

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE NATIONAL INSTITUTES OF HEALTH
GENERALLY COMPLIED WITH FEDERAL
REQUIREMENTS FOR THE PREPARATION
AND RECEIPT OF SELECT AGENT
SHIPMENTS**

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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Report in Brief

Date: December 2018

Report No. A-03-15-00354

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

The National Institutes of Health (NIH) is one of several Federal agencies that ship and receive select agents. In 2015, another Federal agency found that one of its facilities had inadvertently shipped live *Bacillus anthracis*, a select agent which causes the deadly disease anthrax, to 194 laboratories in the United States and other countries. In response to these events, we initiated a review of the policies, procedures, and protocols NIH implemented to ensure the safe shipment of select agents to and from its laboratories.

Our objective was to determine whether NIH has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting laboratory guidance and instruction.

How OIG Did This Review

We reviewed 23 select agent shipments either sent or received by one of NIH's three registered entities from October 1, 2013, through September 30, 2015. We also requested documentation of all inactivated select agents shipped and received during the same period. We reviewed relevant NIH policies, training documentation, and inactivations for compliance with Federal requirements and guidance.

The National Institutes of Health Generally Complied With Federal Requirements for the Preparation and Receipt of Select Agent Shipments

What OIG Found

Generally, NIH has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting laboratory guidance and instruction. However, two NIH registered entities' security plans did not include certain procedures for notifying the Federal Select Agent Program (FSAP) if (1) a select agent shipment is not received within 48 hours after the expected delivery time, (2) a select agent shipment receives damage to the extent that a select agent release may have occurred, or (3) an authorization for a select agent transfer expires or becomes void before the shipment is completed. In addition, we found that NIH's third registered entity had not updated its policies and procedures to ensure compliance with new requirements for shipping select agents that have undergone inactivation.

What OIG Recommends and NIH Comments

We recommend that NIH update two registered entities' security plans to include procedures for notifying FSAP if a select agent (1) shipment is not received within 48 hours after the expected time of delivery, (2) package is received that is damaged to the extent that a release of the select agent may have occurred, (3) shipment will not be completed within 30 calendar days after transfer authorization issuance, or (4) transfer authorization becomes void because the facts supporting the authorization changed. We also recommend that NIH work with its third registered entity to implement a policy to ensure compliance with new requirements for shipping inactive select agents.

In written comments on our draft report, NIH concurred with our findings and recommendations and stated that it has taken actions to implement our recommendations. NIH indicated that it updated its two registered entities' security plans to include procedures for notifying FSAP and that the other NIH registered entity updated its security plan policy covering transfer authorizations.

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INTRODUCTION

WHY WE DID THIS REVIEW

The National Institutes of Health (NIH) is one of several Federal agencies that ship and receive select agents. In 2015, another Federal agency found that one of its facilities had inadvertently shipped live *Bacillus anthracis*, a select agent that causes the deadly disease anthrax, to multiple contract laboratories.¹ An investigation found that 194 facilities in the United States and other countries received live spores from samples that originated at the facility and that the process it used to inactivate *Bacillus anthracis* with radiation was not always effective.

In response to these events, we initiated reviews of the policies, procedures, and protocols implemented by two of the Department of Health and Human Services' (HHS's) divisions, the NIH and the Food and Drug Administration, to ensure the safe shipment of select agents to and from their laboratories. This report details the results of our review of the select agent shipment controls at NIH.

Appendix B contains a list of related Office of Inspector General reports.

OBJECTIVE

Our objective was to determine whether NIH has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting laboratory guidance and instruction.

BACKGROUND

Select Agents

Select agents are biological agents or toxins that HHS and the Department of Agriculture (USDA) have determined pose a threat to humans, animals, plants, or the environment. Regardless of its origin (naturally occurring, engineered, or synthesized), any microorganism or toxin capable of harming living organisms or the environment can be classified as a select agent.

After a 1995 incident in which an individual in the United States unlawfully obtained *Yersinia pestis*, the bacterium that causes plague, Congress enacted section 511 of the Antiterrorism and Effective Death Penalty Act of 1996.² This statute directed the HHS Secretary to promulgate regulations identifying a list of biological agents that have the potential to pose a severe threat to public health and safety, providing procedures governing the transfer of those agents, and establishing safeguards to prevent unauthorized access to those agents for purposes of terrorism or other criminal activities. The HHS Secretary delegated the authority to

¹ *Evaluation of DoD Biological Safety and Security Implementation* (DODIG-2016-078), Apr. 7, 2016. See <https://media.defense.gov/2016/Apr/27/2001714233/-1/-1/1/DODIG-2016-078.pdf> (accessed Sep. 20, 2018).

² P.L. No. 104-132 (enacted Apr. 24, 1996).

regulate select agents to the Centers for Disease Control and Prevention (CDC), which then delegated its authority under this statute to its Division of Select Agents and Toxins (DSAT) and established the CDC Select Agent Program.

After the September 11, 2001, terrorist events and the anthrax attacks, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.³ This statute expanded HHS's authority to regulate the transfer, use, and possession of select agents and granted similar authority to USDA for select agents that pose a threat to animal or plant health or to animal or plant products. USDA delegated its authority to the Animal and Plant Health Inspection Service (APHIS), which established the Agriculture Select Agent Services (AgSAS).

The Federal Select Agent Program

Together, DSAT and AgSAS jointly manage the Federal Select Agent Program (FSAP). FSAP regulates the possession, use, and transfer of biological agents listed in 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73.⁴ FSAP enhances the Nation's oversight of the safety and security of select agents by:

- developing, implementing, and enforcing select agent regulations;
- maintaining a national database of registered entities that possess select agents;
- inspecting entities that possess, use, or transfer select agents;
- ensuring that all individuals who work with these agents undergo a security risk assessment performed by the Federal Bureau of Investigation (FBI) Criminal Justice Information Service;
- providing guidance to regulated entities by developing guidance documents and conducting workshops and webinars; and
- investigating incidents in which noncompliance may have occurred.

Registered Entities

Any laboratory working with select agents must register with FSAP to become a registered entity. All laboratories must comply with Federal regulations regarding biosafety and security if they anticipate working with select agents.

To register to possess select agents, an entity must submit an application package to FSAP, and entity personnel must submit to a security risk assessment conducted by the FBI. FSAP conducts an on-site inspection before issuing a new certificate of registration or renewing an existing registration. Once approved, an entity's registration is valid for a maximum of 3 years

³ P.L. No. 107-188 (enacted June 12, 2002).

⁴ See Appendix C for a summary of Federal requirements referenced in this report.

and may be amended to reflect changes in circumstances such as the replacement of the Responsible Official; changes in ownership, control, or select agent activities; or the addition or removal of any select agents.

As a condition of registration, select agent regulations require registered entities to designate an individual as the Responsible Official who ensures compliance with regulations. In addition, the select agent regulations require entities to develop written plans, provide training, and maintain records of training and other activities. As part of the requirement that registered entities develop written plans, registered entities must develop and implement a written security plan that is sufficient to safeguard each select agent against unauthorized access, theft, loss, or release and develop and implement a written biological safety plan that is commensurate with the risk of the registered entity's select agents given their intended use. Additionally, registered entities are required to provide training on biological safety and security for individuals with access to select agents and maintain records on the training provided to each individual with access to select agents and other activities covered by the select agent regulations.

To transfer a select agent, the registered entities involved in the transfer must obtain an authorization from FSAP. To obtain the authorization, FSAP requires both the shipping and receiving entities to complete the APHIS/CDC Form 2, Request To Transfer Select Agents and Toxins.⁵ Before any transfer can occur, both the shipping and receiving entities must fill out applicable sections of the Form 2 and send it to FSAP for authorization. When the shipment is complete, the receiving entity fills out another section of the form and sends a copy of the completed Form 2 to both the shipping entity and FSAP. FSAP guidance on completing the Form 2 includes some of the requirements for select agent transfers; these requirements are also listed in the Federal select agent regulations.

National Institutes of Health

NIH is the largest source of funding for medical research in the world. It is made up of 27 institutes and centers, each with a specific research agenda often focusing on particular diseases or body systems.

In 2017, NIH's budget was nearly \$31.6 billion, most of which was related to medical research. More than 80 percent of its funding is awarded through approximately 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions around the world. About 10 percent of NIH's budget supports

⁵ In addition to requesting authorization, this form provides the shipping and receiving entities and FSAP with documentation of important aspects of the transfer. This documentation includes a list of each select agent being transferred, the names of shipping entity personnel involved in the shipping process, the address of the shipping entity, the date the select agent or agents were shipped, a description of the packaging, the name of the carrier, the name of the individual who received the shipment, and a statement from that individual about what was received, whether the packaging was damaged, whether the select agent or agents were packaged in accordance with all laws and regulations, and the date the package was received.

projects conducted by nearly 6,000 scientists in its own laboratories, most of which are located on its Bethesda, Maryland, campus.

NIH has three registered entities. They are located at NIH's campus in Bethesda, Maryland (NIH Bethesda); at Rocky Mountain Laboratories (RML) in Hamilton, Montana; and in the Integrated Research Facility (IRF) in Frederick, Maryland. Each of these campuses is composed of multiple laboratories; within each campus, those laboratories that work with select agents together comprise one registered entity. Each campus also has laboratories that do not work with select agents. The NIH Office of the Director leases the select agent laboratories to the National Institute of Allergy and Infectious Diseases (NIAID). Scientific personnel employed by NIAID perform the research.

The NIH Office of Management, Office of Research Services, Division of Occupational Health and Safety (DOHS) provides centralized laboratory safety services to all institutes within NIH. DOHS centralizes policies, procedures, and protocols among all NIH campuses and creates consistency when possible. The Responsible Officials who administer the occupational safety and health programs and policies to ensure that select agent research is performed safely at NIH Bethesda, RML, and IRF are all DOHS employees.

HOW WE CONDUCTED THIS REVIEW

We examined select agent shipment policies and protocols in place at NIH's three registered entities (NIH Bethesda, RML, and IRF) by reviewing 23 select agent shipments either sent or received by NIH during the 2-year period from October 1, 2013, through September 30, 2015. We also requested documentation of all inactivated select agents shipped and received during the same period. We reviewed NIH policies, training documentation, and select agent transfer transactions and inactivations⁶ for compliance with requirements at 42 CFR part 73 and FSAP guidance. We also evaluated these NIH select agent transfers by reviewing information on all Form 2 documents.

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 objectives.

See Appendix A for the details of our audit scope and methodology and Appendix D for information related to select agent shipments we reviewed as part of our audit.

FINDINGS

Generally, NIH has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting

⁶ An inactivation is defined as a procedure to render a select agent or a regulated nucleic acid non-viable or non-toxic while retaining one or more characteristics of interest for future use.

laboratory guidance and instruction. We found that NIH Bethesda's security plan included certain FSAP notification procedures. However, we found that RML's and IRF's security plans did not include procedures for notifying FSAP if a select agent shipment is not received within 48 hours after the expected delivery time, if a select agent shipment receives damage to the extent that a select agent release may have occurred, or if an authorization for a select agent transfer expires or becomes void before the shipment is completed.

Additionally, we found that NIH Bethesda had not updated its policies and procedures to ensure compliance with new requirements for shipping select agents that have undergone inactivation.

TWO REGISTERED ENTITIES' SECURITY PLANS DID NOT INCLUDE CERTAIN PROCEDURES

Two Entities' Security Plans Did Not Include Procedures for Notifying the Federal Select Agent Program if a Select Agent Shipment Is Not Received Within 48 Hours of the Expected Delivery Time

Federal regulations require that a registered entity should immediately notify FSAP if a select agent shipment is not received within 48 hours after the expected delivery time (42 CFR § 73.16(j)). Additionally, Federal regulations provide that a registered entity must have its own written security plan containing procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, or release of select agents or toxins (42 CFR § 73.11(c)(6)). The security plans must also contain provisions and policies for shipping, receiving, and storing select agents and toxins (42 CFR § 73.11(c)(10)). Security plans must also be tested and evaluated annually (42 CFR § 73.11(h)).

We found that RML's and IRF's security plan procedures for preparing and receiving select agent shipments did not include procedures for notifying FSAP if a select agent shipment is not received within 48 hours after the expected delivery time. Officials at both RML and IRF told us that each facility has a separate policy for lost select agent shipments and therefore does not need to include these procedures in their security plans. However, we found that RML's and IRF's separate policies did not specifically state that the entity should immediately contact FSAP if a shipment is 48 hours beyond the expected time of receipt. Having a separate policy does not negate the need to document procedures in RML's and IRF's security plans. Security plans are required, site-specific, and must be annually tested and evaluated to ensure their effectiveness in safeguarding select agents. Therefore, security plans that describe how, when, and why intended recipients need to notify the Responsible Official should further ensure that FSAP receives timely notification of any theft, loss, or release. Timely reporting to FSAP should help safeguard select agents and ensure that FSAP initiates an investigation to locate the package.

Unlike RML and IRF, NIH Bethesda's security plan included procedures for notifying FSAP if select agent shipments are not received within 48 hours of the expected delivery time. During our review of NIH select agent shipments, we noted that one shipment received by NIH Bethesda was delayed in customs and was not received within 48 hours of the expected

delivery time. The Responsible Official at NIH Bethesda followed security plan procedures and notified FSAP of the reason for the delay. Although the shipment was received 8 days after the expected delivery date, both NIH and FSAP were aware of the circumstances. A lack of 48-hour reporting procedures in RML's and IRF's security plans could result in a missing or stolen select agent package not being reported to FSAP or not being reported to FSAP within 48 hours, which could delay the start of an important investigation to locate the package.

Two Entities' Security Plans Did Not Include Procedures for Notifying the Federal Select Agent Program if a Damaged Select Agent Shipment Is Received

Federal regulations require that a registered entity immediately notify FSAP if a select agent shipment is received that is damaged to the extent that the release of a select agent may have occurred (42 CFR § 73.16(j)). Additionally, Federal regulations state that a registered entity must have its own written security plan containing procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, and release of select agents or toxins (42 CFR § 73.11(c)(6)). The security plan must also contain provisions and policies for shipping, receiving, and storing select agents and toxins (42 CFR § 73.11(c)(10)). Security plans must also be tested and evaluated annually (42 CFR § 73.11(h)).

We found that RML's and IRF's security plan procedures for preparing and receiving select agent shipments did not include procedures for notifying FSAP if a select agent shipment is received that is damaged to the extent that the release of a select agent may have occurred. The RML emergency response plan, which is separate from its security plan, required notifying FSAP if a damaged package is received. IRF told us that if a damaged package is received, its personnel would follow guidance outlined in the Form 2 instructions.

RML's inclusion of procedures for damaged packages in its separate emergency response plan does not negate the need to include these procedures in its security plan. It is not sufficient for registered entities to include these procedures only in policies separate from the security plan because regulations do not require that the separate policies be maintained. As a result, the entity may choose to eliminate such policies. The Form 2 instructions addressing damaged shipments are also not an adequate substitute for including procedures in IRF's security plan. The instructions for the Form 2 are insufficient because they are separate from the actual form, and there is no way to know how frequently recipients actually review the forms. Without security plan procedures addressing damaged select agent shipments, there is an increased potential that either RML or IRF might not report a damaged shipment to FSAP and that this could cause a delay in containing a select agent release.

Two Entities' Security Plans Did Not Include Procedures for Notifying the Federal Select Agent Program if an Authorization for a Select Agent Transfer Expires

Federal regulations state that approval of the transfer of a select agent is valid for 30 days from the date of authorization (42 CFR § 73.16(k)). This means that the transfer of the select agent must be completed before expiration of the 30-day period. Approval of a transfer becomes void should there be a change in any of the conditions upon which the approval was based

(e.g., a change in the certificate of registration for the shipping entity or receiving entity or a change in the application for transfer) (42 CFR § 73.16(k)). FSAP provides each transfer an authorization number that is valid for only one transfer of select agents or toxins during the 30-day period. Federal regulations state that transportation ends when the package is received by an intended recipient approved to have access to select agents and toxins (42 CFR § 73.16(h)). However, CDC officials stated that in practice, shipments that extend beyond 30 days are allowed to be completed if the shipment is initiated before the end of the 30-day period.

Additionally, Federal regulations provide that a registered entity must have its own written security plan containing procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, and release of select agents or toxins (42 CFR § 73.11(c)(6)), as well as provisions and policies for shipping, receiving, and storing select agents and toxins (42 CFR § 73.11(c)(10)).

We found that the security plan procedures for preparing and receiving select agent shipments at RML and IRF did not include procedures for notifying FSAP when a select agent transfer is not completed within 30 calendar days after issuance or when facts supporting the authorization change. Officials at both RML and IRF told us that procedures are not needed because personnel follow guidance outlined in the Form 2 instructions. The instructions state that an entity has 30 calendar days to complete an approved transfer and further state that if the transfer does not occur, the receiving entity's Responsible Official must complete Block 42 of the Form 2 indicating whether the shipment occurred and return the signed and dated Form 2 to FSAP. While the Form 2 instructions address reporting a transfer that is not completed before an authorization expires or becomes void, the instructions are not a substitute for including procedures in RML's and IRF's security plans. As previously stated, the instructions for the Form 2 are insufficient because they are separate from the actual form, and there is no way to know how frequently recipients actually review the forms.

During our review of NIH select agent shipments, we noted two shipments, one received by RML and one received by IRF, that were not completed within 30 days. In both cases, RML and IRF requested and FSAP approved an extension to the authorization because the shipments were already in transit at the end of 30 calendar days. Each shipment was ultimately completed. However, in the case of the IRF shipment, FSAP was not notified and did not give approval to extend the authorization until 2 days after the authorization expired.

RML's and IRF's lack of security plan procedures for reporting a transfer that is not completed before an authorization expires or becomes void could result in RML or IRF not returning the Form 2 notifying FSAP that the transfer never occurred. If an authorization remains open, there is a potential that RML or IRF could receive a shipment of a select agent it has neither recently requested nor coordinated and therefore is not expecting.

NIH BETHESDA HAD NOT IMPLEMENTED A POLICY TO ENSURE COMPLIANCE WITH NEW INACTIVE SELECT AGENT SHIPMENT REQUIREMENTS

During the audit period, NIH Bethesda did not record inactivation of select agents because there were no regulations requiring the laboratories to do so. However, Federal regulations at 42 CFR section 73.17(a)(8), effective March 21, 2017, require additional recordkeeping for nonviable and shipped select agents. The new regulation requires a certificate signed by the principal investigator detailing who inactivated the select agent and how it was inactivated. The certificate must travel with the inactivated select agent when it is transferred. NIH officials at RML and IRF changed their policies to comply with the new recordkeeping requirements. As of July 10, 2017, NIH Bethesda had updated its training but not its policies to include these new requirements and had not inactivated and shipped any select agents since the regulation became effective. However, there is a possibility that if NIH Bethesda does not update its policies to match the new regulations, it may transfer inactivated select agents without the required certificate.

RECOMMENDATIONS

We recommend that NIH update RML's and IRF's security plans to include procedures for notifying FSAP if a select agent:

- shipment is not received within 48 hours of the expected time of delivery,
- package is received that is damaged to the extent that a release of the select agent may have occurred,
- shipment will not be completed within 30 calendar days after transfer authorization issuance, or
- transfer authorization becomes void because the facts supporting the authorization changed.

We also recommend that NIH work with NIH Bethesda to implement a policy to ensure compliance with new requirements for shipping inactive select agents.

NIH COMMENTS

In written comments on our draft report, NIH concurred with our findings and recommendations and stated that it has taken actions to implement our recommendations. NIH indicated that it updated RML's and IRF's security plans to include procedures for notifying FSAP and that NIH Bethesda updated its security plan policy covering transfer authorizations. NIH also provided technical comments on our draft report that we incorporated as appropriate into the final report.

NIH's comments, excluding the technical comments, are included as Appendix E.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered select agent transfer and inactivated select agent transfer transactions that took place at NIH from October 1, 2013, through September 30, 2015. We compared NIH shipping and receiving policies to the select agent requirements at 42 CFR part 73 and related FSAP guidance.

We conducted our review from December 2015 through July 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- discussed the NIH select agent program background with NIH personnel;
- reviewed all NIH policies related to shipping and receiving select agents, select agent training, and select agent inactivations and compared them to Federal regulations;
- reviewed all select agent shipping and receiving transactions and associated documentation and communications;
- requested a list of all inactivated, shipped, and received select agents;
- reviewed validations of methods for inactivating select agents;
- reviewed select agent training policies, content, and attestations stating that personnel understood the required trainings;
- reviewed select agent training documentation, certifications, and test scores for a judgmental sample of NIH personnel involved in select agent shipping, receiving, and inactivation;
- discussed FSAP requirements with CDC personnel; and
- discussed the results of our review with NIH officials.

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 objectives.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Summary Report on State, Local, Private, and Commercial Laboratories' Compliance With Select Agent Regulations</i>	<u>A-04-06-01033</u>	1/9/2008
<i>Summary Report on Universities' Compliance With Select Agent Regulations</i>	<u>A-04-05-02006</u>	6/30/2006
<i>Summary Report on Select Agent Security At Universities</i>	<u>A-04-04-02000</u>	3/25/2004

APPENDIX C: FEDERAL REQUIREMENTS

42 CFR § 73.11, Requirements for Security Plans

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. . . .

(c) The security plan must . . . (10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments . . .

(d) . . . (5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release . . .

(f) In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin⁷ must also: (1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin. . . .

(h) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

42 CFR § 73.15, Training Requirements for People with Access to Select Agents

(a) An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where

⁷ Tier 1 select agents are biological agents and toxins that represent the greatest risk of deliberate misuse; have significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or the public confidence; and pose a severe threat to public health and safety. Entities that possess, use, or transfer Tier 1 select agents must adhere to the additional requirements detailed within the Federal select agent regulations.

a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.

(c) Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.

42 CFR § 73.16(j), Transfers

“The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred.”

42 CFR § 73.16(k), Transfers

“An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (*e.g.*, change in the certificate of registration for the sender or recipient, change in the application for transfer).”

42 CFR § 73.17, Records

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: . . . (8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent: (i) A written description of the

validated inactivation procedure or viable select agent removal method used, including validation data; (ii) A written description of the viability testing protocol used; (iii) A written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken; (iv) The name of each individual performing the validated inactivation or viable select agent removal method; (v) The date(s) the validated inactivation or viable select agent removal method was completed; (vi) The location where the validated inactivation or viable select agent removal method was performed; and (vii) A certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

APPENDIX D: NIH SELECT AGENT TRANSFERS

	Entity	Shipping Entity (S)/ Receiving Entity (R)	Packaged Correctly	Form 2 Properly Signed	Shipment Received Within Expected Time	Transfer Completed Within 30-Days	Employee Training Documents Provided
1	NIH Bethesda/IRF	S/R	Y	Y	Y	Y	Y
2	NIH Bethesda/IRF	S/R	Y	Y	Y	Y	Y
3	IRF	R	Y	Y	Y	Y	Y
4	IRF	R	Y	Y	Y	Y	Y
5	IRF	R	Y	Y	Y	Y	Y
6	IRF	R	Y	Y	Y	Y	Y
7	IRF	R	Y	Y	Y	Y	Y
8	IRF	S	Y	Y	Y	Y	Y
9	IRF	R	Y	Y	Y	N*	Y
10	RML	R	Y	Y	Y	Y	Y
11	RML	S	Y	Y	Y	Y	Y
12	RML	R	Y	Y	Y	N†	Y
13	RML	S	Y	Y	Y	Y	Y
14	RML	S	Y	Y	Y	Y	Y
15	RML	S	Y	Y	Y	Y	Y
16	RML	R	Y	Y	Y	Y	Y
17	RML	S	N/A‡	N/A‡	Y	Y	Y
18	RML	S	Y	Y	Y	Y	Y
19	RML	S	Y	Y	Y	Y	Y
20	NIH Bethesda	R	Y	Y	Y	Y	Y
21	NIH Bethesda	R	Y	Y	Y	Y	Y
22	NIH Bethesda	R	N**	Y	N††	Y	Y
23	NIH Bethesda	R	Y	Y	Y	Y	Y

* This shipment exceeded the 30-day authorization period but was completed. CDC officials indicated that in practice shipments are permitted to be completed when the shipment is initiated before the end of the 30-day period. The first communication NIH had with CDC about this shipment was after the 30-day period expired.

† This shipment exceeded the 30-day authorization period but was completed. CDC officials indicated that in practice shipments are permitted to be completed when the shipment is initiated before the end of the 30-day period. On the day the authorization expired, NIH officials communicated to CDC that this shipment would exceed the authorization.

‡ This was an international shipment overseen by the Department of Commerce. A Form 2 authorization is not used for such transfers. Because no Form 2 was prepared, we could not determine whether RML verified that the select agent was packaged correctly.

** Upon receipt, NIH Bethesda noted that the shipment was not properly packaged because it was labeled incorrectly by the shipping organization.

†† This shipment was received more than 48 hours after the time NIH Bethesda expected to receive it. However, in accordance with Federal requirements, NIH Bethesda notified FSAP of this delay before the end of the 48-hour period.

APPENDIX E: NIH COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: October 24, 2018

TO: Gloria Jarmon, Deputy Inspector General for Audit Services, HHS

FROM: Director, NIH

SUBJECT: NIH Comments on Draft Report, *NIH Generally Complied With Federal Requirements for the Preparation and Receipt of Select Agent Shipments (A-03-15-00354)*

Attached are the National Institutes of Health's comments on the draft Office of Inspector General (OIG) report, *NIH Generally Complied With Federal Requirements for the Preparation and Receipt of Select Agent Shipments (A-03-15-00354)*.

NIH appreciates the review conducted by the OIG and the opportunity to provide clarifications on this draft report. If you have questions or concerns, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

/S/ Lawrence A. Tabak, D.D.S., Ph.D. for

Francis S. Collins, M.D., Ph.D.

Attachments

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL DRAFT REPORT ENTITLED: “THE NATIONAL INSTITUTES OF HEALTH GENERALLY COMPLIED WITH FEDERAL REQUIREMENTS FOR THE PREPARATION AND RECEIPT OF SELECT AGENT SHIPMENTS” (A-03-15-00354)

The National Institutes of Health (NIH) appreciates the review conducted by Office of Inspector General (OIG) and the opportunity to provide clarifications on this draft report. NIH respectfully submits the following general comments.

OIG Recommendation 1:

NIH to update RML’s and IRF’s security plans to include procedures for notifying FSAP if a select agent:

- Shipment is not received within 48 hours of the expected time of delivery;
- Package is received that is damaged to the extent that a release of the select agent may have occurred;
- Shipment will not be completed within 30 calendar days after transfer authorization issuance, or
- Transfer authorization becomes void because the facts supporting the authorization changed.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation. NIH updated the Rocky Mountain Lab (RML) and Integrated Research Facility (IRF)’s security plans to include procedures for notifying the Federal Select Agent Program (FSAP).

NIH considers this recommendation closed.

OIG Recommendation 2:

NIH to work with NIH Bethesda to implement a policy to ensure compliance with new requirements for shipping inactive select agents.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation to implement a policy to ensure compliance with new requirements for shipping inactive select agents. The NIH Bethesda Select Agent Program updated its Physical Security Plan about transfer authorizations.

NIH considers this recommendation closed.