

§ 73.12

non-laboratory functions only when escorted and continually monitored by individuals approved under § 73.8;

(3) Provide for the control of access to containers where select agents and toxins are stored by requiring freezers, refrigerators, cabinets, and other containers where stocks of select agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of approved staff, and by using other monitoring measures as needed, such as video surveillance;

(4) Require the inspection of all packages upon entry to and exit from the area;

(5) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual approved under § 73.8;

(6) Require that each approved individual under 73.8 does not share with any other person, his or her unique means (e.g., keycards or passwords) of accessing the area or select agent or toxin;

(7) Require that each individual approved under § 73.8 report any of the following immediately to the Responsible Official:

(i) Any loss or compromise of their keys, passwords, combinations, etc.;

(ii) Any suspicious persons or activities;

(iii) Any loss or theft of select agents or toxins;

(iv) Any release of select agents or toxins; and

(v) Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.

(e) The entity must separate areas where select agents and toxins are stored or used from the public areas of the buildings.

(f) Upon termination of the use, a select agent or toxin must be

(1) Securely stored in accordance with the requirements of this section;

(2) Transferred to another registered facility in accordance with § 73.14; or

(3) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

§ 73.12 Emergency response.

(a) An entity required to register under this part must develop and implement an emergency response plan that meets the requirements of OSHA Hazardous waste operations and emergency response standard at 29 CFR 1910.120. Nothing in this section is to supersede or preempt the enforcement of the emergency response requirements imposed by the other statute or regulation.

(b) The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies.

(c) The emergency response plan must address the following:

(1) The hazards associated with the use of the select agents and toxins;

(2) Any hazards associated with response actions that could lead to a spread of a select agent or toxin;

(3) Planning and coordination with outside parties;

(4) Personnel roles, lines of authority, training, and communication;

(5) Emergency recognition and prevention;

(6) Safe distances and places of refuge;

(7) Site security and control;

(8) Evacuation routes and procedures;

(9) Decontamination;

(10) Emergency medical treatment and first aid;

(11) Emergency alerting and response procedures;

(12) Critique of response and follow-up;

(13) Personal protective and emergency equipment; and

(14) Special procedures needed to address the hazards of specific agents.

§ 73.13 Training.

(a) An entity required to register under this part and falls outside of the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030(a) must provide information and training on safety and security for working with select agents

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.