DEC - 1 2009

TO: (b)(3) - 42 USC 262a(h)

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

SUBJECT: Review of the (b)(3) 42 USC 262a(h)
Compliance With Select Agent Regulations (A-03-09-00350)

The attached final report provides the results of our review of compliance with select agent regulations by the (b)(3) 42 USC 262a(h) in (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) 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 the Centers for Disease Control and Prevention and comply with Federal select agent regulations.

Our objective was to determine whether the (b)(3) 42 USC 262a(h) complied with Federal select agent regulations.

The (b)(3) 42 USC 262a(h) complied with some Federal select agent regulations. Specifically, the (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) had appointed a Responsible Official; developed and implemented security, biosafety, and incident response plans; and complied with select agent transfer requirements. However, the (b)(3) 42 USC 262a(h) did not always restrict access to select agents to approved individuals, maintain required inventory and access records, or ensure that individuals received select agent training. These weaknesses could have compromised the (b)(3) 42 USC 262a(h) 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 (b)(3) 42 USC 262a(h) :

- ensure that only approved individuals are granted access to select agent areas and that unapproved individuals are continuously escorted by an approved individual when accessing select agent areas;

- conduct periodic inventory counts and prepare a written explanation of any discrepancies found in the inventory, including the discrepancy identified in October 2008;

- require principal investigators to document in inventory records each movement of select agents from storage and their return;

- ensure that approved individuals sign the visitors' log when escorting unapproved visitors into select agent areas; and

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

In written comments on our draft report, (b)(3) - 42 USC 262a(h) generally agreed with our findings and recommendations but said that we had overstated the potential consequences of our findings. After considering (b)(3) - 42 USC 262a(h) comments, we maintain that we have accurately characterized the potential consequences of the vulnerabilities identified during our review.

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 at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-03-09-00350 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE (b)(3) - 42 USC 262a(h) (b)(3) 42 USC 262a(h) LABORATORIES' COMPLIANCE WITH SELECT AGENT REGULATIONS

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Daniel R. Levinson
Inspector General

December 2009
A-03-09-00350

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 the (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) an entity in (b)(3) 42 USC 262a(h)

OBJECTIVE

Our objective was to determine whether the (b)(3) 42 USC 262a(h) complied with Federal select agent regulations.

SUMMARY OF FINDINGS

The (b)(3) 42 USC 262a(h) complied with some Federal select agent regulations. Specifically, the (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) had appointed a Responsible Official; developed and implemented security, biosafety, and incident response plans; and complied with select agent transfer requirements. However, the (b)(3) 42 USC 262a(h) did not always restrict access to select agents to approved individuals, maintain required inventory and access records, or ensure that individuals received select agent training. These weaknesses could have compromised the (b)(3) 42 USC 262a(h) 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 (b)(3) 42 USC 262a(h)

- ensure that only approved individuals are granted access to select agent areas and that unapproved individuals are continuously escorted by an approved individual when accessing select agent areas;
- conduct periodic inventory counts and prepare a written explanation of any discrepancies found in the inventory, including the discrepancy identified in October 2008;
- require principal investigators to document in inventory records each movement of select agents from storage and their return;
- ensure that approved individuals sign the visitors' log when escorting unapproved visitors into select agent areas; and
- ensure that training is provided to all individuals before granting them access to select agent areas.

(b)(3) - 42 USC 262a(h) COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, (b)(3) - 42 USC 262a(h) generally concurred with our findings and recommendations but said that we had overstated the potential consequences of our findings. (b)(3) - 42 USC 262a(h) comments are included in their entirety as Appendix B.

After considering (b)(3) - 42 USC 262a(h) comments, we maintain that we have accurately characterized the potential consequences of the vulnerabilities identified during our review.

TABLE OF CONTENTS

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.

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[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).

(b)(3) 42 USC 262a(h)

The (b)(3) 42 USC 262a(h) , including a laboratory at the (b)(3) 42 USC 262a(h) The (b)(3) 42 USC 262a(h) , which CDC has designated as a single entity, consists of biosafety level 2 and 3 facilities[4] registered with CDC to possess, use, and transfer select agents. As of September 18, 2008, 235 approved individuals worked at the (b)(3) 42 USC 262a(h)

The (b)(3) 42 USC 262a(h) Responsible Official approves a security plan and an incident response plan for each building that houses a select agent laboratory. Each select agent laboratory maintains its own biosafety plan based on a template provided by the Responsible Official. Each laboratory also maintains a record of its select agents. Chapter 3035 of the (b)(3) 42 USC 262a(h) Policy Manual," "Working Safely With Hazardous Biological Materials," calls for select agent quarterly inventories, which are conducted according to each select agent building's security plan. The Responsible Official, or an Assistant Responsible Official, reconciles the quarterly inventories to the (b)(3) 42 USC 262a(h) central records.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the (b)(3) 42 USC 262a(h) 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,[5] through February 2009. We limited our review to (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) Specifically, we reviewed 14 laboratories that were actively using select agents to conduct research and 9 laboratories that were not actively using select agents at the time of our review. We did not perform an indepth review of the (b)(3) 42 USC 262a(h) internal control structure. Rather, we limited our review to controls related to compliance with select agent regulations.

We performed our fieldwork at the (b)(3) 42 USC 262a(h) from October 2008 to February 2009.

(b)(3) 42 USC 262a(h) One laboratory handles receipt and storage of all select agent transfers from the (b)(3) 42 USC 262a(h)

[4]Biosafety level 2 is suitable for work involving 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.

[5]70 Fed. Reg. 13294–13325 (Mar. 18, 2005).

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed CDC records related to the (b)(3) 42 USC 262a(h) registrations;
- reviewed the (b)(3) 42 USC 262a(h) select agent security plans, biosafety plans, and incident response plans;
- held discussions with (b)(3) 42 USC 262a(h) officials to gain an understanding of the (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) policies and procedures for implementing select agent regulations;
- tested the (b)(3) 42 USC 262a(h) security, biosafety, and incident response procedures;
- reviewed the (b)(3) 42 USC 262a(h) records related to biosafety and security training;
- reviewed the (b)(3) 42 USC 262a(h) select agent inventory and access records; and
- reviewed the (b)(3) 42 USC 262a(h) 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 (b)(3) 42 USC 262a(h) complied with some Federal select agent regulations. Specifically, the (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) had appointed a Responsible Official; developed and implemented security, biosafety, and incident response plans; and complied with select agent transfer requirements. However, the (b)(3) 42 USC 262a(h) did not always restrict access to select agents to approved individuals, maintain required inventory and access records, or ensure that individuals received select agent training. These weaknesses could have compromised the (b)(3) 42 USC 262a(h) ability to safeguard select agents from accidental or intentional loss and to ensure the safety of individuals who worked with select agents.

SELECT AGENT ACCESS

Pursuant to 42 CFR § 73.10(a), entities may authorize access to select agents only to approved individuals. However, 42 CFR § 73.11(d)(2) permits an entity to allow an unapproved

individual to conduct routine cleaning, maintenance, repairs, or other activities not related to select agents if the individual is continuously escorted by an approved individual.

The (b)(3) 42 USC 262a(h) security plans allowed unapproved individuals to access select agent areas only when the individuals were continuously escorted by an approved individual. To ensure that unapproved individuals did not have unescorted access to select agent areas, the (b)(3) 42 USC 262a(h) secured those areas through biometric fingerprint readers. The (b)(3) 42 USC 262a(h) biosafety plans restricted biometric access to approved individuals. However, we found that an unapproved individual, a contractor who installed and serviced the biometric fingerprint readers, had biometric access and did not require escort by an approved individual. Although the contractor's duties required that he have biometric access, he was not an approved individual.

SELECT AGENT INVENTORY RECORDS

Pursuant to 42 CFR § 73.17(a), "An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part," including "[a]ccurate, current, inventory for each select agent" and a record that documents when the select agent is "moved from storage and by whom and when returned to storage and by whom . . . ." The regulations further require "[a] written explanation of any discrepancies."

One (b)(3) 42 USC 262a(h) laboratory did not maintain accurate, current inventory records on the select agents that it received.[6] The laboratory handled receipt and storage of all transfers from the (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) however, it did not conduct physical counts of the select agents received. Instead, at the time of a February 2007 transfer, the laboratory recorded on the inventory records the amounts listed on the select agent transfer form[7] as the amounts received. For each of the next four quarterly inventories required by chapter 3035 of the (b)(3) 42 USC 262a(h) Policy Manual," the laboratory's records carried forward these same amounts. The laboratory did not conduct a physical count until apprised of our audit in October 2008, at which time the laboratory determined that it had seven vials of select agents that were not recorded in the inventory records.[8] The laboratory then added the seven vials to the inventory records without any written explanation of the discrepancy.

In addition, a principal investigator at another laboratory moved a vial containing a select agent from storage and returned the vial to storage but did not record that the select agent had been moved, by whom it had been moved, or that it had been returned to storage. The principal

[6]Federal regulations (42 CFR § 73.17(a)(1)) require laboratories to maintain records only on select agents in long-term storage. The regulations do not define long-term storage; however, an official stated that the select agents at this laboratory were in long-term storage because they had not been used for a number of years.

[7]The CDC Request To Transfer Select Agents and Toxins form, which is also used by entities that ship select agents under the authority of USDA's Animal and Plant Health Inspection Service (APHIS), is often referred to as the "APHIS/CDC Form 2."

[8]The vials contained several select agents, including (b)(3) 42 USC 262a(h)

investigator had transferred a portion of the select agent to another laboratory, which properly recorded receipt of the select agent in its inventory records.

SELECT AGENT ACCESS RECORDS

Pursuant to 42 CFR § 73.17(a)(4)), an entity must maintain complete records on 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.

The (b)(3) 42 USC 262a(h) security plans required that unapproved individuals, as well as their approved escorts, sign a visitors' log before entering select agent areas. However, the visitors' log at one laboratory revealed an incident in which two unapproved visitors from the maintenance department had signed the log but an approved escort had not. Laboratory officials stated that the visitors had been accompanied by an approved individual who did not sign the log as required.

SELECT AGENT TRAINING

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

The (b)(3) 42 USC 262a(h) did not provide training to one approved individual before he was granted access to select agent areas. In February 2009, we brought this matter to the attention of the Responsible Official, who immediately rescinded the individual's access to select agent areas pending completion of the required training.

RECOMMENDATIONS

We recommend that the (b)(3) 42 USC 262a(h)

- ensure that only approved individuals are granted access to select agent areas and that unapproved individuals are continuously escorted by an approved individual when accessing select agent areas;

- conduct periodic inventory counts and prepare a written explanation of any discrepancies found in the inventory, including the discrepancy identified in October 2008;

- require principal investigators to document in inventory records each movement of select agents from storage and their return;

- ensure that approved individuals sign the visitors' log when escorting unapproved visitors into select agent areas; and

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

(b)(3) - 42 USC 262a(h) COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, (b)(3) - 42 USC 262a(h) generally concurred with our findings and recommendations but said that we had overstated the potential consequences of our findings. (b)(3) - 42 USC 262a(h) also described the corrective actions that it had taken or planned to take. (b)(3) - 42 USC 262a(h) comments are included in their entirety as Appendix B.

After considering (b)(3) - 42 USC 262a(h) comments, we maintain that we have accurately characterized the potential consequences of the vulnerabilities identified during our review.

OTHER MATTER

Federal regulations (42 CFR § 73.14(a)) require each entity to develop and implement a written incident response plan. Pursuant to 42 CFR § 73.14(c)(11), an entity's incident response plan must contain procedures for emergency evacuation.

The (b)(3) 42 USC 262a(h) incident response plans did not include procedures for ensuring the containment of animals infected with select agents in the event of an animal escape or an emergency evacuation by (b)(3) 42 USC 262a(h) personnel. Although Federal regulations do not require procedures for the containment of animals, the absence of such procedures could jeopardize the safety of (b)(3) 42 USC 262a(h) employees and the public.

APPENDIXES

APPENDIX A: 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

(b)(3) 42 USC 262a(h)

SEP 25 2009

TO: Mr. Joseph E. Vengrin
Deputy Inspector General for Audit Services, OIG, HHS

FROM: Director (b)(3) - 42 USC 262a(h)

SUBJECT: Comments on the OIG Draft Report, *Review of the* (b)(3) - 42 USC 262a(h) (b)(3) 42 USC 262a(h) *Compliance With Select Agent Regulations*, (A-03-09-00350)

Attached are the (b)(3) - 42 USC 262a(h) comments on the Office of Inspector General's draft report entitled, *Review of the* (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) *Compliance With Select Agent Regulations*, (A-03-09-00350).

We appreciate the opportunity to review and comment on this report before its publication.

(b)(3) - 42 USC 262a(h)

Attachment

General Comments from the (b)(3) - 42 USC 262a(h) on the Office of Inspector General Draft Report, *Review of the* (b)(3) 42 USC 262a(h) *Compliance with Select Agent Regulations*, A-03-09-00350

The (b)(3) - 42 USC 262a(h) appreciates the review conducted by the OIG and the opportunity to comment on this draft report. We wish to acknowledge the OIG audit team for their professional and thorough review. (b)(3) - 42 USC 262a(h) respectfully submits the following general comments.

I. Summary

As the Nation's premier biomedical research institution and a leader in biodefense research, (b)(3) - 42 USC 262a(h) takes its responsibility to safeguard all potentially dangerous organisms and toxins very seriously and strives to improve continuously our Select Agent Program (SAP).

We believe, however, that statements made in the summary of findings paragraph found in the OIG transmittal memorandum, and on the first page of the Executive Summary, do not provide a complete, accurate description of our SAP.

The (b)(3) - 42 USC 262a(h) is comprehensive, robust, and in many instances far exceeds the Federal requirements. We have developed and instituted procedures and programs that comply fully with all of the requirements of the Rule.

The auditors identified a small number of items (five) that were single, isolated instances of departure that should not result in characterization of our SAP as complying with "some of the regulations." At no time did any of these five instances result in situations that (as stated in the OIG draft report) "*could have compromised the* (b)(3) 42 USC 262a(h) *ability to safeguard select agents from accidental or intentional loss and to ensure the safety of individuals who worked with select agents.*" We feel strongly that the potential consequences of these few isolated departures are overstated and the actual facts and circumstances surrounding the incidents do not support this conclusion.

The small number of departures, and the fact that they were identified and addressed expeditiously, reflects the full measure of (b)(3) - 42 USC 262a(h) compliance with the regulations and the OIG report should accurately reflect this. We suggest that the summary findings be amended as follows to more accurately reflect the audit team's findings:

> *The* (b)(3) 42 USC 262a(h) *complied with the Federal select agent regulations. However, five instances were identified in which departures occurred. Program elements relating to these departures should be reviewed and modified or amended to ensure they are not repeated and to further improve the* (b)(3) - 42 USC 262a(h) *Select Agent Program.*

General Comments from the (b)(3) - 42 USC 262a(h) on the Office of Inspector General Draft Report, *Review of the* (b)(3) 42 USC 262a(h) *Compliance with Select Agent Regulations*, A-03-09-00350

Based on the audit team's findings and conclusions, the draft report includes several recommendations for (b)(3) - 42 USC 262a(h) consideration. These recommendations, and the (b)(3) - 42 USC 262a(h) response, follow.

II. Select Agent Access

OIG Recommendation

- Ensure that only approved individuals are granted access to select agent areas and that unapproved individuals are continuously escorted by an approved individual when accessing select agent areas.

(b)(3) - 42 USC 262a(h) Response

We concur that the access controls described in this recommendation are critical to a well-run SAP and believe that our systems and procedures fully implement this recommendation. Immediate action was taken by the (b)(3) - 42 USC 262a(h) to rectify the isolated situation described in the draft report. Training of the individual in question, a security contractor, was conducted on March 10, 2009; the request for a Security Risk Assessment (SRA) was submitted on March 17, 2009; and notification of an acceptable SRA was received from the Centers for Disease Control and Prevention (CDC) on April 29, 2009. Further, procedures have been amended to ensure that staff (contract or Federal) whose jobs do not include actual access to select agents but involve critical infrastructure will have favorable SRAs.

III. Select Agent Inventory Records

OIG Recommendation

- Conduct periodic inventory counts and prepare a written explanation of any discrepancies found in the inventory, including the discrepancy identified in October 2008.

(b)(3) - 42 USC 262a(h) Response

We concur that (b)(3) - 42 USC 262a(h) should conduct periodic inventory counts in order to maintain accurate inventories and explain any discrepancies. We believe that such a system is now, and has been, in place at the (b)(3) - 42 USC 262a(h)

The (b)(3) - 42 USC 262a(h) conducts inventory counts quarterly; more often than any other entity in the country. The inventory logs reviewed by the auditors reflected this practice. The "discrepancy" identified in October 2008 involved historical specimens, some of which were stored in sealed envelopes

General Comments from the [redacted] on the Office of Inspector General Draft Report, *Review of the* [redacted] *Compliance with Select Agent Regulations*, A-03-09-00350

unopened since 1960. Upon receipt of the samples, the receiving laboratory conducted an inventory and accounted for all of the vials and sealed envelopes received. Inventories were conducted in the same manner, quarterly, thereafter. In preparation for the OIG visit, to facilitate the review, the receiving laboratory opened the envelopes and placed the contents in freezer boxes. It was at this time that the seven additional vials were found. The seven vials were immediately added to the inventory and it was so noted in the log. At no time, were the vials and sealed envelopes compromised or subjected to conditions that could have resulted in loss, theft or diversion. Further, the sealed envelopes constituted "containers" which are acceptable under 42CFR72 § 331.17. The OIG is however correct that the individual conducting the inventory did not explain the addition of the vials to the inventory in the log. [redacted] has taken steps to ensure a higher degree of accuracy in recordkeeping by creating a standardized template for use by investigators to better ensure that the inventories fully and accurately reflect the name and characteristics of the organism; the quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source; where stored (e.g., building, room, and freezer); and when moved from storage and by whom, and when returned to storage and by whom, as required by 42CFR72 § 331.17.

OIG Recommendation

- Require principal investigators to document in inventory records each movement of select agents from storage and their return.

[redacted] Response

We concur with this recommendation. The OIG draft report correctly noted an instance where an investigator removed and replaced a vial in storage without noting the manipulation in the inventory log. The subculture of the vial was however correctly noted in transfer records and therefore a complete record of the activity and transfer was captured. [redacted] has taken steps to ensure a higher degree of accuracy in recordkeeping by creating a standardized template for use by investigators to better ensure that the inventories fully and accurately reflect the name and characteristics of the organism; the quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source; where stored (e.g., building, room, and freezer); and when moved from storage and by whom, and when returned to storage and by whom, as required by 42CFR72 § 331.17.

In addition to our comments above, we suggest that the previous two OIG recommendations be collapsed into one that states that [redacted]

"*should standardize inventory recordkeeping among select agent laboratories to better ensure that the inventories fully and accurately reflect the name and characteristics of the organism; the*

General Comments from the (b)(3) - 42 USC 262a(h) on the Office of Inspector General Draft Report, *Review of the* (b)(3) 42 USC 262a(h) *Compliance with Select Agent Regulations*, A-03-09-00350

quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source; where stored (e.g., building, room, and freezer); and when moved from storage, by whom and when returned to storage and by whom as required by 42CFR72 § 331.17."

IV. Select Agent Access Records

OIG Recommendation

- Ensure that approved individuals sign the visitors' log when escorting unapproved visitors into select agent areas.

NIH Response

We concur with this recommendation. (b)(3) - 42 USC 262a(h) Policy requires escorts to sign visitor log books and we will take action to further emphasize this requirement during upcoming select agent training sessions. We will also review visitor logs quarterly to ensure that escorts are being consistently identified.

V. Select Agent Training

OIG Recommendation

- Ensure that training is provided to all individuals before granting them access to select agent areas.

NIH Response

We concur that all individuals should be properly trained before granting them access to select agent areas. We believe that data show, and this audit verifies, that our training policies and procedures have ensured, and continue to ensure, full implementation of this recommendation. (b)(3) - 42 USC 262a(h) carefully ensures that all individuals receive training prior to allowing access to select agents. The one individual in question was SRA approved and had received training previously. Due to his international travel schedule, he missed select agent **re-training**. He did not access any select agent laboratories during this training hiatus. The RO removed his access when the situation was identified.

9/18/09