Report in Brief
Date: December 2018
Report No. A-03-15-00354

U.S. DEPARTMENT OF HEALTH & 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

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.

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.