DEC 2 2 2008

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

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

SUBJECT: Review of Select Agent Transfers To and From the Edward R. Roybal Laboratory During the Period January 1, 2006, Through March 31, 2007 (A-02-07-02010)

The attached final report provides the results of our review of select agent transfers to and from the Centers for Disease Control and Prevention (CDC) Edward R. Roybal Laboratory (Roybal) in Atlanta, Georgia, during the period January 1, 2006, through March 31, 2007.

CDC's Division of Select Agents and Toxins (DSAT) is responsible for regulating select agents and toxins (referred to as "select agents"), which are biological materials that have the potential to pose a severe threat to public health and safety. Government agencies, research organizations, and legal entities that use, possess, or transfer select agents must register with DSAT and comply with select agent regulations. (We refer collectively to these organizations as "entities.") Entities may authorize access to select agents only to individuals approved by the Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"). Also, entities must develop and implement written security plans designed to safeguard select agents. Entities use the CDC Request To Transfer Select Agents and Toxins form (Form 2) to initiate select agent transfers, obtain DSAT approval, and document receipt of select agents.

The objective of our review was to determine whether only approved individuals accessed select agents transferred to and from Roybal.

Of the 112 select agent transfers to and from Roybal during the audit period, 51 transfers (46 percent) were accessed only by approved individuals at the receiving entities. However, unapproved individuals at the receiving entities accessed the remaining 61 transfers (54 percent). Of the 61 improperly handled transfers, 37 were shipped from Roybal to non-CDC entities and 24 were shipped from non-CDC entities to Roybal. All 61 transfers were shipped by one common carrier, [redacted] Allowing unapproved individuals to handle select agents increased the risk that the agents could be lost or stolen, thereby potentially posing a severe threat to public health and safety.

We attributed the improperly handled transfers to the following:

- The sending entities did not use a common carrier that offered restricted service and thus did not ensure delivery only to the individual(s) specified on the shipping label.

- Form 2 did not require entities to identify the common carrier used or the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals signed for the package.

- The receiving entities had inadequate or no security plan procedures, or did not follow established procedures, designed to mitigate the risk that unapproved individuals might accept delivery of select agents from a common carrier.

- DSAT's monitoring and enforcement efforts did not focus on procedures for mitigating the risk that unapproved individuals might accept delivery of select agents from a common carrier.

We recommend that CDC direct DSAT to:

- ensure that only approved individuals accept delivery of select agent packages by:

    - requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals and

    - amending Form 2 to include the name of the common carrier that will provide restricted service and the name of the individual who accepted delivery of the select agent package from the common carrier;

- require all entities registered to use, possess, or transfer select agents to implement security plan procedures designed to identify and mitigate the risk that unapproved individuals might sign for and accept delivery of select agent packages from common carriers; and

- strengthen its monitoring efforts by:

    - amending its site inspection process to include a review of procedures for initial acceptance of select agent packages from common carriers and

    - implementing follow-up procedures to verify that only approved individuals signed for and accepted delivery of select agent packages from common carriers.

In its comments on our draft report, CDC concurred in principle with our recommendation to require entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved

individuals. CDC stated that it would carefully evaluate the advantages and disadvantages of implementing that recommendation. CDC fully concurred with our other recommendations.

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 e-mail at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-02-07-02010 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF SELECT AGENT TRANSFERS TO AND FROM THE EDWARD R. ROYBAL LABORATORY DURING THE PERIOD JANUARY 1, 2006, THROUGH MARCH 31, 2007

[redacted]

Daniel R. Levinson
Inspector General

December 2008
A-02-07-02010

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, Public Law 107-188, requires the Department of Health and Human Services (HHS) to regulate select agents and toxins (referred to as "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), Division of Select Agents and Toxins (DSAT). In collaboration with the U.S. Department of Agriculture, DSAT establishes select agent regulations and monitors and enforces compliance with the regulations.

Any government organization (Federal, State, or local), academic institution, research organization, or other legal entity that uses, possesses, or transfers select agents must register with DSAT and comply with select agent regulations. (We refer collectively to these organizations as "entities.") Pursuant to 42 CFR § 73.10(a), entities may authorize access to select agents only to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"). Also, 42 CFR § 73.11(a) states that entities must develop and implement written security plans designed to safeguard select agents against unauthorized access, theft, loss, or release.

Registered entities may obtain select agents from a CDC laboratory, such as the Edward R. Roybal Laboratory (Roybal), located in Atlanta, Georgia, or from any non-CDC entity in the United States. Select agents are transferred between entities via common carrier or via hand delivery by a sending entity employee to a receiving entity employee. Entities use the CDC Request To Transfer Select Agents and Toxins form (Form 2) to initiate transfers, obtain DSAT approval, and document receipt of select agents.

OBJECTIVE

The objective of our review was to determine whether only approved individuals accessed select agents transferred to and from Roybal.

SUMMARY OF FINDINGS

Of the 112 select agent transfers to and from Roybal from January 1, 2006, through March 31, 2007, 51 transfers (46 percent) were accessed only by approved individuals at the receiving entities. However, unapproved individuals at the receiving entities accessed the remaining 61 transfers (54 percent). Of the 61 improperly handled transfers, 37 were shipped from Roybal to non-CDC entities and 24 were shipped from non-CDC entities to Roybal. All 61 transfers were shipped by one common carrier, [redacted] Allowing unapproved individuals to handle select agents increased the risk that the agents could be lost or stolen, thereby potentially posing a severe threat to public health and safety.

We attributed the improperly handled transfers to the following:

- The sending entities did not use a common carrier that offered restricted service and thus did not ensure delivery only to the individual(s) specified on the shipping label.

- Form 2 did not require entities to identify the common carrier used or the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals signed for the package.

- The receiving entities had inadequate or no security plan procedures, or did not follow established procedures, designed to mitigate the risk that unapproved individuals might accept delivery of select agents from a common carrier.

- DSAT's monitoring and enforcement efforts did not focus on procedures for mitigating the risk that unapproved individuals might accept delivery of select agents from a common carrier.

RECOMMENDATIONS

We recommend that CDC direct DSAT to:

- ensure that only approved individuals accept delivery of select agent packages by:

    - requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals and

    - amending Form 2 to include the name of the common carrier that will provide restricted service and the name of the individual who accepted delivery of the select agent package from the common carrier;

- require all entities registered to use, possess, or transfer select agents to implement security plan procedures designed to identify and mitigate the risk that unapproved individuals might sign for and accept delivery of select agent packages from common carriers; and

- strengthen its monitoring efforts by:

    - amending its site inspection process to include a review of procedures for initial acceptance of select agent packages from common carriers and

    - implementing follow-up procedures to verify that only approved individuals signed for and accepted delivery of select agent packages from common carriers.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In its comments on our draft report, CDC concurred in principle with our recommendation to require entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals. CDC stated that it would carefully evaluate the advantages and disadvantages of implementing that recommendation. CDC fully concurred with our other recommendations.

CDC's comments, except for 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, Public Law 107-188, 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), Division of Select Agents and Toxins (DSAT). In collaboration with the U.S. Department of Agriculture, DSAT establishes select agent regulations and monitors and enforces compliance with the regulations.[1]

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

Select Agent Regulations

Pursuant to 42 CFR § 73.10(a), entities may authorize access to select agents only to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"). Also, 42 CFR § 73.11(a) states that entities must develop and implement written security plans designed to safeguard select agents against unauthorized access, theft, loss, or release. Pursuant to 42 CFR § 73.9, an entity that transfers select agents must designate a Responsible Official who has the authority and responsibility to act on behalf of the entity and ensure compliance with select agent regulations.

Select Agent Transfer Process[2]

Registered entities may obtain select agents from a CDC laboratory, such as Roybal, located in Atlanta, Georgia, or from any non-CDC entity in the United States. Select agents are transferred between entities via common carrier[3] or via hand delivery by a sending entity employee to a receiving entity employee.

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[1]DSAT regulates select agents and toxins that could pose a severe threat to public health and safety. The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), regulates select agents and toxins that could pose a severe threat to animal or plant health. DSAT and APHIS coordinate regulatory activities for those agents that affect both humans and animals (known as overlap select agents and toxins). For purposes of this report, "select agents" refers to all agents and toxins covered under CDC regulations (42 CFR §§ 73.3 and 73.4).

[2]We obtained information on the select agent transfer process from 42 CFR § 73.16 and interviews with officials of DSAT, the Edward R. Roybal Laboratory (Roybal), and common carriers.

[3]Common carriers, which offer transportation services at established rates, are regulated by the U.S. Department of Transportation (DOT) and are not subject to 42 CFR § 73. Therefore, common carrier employees are not required to be approved individuals.

To initiate a transfer, the receiving entity enters its name and registration number, as well as the name and proposed use of the requested select agent, on the CDC Request To Transfer Select Agents and Toxins form (Form 2).[4] The Responsible Official of the receiving entity signs the form and faxes it to the sending entity. The sending entity then enters its name, registration number, and quantity of the select agent to be transferred on the form. The Responsible Official of the sending entity signs the form and faxes it to DSAT. DSAT verifies the information provided; assigns the transfer a unique approval number, which is valid for 30 days; and faxes the approved form to both the sending and receiving entities. If the transfer does not occur within 30 days, the approval is considered null and void and the transfer may not be completed.

Upon receipt of the approved Form 2, the sending entity packages the select agent in accordance with applicable packaging and shipping laws and places inside the package an updated form containing the date that the select agent is scheduled to leave the facility. If the select agent is to be shipped via common carrier, the sending entity also includes the tracking number on the form and, in accordance with instructions from the receiving entity, enters on the common carrier's shipping label the name and address of the individual(s) designated to accept the package. The common carrier delivers the package to the address indicated and, depending on the level of service used, may or may not ensure delivery to the individual(s) identified on the shipping label.

Within 2 business days of receiving the package, the receiving entity's Responsible Official faxes an updated version of Form 2, containing the date that the select agent was received, to both the sending entity and DSAT. (The name of the individual at the receiving entity who accepted the package from the common carrier is not included on the form.) The transfer is then considered complete.

Previous Office of Inspector General Reviews

During previous reviews, we identified three instances in which a common carrier had delivered select agent packages to non-CDC entities and left the packages with unapproved individuals.[5] For example, for one transfer from Roybal to a local government entity, the common carrier erroneously delivered the package to a medical center shipping and receiving facility located on the same campus as the entity. At the medical center, an unapproved individual accepted delivery and took possession of the package. The package was subsequently transported to the local entity and was left in the possession of a second unapproved individual. The package was then placed on a receiving cart, where it remained until an approved individual took possession of it and checked the select agent into the laboratory. Based on the results of these reviews, we initiated a review of select agent transfers to and from Roybal because it handles a large number of select agent transfers.

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[4]Form 2, which is also used by entities that ship select agents under the authority of APHIS, is often referred to as the "APHIS/CDC Form 2."

[5]We conducted the prior reviews at a private entity (A-12-05-00007), a local government entity (A-12-05-00002), and a university (A-12-05-22212).

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our review was to determine whether only approved individuals accessed select agents transferred to and from Roybal.

Scope

Our audit covered select agent transfers to and from Roybal during the period January 1, 2006, through March 31, 2007.[6] We focused on access to select agents from the point of delivery to check-in at the laboratory at the receiving entity.

We did not perform an indepth review of DSAT's internal control structure. Rather, we reviewed pertinent DSAT controls relating to the transfer of select agents. In addition, we gained an understanding of procedures governing select agent transfers implemented by Roybal, other entities, and common carriers involved in the transfers reviewed.

We performed our fieldwork at DSAT's headquarters and at Roybal in Atlanta, Georgia, from May 2007 through February 2008.

Methodology

To accomplish our objective, we:

- reviewed relevant Federal laws, regulations, and guidance;
- gained an understanding of the role of DSAT, entities, and common carriers in the select agent transfer process;
- reviewed entities' security plan procedures for the receipt of select agents;
- identified a total population of 112 select agent transfers completed during our audit period;
- obtained a list of approved individuals at the entities that received the transferred select agents;
- reviewed the common carriers' electronic tracking data to determine who signed for and accepted delivery of the 104 select agent packages delivered via common carrier;

[6]In a separate review, we are examining transfers of select agents between non-CDC entities.

- interviewed entity officials to determine who accessed the eight hand-delivered select agent packages; and

- reviewed common carriers' transportation security plans and shipping cost information.

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

Of the 112 select agent transfers to and from Roybal from January 1, 2006, through March 31, 2007, 51 transfers (46 percent) were accessed only by approved individuals at the receiving entities.[7] However, unapproved individuals at the receiving entities accessed the remaining 61 transfers (54 percent). Of the 61 improperly handled transfers, 37 were shipped from Roybal to non-CDC entities and 24 were shipped from non-CDC entities to Roybal. All 61 transfers were shipped by one common carrier, [redacted]. Allowing unapproved individuals to handle select agents increased the risk that the agents could be lost or stolen, thereby potentially posing a severe threat to public health and safety.

We attributed the improperly handled transfers to the following:

- The sending entities did not use a common carrier that offered restricted service and thus did not ensure delivery only to the individual(s) specified on the shipping label.

- Form 2 did not require entities to identify the common carrier used or the individual who accepted delivery of the package from the common carrier. DSAT could have used this information to verify that only approved individuals signed for the package.

- The receiving entities had inadequate or no security plan procedures, or did not follow established procedures, designed to mitigate the risk that unapproved individuals might accept delivery of select agents from a common carrier.

- DSAT's monitoring and enforcement efforts did not focus on procedures for mitigating the risk that unapproved individuals might accept delivery of select agents from a common carrier.

Appendix A contains details on the number of entities where transfers were received by unapproved individuals and information on DSAT site inspections of those entities.

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[7]Of the 51 properly handled transfers, 43 were shipped by common carrier: 39 by [redacted], 2 by [redacted] and 2 by [redacted]. The remaining eight transfers were hand-delivered.

RESTRICTED TRANSPORTATION SERVICE NOT USED

All 61 transfers that were accessed by unapproved individuals were shipped via [redacted], which does not provide restricted service requiring delivery only to the individual(s) specified on the shipping label. [redacted] provides delivery to the address on the shipping label and obtains the signature of any individual at that address who will sign for and accept delivery of the package. For example, Roybal shipped a select agent via [redacted] to a university. On the shipping label, Roybal entered the address of the entity and the name of the approved individual who should sign for the package. [redacted] delivered the package to the correct address but not to the approved individual specified on the label. Instead, an unapproved individual signed for the package. Subsequently, an approved individual took possession of the select agent from the unapproved individual and checked it into the laboratory.

Some common carriers, such as [redacted] and [redacted], offer restricted service to ensure delivery only to the individual(s) specified on the shipping label.[8] If the individual(s) specified on the label is not available at the time of delivery, such common carriers retain possession of the package until it can be delivered to the specified individual(s). Thus, until the approved individual(s) is available to accept the package, the select agent remains in the transportation system, outside the authority of the select agent regulations.

Although Federal regulations do not require sending entities to use restricted service, such a requirement would greatly reduce the risk that unapproved individuals might sign for and take possession of select agent packages. Similarly, requiring that the shipping label include the names of at least two approved individuals would minimize the time that select agents remain outside the authority of the select agent regulations.

FORM 2 DEFICIENCIES

Form 2 provides DSAT with important information on select agent transfers from the time of the initial request for the transfer through the delivery of the package. However, the form does not require sending entities to identify the common carrier that will deliver the package, nor does it require receiving entities to indicate the name of the individual who accepted delivery of the package from the common carrier. DSAT could use this information to verify that only approved individuals accessed select agent transfers. Specifically, DSAT could obtain from the common carrier the electronic signature of the individual who signed for the package and compare the name of that individual against the receiving entity's list of approved individuals.

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[8]For our population, the average cost to ship a select agent package using [redacted] was [redacted]. The average cost to ship a package using restricted service would have been approximately [redacted] for [redacted] and [redacted] for [redacted]. The actual cost varies by package weight and/or shipping distance.

SECURITY PLANNING AND IMPLEMENTATION DEFICIENCIES

Pursuant to 42 CFR § 73.11, entities must develop and implement a written security plan designed to safeguard select agents against unauthorized access, theft, loss, or release. Each entity develops its security plan based on a site-specific risk assessment.

Entities With Inadequate Security Plan Procedures

For 44 of the 61 transfers accessed by unapproved individuals, the receiving entities had inadequate written security plan procedures for initial acceptance of select agent packages from common carriers.

For example, Roybal's security plan contained detailed procedures for accepting delivery of a select agent package from a common carrier and delivering the package to the addressee. However, the plan did not specify that the individual accepting the package and delivering it to the addressee must be approved. Consequently, unapproved Roybal personnel signed for and accepted delivery of 24 packages containing select agents such as Bacillus anthracis (anthrax).[9] Each package was then temporarily stored in an unsecured area. After being notified that the package had arrived, the addressee or another approved individual came to the unsecured area, took possession of the select agent, and hand-carried the package to the laboratory.

Entities With No Security Plan Procedures

For 14 of the 61 transfers accessed by unapproved individuals, the receiving entities had no written security plan procedures for initial acceptance of select agent packages from common carriers.

For example, a State laboratory's security plan contained procedures for receiving and safely opening a select agent package in the laboratory. However, the plan did not address how to handle and limit access to the package from the time of delivery to the mailroom until check-in at the laboratory. Moreover, this entity, which shared office space with a county health department, did not have full-time personnel assigned to the mailroom. Rather, an employee of either the State laboratory or the county was randomly chosen each day to receive and distribute mail. On one occasion, an unapproved county employee signed for and accepted delivery of a package containing Bacillus anthracis. The employee then hand-carried the package to the State laboratory's Responsible Official, who checked the select agent into the laboratory.

Entities That Did Not Follow Security Plan Procedures

For 3 of the 61 transfers accessed by unapproved individuals, the receiving entities had written security plan procedures for initial acceptance of select agent packages from common carriers. However, employees at these entities did not always follow the procedures.

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[9]Bacillus anthracis is the causative agent of anthrax, a disease that has been categorized by CDC as having a high potential for use in bioterrorism.

For example, a non-CDC Federal laboratory's security plan stated that the common carrier would be directed to wait until an approved individual could be contacted to accept delivery of the select agent. However, in one instance, an unapproved mailroom employee disregarded established procedures and accepted delivery of a package containing Francisella tularensis (rabbit fever).[10] Subsequently, an approved individual came to the mailroom, took possession of the select agent, and checked it into the laboratory.

INADEQUATE MONITORING AND ENFORCEMENT

Pursuant to 42 CFR § 73.18, DSAT conducts periodic site inspections to monitor and enforce compliance with select agent regulations. Site inspections are conducted before an entity is initially registered to send and/or receive select agents and at least every 3 years thereafter.

During its site inspections, DSAT did not adequately monitor or enforce compliance with 42 CFR § 73.11(a),which requires that entities develop and implement written security plans designed to safeguard select agents against unauthorized access, theft, loss, or release. During our audit period, DSAT performed site inspections at 20 entities that received 46 of the 61 select agent transfers accessed by unapproved individuals. However, as shown in Appendix A, DSAT cited only three of these entities for having inadequate or no procedures designed to mitigate the risk that unapproved individuals might sign for and accept delivery of select agent packages upon their initial receipt from common carriers.

According to DSAT officials, its inspectors receive periodic training on how to conduct site inspections and are provided with a checklist for determining whether an entity meets the requirements of the regulations, including security over access to select agents. However, the checklist does not contain specific steps to determine whether the entity has adequate procedures to ensure that only approved individuals sign for and accept delivery of select agent packages from common carriers. Moreover, DSAT officials acknowledged that inspectors were not required to determine whether unapproved individuals had signed for and accepted delivery of select agent packages.

RECOMMENDATIONS

We recommend that CDC direct DSAT to:

- ensure that only approved individuals accept delivery of select agent packages by:
    - requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals and

[10]Francisella tularensis is the causative agent of rabbit fever, a highly infectious disease with severe flu-like symptoms.

- amending Form 2 to include the name of the common carrier that will provide restricted service and the name of the individual who accepted delivery of the select agent package from the common carrier;

- require all entities registered to use, possess, or transfer select agents to implement security plan procedures designed to identify and mitigate the risk that unapproved individuals might sign for and accept delivery of select agent packages from common carriers; and

- strengthen its monitoring efforts by:

  - amending its site inspection process to include a review of procedures for initial acceptance of select agent packages from common carriers and

  - implementing follow-up procedures to verify that only approved individuals signed for and accepted delivery of select agent packages from common carriers.

CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

In its comments on our draft report, CDC concurred in principle with our recommendation to require entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals. CDC stated that it would carefully evaluate the advantages and disadvantages of implementing that recommendation. CDC fully concurred with our other recommendations. CDC also provided technical comments, which we addressed as appropriate.

CDC's comments, except for technical comments, are included as Appendix B.

OTHER MATTERS

NULL AND VOID TRANSFERS

DSAT declared 7 of the 61 transfers that were accessed by unapproved individuals to be null and void because it believed that the transfers did not occur within the 30-day approval period. Officials of the receiving entities stated, however, that all seven transfers took place within the 30-day approval period and that they had faxed an updated Form 2, indicating receipt of the package, to the Responsible Official of Roybal (the sending entity). However, they had not faxed an updated Form 2 to DSAT as required because they misunderstood the instructions accompanying the form. Specifically, although the form provides DSAT's address and fax number, the instructions state that the updated form should be sent to CDC. Officials at the entities mistakenly believed that faxing the form to Roybal (a CDC laboratory) constituted compliance with the instructions. Moreover, DSAT had no procedures for following up with entities to determine why approved transfers did not take place. Consequently, DSAT was unaware that transfers declared null and void had actually been shipped.

SELECT AGENT PACKAGING REQUIREMENTS

Pursuant to CDC regulations (42 CFR § 73.16(i)), an entity that transfers a select agent to another entity must comply with all applicable packaging and shipping laws. DOT regulations (49 CFR § 173.134) classify infectious substances as Category A or B substances and provide packaging requirements for each category. Category A includes substances that are shipped in a form capable of causing death or permanent disability to humans or animals, and Category B includes all other infectious substances. DOT lists Category A infectious substances in the Federal Register ((71 Fed. Reg. 32245, 32246) (June 2, 2006)). However, this list does not include all substances classified as select agents under CDC regulations (42 CFR §§ 73.3 and 73.4), nor does it provide guidance on shipping select agents that are not listed as Category A substances. DSAT did not coordinate with DOT to ensure that entities had comprehensive guidance for packaging all select agents.

APPENDIXES

APPENDIX A

SELECT AGENT TRANSFERS ACCESSED BY UNAPPROVED INDIVIDUALS

Security Plan Deficiencies	Transfers Received by Unapproved Individuals	Entities	DSAT[1] Inspections	DSAT Citations for Unapproved Access to Transfers
Inadequate procedures	44	15	11	1
No procedures	14	14	7	2
Procedures not followed	3	3	2	-
Total	**61**	**32**	**20**	**3**

[1]DSAT = Division of Select Agents and Toxins of the Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 3 2008

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

FROM: Director
Centers for Disease Control and Prevention

SUBJECT: Office of Inspector General's Draft Report: "Review of Select Agent Transfers To and From the Edward R. Roybal Laboratory during the Period January 1, 2006 through March 31, 2007"
(A-02-07-02010)

The Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins (DSAT) appreciates the opportunity to review and comment on the Office of Inspector General's draft report, "Review of Select Agent Transfers To and From the Edward R. Roybal Laboratory during the Period January 1, 2006 through March 31, 2007." Thank you for your review of this important issue.

As stated in the draft, the objective of this review was to determine whether only approved individuals accessed select agent transfers to and from the CDC Roybal campus. The draft identified four findings regarding the improperly handled transfers and also provided the following recommendations to address these findings:

Office of Inspector General (OIG) Recommendation: CDC direct DSAT to ensure that only approved individuals accept delivery of select agent packages by requiring entities that ship select agents via common carrier to (1) use restricted service and (2) include on the common carrier's shipping label the names of a minimum of two approved individuals.

DSAT Response: DSAT concurs in principle with this recommendation. In accordance with the Select Agent Regulations (42 C.F.R. Part 73, 9 C.F.R. Part 121, 7 C.F.R. Part 331), DSAT strives to ensure that shipments containing select agents and toxins are safeguarded against unauthorized access, as well as against thefts, losses, or releases. It is important to note that of the approximately 2,500 transfers that have occurred since 2003, there has only been one confirmed loss of a select agent that occurred during shipment. This loss was investigated by the Department of Justice/Federal Bureau of Investigation (FBI) and the FBI determined that there was no criminal intent.

Given the concerns identified by this audit and consideration of the other possible vulnerabilities that may occur during the shipment of select agents and toxins, DSAT is currently reviewing how entities ship select agents and toxins and evaluating ways to improve this process to ensure that the shipment of select agents and toxins is not only safeguarded against unauthorized access, but also

against theft, loss, or release. One consideration is whether any additional risks are created by possibly keeping a select agent package in the transportation system longer than usual due to the requirements of a restricted service, such as the package being returned to sender if the identified recipient is unavailable.

DSAT wants to ensure that the implementation of this recommendation will not cause an undue financial burden on the regulated community, given the balance of risks and benefits (in the footnote on page 5 of the draft report, OIG notes that the average cost to ship a package using restricted service would have been approximately [redacted] for [redacted] and [redacted] for [redacted], compared with [redacted] for [redacted]. In addition, DSAT has confirmed that only [redacted] has the restricted transportation service that is being recommended by OIG. When DSAT contacted [redacted], it was informed that [redacted] does not have a restricted transportation service. DSAT also wants to ensure that implementation of this recommendation will not impede research, as was mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). DSAT will carefully evaluate the advantages and disadvantages of implementing this recommendation as currently described.

OIG Recommendation: CDC direct DSAT to ensure that only approved individuals accept delivery of select agent packages by amending Form 2 to include the name of the common carrier that will provide restricted service and the name of the individual who accepted delivery of the select agent package from the common carrier.

DSAT Response: DSAT concurs with this recommendation. Currently under review by the Office of Management and Budget (OMB), DSAT and the U.S. Department of Agriculture/Animal and Plant Health Inspection Service (APHIS) have revised the "Request to Transfer Select Agents and Toxins" form (APHIS/CDC Form 2) to not only include the name of the carrier (e.g., FedEx or "hand-carried" by the sending or receiving entity) and the name of the individual who packages the shipment, but to also include the name of the individual who accepts the delivery of the select agent package from the carrier. The changes to the APHIS/CDC Form 2 will make CDC and APHIS aware of any unauthorized access that may have occurred during the packaging and receipt of the select agent shipment.

OIG Recommendation: CDC direct DSAT to require all entities registered to possess, use, or transfer select agents to implement security plan procedures designed to identify and mitigate the risk that unapproved individuals might sign for and accept delivery of select agent packages from common carriers.

DSAT Response: DSAT concurs with this recommendation. Section 73.11 of the Select Agent Regulations (42 C.F.R. 73.11) requires that an entity develop and implement a written security plan that is sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. The security plan must also be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. This risk assessment should include how the entity ships and receives select agents and toxins.

On April 18, 2007, DSAT provided to the regulated entities informational documents to assist entities in complying with the security requirements of the Select Agent Regulations. These documents should assist entities in developing or revising a written security plan and in performing a site-specific risk assessment. The documents are available on the National Select Agent Registry (NSAR) website at http://www.selectagents.gov/complianceAssistance.htm.

Additional guidance is currently being developed in collaboration with the Department of Transportation to provide entities with information on the regulations governing the transportation of select agents and toxins. In addition, DSAT, in coordination with APHIS, is developing two educational workshops with the theme of "Management Oversight" to inform Responsible Officials of their legal responsibilities for implementing the Select Agent Regulations. These workshops are scheduled for Fall 2008 and Summer 2009.

OIG Recommendation: CDC direct DSAT to strengthen its monitoring efforts by amending its site inspection process to include a review of procedures for initial acceptance of select agent packages from common carriers.

DSAT Response: DSAT concurs with this recommendation. Even though DSAT inspectors received training on how to perform site inspections and were provided with a "Security" checklist for ensuring that an entity meets the security requirements of the regulations, this audit identified that only three of the twenty entities that were identified as having transfers accessed by unapproved individuals and were inspected by DSAT were cited by inspectors for lacking procedures to ensure only authorized individuals ship or receive select agents. To ensure consistency among the inspectors, DSAT has revised its standard operating procedure (SOP) involving inspections to include an expectation that inspectors review shipping and receiving protocols to determine if unapproved individuals signed for and accepted delivery of select agent packages upon initial receipt from carriers. DSAT also has improved the inspection process by having inspectors review security plans in advance of the inspection to verify that the plans include such protocols. Once on-site, the inspectors verify the information through inspection of the facility and querying the staff.

Recognizing the importance of having a well-trained inspection staff, DSAT has designated a Training Officer that oversees training activities for inspectors, conducts bi-weekly inspector training sessions, and provides information exchange to inspectors through e-mails from the DSAT Deputy Director.

OIG Recommendation: CDC direct DSAT to strengthen its monitoring efforts by implementing follow-up procedures to verify that only approved individuals signed for and accepted delivery of select agent packages from common carriers.

DSAT Response: DSAT concurs with this recommendation. As discussed above, the revised APHIS/CDC Form 2 that is currently under review by OMB will not only include the name of the carrier (e.g., [redacted] or "hand-carried" by the sending or receiving entity) and the name of the individual who packages the shipment, but also will include the name of the individual who accepts the delivery of the select agent package from the carrier. To address this recommendation, DSAT will strengthen its monitoring efforts by developing a quality control checklist that will

ensure that the DSAT reviewer confirms that no unauthorized access occurred during the transfer process by checking the name of the individuals identified on the APHIS/CDC Form 2 as packaging and receiving the select agent shipment against the list of Security Risk Assessment-approved individuals at the sending and receiving entities. The changes to the APHIS/CDC Form 2 and the new follow-up procedures will make CDC and APHIS aware of any unauthorized access that may have occurred during the packaging and receipt of the select agent shipment.

OTHER MATTERS:

The audit also identified the following two other matters:

Summary of OIG Finding Regarding Null and Void Transfers: DSAT declared 7 of the 61 transfers that were accessed by unapproved individuals to be null and void because it believed that the transfers did not occur within the 30-day approval period. Officials of the receiving entities stated, however, that all seven transfers took place within the 30-day approval period and that they had faxed an updated Form 2 indicating receipt of the package to the Responsible Official at the CDC. The instructions to fax the updated form to "CDC" were misunderstood by some as the CDC Responsible Official rather than DSAT.

DSAT Response: In June 2007, DSAT followed-up on any transfers with "null/void" status to determine if the shipment had occurred. Out of the 103 "null/void" transfers that were followed-up, DSAT confirmed that 6 transfers had occurred without DSAT's knowledge. As a result of this follow-up, DSAT changed its transfer standard operating procedures in June 2007 to include obtaining written confirmation from the sender or the recipient regarding the transfer of select agents prior to finalizing the transfer record. In addition, the revised APHIS/CDC Form 2 currently under review by OMB has been revised to request that the recipient Responsible Official confirm if the transfer did not occur within 30 days of the authorization.

Summary of OIG Finding Regarding Select Agent Packaging Requirements: Pursuant to CDC regulations (42 CFR § 73.16(i)), an entity that transfers a select agent to another entity must comply with all applicable packaging and shipping laws. Department of Transportation (DOT) regulations (49 CFR § 173.134) classify infectious substances as Category A or B substances and provide packaging requirements for each category. DSAT did not coordinate with DOT to ensure that entities had comprehensive guidance for packaging all select agents.

DSAT Response: To assist DOT in determining whether entities transferring select agents are complying with DOT regulations, in March 2008, DSAT provided DOT with a list of entities that perform transfers involving select agents. DOT has performed 12 inspections of these entities.

In addition, DSAT is working with DOT to develop guidance for the regulated community on the shipping and packaging of select agents. This guidance will include information on all applicable domestic and international shipping regulations and guidance and will be available to the regulated community via the NSAR website (www.selectagents.gov).

Technical comments on the draft report are provided in the attachment. We appreciate your consideration of the comments contained in this memo and the technical comments as you develop

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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.

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

Attachment