

agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). 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.¹³

(b) Refresher training must be provided annually.

(c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of training, a description of the training provided, and the means used to verify that the employee understood the training.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

EFFECTIVE DATE NOTE: At 77 FR 61081, Oct. 5, 2012, § 121.15 was revised, effective Apr. 3, 2013. For the convenience of the user, the revised text is set forth as follows:

§ 121.15 Training.

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

(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. 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; and

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas 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.

(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.

(d) The responsible official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

§ 121.16 Transfers.

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by APHIS or CDC prior to the transfer.¹²

(b) In addition to any permit required under part 122 of this subchapter, a transfer may be authorized if:

(1) The sender:

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all the requirements of this part;

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred; or

(iii) Is transferring the select agent or toxin from outside of the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from APHIS or CDC provided that, at least 7 calendar days prior to the transfer, the sender reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the Administrator may authorize a transfer

¹³For guidance, see the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories." This document is available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

¹²The requirements of this section do not apply to transfers within a registered entity (i.e., the sender and the recipient are covered by the same certificate of registration).

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of a select agent or toxin not otherwise eligible for transfer under this part under conditions prescribed by the Administrator.

(e) To obtain authorization for a transfer, APHIS/CDC Form 2 must be submitted.

(f) After authorization is provided by APHIS or CDC, the packaging of the select agent(s) and toxin(s) is performed by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins and is in compliance with all applicable laws concerning packaging.

(g) The sender must comply with all applicable laws governing shipping.

(h) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

(i) The recipient must submit a completed APHIS/CDC Form 2 within 2 business days of receipt of a select agent or toxin.

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

(k) 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).

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61081, Oct. 5, 2012]

§ 121.17 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:

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (e.g., strain designation, GenBank Accession number, etc.);

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) Where stored (e.g., building, room, and freezer);

(iv) When moved from storage and by whom and when returned to storage and by whom;

(v) The select agent used and purpose of use;

(vi) Records created under § 121.16 or 42 CFR 73.16 (Transfers);

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient; and

(viii) Records created under § 121.19 or 42 CFR 73.19 (Notification of theft, loss, or release);

(2) An accurate, current accounting of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

(3) An accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) The initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.);

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom;

(v) Where stored (e.g., building, room, and freezer);