

§ 73.17

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 packaging and 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 two business days of receipt of a select agent or toxin.

(j) The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins 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).

(1) A registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of § 73.3(d) must:

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*i.e.*, reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins.

(2) Report to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious

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activity related to a toxin listed in § 73.3(d) of this part.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61115, Oct. 5, 2012; 79 FR 26862, May 12, 2014]

§ 73.17 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 § 73.16 and 9 CFR 121.16 (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 § 73.19 and 9 CFR part 121.19 (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) 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),

(vi) When moved from storage and by whom and when returned to storage and by whom including quantity amount,

(vii) Records created under § 73.16 and 9 CFR part 121.16 (Transfers),

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient,

(ix) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release), and

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom,

(4) A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator,

(5) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry,

(6) Accurate, current records created under § 73.9 and 9 CFR part 121.9 (Responsible Official), § 73.11 and 9 CFR part 121.11 (Security), § 73.12 and 9 CFR part 121.12 (Biosafety), § 73.14 and 9 CFR part 121.14 (Incident response), and § 73.15 and 9 CFR part 121.15 (Training), and

(7) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for three

years and promptly produced upon request.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61115, Oct. 5, 2012]

§ 73.18 Inspections.

(a) Without prior notification, the HHS Secretary, 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.

(b) Prior to issuing a certificate of registration to an individual or entity, the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with this part.

§ 73.19 Notification of theft, loss, or release.

(a) Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported immediately by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information),

(ii) An estimate of the quantity lost or stolen,

(iii) An estimate of the time during which the theft or loss occurred,

(iv) The location (building, room) from which the theft or loss occurred, and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

(b) Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual