

§ 121.16

9 CFR Ch. I (1–1–06 Edition)

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.¹²

(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.

§ 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.¹³

(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.

¹²For 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.

¹³The 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).

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

(g) 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.

(h) 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).

(i) The sender must comply with all applicable laws governing packaging and shipping.

§ 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 nucleic acids, and recombinant organisms) 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: