this section and must be authorized by CDC or APHIS prior to the transfer.[4]

(b) 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 requirements in 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 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 CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the HHS Secretary may authorize a transfer of a select agent or toxin, not otherwise eligible for transfer under this part under conditions prescribed by the HHS Secretary.

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

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

(g) 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.

(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 concerning packaging and shipping.

[4] This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

§ 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) 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:

(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) 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,

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

(4) 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,

(5) 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

(6) 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.

§ 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 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 or entity must immediately notify CDC or APHIS.

(1) The release of a select agent or toxin must be reported 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