

(b) An entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official.

(c) The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen for diagnosis or verification.

(1) The identification of the select agent or toxin must be immediately reported by telephone, facsimile, or e-mail. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(2) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

§ 331.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (*e.g.*, carries, uses, or manipulates) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) An individual's security risk assessment may be expedited upon written request by the responsible official and a showing of good cause (*e.g.*, agri-

cultural emergencies, national security, or a short-term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(f) An individual's access approval may be denied, limited, or revoked if:

(1) The individual is within any of the categories described in 18 U.S.C. 175b;

(2) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) It is determined that such action is necessary to protect plant health or plant products.

(g) An individual may appeal the Administrator's decision to deny, limit, or revoke access approval under § 331.20.

(h) Access approval is valid for a maximum of 5 years.

(i) The responsible official must immediately notify APHIS or CDC when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

§ 331.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control;

(2) Contain provisions for the control of access to select agents and toxins;

(3) Contain provisions for routine cleaning, maintenance, and repairs;

(4) Establish procedures for removing unauthorized or suspicious persons;

(5) Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes;

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records; and

(7) Contain provisions for ensuring that all individuals with access approval from the Administrator or the HHS Secretary understand and comply with the security procedures.

(d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:

(1) Allow access only to individuals with access approval from the Administrator or the HHS Secretary;

(2) Allow individuals not approved for access by the Administrator or the HHS Secretary to conduct routine cleaning, maintenance, repairs, and other activities not related to select agents or toxins only when continuously escorted by an approved individual;

(3) Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (e.g., card access system, lock boxes);

(4) Inspect all suspicious packages before they are brought into or removed from an area where select agents or toxins are used or stored;

(5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the Administrator or the HHS Secretary, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release; and

(6) Require that individuals with access approval from the Administrator or the HHS Secretary refrain from sharing with any other person their

unique means of accessing a select agent or toxin (e.g., keycards or passwords);

(7) Require that individuals with access approval from the Administrator or the HHS Secretary immediately report any of the following to the responsible official:

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

(ii) Any suspicious persons or activities;

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

(iv) Any release of a select agent or toxin; and

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

(8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) In developing a security plan, an individual or entity should consider the document entitled, "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents," in *Morbidity and Mortality Weekly Report* (December 6, 2002); 51 (No. RR-19):1-6. This document is available on the Internet at <http://www.cdc.gov/mmwr>.

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

§331.12 Biocontainment.

(a) An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use.⁴ The biocontainment plan must contain sufficient information and documentation to describe the containment procedures.

(b) The biocontainment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure

⁴Technical assistance and guidance may be obtained by contacting APHIS.