

§ 121.12

9 CFR Ch. I (1–1–06 Edition)

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.

§ 121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin,

given its intended use.⁸ The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider the following:

(1) The CDC/NIH publication, “Biosafety in Microbiological and Biomedical Laboratories.” This document may be obtained from the U.S. Government Printing Office. It is also available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR 1910.1200 and 1910.1450.

(3) The “NIH Guidelines for Research Involving Recombinant DNA Molecules.” This document is available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

(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.

§ 121.13 Restricted experiments.⁹

(a) An individual or entity may not conduct a restricted experiment with a VS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the Administrator. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any

⁸Technical assistance and guidance may be obtained by contacting APHIS.

⁹For guidance, see the NIH publication, “NIH Guidelines for Research Involving Recombinant DNA Molecules.” This document is available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.