

and toxins to each individual approved for access under § 73.8 and each unapproved individual working in, or visiting, areas where select agents and toxins are handled or stored. The information and training must meet the requirements of this section and must ensure that all individuals who work in, or visit, the areas understand the hazards of select agents and toxins present in the area.

(b) The entity must provide information and training at the time of an individual's initial assignment to a work area where select agents or toxins are present and prior to assignments involving new exposure situations. The entity must provide refresher training annually.

(c) The Responsible Official must provide appropriate training in safety, containment, and security to all individuals with access to areas where select agents and toxins are handled or stored.

(d) In lieu of initial training for those individuals already involved in handling select agents or toxins, the Responsible Official may certify in writing that the individual has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities.

(e) The entity must ensure that each individual with access to areas where select agents or toxins are handled or stored received and understood the training required by this section unless certified under paragraph (d) of this section. The entity must record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training.

§ 73.14 Transfers.

A select agent or toxin may not be transferred from one entity to another entity within the United States (regardless of whether the transfer is interstate or intrastate), or received by an entity in the United States from an entity outside the United States, unless:

(a) The sender:

(1) Has a certificate of registration that covers the transfer of the particular select agent or toxin to be transferred,

(2) Meets the exemption requirements under § 73.6 (a) for the particular select agent or toxin to be transferred, or

(3) Is transferring the select agent or toxin from outside the United States (and all import requirements are met);

(b) The recipient has a certificate of registration that includes the particular select agent or toxin to be transferred;

(c) Prior to the transfer, the recipient and sender completes CDC Form EA-101, and the recipient submits to the HHS Secretary in accordance with § 73.21 a completed CDC Form EA-101.

(d) CDC has authorized the transfer based on the finding that the recipient has a certificate of registration covering the transfer of the select agent or toxin;

(e) The sender complies with all applicable laws concerning packaging and shipping;

(f) The Responsible Official of the recipient provides a completed paper copy or facsimile transmission of CDC Form EA-101 to the sender and to the HHS Secretary within 2 business days of receipt of the select agent or toxin; and

(g) The recipient immediately reports to the HHS Secretary if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package received containing select agents or toxins has been leaking or was otherwise damaged.

(h) When the select agents or toxins are consumed or destroyed after a transfer, the recipient must within five business days report such fact to the HHS Secretary in accordance with § 73.21 on a CDC Form EA-101.

NOTE TO § 73.14: This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

§ 73.15 Records.

The Responsible Official must maintain complete records relating to the activities covered by this Part. Such records include:

(a) An entity required to register under this part must maintain an up-to-date, accurate list of the individuals approved under § 73.8 for access to select agents and toxins.

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(b) The entity must maintain an accurate, current inventory of each select agent and toxin held. The inventory records must include the following information for each select agent and toxin:

- (1) The name, characteristics, and source data;
- (2) The quantity held on the date of the first inventory (toxins only);
- (3) The quantity acquired, the source, and date of acquisition;
- (4) The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;
- (5) The quantity used and date(s) of the use (toxins only);
- (6) The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);
- (7) The current quantity held (toxins only);
- (8) Any select agent or toxin lost, stolen, or otherwise unaccounted for; and
- (9) A written explanation of any discrepancies.

(c) The entity must maintain the following records:

- (1) For access to the select agents or toxins:
 - (i) The name of each individual who has accessed any select agent or toxin;
 - (ii) The select agent or toxin used;
 - (iii) The date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures;
 - (iv) The quantity removed (toxins only);
 - (v) The date the select agent or toxin was returned to the long-term storage or holdings for stock cultures; and
 - (vi) The quantity returned (toxins only);
- (2) For access to the area where select agents are used or stored:
 - (i) The name of each individual who has accessed the area;
 - (ii) The date and time the individual entered the area;
 - (iii) The date and time the individual left the area; and
 - (iv) For individuals not approved under § 73.8, the individual approved

under § 73.8 who accompanied the unapproved individual into the area.

(d) The entity must implement a system to ensure that all records and databases created under paragraphs (b) and (c) of this section are accurate, and that the authenticity of records may be verified.

(e) The entity must create a record concerning inspections conducted under § 73.10(b).

(f) Safety, security, and emergency response plans.

(g) Training records.

(h) Transfer documents (CDC Form EA-101) and permits.

(i) Safety and security incident reports.

(j) The entity must maintain all records created under this part for three years.

§ 73.16 Inspections.

The HHS Secretary, without prior notification and with or without cause, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

§ 73.17 Notification for theft, loss, or release.

(a) Upon discovery of a theft or loss of a select agent or toxin, an entity required to register under this part must immediately notify the HHS Secretary and State and local law enforcement. The notification must be reported to the HHS Secretary by either telephone, facsimile, or e-mail in accordance with § 73.21.

(b) Thefts or losses must be reported whether the select agent or toxin is subsequently recovered or the responsible parties are identified.

(c) When reporting a theft or loss, the entity must provide the following information:

- (1) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);
- (2) An estimate of the quantity lost or stolen;
- (3) An estimate of the time during which the theft or loss occurred; and
- (4) The location (building, room) from which the theft or loss occurred.