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 following:

(1) “Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests” (Robert P. Kahn and S.B. Mathur eds., 1999); and


(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.

§ 331.13 Restricted experiments.

(a) An individual or entity may not conduct the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:

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

5For guidance, see the NIH publication, “NIH Guidelines for Research Involving Recombinant DNA Molecules.” This document is available on the Internet at http://Continued
§ 331.14 Incident response.

(a) An individual or entity required to register under this part must develop and implement a written incident response plan. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity’s response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

(c) The incident response plan must also contain the following information:

1. The name and contact information (e.g., home and work) for the individual or entity (e.g., responsible official, alternate responsible official(s), biosafety officer, etc.);

2. The name and contact information for the building owner and/or manager, where applicable;

3. The name and contact information for tenant offices, where applicable;

4. The name and contact information for the physical security official for the building, where applicable;

5. Personnel roles and lines of authority and communication;

6. Planning and coordination with local emergency responders;

7. Procedures to be followed by employees performing rescue or medical duties;

8. Emergency medical treatment and first aid;

9. A list of personal protective and emergency equipment, and their locations;

10. Site security and control;

11. Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge; and

12. Decontamination procedures.

(d) 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.

§ 331.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment and security to each individual with access approval from the Administrator or the HHS Secretary before he/she has such access. In addition, an individual or entity must provide information and training on biocontainment and security to each individual not approved for access by the Administrator or the HHS Secretary.


6 Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

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