DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP 25 2009

TO: Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention

FROM: Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Review of Compliance With Select Agent Regulations by the Centers for Disease Control and Prevention, [redacted] Laboratories [redacted]

The attached final report provides the results of our review of compliance with select agent regulations by the Centers for Disease Control and Prevention (CDC), [redacted] Laboratories [redacted] located in [redacted] This review was part of a series of reviews of Federal laboratories' compliance with select agent regulations.

Select agents are biological materials that have the potential to pose a severe threat to public health and safety. Any government agency (Federal, State, or local), academic institution, research organization, or other legal entity that possesses, uses, or transfers select agents must register with CDC and comply with Federal select agent regulations.

Our objective was to determine whether the Laboratories complied with Federal select agent regulations.

The Laboratories complied with some Federal select agent regulations. Specifically, the Laboratories had appointed a Responsible Official; restricted access to select agents to approved individuals; developed and implemented security, biosafety, and incident response plans; maintained the required inventory and access records; and complied with select agent transfer requirements. However, the Laboratories did not always ensure that individuals received select agent training before they accessed select agent areas. In addition, the Laboratories did not always comply with security plan requirements for coding electronic cards used to access select agent areas and storage freezers. These weaknesses could have compromised the Laboratories' ability to safeguard select agents from accidental or intentional loss and to ensure the safety of individuals who worked with select agents.

We recommend that the Laboratories:

- ensure that training is provided to all individuals before granting them access to select agent areas and

- ensure that electronic access cards are coded in compliance with the Laboratories' security plan.

In its written comments on our draft report, CDC concurred with our findings. CDC provided information on actions taken to ensure that training is provided to individuals before granting them access to select agent areas and to ensure that electronic access cards are properly coded.

This report contains restricted, sensitive information that may be exempt from release under the Freedom of Information Act, 5 U.S.C. § 552. The report will not be posted on the Internet. If information in the report is released pursuant to a request under the Act, the restricted, sensitive information and other information exempt from release will be redacted.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. 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 email at Lori.Pilcher@oig.hhs.gov. Please refer to report number [redacted] in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF COMPLIANCE WITH SELECT AGENT REGULATIONS BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION,

[redacted]

LABORATORIES

[redacted]

Daniel R. Levinson
Inspector General

September 2009

[redacted]

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. § 262a, requires the Department of Health and Human Services (HHS) to regulate select agents, which are biological 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). In collaboration with the U.S. Department of Agriculture, CDC establishes select agent regulations and monitors and enforces compliance with the regulations.

Any government agency (Federal, State, or local), academic institution, research organization, or other legal entity that possesses, uses, or transfers select agents must register with CDC and comply with Federal select agent regulations. (We refer collectively to these organizations as "entities.") Entities must, among other things, appoint a Responsible Official to ensure compliance with the regulations; restrict access to select agents to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"); develop and implement security, biosafety, and incident response plans; provide training on biosafety and security; maintain detailed select agent inventory and access records; and comply with select agent transfer requirements.

Following the 2001 terrorist attacks and anthrax release, we conducted a series of reviews of compliance with Federal select agent regulations by State, local, nonprofit, and university laboratories. In April 2008, we began a series of similar reviews at six Federal entities. This review, one in the series, addresses compliance by CDC's [redacted] Laboratories [redacted] an entity in [redacted]

OBJECTIVE

Our objective was to determine whether the Laboratories complied with Federal select agent regulations.

SUMMARY OF FINDINGS

The Laboratories complied with some Federal select agent regulations. Specifically, the Laboratories had appointed a Responsible Official; restricted access to select agents to approved individuals; developed and implemented security, biosafety, and incident response plans; maintained the required inventory and access records; and complied with select agent transfer requirements. However, the Laboratories did not always ensure that individuals received select agent training before they accessed select agent areas. In addition, the Laboratories did not always comply with security plan requirements for coding electronic cards used to access select agent areas and storage freezers. These weaknesses could have compromised the Laboratories' ability to safeguard select agents from accidental or intentional loss and to ensure the safety of individuals who worked with select agents.

RECOMMENDATIONS

We recommend that the Laboratories:

- ensure that training is provided to all individuals before granting them access to select agent areas and

- ensure that electronic access cards are coded in compliance with the Laboratories' security plan.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In its written comments on our draft report, CDC concurred with our findings. CDC provided information on actions taken to ensure that training is provided to individuals before granting them access to select agent areas and to ensure that electronic access cards are properly coded. CDC also provided technical comments, which we addressed as appropriate. CDC's comments, excluding technical comments, are included as Appendix B.

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INTRODUCTION

BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. § 262a, requires the Department of Health and Human Services (HHS) to regulate select agents, which are biological 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). In collaboration with the U.S. Department of Agriculture (USDA), CDC establishes select agent regulations and monitors and enforces compliance with the regulations.[2]

Any government agency (Federal, State, or local), academic institution, research organization, or other legal entity that possesses, uses, or transfers select agents must register with CDC and comply with Federal select agent regulations. (We refer collectively to these organizations as "entities.")

Federal Select Agent Regulations

Federal select agent regulations (42 CFR part 73) require that entities, among other things, appoint a Responsible Official to ensure compliance with the regulations; restrict access to select agents to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"); develop and implement security, biosafety, and incident response plans; provide training on biosafety and security; maintain detailed select agent inventory and access records; and comply with select agent transfer requirements. Appendix A contains the specific Federal regulations relevant to this review.

Office of Inspector General Reviews

Following the 2001 terrorist attacks and anthrax release, we conducted a series of reviews of compliance with Federal select agent regulations by State, local, nonprofit, and university laboratories. In April 2008, we began a series of similar reviews at six Federal entities. This review is one in the series.

Division of Vector-Borne Infectious Diseases Laboratories

CDC operates the [redacted] Laboratories [redacted] located in [redacted] The Laboratories, which CDC has designated as a single

[1] For purposes of this report, "select agents" refers to all agents and toxins listed in 42 CFR §§ 73.3 and 73.4.

[2] CDC regulates select agents that could pose a severe threat to public health and safety. USDA regulates select agents and toxins that could pose a severe threat to animal or plant health. CDC and USDA coordinate regulatory activities for those agents that affect both humans and animals (known as overlap select agents and toxins).

entity, consist of biosafety level 2 and 3 facilities[3] that are registered with CDC to possess, use, and transfer select agents. As of August 2008, 168 approved individuals worked at the Laboratories.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the Laboratories complied with Federal select agent regulations.

Scope

Our review covered the period April 18, 2005, the effective date of HHS's final rule for implementing select agent regulations,[4] through September 30, 2008. We limited our review to 17 of the Laboratories' 72 facilities. We did not perform an indepth review of the Laboratories' internal control structure. Rather, we limited our review to controls related to the Laboratories' compliance with select agent regulations.

We performed our fieldwork at the Laboratories in [redacted] from October 2008 through January 2009.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed CDC records related to the Laboratories' registration;
- reviewed the Laboratories' select agent security plan, biosafety plan, and incident response plan;
- held discussions with officials of the Laboratories to gain an understanding of the Laboratories' policies and procedures for implementing select agent regulations;
- reviewed the Laboratories' security, biosafety, and incident response procedures;

[3] Biosafety level 2 is suitable for work involving select agents of moderate potential hazard to personnel and the environment. Biosafety level 3 is appropriate for a laboratory with select agents that have a known potential for aerosol transmission, that may cause serious and potentially lethal infections, and that are indigenous or exotic in origin.

[4] 70 Fed. Reg. 13294–13325 (Mar. 18, 2005).

- reviewed the Laboratories' records related to biosafety and security training;
- reviewed the Laboratories' select agent inventory and access records; and
- reviewed the Laboratories' procedures for transferring select agents.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

The Laboratories complied with some Federal select agent regulations. Specifically, the Laboratories had appointed a Responsible Official; restricted access to select agents to approved individuals; developed and implemented security, biosafety, and incident response plans; maintained the required inventory and access records; and complied with select agent transfer requirements. However, the Laboratories did not always ensure that individuals received select agent training before they accessed select agent areas. In addition, the Laboratories did not always comply with security plan requirements for coding electronic cards used to access select agent areas and storage freezers. These weaknesses could have compromised the Laboratories' ability to safeguard select agents from accidental or intentional loss and to ensure the safety of individuals who worked with select agents.

SELECT AGENT TRAINING

Regulations (42 CFR § 73.15(a)) require entities to provide biosafety and security training to individuals before they access select agent areas.

The Laboratories did not provide biosafety and security training to 88 of the 168 approved individuals before granting the individuals access to select agent areas. Although the individuals subsequently received training, it was sometimes delayed by as long as 1 year. According to the Responsible Official, the delays in providing training resulted from difficulties encountered in coordinating training with human resources personnel and the principal investigators requesting the training.

SECURITY PLAN

Regulations (42 CFR § 73.11(c)) require entities to develop and implement a written security plan to safeguard select agents against unauthorized access.

The Laboratories' security plan required its Security Office to enter authorization codes on the electronic cards that approved individuals used to access select agent areas and the freezers where select agents were stored. According to the security plan, authorization was to be

restricted to the specific select agent areas and storage freezers to which each individual had been granted access. For example, security guards were granted access to select agent areas but not to the storage freezers. However, at one of the Laboratories' facilities, the authorization code that the Security Office entered on the electronic cards allowed all approved individuals to access all select agent areas and freezers, regardless of whether the individuals were approved for such access.

RECOMMENDATIONS

We recommend that the Laboratories:

- ensure that training is provided to all individuals before granting them access to select agent areas and
- ensure that electronic access cards are coded in compliance with the Laboratories' security plan.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In its written comments on our draft report, CDC concurred with our findings. CDC provided information on actions taken to ensure that training is provided to individuals before granting them access to select agent areas and to ensure that electronic access cards are properly coded. CDC also provided technical comments, which we addressed as appropriate. CDC's comments, excluding technical comments, are included as Appendix B.

APPENDIXES

FEDERAL SELECT AGENT REGULATIONS

- Regulations (42 CFR §§ 73.3 and 73.4) list select agents and toxins, which are biological materials that have the potential to pose a severe threat to public health and safety (referred to as "select agents" for purposes of the report and this Appendix).

- Regulations (42 CFR § 73.7(a)) require that an individual or entity not possess, use, or transfer select agents without a certificate of registration issued by the Secretary of the U.S. Department of Health and Human Services (HHS).

- Regulations (42 CFR § 73.7(b)) require each entity to designate an individual to be its Responsible Official.

- Regulations (42 CFR § 73.7(h)) require an entity to amend its registration to reflect changes in circumstances (personnel changes, changes in the activities involving any select agent, or the addition or removal of select agents).

- Regulations (42 CFR § 73.9(a)) require that the Responsible Official have the authority and responsibility to act on behalf of the entity and ensure the entity's compliance with requirements of the select agent regulations.

- Regulations (42 CFR § 73.10(a)) require an entity to authorize access to select agents only to individuals approved by the HHS Secretary following a security risk assessment by the Attorney General (referred to as "approved individuals").

- Regulations (42 CFR § 73.10(j)) require the Responsible Official to immediately notify the Centers for Disease Control and Prevention (CDC) (or the U.S. Department of Agriculture) when an individual's access to select agents is terminated and the reasons for the termination.

- Regulations (42 CFR § 73.11(a)) require entities to develop and implement a written security plan. The security plan must be sufficient to safeguard select agents against unauthorized access, theft, loss, or release.

- Regulations (42 CFR § 73.11(b)) require that the entity's security plan be designed according to a site-specific risk assessment and provide protection in accordance with the risk of the select agent, given its intended use.

- Regulations (42 CFR § 73.11(c)) require the entity's security plan to contain procedures for physical security, inventory control, and information systems control, as well as provisions for controlling access to select agents. In addition, each entity's plan must contain provisions for routine cleaning, maintenance, and repairs and procedures for removing unauthorized or suspicious persons. Each plan must describe procedures for addressing the loss or compromise of keys, passwords, or combinations and protocols for changing access numbers or locks following staff changes. Plans also must contain procedures for reporting unauthorized or suspicious persons or activities; the loss, theft, or release of select agents; or

the alteration of inventory records, as well as procedures for ensuring that all approved individuals understand and comply with security procedures.

- Regulations (42 CFR § 73.11(d)) require entities to allow access to select agents only to approved individuals. However, unapproved individuals who conduct routine cleaning, maintenance, repairs, or other activities not related to select agents may access select agent areas only when continuously escorted by an approved individual. In addition, freezers, refrigerators, cabinets, and other containers where select agents are stored are required to be secured against unauthorized access. The security plan also must contain procedures for intraentity transfers of select agents, the avoidance of sharing individuals' unique means of access to select agents, and the separation of select agent areas from public areas.

- Regulations (42 CFR § 73.11(f)) require entities to review annually and revise, as necessary, their security plan. Further, entities must conduct drills or exercises at least annually to test and evaluate the effectiveness of their plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

- Regulations (42 CFR § 73.12(a)) require entities to develop and implement a written biosafety plan that is commensurate with the risk of the agent, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

- Regulations (42 CFR § 73.12(d)) require entities to review annually and revise, as necessary, their biosafety plan. Further, entities must conduct drills or exercises at least annually to test and evaluate the effectiveness of their plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

- Regulations (42 CFR § 73.14(a)) require entities to develop and implement a written incident response plan. The incident response plan must be coordinated with any entitywide plans, kept in the workplace, and available to employees for review.

- Regulations (42 CFR § 73.14(c)) require each entity's incident response plan to contain information related to names and contact information for responsible entity and building officials, personnel roles and lines of authority and communication, planning and coordination with local emergency responders, procedures for employees performing rescue or medical duties, a list of personal protective and emergency equipment, site security and control, procedures for emergency evacuation, and decontamination procedures.

- Regulations (42 CFR § 73.14(d)) require entities to review and revise, as necessary, their incident response plans. Further, entities must conduct drills or exercises at least annually to test and evaluate the effectiveness of their plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

- Regulations (42 CFR § 73.15(a)) require entities to provide information and training on biosafety and security to individuals before they access select agent areas.

- Regulations (42 CFR § 73.15(b)) require entities to provide annual refresher training for approved individuals.

- Regulations (42 CFR § 73.15(c)) require entities to maintain a record of training provided to each individual. The record must include the name of the individual, the date of the training, a description of the training, and the means used to verify that the employee understood the training.

- Regulations (42 CFR § 73.16) require entities to transfer a select agent only to an entity registered to possess that particular select agent. Each transfer must be authorized by CDC (or the U.S. Department of Agriculture) before the transfer. In addition, the sender must comply with all laws concerning packaging and shipping.

- Regulations (42 CFR §§ 73.17(a)(1) and 73.17(a)(2)) require entities to maintain complete records relating to select agent inventories.

- Regulations (42 CFR § 73.17(a)(3)) require entities to maintain a current list of all approved individuals.

- Regulations (42 CFR § 73.17(a)(4)) require entities to maintain complete records related to 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.

- Regulations (42 CFR § 73.17(b)) require entities to implement a system to ensure that all records and databases created under 42 CFR part 73 are accurate, that access to them is controlled, and that their authenticity may be verified

DEPARTMENT OF HEALTH & HUMAN SERVICES | Public Health Service

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

AUG 31 2009

TO: Joseph E. Vengrin
Deputy Inspector General for Audit Services

FROM: Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention

SUBJECT: Office of the Inspector General's Draft Report: Compliance with Select Agent Regulation – [redacted]

The Centers for Disease Control and Prevention (CDC), [redacted] appreciates the opportunity to review and comment on the Office of the Inspector General's (OIG) draft report entitled, "Compliance with Select Agent Regulation – [redacted]" Thank you for your review of the [redacted] Laboratory to ensure compliance with select agent regulations.

As stated in the draft report, the objective of the review was to determine whether [redacted] Laboratory complies with Federal select agent regulations. The draft report identified two findings for which recommendations were made. [redacted] has addressed these recommendations and made changes to their select agent program procedures. Below are OIG's recommendations as well as details on the corrective measures taken by [redacted]

Office of the Inspector General (OIG) Recommendation #1: Ensure that training is provided to all individuals before granting them access to select agent areas.

[redacted] **Response:** [redacted] concurs with this finding and has instituted the following training procedures to ensure adherence to regulations 42 CFR Part 73.15 (a), 7 CFR Part 331.15 (a), and 9 CFR Part 121.15 (a):

1) Developed select agent training course - A select agent training course has been developed which examines all select agent regulatory requirements contained in 42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121 and includes the review of other pertinent regulations and guidelines. This training communicates site-specific information explaining how select agent regulations are followed at [redacted] Beginning in January 2009, the new select agent training has been consistently administered to individuals beginning employment and when requesting access to select agents at [redacted], and is required before access to any select agent or select agent registered

area at [redacted] is granted. Additionally, individuals are required to read the laboratory site-specific Biosafety Plan, the Biosecurity Plan, and the Incident Response Plan, as well as other pertinent materials. Individuals are evaluated by use of a written exam administered by the Responsible Official (RO). In addition to written exams, individuals are evaluated by their supervisors.

2) Required annual training - Traditionally, annual training has been conducted at [redacted] during the period of October to December for all Security Risk Assessment (SRA)-approved individuals; however, as of January 2009, select agent training is now administered by the RO during an individual's birth month along with other annual requirements such as respirator fit testing and safety evaluations. The select agent annual training program requirements include a complete review of all manuals and plans which are documented by use of a manual review log. This log is signed by a supervisor or a peer who verifies that an individual understands the material. In addition, a series of review slides highlighting recent changes to the training program as well as frequently asked questions are provided by the RO. Upon completion of the training program a written exam is administered and evaluated by the RO prior to the individual receiving access to select agents and/or access to select agent areas.

3) Developed approval form - Access to select agent areas at [redacted] is granted by use of the *Select Agent Access Form*. On this approval form, individuals request access to specific designated select agent areas. The form requires signatures from both the applicant and their supervisor. Following supervisory approval the form requires RO approval. The RO verifies an individual's SRA approval and ensures that the applicant has completed their required select agent training. In addition, the RO ensures that the requested access is consistent with the entity registration documents for the Principal Investigator. If an individual is delinquent on training or SRA approval, access is denied until these requirements are fulfilled.

Once all the required elements on the approval are completed, the approval form is forwarded to security personnel who assign appropriate accesses. A final review of all procedures is performed by a physical security specialist. In addition to obtaining training and approval for access to select agents and areas that house select agents, all [redacted] Laboratory employees must annually meet safety requirements such as respirator fit testing, risk assessment of their duties, and evaluation of required immunizations.

With strict adherence to the processes outlined above, the [redacted] Laboratory will maintain compliance with the training requirements as stated in 42 CFR Part 73.15 (a), 7 CFR Part 331.15(a), and 9 CFR Part 121.15(a).

Office of the Inspector General (OIG) Recommendation #2: Ensure that electronic access cards are coded in compliance with the [redacted] Laboratories security plan.

[redacted] **Response:** [redacted] concurs with this OIG finding and has instituted the following safeguards to address this recommendation:

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Background

[redacted]

Corrective Measures Taken

[redacted] Additionally, a physical security specialist currently reviews all access changes made by his staff to reduce human error.

Access reports encompassing the time period before the access codes were corrected show no access to any storage freezer by support or security personnel. Additionally, subsequent annual inventory verifications reveal no missing select agent long-term storage materials contained in the storage freezers in question.

[redacted] contends the changes in process and procedures will protect against further errors in assignment of access to registered areas and agents; hence, [redacted]s now in full compliance with 42 CFR Part 73.11(c), 7 CFR Part 331.11(c), and 9 CFR Part 121.11(c).

Technical comments on the draft report are provided in the attachment. We appreciate your

Page 4 - Joseph E. Vengrin

consideration of the comments contained in this memo and the technical comments as you develop the final report. We are happy to discuss any of these comments with you. Please direct any questions regarding these comments to Mr. Shaun Ratliff by telephone at (404) 639-2809 or by e-mail at iggao@cdc.gov.

Respectfully,

Thomas R. Frieden M.D., M.P.H.
Director, CDC, and
Administrator, Agency for Toxic
Substance and Disease Registry

Attachment

Office of Inspector General note: We have removed CDC's technical comments from this Appendix.