



JUN 30 2006

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 Universities' Compliance With Select Agent Regulations
(A-04-05-02006)

The attached final report summarizes the results of our reviews of 15 universities' compliance with select agent regulations for the period November 2003 to November 2004. Due to the sensitivity of the issues we identified, we restricted the distribution of each report to the individual university and the Centers for Disease Control and Prevention (CDC). We are providing this summary report for CDC's use in reducing vulnerabilities at laboratories with select agents.

Our objective was to determine whether each of the 15 universities had established controls over select agents in compliance with Federal regulations.

As required, each of the 15 universities had appointed a "Responsible Official" to provide management oversight of its select agent program. However, at 11 of the 15 universities, certain other controls did not comply with Federal regulations. The 11 universities had weaknesses in at least 1 control area that could have compromised the ability to safeguard select agents from accidental or intentional loss:

- Eight universities had weaknesses in their inventory and/or access records. Some inventory records contained incomplete user names or were difficult to decipher. Access records did not always identify individuals who had entered select agent areas or the dates and times of access.
- Six universities had weaknesses in access controls, including procedures for issuing electronic access keys to select agent areas.
- Six universities had weaknesses in their security plans. In four cases, the universities had not used a systematic approach to identify threats or had not identified all relevant threats.
- Three universities had not provided training to one or more individuals with access to select agents or had not documented the means used to verify that individuals understood the training.

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- Three universities' emergency response plans did not address one or more required areas.

Officials of the 11 universities generally agreed with our recommendations to strengthen their security controls.

We recommend that CDC resolve the recommendations in the 11 individual reports.

In written comments on our draft report, CDC stated that the results of our audits were generally consistent with the findings of its own inspections and that it was actively addressing the concerns raised in our draft report.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions about this report, please do not hesitate to call me, or your staff may contact Joseph J. Green, Assistant Inspector General for Grants and Internal Activities, at (202) 619-1166 or through e-mail at Joe.Green@oig.hhs.gov. Please refer to report number A-04-05-02006 in all correspondence.

Attachment

cc:

Gerald Parker
Acting Assistant Secretary for
Public Health Emergency Preparedness

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SUMMARY REPORT ON
UNIVERSITIES' COMPLIANCE
WITH SELECT AGENT
REGULATIONS**



Daniel R. Levinson
Inspector General

June 2006
A-04-05-02006

Office of Inspector General

<http://oig.hhs.gov>

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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, materials that have the potential to pose a severe threat to public health and safety.¹

Within HHS, this responsibility has been delegated 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. As of January 2006, 96 colleges and universities were registered with CDC.

Federal regulations implementing the Act's provisions require entities that possess select agents to meet certain requirements.² 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 emergency response plans. This report summarizes the results of our reviews of 15 universities' compliance with these requirements for the period November 2003 to November 2004.

OBJECTIVE

Our objective was to determine whether each of the 15 universities had established controls over select agents in compliance with Federal regulations. Specifically, we determined whether each university had:

- appointed a Responsible Official,
- maintained accountability for select agents by keeping inventory and access records,

¹For purposes of this report, "select agents" refers to all agents and toxins under the regulation of the Centers for Disease Control and Prevention pursuant to 42 CFR §§ 73.4 and 73.5 of the interim final rules (67 Federal Register 76886 (Dec. 13, 2002) (codified at 42 CFR part 73 (2004)) in effect during our audit period.

²Effective April 18, 2005, after our audit period, HHS issued final rules for the possession, use, and transfer of select agents (42 CFR part 73). The final rules primarily changed the structure and format, but not the substance, of the interim final rules in effect during our audit period. For purposes of this report, we refer only to the 2004 edition of the Code of Federal Regulations.

- restricted access to select agents to those individuals who had received acceptable security risk assessments,³
- developed and implemented a security plan for select agents,
- provided training to individuals with access to select agents, and
- developed an emergency response plan.

SUMMARY OF FINDINGS

Each of the 15 universities had appointed a Responsible Official to provide management oversight of its select agent program. However, at 11 of the 15 universities, certain other controls did not comply with Federal regulations. The 11 universities had weaknesses in at least 1 control area that could have compromised the ability to safeguard select agents from accidental or intentional loss:

- ***Accountability for Select Agents.*** Eight universities had weaknesses in their inventory and/or access records. Some inventory records contained incomplete user names or were difficult to decipher. Access records did not always identify individuals who had entered select agent areas or the dates and times of access.
- ***Restricted Access to Select Agents.*** Six universities had weaknesses in access controls, including procedures for issuing electronic access keys to select agent areas.
- ***Security Plans.*** Six universities had weaknesses in their security plans. In four cases, the universities had not used a systematic approach to identify threats or had not identified all relevant threats.
- ***Training.*** Three universities had not provided training to all individuals with access to select agents or had not documented the means used to verify that individuals understood the training.
- ***Emergency Response Plans.*** Three universities' emergency response plans did not address all required areas.

Officials of the 11 universities generally agreed with our recommendations to strengthen their security controls.

³Security risk assessments are detailed reviews conducted by the U.S. Attorney General to ensure that persons who may need access to select agents meet safeguard and security requirements as specified in 42 CFR § 73.8.

RECOMMENDATION

We recommend that CDC resolve the recommendations in the 11 individual reports.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In written comments on our draft report, CDC stated that the results of our audits were generally consistent with the findings of its own inspections and that it was actively addressing the concerns raised in our draft report.

CDC's comments are included in their entirety as the appendix to this report.

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INTRODUCTION

BACKGROUND

Federal Oversight of Select Agent Security

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, materials that have the potential to pose a severe threat to public health and safety.¹ Within HHS, this responsibility has been delegated 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. As of January 2006, 96 colleges and universities were registered with CDC.

To implement the Act's provisions, on December 13, 2002, HHS issued an interim final rule (42 CFR part 73) 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 subsequent Federal regulations 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 by individuals approved by the HHS Secretary based on security risk assessments by the U.S. Attorney General,³
- develop and implement security plans that establish policies and procedures to protect public health and safety,

¹For purposes of this report, "select agents" refers to all agents and toxins under the regulation of the Centers for Disease Control and Prevention pursuant to 42 CFR §§ 73.4 and 73.5 of the interim final rules (67 Federal Register 76886 (Dec. 13, 2002) (codified at 42 CFR part 73 (2004)) in effect during our audit period.

²HHS issued final rules for the possession, use, and transfer of select agents (42 CFR part 73) on March 18, 2005. All provisions of these final rules superseded those in the interim final rules when the final rules became effective on April 18, 2005, after our audit period. The final rules primarily changed the structure and format, but not the substance, of the interim final rules in effect during our audit period. For purposes of this report, we refer only to the 2004 edition of the Code of Federal Regulations.

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 § 73.8.

- provide information and training on safety and security to all employees who work with select agents, and
- develop and implement emergency 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. This report summarizes our findings at those universities.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether each of the 15 universities had established controls over select agents in compliance with Federal regulations. Specifically, we determined whether each university had:

- appointed 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 for select agents,
- provided training to individuals with access to select agents, and
- developed an emergency response plan.

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

Scope

We reviewed 15 universities registered with CDC as possessing, using, or transferring select agents. The universities received HHS grant funds and represented a mix of public and private universities located throughout the United States.

Our review covered the period November 12, 2003, through November 17, 2004. We conducted our fieldwork at CDC and the 15 universities during 2004.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal requirements,
- reviewed CDC records on laboratory registrations,
- interviewed university officials about their select agent programs,
- toured selected registered areas and observed and tested selected security procedures,
- interviewed principal investigators to determine whether their practices were consistent with the universities' policies for select agents,
- reviewed inventory records for more than 50 select agents,
- reviewed records pertaining to 344 individuals approved by HHS to access select agents,
- reviewed the universities' select agent security plans,
- reviewed select agent training records, and
- reviewed emergency response plans.

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

FINDINGS AND RECOMMENDATION

Each of the 15 universities had appointed a Responsible Official to provide management oversight of its select agent program. However, at 11 of the 15 universities, certain other controls did not comply with Federal regulations. As shown in the table on the following page, the 11 universities had weaknesses in at least 1 control area that could have compromised the ability to safeguard select agents from accidental or intentional loss.

Control Weakness Areas

University	Control Area					Number of Areas With Weaknesses
	Accountability	Restricted Access	Security Plan	Training	Emergency Response Plan	
1						0
2	X	X	X	X		4
3						0
4		X	X			2
5	X					1
6						0
7	X	X	X	X	X	5
8	X		X	X		3
9	X					1
10						0
11	X	X	X			3
12	X		X		X	3
13	X					1
14		X				1
15		X			X	2
Total	8	6	6	3	3	26

CONTROL WEAKNESSES

Accountability for Select Agents

Regulations (42 CFR § 73.15) require that the Responsible Official maintain complete records pertaining to select agent activities. Pursuant to section 73.15(b), an entity must maintain an accurate, current inventory of each select agent held. Pursuant to section 73.15(c)(2), an entity must maintain records of access to the areas in which select agents are stored. These records must include (1) the name of each individual who accessed the area; (2) the date and time that the individual entered the area; (3) the date and time that the individual left the area; and (4) for individuals not approved under section 73.8, the name of the individual approved under section 73.8 who accompanied the unapproved individual into the area.

Eight universities did not maintain inventory and/or access records as required by the regulations. The specific weaknesses, some of which we identified at more than one university, follow:

- Inventory records at three universities were incomplete. The records at one university had incomplete user names, and some entries were difficult to decipher due to illegibility, jargon, or shorthand. Officials of another university stated that the university could not verify inventory records because it lacked qualified personnel to safely perform this function. The third university's procedures did not

require inventory records to account for select agents located in research equipment.

- Records of access to select agent areas at seven universities were missing information, such as the names of the individuals who had accessed the areas or the dates and times of access.

Restricted Access to Select Agents

Regulations (42 CFR § 73.8(b)) state: “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 . . . based on a security risk assessment by the Attorney General.” Pursuant to 42 CFR §§ 73.11(a) and (b)(5), entities must develop and implement a security plan, and the plan must provide for the control of access to select agents.

Six universities had weaknesses that could have allowed access to select agent areas by unapproved individuals. The specific weaknesses, some of which we identified at more than one university, follow:

- One university did not have procedures to prevent unapproved individuals from tampering with the computer system used to generate electronic access keys to select agent laboratories. Thus, unapproved individuals could have generated the keys for themselves or other unapproved individuals.
- At one university, the security office granted electronic access keys to individuals without first determining whether the individuals had acceptable security risk assessments.
- Five universities did not implement all of the access procedures in their security plans as required by the regulations. For example, although one university’s plan called for the use of security guards to restrict access to select agent areas, guards were not always present at their posts. Another university did not always issue visitor badges as required by its plan, and a third had not installed an identification system called for in its plan.

Security Plans for Select Agents

Regulations (42 CFR § 73.11(a)) require each entity to “develop and implement a security plan establishing policy and procedures that ensure the security of areas containing select agents and toxins.” Section 73.11(a) also requires that “The security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated . . .” Pursuant to section 73.11(b), in addition to meeting other requirements, the plan must (1) contain provisions for routine cleaning, maintenance, and repairs; (2) contain procedures for reporting and removing unauthorized persons; and (3) establish procedures for securing the area when individuals

approved under section 73.8 are not present (e.g., a card access system, key pads, or locks), including protocols for changing access numbers or locks following staff changes.

Although all 15 universities had security plans, 6 of the plans did not meet 1 or more requirements of the regulations. The specific weaknesses, some of which we identified at more than one university, follow:

- Four universities had not used a systematic approach to identify threats or had not identified all relevant threats. As a result, the universities had not detected weaknesses such as unlocked laboratory doors when researchers were not present or fire alarm systems that unlocked laboratory doors when activated.
- Four universities' security plans were missing required policies and procedures to address access by cleaning, maintenance, and repair personnel; reporting and removing unauthorized individuals; or changing access numbers or locks following staff changes.

Select Agent Training

Regulations (42 CFR § 73.13) set forth specific training requirements for individuals approved for access to select agents and unapproved individuals working in or visiting areas where select agents are handled or stored. Pursuant to section 73.13(b), an entity must provide information and training at the time of an individual's initial assignment to a work area where select agents are present and prior to assignments involving new exposure situations. Pursuant to section 73.13(c), the Responsible Official must provide appropriate training in safety, containment, and security to all individuals with access to areas where select agents are handled or stored. Pursuant to section 73.13(e), the entity must record the identity of the individual trained, the date of training, and the means used to verify that the individual understood the training.

Three universities had not provided or documented select agent training as required. The specific weaknesses, some of which we identified at more than one university, follow:

- Two universities had not provided training to all individuals with access to select agents.
- Two universities had not documented the means used to verify that individuals understood the training.

Emergency Response Plans

Regulations (42 CFR § 73.12(a)) require an entity to develop and implement an emergency response plan that meets the requirements of the Occupational Safety and Health Administration's hazardous waste operations and emergency response standards. Section 73.12(b) requires that the plan address events such as bomb threats, severe weather (e.g., hurricanes and floods), earthquakes, power outages, and other natural disasters or

emergencies. Section 73.12(c) sets forth additional safeguards that must be included in the plan, such as evacuation routes and procedures and personal protective and emergency equipment.

Three universities' emergency response plans did not meet one or more of the requirements of the regulations.

UNIVERSITIES' RESPONSES

Officials of the 11 universities with identified weaknesses generally agreed with our recommendations to strengthen controls over select agents and stated that they had begun implementing our recommendations or alternative procedures to comply with the regulations.

However, one university disagreed with our finding that it lacked accountability for select agents, even though the university had not verified its inventory records in 8 years. Another university did not agree with a specific method we recommended to strengthen access records but stated that it would take alternative steps to ensure the accuracy of those records.

RECOMMENDATION

We recommend that CDC resolve the recommendations in the 11 individual reports.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In its April 7, 2006, written comments on our draft report, CDC stated that the results of our audits were generally consistent with the findings of its own inspections of university laboratories and that it was actively addressing the concerns raised in our draft report. CDC also pointed out that it was working with the Department of Agriculture's Animal and Plant Health Inspection Service to develop additional guidance materials to assist entities in developing physical security and emergency response plans.

CDC's comments are included in their entirety as the appendix to this report.

APPENDIX



DEPARTMENT OF HEALTH & HUMAN SERVICES

APPENDIX

Public Health Service

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

APR 7 2006

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

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

SUBJECT: HHS Office of Inspector General's Draft Report - Summary Report on Universities' Compliance With Select Agent Regulations (A-04-05-02006)

Thank you for the opportunity to review the subject draft report dated March 7, 2006. Following are CDC's comments in response to the recommendation.

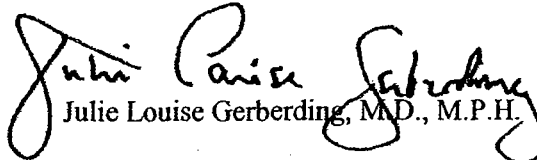
OIG Recommendation: That CDC resolve the recommendations in the 11 individual reports.

CDC Response: CDC's Coordinating Office for Terrorism Preparedness and Emergency Response, Division of Select Agents and Toxins (DSAT), finds that the results of the HHS OIG individual university audits generally agree with DSAT inspection findings. DSAT confirms that 13 of the 26 identified compliance weaknesses observed during the OIG audits of 11 universities have already been corrected. Prior to receipt of the HHS OIG April 2005 individual audit report for University #13, DSAT had identified similar weaknesses at this university, and on September 24, 2004, referred University #13 to the Office of Counsel to the HHS Inspector General for possible enforcement actions.

For those entities not already scheduled for an inspection, DSAT will immediately contact the universities with the remaining 12 observed weaknesses and schedule inspections to ensure that these entities have corrected the identified weaknesses.

DSAT, in conjunction with the Select Agent Program of the U. S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), currently is developing additional guidance materials to assist entities in developing physical security and emergency response plans. On March 7-9, 2006, CDC and APHIS hosted a meeting of biosecurity experts as a first step in developing additional guidance that will assist entities in complying with the physical security requirements of the select agent rules. It is anticipated that joint CDC and APHIS guidance will be available to entities by the end of this fiscal year.

CDC appreciates OIG's review of these important matters and is actively addressing the concerns raised in the draft. Please direct any questions regarding these comments to Ms. Helen 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.