing capacity of another jurisdiction.
- Ninety-six percent of States (51 of 53) reported the capacity to test and report the viruses that cause smallpox, cowpox, and chickenpox.
- Ninety-four percent of States (50 of 53) reported having the instrumentation and staff to perform required laboratory tests.
- Eighty-seven percent of States (46 of 53) reported training public health laboratory personnel on all required shipping-related tasks.

Less than 65 percent of States reported meeting all elements in five of nine testing and reporting requirements we reviewed, and less than 10 percent of States reported meeting all elements in two of these five requirements:

- Sixty-four percent of States (34 of 53) reported developing all required elements of a laboratory operational plan.
- Forty-two percent of States (22 of 53) reported testing the competency of their Bioterrorism Laboratory Coordinator or designated trainer to advise laboratory personnel on required shipping-related elements.
- Thirty-two percent of States (17 of 53) reported conducting exercises to monitor compliance with their timeliness policy for reporting test results.
- Nine percent of States (5 of 53) reported testing the ability of sentinel laboratories to ship biological specimens during all three required timeframes: weeknights, weekends, and holidays.

- Six percent of States (3 of 53) reported using at least the CDC-endorsed definition of basic sentinel laboratory to identify sentinel laboratories in their jurisdictions and maintained a database of sentinel laboratories including all seven required elements.

RECOMMENDATION

The CDC Public Health Emergency Preparedness Cooperative Agreement provides funds to States to increase their public health preparedness and response capabilities. To improve public health laboratory preparedness, States must meet specific requirements to decrease the time needed to detect and report biological threats to public health. These requirements have remained unchanged since 2005 and should be completed in 5 years, ending in 2010.

All States reported meeting at least three of the testing and reporting requirements we reviewed, but no State met all nine.

At least 87 percent of States reported meeting all elements in four of nine requirements that we reviewed. Less than 65 percent of States reported meeting all elements in the other five requirements, and less than 10 percent of States reported meeting all elements in two of these five requirements.

We recommend that CDC continue to assist States in meeting Cooperative Agreement requirements intended to decrease the time needed to detect and report biological public health threats. There are 2 years remaining before States must complete all laboratory preparedness requirements. Therefore, CDC should place special emphasis on improving performance for the two requirements met by less than 10 percent of States. CDC could improve performance for these requirements by the following two methods:

- determining why less than 10 percent of States conducted tests of their sentinel laboratories' shipping capabilities outside of regular business hours and providing assistance to States on how to increase the number of tests conducted, and
- ensuring that States use a consistent method to identify sentinel laboratories to include in their databases and that the databases include all required elements.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CDC concurred with our overall recommendation that it should continue to assist States in meeting the Cooperative Agreement requirements intended to decrease the time needed to detect and report biological public health threats. However, CDC suggested that OIG revise the two methods we provided on improving performance for the requirements met by less than 10 percent of States.

OIG agreed with the recommended changes to the first method and revised the report accordingly, but did not incorporate the recommended revisions for the second method because we do not consider them to be consistent with the Cooperative Agreement.

CDC also provided general and technical comments on our draft report. In its general comments, CDC noted that States have until 2010 to meet all the requirements we reviewed and requested that this information be stated prominently in our final report. CDC also recommended that OIG provide background information on how the Cooperative Agreement requirements were developed.

OIG added an additional reference to the 2010 completion date in the Recommendation section of this final report, but did not describe how the requirements were developed because that information is not necessary to explain our report findings. Finally, we have incorporated responses to CDC's technical comments as appropriate.

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I N T R O D U C T I O N

OBJECTIVE

To assess the extent to which State public health laboratories have made progress toward the Centers for Disease Control and Prevention's (CDC) requirements intended to decrease the time needed to detect and report biological public health threats.

BACKGROUND

Funding for Public Health Emergency Preparedness and Response

Since 2002, the Department of Health and Human Services (HHS) has made available more than \$7 billion in funding to increase State and local public health preparedness and emergency response capabilities.¹ These funds were awarded through the Office of the Assistant Secretary for Preparedness and Response, CDC, and the Health Resources and Services Administration.²

In 2006, through its Public Health Emergency Preparedness Cooperative Agreement (Cooperative Agreement), CDC allocated approximately \$766 million to 62 awardees to meet nine preparedness goals.^{3 4} See Appendix A for an overview of the nine preparedness goals. Preparedness Goal 3: Detect and Report is the only goal that focuses on public health laboratory testing and reporting of biological threats. This goal contains two required critical tasks, with a total of 11 specific requirements. Further, these requirements contain multiple elements that State public health laboratories must meet to decrease the time needed to detect and report public health threats. These critical tasks and requirements have remained unchanged since 2005 and should be completed in 5 years, ending in 2010. See Appendix B for the full text of the public health laboratory testing critical tasks and requirements.

¹ HHS News Release, July 17, 2007. Available online at <http://www.hhs.gov/news/press/2007pres/07/pr20070717c.html>. Accessed on December 18, 2007.

² Ibid.

³ 2006 CDC Public Health Emergency Preparedness Cooperative Agreement Announcement (hereafter referred to as Cooperative Agreement), pp. 48–50. Available online at <http://www.bt.cdc.gov/planning/coopagreement/pdf/fy06announcement.pdf>. Accessed on December 20, 2007.

⁴ The 62 awardees are the 50 States, the District of Columbia, Los Angeles County, Chicago, New York City, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin jurisdictions.

Public Health Laboratory Preparedness

As of December 2007, there were 247 public health laboratories in the United States.⁵ All States have at least one public health laboratory, and larger States have multiple public health laboratories that operate as a system. State public health laboratories play a crucial role in public health preparedness and response by testing specimens from patients to identify the agents that cause illness. They then provide the test results to health care professionals in the community so an appropriate public health response can be initiated. However, State public health laboratories rely on private clinical laboratories, which are not under the authority of State public health laboratories, to obtain specimens from patients.

Clinical laboratories are often the first line of defense in public health response because they perform diagnostic tests ordered by physicians. Some clinical laboratories also perform tests to rule out the presence of specific biological agents in specimens from patients. In addition, they ship specimens to a confirmatory laboratory, usually the State public health laboratory, when further testing is required.

Not all clinical laboratories have the capabilities to perform tests to rule out the presence of specific biological agents and ship specimens to a confirmatory laboratory. Clinical laboratories with these capabilities are known as sentinel laboratories. CDC defines sentinel laboratories as basic or advanced depending on their policies and procedures, as well as available equipment and staff training. See Appendix C for the CDC-endorsed definitions of basic and advanced sentinel laboratories.⁶

Related Office of Inspector General Work

A 2002 report by the Office of Inspector General (OIG) found that State and local public health infrastructure was underprepared to detect and respond to bioterrorism.⁷ Insufficient laboratory capacity, supported to a large extent by clinical laboratories, was partially responsible for this lack of preparedness.

⁵ "Clinical Laboratory Improvement Amendments (CLIA) Update," Division of Laboratory Services, Centers for Medicare & Medicaid Services (CMS), Laboratories by Type of Facility, December 2007. Available online at <http://www.cms.hhs.gov/CLIA/downloads/factype.pdf>. Accessed on April 23, 2008.

⁶ These definitions were approved by the Laboratory Response Network (LRN) Leadership Council. The LRN is a collaborative effort of CDC, the Federal Bureau of Investigation, and the Association of Public Health Laboratories.

⁷ OEI-02-01-00550, "State and Local Bioterrorism Preparedness."

In a 2007 report, OIG found that opportunities existed to improve State public health laboratory coordination with clinical laboratories to decrease the time needed to detect and report a pandemic influenza outbreak.⁸

METHODOLOGY

Scope

In June 2007, we surveyed public health laboratory officials in all 50 States, the District of Columbia, New York City, and Los Angeles County (hereafter referred to as 53 States).⁹ We asked the extent to which they met 9 of the 11 laboratory testing and reporting requirements for biological threats specified by the 2006 Cooperative Agreement. The survey reporting period was from June 2006 to June 2007.

We excluded two Cooperative Agreement public health laboratory testing and reporting requirements from our study. We did not assess whether laboratories met the minimum requirements of the Select Agent Regulation or U.S. Patriot Act of 2001 (Requirement 7). Oversight of this requirement does not fall solely under HHS. We also did not assess States' compliance with the Public Health Information Network (PHIN) as specified by Requirement 11 because CDC officials stated that they had plans to substantially revise PHIN requirements around the time we started our study.

We focused our study on biological testing of specimens from humans because the most recent threats to public health have been biological in nature (e.g., anthrax, salmonella, E. coli). We did not ask States about their public health laboratory chemical or radiological testing capabilities.

Data Collection

We contacted the Cooperative Agreement Coordinators in 53 States to determine the most appropriate contacts to receive our public health laboratory preparedness survey. We sent an electronic survey to the public health laboratory official identified by the Cooperative Agreement Coordinator in each State.

⁸ OEI-04-07-00670, "Laboratory Preparedness for Pandemic Influenza."

⁹ We excluded Chicago from our study because it does not maintain jurisdiction over a public health laboratory.

We requested responses to our survey about the nine biological laboratory testing and reporting requirements under review. We also requested supporting documentation where applicable. We had a 100-percent survey response rate.

Data Analysis

We reviewed survey responses and supporting documents to determine the total number of States that reported meeting each of the nine testing and reporting requirements under review.

With the exception of Requirement 10, all of the requirements under review contain multiple elements. We considered that a State met a requirement if it reported conducting or developing all elements contained in the requirement.

For example, to meet Requirement 2, States must test the competency of their Bioterrorism Laboratory Coordinator, or designated trainer, to advise laboratory personnel on five shipping-related elements: (1) specimen collection, (2) packaging, (3) labeling, (4) shipping, and (5) maintaining chain-of-custody. We considered that a State met Requirement 2 if it reported meeting all five shipping-related elements.

Similarly, to meet Requirement 5, States must develop operational plans that include 11 elements. We considered that a State met Requirement 5 if it reported that its operational plans contained all 11 elements.

Further, we noted cases in which States reported conducting or developing some, but not all, of the required elements.

Limitations

We relied on self-reported survey responses and supporting documentation to determine whether States met each testing and reporting requirement. We did not confirm the States' ability to meet the requirements.

Finally, we did not evaluate whether the Cooperative Agreement requirements and all elements decrease the time to detect and report public health threats as intended.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

F I N D I N G

All States reported meeting at least three of the CDC public health laboratory testing and reporting requirements that we reviewed, but no State met all nine

Under the Cooperative Agreement, State public health laboratories must meet specific requirements intended to decrease the time needed to detect and report

biological public health threats. States reported meeting the public health laboratory biological testing and reporting requirements that we reviewed to varying degrees. See Appendix D for the number of States grouped by the number of requirements that they reported meeting.

In addition, States reported meeting the nine testing and reporting requirements that we reviewed to differing extents. For example, all States reported meeting Requirement 6, and three States reported meeting Requirement 1.

Table 1 shows the number of States that reported meeting each public health laboratory biological testing and reporting requirement reviewed.

Table 1: States Reporting That They Met Each Public Health Laboratory Biological Testing and Reporting Requirement		
Requirement*	Number of States That Reported Meeting the Requirement	Percentage of States That Reported Meeting the Requirement
Requirement 6: Ensuring availability of a Biosafety Level-3 (BSL-3) facility **	53	100%
Requirement 9: Ensuring the testing and reporting of selected viruses	51	96%
Requirement 8: Ensuring necessary instrumentation and staff	50	94%
Requirement 4: Ensuring laboratory personnel training	46	87%
Requirement 5: Developing laboratory operational plans	34	64%
Requirement 2: Testing the Bioterrorism Laboratory Coordinator	22	42%
Requirement 10: Monitoring a timeliness policy for reporting results	17	32%
Requirement 3: Testing sentinel laboratory shipping capability	5	9%
Requirement 1: Maintaining a sentinel laboratory database	3	6%

* We excluded Requirements 7 and 11 from our review.

** BSL is a four-tiered system (BSL-1, BSL-2, BSL-3, BSL-4) that provides increasing levels of safety for laboratory workers and containment of biological agents.

At least 87 percent of States reported meeting all elements in four of nine testing and reporting requirements that we reviewed

All States reported the availability of a Biosafety Level-3 facility or had an agreement to use the testing capacity of another jurisdiction. Public health laboratories must ensure the availability of a BSL-3 facility to maintain the safety of laboratory personnel conducting tests on dangerous biological agents. BSL-3 facilities are also designed to prevent the escape of dangerous biological agents into the environment.

All States reported having BSL-3 testing capacity, as specified by Requirement 6. Ninety-four percent of States (50 of 53) reported that they have an operational BSL-3 facility. The three States without a facility reported satisfying the requirement for BSL-3 capacity through formal arrangements with other jurisdictions.

Ninety-six percent of States reported the capacity to test and report specimens suspected of containing the viruses that cause smallpox, cowpox, and chickenpox. The virus that causes smallpox (*Variola major*) is considered a critical biological agent because of its threat to public health if used in a terrorist event.¹⁰ Although they are not considered to be critical biological agents, the viruses that cause cowpox (*Vaccinia*) and chickenpox (*Varicella*) may lead to a skin rash that resembles a rash caused by the smallpox virus. Therefore, laboratories must be able to test for the viruses that cause cowpox and chickenpox to rule out the possibility that a pox-like skin rash was caused by the smallpox virus.

Ninety-six percent of States (51 of 53) reported having the capability to test and report specimens suspected of containing *Variola major*, *Vaccinia*, and *Varicella*, as specified by Requirement 9.

Ninety-six percent of States (51 of 53) reported having the capability to conduct tests to rule out the presence of *Variola major* and report specimens suspected of that virus.¹¹ Of this group, 40 of 51 States reported in-State testing capability to rule out *Variola major* and the remainder reported satisfying this requirement through formal arrangements with other jurisdictions.

All 53 States reported having in-State capacity to test and report *Vaccinia* and *Varicella* in specimens.

¹⁰ CDC. "Critical Biological Agents: Disease Reporting as a Tool for Determining Bioterrorism Preparedness," p. 1. Available online at <http://www2.cdc.gov/phlp/docs/cdc.horton.web.pdf>. Accessed on December 20, 2007.

¹¹ Due to safety concerns, CDC allows only a limited number of laboratories to perform testing that specifically identifies *Variola major*.

Ninety-four percent of States reported having the appropriate instrumentation and appropriately trained staff to perform selected CDC laboratory tests.

Public health laboratories must have appropriate instrumentation and trained staff to perform specific laboratory tests to identify biological agents that threaten public health.¹²

Ninety-four percent of States (50 of 53) reported having the instrumentation and staff to perform the laboratory tests specified by Requirement 8.

Eighty-seven percent of States reported that public health laboratory personnel are trained on all five required shipping-related elements.

It is often necessary to ship specimens to a laboratory with more advanced testing expertise to positively identify biological agents that threaten public health. Laboratory specimens must be properly handled at all stages of the shipping process to ensure personnel safety and to maintain specimen integrity.

Eighty-seven percent of States (46 of 53) reported training public health laboratory personnel on all five required shipping-related elements as specified by Requirement 4: (1) packaging, (2) labeling, (3) shipping, (4) coordinating routing, and (5) maintaining chain-of-custody.¹³ Almost all States conducted training, but not on all five elements as required by the Cooperative Agreement.

Less than 65 percent of States reported meeting all elements in five of nine testing and reporting requirements that we reviewed, and less than 10 percent of States reported meeting all elements in two of these five requirements

Sixty-four percent of States reported developing laboratory operational plans that contained all 11 required elements. By developing operational plans for laboratory practices, laboratory officials can define procedures and assign responsibility in advance of a public health event. In addition, written plans help to ensure consistency and continuity in laboratory practices.

¹² The Cooperative Agreement requires at least one public health laboratory in each jurisdiction to have the appropriate instrumentation and trained staff to perform Polymerase Chain Reaction and Time-Resolved Fluorescence.

¹³ All States that participated in the pilot phase of this study informed us that they consider coordinating routing to be a part of maintaining chain-of-custody. Therefore, our survey asked about maintaining chain-of-custody only. If a State responded that it conducted training on maintaining chain-of-custody, we also gave the State credit for conducting training on coordinating routing.

Sixty-four percent of States (34 of 53) reported that their public health laboratories have developed operational plans that contain all 11 elements specified by Requirement 5.

Table 2 shows that at least 81 percent of States (43 of 53) reported developing at least one element of the operational plan, but not all 11 elements as required by the Cooperative Agreement.

Table 2: States Reporting That They Had Developed Required Elements of an Operational Plan

Required Element*	Number of States That Reported Developing Element	Percentage of States That Reported Developing Element
Worker safety	53	100%
Sample transport and handling	52	98%
Appropriate working conditions	52	98%
Threat assessment	52	98%
Secure storage of critical agents	52	98%
Quality control and assurance	51	96%
Adherence to laboratory practices	51	96%
Staffing and training of personnel	50	94%
Intake and testing prioritization	48	91%
Proficiency testing	47	89%
Appropriate levels of supplies and equipment	43	81%

* See Requirement 5 in Appendix B for the text of the required elements.

Forty-two percent of States reported testing the competency of their Bioterrorism Laboratory Coordinator, or designated trainer, to advise laboratory personnel on all five required shipping-related elements.

Laboratory personnel must properly handle laboratory specimens at all stages of the shipping process to ensure personnel safety and to maintain specimen integrity. A central point of contact for shipping-related advice ensures that laboratory personnel receive accurate and consistent information.

Forty-two percent of States (22 of 53) reported testing the competency of their Bioterrorism Laboratory Coordinator (Coordinator), or a designated trainer, to advise laboratory personnel on all five shipping-related elements as specified by Requirement 2: (1) specimen collection, (2) packaging, (3) labeling, (4) shipping, and (5) maintaining chain-of-custody.

Fifty percent of States (11 of 22) that reported testing the competency of their Coordinator, or designated trainer, on all five elements noted that a person other than the Coordinator (e.g., Safety Officer, Packaging and

Shipping Coordinator) advised laboratory personnel on shipping procedures.

Table 3 shows that at least 49 percent of States (26 of 53) reported testing the competency of their Coordinator or designated trainer to advise on at least one element, but not on all five elements as required by the Cooperative Agreement.

Table 3: States Reporting That Their Public Health Laboratories Tested Their Coordinator’s Competency To Advise on Required Shipping-Related Elements

Element	Number of States Reporting Tests	Percentage of States Reporting Tests
Packaging	30	57%
Shipping	30	57%
Labeling	29	55%
Specimen collection	26	49%
Chain-of-custody	26	49%

Thirty-two percent of States reported conducting exercises to monitor compliance with their timeliness policy for reporting test results.

To ensure timely responses to public health events, States establish timeframes for reporting confirmatory results to sentinel laboratories seeking assistance in identifying biological agents. By monitoring timeliness policy compliance, State personnel may identify weaknesses in their policies in advance of a real event.

Thirty-two percent of States (17 of 53) reported conducting exercises to monitor compliance with their timeliness policy on sending confirmatory results to sentinel laboratories (Requirement 10).¹⁴ Three States reported that they did not conduct exercises, but considered monitoring their response times to real events (e.g., suspected plague and anthrax incidents) to be tests of their timeliness policies.¹⁵

Although 32 percent of States conducted exercises, 68 percent of States (36 of 53) reported having a written timeliness policy for reporting confirmatory results to sentinel laboratories. These States reported that their public health laboratory timeliness policies established

¹⁴ The Cooperative Agreement requires States to monitor compliance with their timeliness policy, but it does not specify how. During the pilot phase of this study, States informed us that they monitored compliance through exercises. Therefore, we used exercises as an indicator of compliance.

¹⁵ Our survey did not ask States whether they used real events to monitor compliance with their timeliness policy.

specific timeframes for confirming the presence of bioterrorism and/or nonbioterrorism agents in specimens. For example, one State established an 8-hour timeframe for preliminary identification of both anthrax and West Nile Virus. Another State established the timeframe for preliminary identification of anthrax as 4 to 6 hours.

Nine percent of States reported testing the ability of sentinel laboratories to ship biological specimens to a confirmatory laboratory on weeknights, weekends, and holidays. Because a public health event can occur at any time, sentinel laboratories must be prepared to ship biological specimens to an appropriate confirmatory laboratory 24 hours a day, 7 days a week.

Nine percent of States (5 of 53) reported testing sentinel laboratories' ability to ship specimens during all three timeframes specified by Requirement 3—weekends, weeknights, and holidays. Fifty-three percent of States (28 of 53) reported not conducting tests in any of the three specified timeframes.

Table 4 shows that a minimum of 23 percent of States (12 of 53) reported conducting tests in at least one required timeframe, but not in all three timeframes as required by the Cooperative Agreement.

Table 4: States Reporting That Their Public Health Laboratories Tested the Ability of Sentinel Laboratories To Ship Specimens During Three Required Timeframes		
Required Timeframe	Number of States Reporting Tests	Percentage of States Reporting Tests
Weekends	19	36%
Weeknights	15	28%
Holidays	12	23%

In contrast to tests conducted on weeknights, weekends, and holidays, 72 percent of States (38 of 53) reported testing sentinel laboratories' ability to ship specimens to a confirmatory laboratory, usually the State public health laboratory, on weekdays during regular business hours. States reported that sentinel laboratories are tested on weekdays during regular business hours by three predominant methods: (1) State

packaging and shipping drills, (2) the College of American Pathologists' Laboratory Preparedness Survey, and (3) routine shipments.¹⁶

Table 4 on the previous page shows the number of States that reported testing sentinel laboratories' ability to ship specimens during the three required timeframes. However, the table does not give an indication of the percentage of all sentinel laboratories in the United States that participated in testing.

Based on their respective criteria, States estimated that there were 4,079 to 4,199 sentinel laboratories in their jurisdictions. The total number of sentinel laboratories in the United States depends on the criteria used by each State to designate a laboratory as a sentinel laboratory. States use different criteria when designating a sentinel laboratory. Some States use the CDC-endorsed definition of basic and advanced sentinel laboratory, while other States base this designation on the laboratory's testing and shipping capabilities.

For example, one State reported that it considers the least technically capable laboratory to be a sentinel laboratory as long as it can recognize when to send specimens to the State. Another State reported that it does not have a written definition for sentinel laboratory, but considers all hospital and Indian Health Services' laboratories that perform microbiology testing to be sentinel laboratories.

Table 5 shows that States reported testing between 8 and 14 percent of sentinel laboratories' (337 to 559 laboratories) ability to ship specimens during the three required timeframes.¹⁷

Required Timeframe	Number of Sentinel Laboratories Tested	Percentage of Sentinel Laboratories Tested out of All Sentinel Laboratories, (n=4,079)
Weekends	559	14%
Holidays	497	12%
Weeknights	337	8%

¹⁶ In the College of American Pathologists' Laboratory Preparedness Survey, laboratories receive specimens and are evaluated on how well they follow established procedures, including packaging and shipping.

¹⁷ To be conservative, we used the low range of the total estimate of sentinel laboratories when calculating percentages.

In contrast to the percentage of sentinel laboratories tested on weeknights, weekends, and holidays, States reported testing the ability of 29 percent of sentinel laboratories (1,175 laboratories) to ship specimens on weekdays during regular business hours.

Six percent of States used at least the CDC-endorsed definition of basic sentinel laboratory to identify sentinel laboratories in their jurisdictions and maintained a database of sentinel laboratories including all seven required elements. Public health laboratories rely on sentinel laboratories to obtain specimens from patients. Therefore, it is critical that States accurately identify sentinel laboratories in their jurisdictions and maintain a database of their contact information and testing capabilities.

To meet Requirement 1, States must use the CDC-endorsed definition of sentinel laboratory to identify sentinel laboratories in their jurisdictions and develop a sentinel laboratory database including seven required elements.

The CDC-endorsed definition of sentinel laboratory includes definitions for a basic and an advanced sentinel laboratory. The Cooperative Agreement does not specify whether States should use the basic or advanced definition when determining which laboratories to include in their databases. To be conservative, we considered a State to have used the CDC-endorsed definition of sentinel laboratory if its definition contained at least the four elements of a basic sentinel laboratory.¹⁸

Although all but one State maintained a sentinel laboratory database, only 6 percent of States (3 of 53) reported using at least the four elements of the CDC-endorsed definition of basic sentinel laboratory when determining which laboratories to include in their database and maintaining a database containing all seven required database elements.

Sixty-four percent of States (34 of 53) reported that they use at least the four elements of the CDC-endorsed definition of basic sentinel laboratory when designating a laboratory as a sentinel laboratory. In most cases, State definitions of sentinel laboratory also included some elements of an advanced sentinel laboratory.

¹⁸ The Cooperative Agreement does not contain the CDC-endorsed definition of sentinel laboratory. We obtained the definition directly from CDC officials.

Table 6 shows that at least 74 percent of States (39 of 53) used at least one element of the CDC-endorsed definition of a basic sentinel laboratory, but not all four elements, in their State definition.

Table 6: States Reporting That They Incorporate At Least the Required Elements of the CDC-endorsed Definition of Basic Sentinel Laboratory in Their State Definition		
Required Element	Number of States That Incorporated Element	Percentage of States That Incorporated Element
The laboratory has policies and procedures for referring suspicious samples to the nearest Laboratory Response Network (LRN) laboratory in its jurisdiction.*	50	94%
The laboratory is certified under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) by CMS.	46	87%
The laboratory is inspected by a CMS agent, a CMS-approved accreditation organization, or the State (for CLIA-exempt laboratories).	45	85%
The laboratory has policies and procedures for referring samples to an advanced sentinel laboratory.	39	74%

* The LRN is a system of public health and clinical laboratories through which unidentified specimens are progressively tested until a positive identification is obtained. Laboratories in the LRN are categorized into three levels according to their expertise: sentinel, reference, and national.

States must maintain a sentinel laboratory database that includes seven required elements. Although all States but one maintained a sentinel laboratory database, 9 percent of States (5 of 53) maintained a database with all 7 required elements.

Table 7, on the following page, shows that at least 17 percent of States (9 of 53) reported developing at least one element of the database, but not all seven elements as required by the Cooperative Agreement. See Requirement 1 in Appendix B for the full text of the required elements.

F I N D I N G

Table 7: States in Which Public Health Laboratories Maintain the Required Elements of a Sentinel Laboratory Database		
Element	Number of States That Maintained Element	Percentage of States That Maintained Element
Name	52	98%
Contact information	50	94%
Certification status	33	62%
BioSafety level	29	55%
Partnership in State or CDC Health Alert Network	28	53%
Rule out capability of selected bioterrorism agents	17	32%
Contact information for out-of-State confirmatory laboratories used by the jurisdiction's sentinel laboratories	9	17%

R E C O M M E N D A T I O N

The CDC Public Health Emergency Preparedness Cooperative Agreement provides funds to States to increase their public health preparedness and response capabilities. To improve public health laboratory preparedness, States must meet specific requirements to decrease the time needed to detect and report biological threats to public health. These requirements have remained unchanged since 2005 and should be completed in 5 years, ending in 2010.

All States reported meeting at least three of the testing and reporting requirements we reviewed, but no State met all nine.

At least 87 percent of States reported meeting all elements in four of nine requirements that we reviewed. Less than 65 percent of States reported meeting all elements in the other five requirements, and less than 10 percent of States reported meeting all elements in two of these five requirements.

We Recommend That CDC Continue To Assist States in Meeting Cooperative Agreement Requirements Intended To Decrease the Time Needed To Detect and Report Biological Public Health Threats

There are 2 years remaining before States must complete all laboratory preparedness requirements. Therefore, CDC should place special emphasis on improving performance for the two requirements met by less than 10 percent of States. CDC could improve performance for these requirements by the following two methods:

- Determining why less than 10 percent of States conducted tests of their sentinel laboratories' shipping capabilities outside of regular business hours, and providing assistance to States on how to increase the number of tests conducted. Because a public health event can occur at any time, sentinel laboratories must be prepared to ship biological specimens to an appropriate confirmatory laboratory 24 hours a day, 7 days a week. We recognize that sentinel laboratories are not under the authority of State public health laboratories and that States must rely on voluntary sentinel laboratory participation in shipping tests. However, during a real event, States can conduct confirmatory testing and report results only as quickly as they receive properly shipped specimens from sentinel laboratories.
- Ensuring that States use a consistent method to identify sentinel laboratories to include in their databases and that the databases

R E C O M M E N D A T I O N

include all required elements. CDC should determine whether the method of identifying sentinel laboratories should be based on the current CDC-endorsed definitions of sentinel laboratory or by another method, such as the laboratory's testing and shipping capabilities. If the identification is based on the CDC-endorsed definitions, CDC should clarify whether State databases should include basic and/or advanced sentinel laboratories. By assisting States to consistently identify sentinel laboratories, CDC can help ensure that States are working with the appropriate population of sentinel laboratories intended by the Cooperative Agreement. By ensuring that sentinel laboratory databases include all required elements, States will have the information necessary to coordinate with laboratories that will play a key role in a public health response before an event occurs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CDC concurred with our overall recommendation that it should continue to assist States in meeting the Cooperative Agreement requirements intended to decrease the time needed to detect and report biological public health threats.

However, CDC did not concur with the first method we provided on improving performance for the requirements met by less than 10 percent of States. OIG agreed with CDC's recommended changes to our first method and revised the report accordingly.

Regarding the second method, CDC concurred that it should determine how sentinel laboratories are identified. However, CDC noted that States should have some flexibility in determining the functional criteria for a laboratory to be considered a sentinel laboratory. CDC also proposed that we revise our language to reflect that CDC should work with States to assess the effectiveness of different definitions of a sentinel laboratory and provide States with guidance on the basic criteria for a laboratory to be included in a database of sentinel laboratories. OIG did not incorporate these recommended changes because we do not consider them to be consistent with the Cooperative Agreement requirement for States to use the CDC-endorsed definition of a sentinel laboratory when developing their databases.

CDC also provided general and technical comments on our draft report. In its general comments, CDC noted that States have until 2010 to meet

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all the requirements we reviewed and requested that this information be stated prominently in our final report. CDC also recommended that OIG provide background information on how the Cooperative Agreement requirements were developed.

We noted in our draft report that States have until 2010 to complete the Cooperative Agreement requirements we reviewed. This information was included in the Background section of the Executive Summary and Introduction. We have also added this information in the Recommendation sections of this final report. We did not add additional background information on how the Cooperative Agreement requirements were developed because that information is not necessary to explain our report findings.

Finally, we have incorporated responses to CDC's technical comments as appropriate. The full text of CDC's comments is provided in Appendix E.

A P P E N D I X ~ A

Overview of the Centers for Disease Control and Prevention's Nine Public Health Emergency Preparedness Goals

1. **Preparedness Goal 1, Prevent:** This goal contains six critical tasks intended to increase the use and development of interventions known to prevent human illness from chemical, biological, and radiological agents and from naturally occurring health threats.
2. **Preparedness Goal 2, Prevent:** This goal contains seven critical tasks intended to decrease the time needed to classify health events as terrorism or naturally occurring, in partnership with other agencies.
3. **Preparedness Goal 3, Detect/Report:** This goal contains two critical tasks intended to decrease the time needed to detect and report chemical, biological, and radiological agents that cause threats to the public's health in tissue, food, or environmental samples.
4. **Preparedness Goal 4, Detect/Report:** This goal contains six critical tasks intended to improve the timeliness and accuracy of information regarding threats to the public's health as reported by clinicians and through electronic early event detection, in real time, to those who need to know.
5. **Preparedness Goal 5, Investigate:** This goal contains four critical tasks intended to decrease the time needed to identify causes, risk factors, and appropriate interventions for those affected by threats to the public's health.
6. **Preparedness Goal 6, Control:** This goal contains 33 critical tasks intended to decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.
7. **Preparedness Goal 7, Recover:** This goal contains two critical tasks intended to decrease the time needed to restore health services and environmental safety to preevent levels.
8. **Preparedness Goal 8, Recover:** This goal contains three critical tasks intended to increase the long-term followup provided to those affected by threats to the public's health.
9. **Preparedness Goal 9, Improve:** This goal contains four critical tasks intended to decrease the time needed to implement recommendations from after-action reports following threats to the public's health.

A P P E N D I X ~ B

Centers for Disease Control and Prevention's Preparedness Goal 3: Detect and Report

Decrease the time needed to detect and report chemical, biological, and radiological agents that cause threats to the public's health in tissue, food, or environmental samples.

Target Capability: Public Health Laboratory Testing

Required Critical Task 1:

Increase and maintain relevant laboratory support for identification of biological, chemical, radiological, and nuclear agents in clinical (human and animal), environmental, and food specimens.

Requirement 1: Develop and maintain a database of all sentinel (biological)/Level Three (chemical) laboratories in the jurisdiction using the Centers for Disease Control and Prevention (CDC)-endorsed definition, which includes:

- Name
- Contact information
- Biosafety Level (BSL)
- Whether the laboratory is a health alert network partner
- Certification status
- Capability to rule out Categories A and B bioterrorism agents per State-developed proficiency testing or College of American Pathologists bioterrorism module proficiency testing
- Names and contact information for in-State and out-of-State reference laboratories used by each of the jurisdiction's sentinel/Level Three laboratories

Requirement 2: Test the competency of a chemical terrorism laboratory coordinator and bioterrorism laboratory coordinator to advise on proper collection, packaging, labeling, shipping, and chain-of-custody of blood, urine, and other clinical specimens.

Requirement 3: Test the ability of sentinel/Level Three labs to send specimens to a confirmatory Laboratory Response Network (LRN) laboratory on nights, weekends, and holidays.

Requirement 4: Package, label, ship, coordinate routing, and maintain chain-of-custody of clinical, environmental, and food specimens/samples to laboratories that can test for agents used in biological and chemical terrorism.

Requirement 5: Continue to develop or enhance operational plans and protocols that include:

- Specimen/samples transportation and handling
- Worker safety
- Appropriate BSL working conditions for each threat agent
- Staffing and training of personnel
- Quality control and assurance
- Adherence to laboratory methods and protocols
- Proficiency testing to include routine practicing of LRN-validated assays as well as participation in the LRN's proficiency testing program electronically through the LRN Web site
- Threat assessment in collaboration with local law enforcement and the Federal Bureau of Investigation to include screening for radiological, explosive, and chemical risk of samples
- Intake and testing prioritization
- Secure storage of critical agents
- Appropriate levels of supplies and equipment needed to respond to bioterrorism events, with a strong emphasis on surge capacities needed to effectively respond to a bioterrorism incident

Requirement 6: Ensure the availability of at least one operational BSL-3 facility in your jurisdiction for testing for biological agents. If one is not immediately available, BSL-3 practices, as outlined in the CDC-National Institutes of Health publication "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, should be used (see www.cdc.gov/od/ohs) or formal arrangements (i.e., Memorandum of Understanding) should be established with a neighboring jurisdiction to provide this capacity.

Requirement 7: Ensure that laboratory registration, operations, safety, and security are consistent with both the minimum requirements set forth in Select Agent Regulation (42 CFR 73) and the U.S. Patriot Act of 2001 (P.L. No. 107-56) and subsequent updates.

Requirement 8: Ensure that at least one public health laboratory in your jurisdiction has the appropriate instrumentation and appropriately trained staff to perform CDC-developed and validated real-time rapid assays for nucleic acid amplification (Polymerase Chain Reaction) and antigen detection (Time-Resolved Fluorescence).

Requirement 9: Ensure the capacity for LRN-validated testing and reporting of Variola major, Vaccinia, and Varicella viruses in human and environmental samples either in the public health laboratory or through agreements with other LRN laboratories.

Required Critical Task 2:

Increase the exchange of laboratory testing orders and results.

Requirement 10: Monitor compliance with public health agency (or public health agency lab) policy on timeliness of reporting results from a confirmatory LRN lab back to the sending sentinel/Level Three lab (i.e., feedback and linking of results to relevant public health data) with a copy to CDC as appropriate.

Requirement 11: Comply with Public Health Information Network Preparedness “Connecting Laboratory Systems” and “Outbreak Management” Functional Areas to enable the linkage of laboratory orders and results from sentinel/Level Three and confirmatory LRN labs to relevant public health data, and maintenance of chain-of-custody.

A P P E N D I X ~ C

Sentinel Laboratory Definitions Endorsed by the Centers for Disease Control and Prevention

Basic Sentinel Clinical Laboratory:

1. The laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare & Medicaid Services (CMS) for the applicable subspecialty within the specialty of microbiology.
2. The laboratory is inspected successfully by CMS, a CMS agent, a CMS-approved accreditation organization, or, for a CLIA-exempt laboratory, by that laboratory's State.
3. The laboratory has policies and procedures for referral of diagnostic specimens to an Advanced Sentinel Laboratory.
4. The laboratory has policies and procedures for direct referral of suspicious specimens or isolates to the nearest Laboratory Response Network (LRN) reference laboratory in its jurisdiction.

Advanced Sentinel Clinical Laboratory:

1. The laboratory is certified under CLIA by CMS for the applicable subspecialty within the specialty of microbiology and meets the requirements to perform high-complexity testing.
2. The laboratory is inspected successfully by CMS, a CMS agent, a CMS-approved accreditation organization, or, for a CLIA-exempt laboratory, by that laboratory's State.
3. The laboratory has policies and procedures for direct referral of suspicious specimens or isolates to the nearest LRN reference laboratory in its jurisdiction.

In addition to the above criteria, Advanced Sentinel Laboratories shall meet the following:

4. Have a Class II or higher Certified Biological Safety Cabinet.
5. Comply with Biosafety Level 2 (BSL-2) practices.¹⁹
6. Have policies and procedures in place for use of additional respiratory protection, including a definition of when such use is necessary, as well as documentation of safe use (e.g., N-95 fit-testing).
7. Have policies and procedures, including the LRN Sentinel Level Clinical Microbiology Laboratory Guidelines, that are available and can be downloaded from the American Society for Microbiology Web site: <http://www.asm.org/Policy/index.asp?bid=6342>.

¹⁹ Department of Health and Human Services. "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition.

8. All personnel have been trained, with demonstrated competency, and are fully aware of the details contained within each LRN Sentinel Level Clinical Microbiology Laboratory Guideline.

9. Personnel have been trained and certified in guidelines on packing and shipping of infectious substances.²⁰

10. Have procedures to track and account for decontamination of laboratory biological waste (specimens, cultures). At a minimum, ensure that any contract or procedure for waste/disposal is available for inspection in the laboratory safety or waste disposal manual.

It is further highly recommended that Advanced Sentinel Laboratories comply with the following:

11. The microbiology laboratory operates under negative pressure as recommended by the American Institute of Architecture (AIA) Guidelines for Construction of Healthcare Facilities.²¹ If a microbiology laboratory is planning to remodel or construct a new facility, it should be designed to operate under negative air pressure as recommended by the AIA. This applies only to new construction or remodeling.

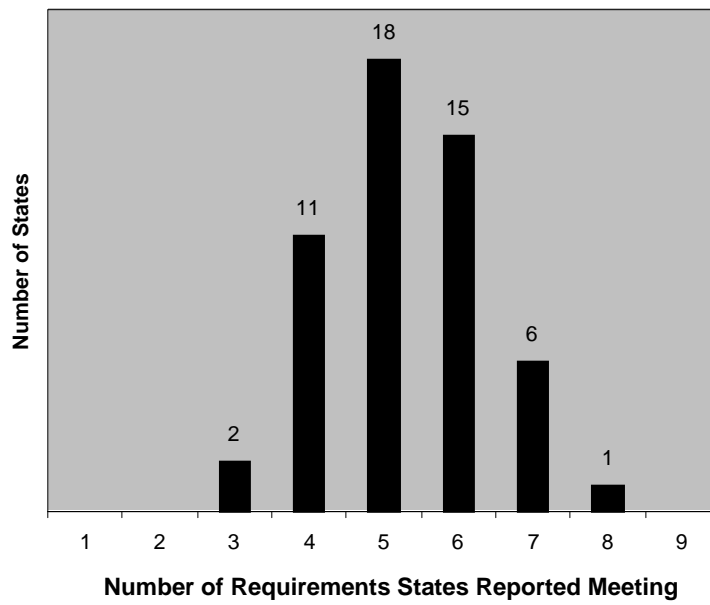
12. There is onsite, terminal decontamination capability, e.g., autoclaving, for disposal of wastes categorized as BSL-3 or Select Agent.

²⁰ Federal Register, Part IV, Department of Transportation, 49 CFR pt. 172, Hazardous Materials: Security Requirements for Offerors and Transporters of Hazardous Materials; Final Rule.

²¹ American Institute of Architecture. "Guidelines for Construction of Healthcare Facilities," 2001 Edition.

A P P E N D I X ~ D

States Grouped by the Number of Centers for Disease Control and Prevention Public Health Laboratory Testing and Reporting Requirements They Reported Meeting



A P P E N D I X ~ E

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

SEP 11 2008

TO: Daniel R. Levinson
Inspector General

FROM: Director
Centers for Disease Control and Prevention

SUBJECT: HHS Office of Inspector General's Draft Report – Public Health
Laboratory Testing to Detect and Report Biological Threats
(OEI-04-07-00750)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) Office of Evaluation and Inspections' July 9, 2008, draft report, "Public Health Laboratory Testing To Detect and Report Biological Threats," (OEI-04-07-00750).

As stated in the draft report, the purpose of this review was to determine the extent to which state public health laboratories met the Centers for Disease Control and Prevention's (CDC) public health laboratory requirements in the 2006 Public Health Emergency Preparedness (PHEP) cooperative agreement intended to decrease the time needed to detect and report biological public health threats.

General CDC Comments

Timeline for Achieving Requirements

As the current PHEP cooperative agreement is a five-year project, grantees have until 2010 to complete all required critical tasks stipulated in the PHEP cooperative agreement program announcement and subsequent continuation guidance. The OIG study's reporting period was June 2006 through June 2007 based on guidance in the 2006 PHEP cooperative agreement. The expectation that states would be able to meet all of the requirements included in the 2006 guidance during the time period covered by the study is not appropriate or correct. Reaching an endpoint or fully accomplishing the tasks should be achieved within the five-year project period, not necessarily within the annual budget period. This should be stated prominently throughout the OIG report, so readers are not misled into thinking that grantees have not met PHEP requirements.

A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Acting Regional Inspector General for Evaluation and Inspections in the Atlanta regional office, and Dwayne F. Grant, Deputy Regional Inspector General.

Mary-Elizabeth Harmon served as the lead analyst for this study. Other principal Office of Evaluation and Inspections staff from the Atlanta regional office who contributed to this report include Peggy W. Daniel; central office staff who contributed include Mark Richardson; Jodi Nudelman from the New York regional office also contributed.