



JAN - 9 2008

TO: Julie L. Gerberding, M.D., M.P.H.
Director
Centers for Disease Control and Prevention

FROM: Daniel R. Levinson *Daniel R. Levinson*
Inspector General

SUBJECT: Summary Report on State, Local, Private, and Commercial Laboratories'
Compliance With Select Agent Regulations (A-04-06-01033)

The attached final report summarizes the results of our reviews of eight State, local, private, and commercial laboratories' compliance with select agent regulations during various periods from November 2003 to September 2005. Because of the sensitivity of the issues we identified, we restricted the distribution of each report to the individual entity and the Centers for Disease Control and Prevention (CDC). The individual reports are also exempt from disclosure under the Freedom of Information Act. We are providing this summary report for CDC's use in reducing vulnerabilities at laboratories that possess, use, or transfer select agents.

Our objectives were to (1) summarize the findings in our eight individual reports and (2) determine whether CDC had resolved the audit recommendations in those reports in a timely manner.

Our individual reports found that, as required, each of the eight entities had appointed a "Responsible Official" to provide management oversight of its select agent program. However, certain other controls at all eight entities did not comply with Federal regulations. Each entity had weaknesses in at least one control area that could have compromised the ability to safeguard select agents from accidental or intentional loss:

- **Accountability for Select Agents.** Four entities had incomplete inventory or access records.
- **Restricted Access to Select Agents.** Three entities had weaknesses in access controls. Two of these entities had allowed unapproved individuals to accept and handle select agent packages. The third entity had authorized an unapproved individual to access select agents.

- **Security Plans.** Five entities' security plans did not meet one or more of the regulatory requirements. Three of these entities' security plans were not sufficient to safeguard select agents and/or were missing required policies and procedures. One entity had not fully implemented its security plan controls.
- **Training.** Four entities had not documented select agent training as required. The entities' records did not document that all approved individuals or visitors had received the necessary training or the means used to verify that individuals understood the training.
- **Incident Response Plans.** Three entities' incident response plans did not contain all required elements.

Officials of the eight entities agreed with our recommendations to strengthen their security controls and stated that they had begun implementing our recommendations or alternative procedures to comply with the regulations. However, as of March 31, 2007, CDC had not resolved the audit recommendations by submitting audit clearance documents for any of our reports to the eight entities. These recommendations had exceeded the required 6-month resolution period.

We recommended in our draft report that CDC resolve the recommendations in our eight reports as required. In comments on our draft report, CDC stated that it had resolved our recommendations at five of the eight entities and that the remaining three entities had withdrawn their certificates of registration and no longer possessed select agents. CDC attached audit clearance documents resolving the recommendations in our reports to all eight entities. Therefore, this final report contains no recommendation.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, within 10 business days after this report is issued, it will be posted on the Internet at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori S. Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through e-mail at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-04-06-01033 in all correspondence.

Attachment

cc:

RADM W. Craig Vanderwagen, M.D.
Assistant Secretary for
Preparedness and Response

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SUMMARY REPORT ON STATE,
LOCAL, PRIVATE, AND
COMMERCIAL LABORATORIES'
COMPLIANCE WITH SELECT
AGENT REGULATIONS**



Daniel R. Levinson
Inspector General

January 2008
A-04-06-01033

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR part 5.)

OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.



EXECUTIVE SUMMARY

BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188 (the Act), charges the Department of Health and Human Services (HHS) with the responsibility to regulate select agents, which are materials that have the potential to pose a severe threat to public health and safety. Within HHS, this responsibility has been assigned to the Centers for Disease Control and Prevention (CDC). CDC oversees select agents and registers all entities in the United States that possess, use, or transfer select agents.

Federal regulations implementing the Act's provisions require entities that possess, use, or transfer select agents to meet certain requirements. Such entities must, among other things, appoint a "Responsible Official" to ensure compliance with the regulations, maintain detailed records of all select agent activities, restrict access to select agents to approved individuals, develop and implement security plans, provide appropriate training, and develop and implement incident response plans.

This report summarizes our reports on eight entities' compliance with these requirements during various periods from November 2003 to September 2005. Pursuant to Office of Management and Budget Circular A-50, CDC was required to resolve the audit recommendations in those reports within 6 months after their issuance.

OBJECTIVES

Our objectives were to (1) summarize the findings in our eight individual reports and (2) determine whether CDC had resolved the audit recommendations in those reports in a timely manner.

SUMMARY OF FINDINGS

Control Weaknesses

Each of the eight entities had appointed a Responsible Official to provide management oversight of its select agent program. However, certain other controls at all eight entities did not comply with Federal regulations. Each entity had weaknesses in at least one control area that could have compromised the ability to safeguard select agents from accidental or intentional loss:

- **Accountability for Select Agents.** Four entities had incomplete inventory or access records.
- **Restricted Access to Select Agents.** Three entities had weaknesses in access controls. Two of these entities had allowed unapproved individuals to accept and

handle select agent packages. The third entity had authorized an unapproved individual to access select agents.

- **Security Plans.** Five entities' security plans did not meet one or more of the regulatory requirements. Three of these entities' security plans were not sufficient to safeguard select agents and/or were missing required policies and procedures. One entity had not fully implemented its security plan controls.
- **Training.** Four entities had not documented select agent training as required. The entities' records did not document that all approved individuals or visitors had received the necessary training or the means used to verify that individuals understood the training.
- **Incident Response Plans.** Three entities' incident response plans did not contain all required elements.

Officials of the eight entities agreed with our recommendations to strengthen their security controls and stated that they had begun implementing our recommendations or alternative procedures to comply with the regulations.

Resolution of Audit Recommendations

As of March 31, 2007, CDC had not resolved the audit recommendations in any of our reports to the eight entities. These recommendations had exceeded the required 6-month resolution period.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

We recommended in our draft report that CDC resolve the recommendations in our eight reports as required. In comments on our draft report (Appendix B), CDC stated that it had resolved our recommendations at five of the eight entities and that the remaining three entities had withdrawn their certificates of registration and no longer possessed select agents. CDC attached audit clearance documents resolving the recommendations in our reports to all eight entities. Therefore, this final report contains no recommendation.

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INTRODUCTION

BACKGROUND

Federal Oversight of Select Agents

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188 (the Act), was enacted to strengthen the Nation’s ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Act charges the Department of Health and Human Services (HHS) with the responsibility to regulate select agents, which are materials that have the potential to pose a severe threat to public health and safety.¹ Within HHS, this responsibility has been assigned to the Centers for Disease Control and Prevention (CDC). CDC oversees select agents and registers entities in the United States that possess, use, or transfer select agents.

To implement the Act’s provisions, on December 13, 2002, HHS issued an interim final rule to “provide protection against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts.” The interim final rule and the subsequent final rule, which was effective April 18, 2005, were codified at 42 CFR part 73 and require entities that possess, use, or transfer select agents to meet certain requirements.² Such entities must, among other things:

- appoint a “Responsible Official” to ensure compliance with the regulations,
- maintain select agent inventory and access records that contain specific information detailed in the regulations,
- allow access to select agents only to individuals approved by the HHS Secretary based on security risk assessments conducted by the U.S. Attorney General,³
- develop and implement security plans that establish policies and procedures to protect public health and safety,
- provide information and training on safety and security to all employees who work with select agents, and

¹For purposes of this report, “select agents” refers to all agents and toxins identified by the Centers for Disease Control and Prevention in regulations (42 CFR §§ 73.3 and 73.4 of the final rule).

²The final rule was issued during the audit period and superseded the interim final rule. The changes in the final rule had no substantive impact on our audit work. For purposes of this report, we refer only to the 2005 edition of the Code of Federal Regulations containing the final rule.

³Security risk assessments are detailed reviews conducted by the U.S. Attorney General to ensure that persons who need access to select agents meet security requirements as specified in 42 CFR § 73.10(a).

- develop and implement incident response plans to deal with potential health and safety hazards.

The regulations also authorize the Office of Inspector General to investigate, and impose civil monetary penalties against, any individual or entity for violation of the regulations.

Office of Inspector General Reviews of Select Agent Security

Following the 2001 terrorist attacks and anthrax release, we initiated a series of reviews of security at laboratories with select agents. After reviewing 11 universities in 2002, we issued a report summarizing serious weaknesses that could have compromised the security of select agents at the universities.⁴ Because of the widespread weaknesses identified in our initial reviews and the subsequent issuance of stronger legal requirements, we conducted a second series of reviews at 15 universities during 2004 and issued another summary report.⁵

In 2005, we began reviews at eight State, local, private, and commercial laboratories registered with CDC to possess, use, or transfer select agents. This report summarizes the findings in our individual reports to the eight entities.

Audit Resolution

In resolving audit recommendations, CDC must comply with Office of Management and Budget Circular A-50, section 8.a(2), which requires “. . . prompt resolution and corrective actions on audit recommendations. Resolution shall be made within a maximum of six months after issuance of a final report Corrective action should proceed as rapidly as possible.”

The HHS “Grants Administration Manual,” section 1-105, sets forth departmental policies and procedures for resolving recommendations pertaining to grants, contracts, and cooperative agreements. Departmental officials informed us that the Department follows these procedures when resolving all audit recommendations, including those that do not pertain to grants, contracts, or cooperative agreements. According to section 1-105-30(B)(1) of the manual, resolution is normally deemed to occur when:

- a final decision on the amount of any monetary recovery has been reached;
- a satisfactory plan of action, including time schedules, to correct all deficiencies has been established; and
- the report has been cleared from the HHS tracking system by submission and acceptance of an audit clearance document(s).

⁴“Summary Report on Select Agent Security at Universities” (A-04-04-02000, issued March 25, 2004).

⁵“Summary Report on Universities’ Compliance With Select Agent Regulations” (A-04-05-02006, issued June 30, 2006).

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to (1) summarize the findings in our eight individual reports and (2) determine whether CDC had resolved the audit recommendations in those reports in a timely manner.

Scope

Our reviews of the eight entities covered various periods from November 12, 2003, through September 23, 2005. We conducted our fieldwork at the eight entities during 2005 and at CDC in Atlanta, Georgia, during March and April 2007.

We assessed the status of CDC's resolution of the audit recommendations in our individual reports as of March 31, 2007, which was 6 months after the date on which we issued the last of our eight reports.

Methodology

To accomplish our objectives, we analyzed the findings and recommendations presented in our eight individual reports and reviewed documents related to CDC's resolution of the recommendations in those reports.

Appendix A presents details on the objective and methodology of our audits at the eight entities.

We performed our reviews in accordance with generally accepted government auditing standards.

FINDINGS

Each of the eight entities had appointed a Responsible Official to provide management oversight of its select agent program. However, certain other controls at all eight entities did not comply with Federal regulations. As shown in the table on the following page, each entity had weaknesses in at least one control area that could have compromised the ability to safeguard select agents from accidental or intentional loss.

Control Weakness Areas

Entity	Control Area					Number of Areas With Weaknesses
	Accountability	Restricted Access	Security Plan	Training	Incident Response Plan	
1	X	X				2
2				X		1
3		X	X			2
4		X	X			2
5	X				X	2
6			X	X	X	3
7	X		X	X		3
8	X		X	X	X	4
Total	4	3	5	4	3	19

As of March 31, 2007, CDC had not resolved the audit recommendations in any of our reports to the eight entities. These recommendations had exceeded the required 6-month resolution period.

CONTROL WEAKNESSES

Accountability for Select Agents

Regulations (42 CFR § 73.17) require that the Responsible Official maintain complete records pertaining to select agent activities. Pursuant to 42 CFR § 73.17(a)(1), an entity must maintain an accurate, current inventory for each select agent held in long-term storage. The inventory must specify the name and characteristics, including source and strain, of the select agent; the quantity acquired; the storage location; the date and time moved from or to storage and by whom; and the select agent used and purpose of use. Pursuant to 42 CFR § 73.17(a)(4), the entity also must maintain information about all entries into areas containing select agents, including the name of the individual, name of the escort (if applicable), and date and time of entry. These records must be maintained for 3 years and produced upon request (42 CFR § 73.17(c)).

Four entities did not maintain inventory and/or access records as required by the regulations. Some entities had more than one weakness in this control area.

- Three entities had incomplete inventory records. The records at two of these entities contained the initials of the individuals who moved select agents from or to storage; however, the entities did not maintain a legend to cross-reference the initials recorded to the list of approved individuals. At the third entity, records were missing the select

agent's source and strain, the quantity acquired, the storage location, and the date and time of movement.

- Three entities had incomplete access records. The records at these entities did not always include the names of the people accessing the select agent areas or the dates and times of access. At one entity, for example, the records did not always show the names of the approved individuals who escorted unapproved individuals. At another entity, the Responsible Official stated that an approved individual had escorted a maintenance contractor employee into the select agent laboratory. However, no documentation supported this statement.

Restricted Access to Select Agents

Pursuant to 42 CFR § 73.10(a), an entity “may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary . . . following a security risk assessment by the Attorney General.”

Three entities had weaknesses that could have allowed access to select agents by unapproved individuals.

- Two entities had allowed unapproved individuals to accept and handle select agent packages delivered to their facilities. At one entity, an employee who was not an approved individual accepted delivery of a select agent shipment. At the other entity, a select agent was mistakenly delivered to the loading dock of an unrelated organization located next to the entity. (The unrelated organization was not a registered entity.) An unapproved individual from that organization accepted delivery of the select agent package and then hand-carried the package to the entity's reception area, where he delivered the package to an entity employee who also was not an approved individual.
- One entity had authorized an unapproved individual to access select agents. Access records indicated, however, that this individual had not entered the laboratory that housed select agents.

Security Plans for Select Agents

Pursuant to 42 CFR § 73.11(a), an entity is required to develop and implement a written security plan that is sufficient to safeguard select agents against unauthorized access, theft, loss, or release. Among other things, the plan must describe procedures for inventory control; routine cleaning, maintenance, and repairs; removal of unauthorized or suspicious persons; loss or compromise of keys, passwords, and combinations; inspection of suspicious packages; and chain-of-custody documentation during intraentity transfers (42 CFR §§ 73.11(c) and (d)).

Although all eight entities had security plans, five entities' plans did not meet one or more of the regulatory requirements.

- Three entities' security plans were not sufficient to safeguard select agents. At one entity, the plan instructed security personnel, located at the front desk, and receiving clerks, located in the shipping area, to receive and hold select agent shipments, even though they were not approved individuals as required by 42 CFR § 73.10(a). At a second entity, the security plan did not identify and mitigate the risk of misdeliveries from commercial carriers, which was a known risk according to the Responsible Official. A third entity's security plan did not include procedures for the receipt of select agents, contrary to chain-of-custody documentation requirements.
- Three entities' security plans were missing required policies and procedures for inventory control; routine cleaning, maintenance, and repairs; removal of unauthorized individuals; loss or compromise of keys, passwords, and combinations; or chain-of-custody documentation for select agent transfers.
- One entity had not fully implemented its security plan controls to ensure that only approved individuals could gain entry to select agent laboratories.

Select Agent Training

Regulations (42 CFR § 73.15) require specific training for individuals approved for access to select agents and individuals not approved for access but working in or visiting areas where select agents are handled or stored. Pursuant to 42 CFR § 73.15(c), an entity must record the training provided, the identity of the individual trained, the training date, and the means used to verify that the individual understood the training.

Four entities had not documented select agent training as required. Some entities had more than one weakness in this control area.

- Two entities did not maintain records to document that all approved individuals had received the necessary training.
- Two entities had not documented the means used to verify that individuals understood the training.
- One entity did not maintain records to document that all visitors had received the required training.

Incident Response Plans

Pursuant to 42 CFR § 73.14(b), entities must develop a written incident response plan that fully describes procedures for responding to theft, loss, or release of select agents; inventory

discrepancies; security breaches; bomb threats; workplace violence; suspicious packages; and other emergencies, such as fires, gas leaks, explosions, or power outages.

Three entities' incident response plans did not meet one or more of these requirements. At two of these entities, for example, incident response plans did not describe procedures for responding to the theft, loss, or release of select agents; inventory discrepancies; or security breaches.

ENTITIES' RESPONSES

Officials of all eight entities agreed with our recommendations to strengthen their security controls and stated that they had begun implementing our recommendations or alternative procedures to comply with the regulations.

RESOLUTION OF AUDIT RECOMMENDATIONS

As of March 31, 2007, CDC had not resolved the audit recommendations in any of our reports to the eight entities. Specifically, CDC had not submitted audit clearance documents to resolve the recommendations, all of which were past due for resolution. Nevertheless, CDC reported that six of the eight entities had taken corrective actions and that the two other entities had withdrawn from the select agent program and were no longer authorized to possess select agents.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

We recommended in our draft report that CDC resolve the recommendations in our eight reports as required. In comments on our draft report, CDC stated that it had resolved our recommendations at five of the eight entities and that two of the entities had withdrawn their certificates of registration and no longer possessed select agents. CDC also stated that the remaining entity, which had been referred to the Office of Counsel to the Inspector General for possible enforcement actions, subsequently withdrew its certificate of registration and no longer possessed select agents. CDC attached audit clearance documents resolving the recommendations in our reports to all eight entities. Therefore, this final report contains no recommendation.

CDC's comments, except the attachments, are included as Appendix B.

APPENDIXES

OBJECTIVE AND METHODOLOGY OF INDIVIDUAL AUDITS

OBJECTIVE

Our objective was to determine whether each of the eight entities had established controls over select agents in compliance with Federal regulations. Specifically, we determined whether each entity had:

- designated a Responsible Official,
- maintained accountability for select agents by keeping inventory and access records,
- restricted access to select agents to those individuals who had received acceptable security risk assessments,
- developed and implemented a security plan to safeguard select agents,
- provided and documented training on biosafety and security, and
- developed an incident response plan that contained all required elements.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal requirements,
- analyzed Centers for Disease Control and Prevention records on laboratory registrations,
- interviewed entity officials about their select agent programs,
- toured selected registered areas and tested selected security procedures,
- interviewed principal investigators to determine whether their practices were consistent with the entities' policies for select agents,
- reviewed inventory records for a total of 27 select agents,
- reviewed records on the 85 individuals approved by the Secretary of the Department of Health and Human Services to access select agents,
- evaluated the entities' select agent security plans,
- reviewed select agent training records, and
- reviewed incident response plans.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 23 2007

TO: Daniel R. Levinson
Inspector General
Department of Health and Human Services (HHS)

FROM: Director
Centers for Disease Control and Prevention (CDC)

SUBJECT: Summary Report on State, Local, Private, and Commercial Laboratories'
Compliance with Select Agent Regulations (A-04-06-01033)

Thank you for the opportunity to review the Office of Inspector General's (OIG) draft report entitled "Summary Report on State, Local, Private, and Commercial Laboratories' Compliance With Select Agent Regulations," report number A-04-06-01033.

As stated in the draft, the objective of this audit was to summarize the findings in the eight individual reports and to determine whether or not the Centers for Disease Control and Prevention (CDC) had resolved the audit recommendations in those reports in a timely manner. The draft identified in each entity weaknesses in at least one control area that could have compromised the ability to safeguard select agents from accidental or intentional loss.

As noted in the attached correspondence to you dated June 28, 2007, CDC confirmed that recommendations had been resolved at five of the eight entities; two of the eight entities had withdrawn their certificates of registration and were no longer in possession of select agents and toxins; and one of the eight entities was referred to the HHS Office of Counsel to the Inspector General (OCIG) for possible enforcement actions. CDC can now confirm that, as of August 20, 2007, the entity that had been referred to OCIG has withdrawn its certificate of registration with CDC's Division of Select Agents and Toxins and is no longer in possession of select agents and toxins.

Also attached are the OIG clearance documents (OCD) for each of the eight individual audits that were the subject of the summary report as requested by OIG staff in an e-mail dated July 25, 2007.

CDC appreciates OIG's review of "State, Local, Private, and Commercial Laboratories' Compliance With Select Agent Regulations." If your office needs additional information to close out the eight individual audits or the summary report, please have them contact Ms. Helen

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Kuykendall, Program Analyst, CDC, by telephone at (404) 639-7075, or by e-mail at HKuykendall@cdc.gov.


Julie Louise Gerberding, M.D., M.P.H.

Attachments