

Pennsylvania, 75250-7954 or call in the Washington, DC metropolitan area 202-512-1800 or outside that area call toll free 1-866-512-1800. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia. This publication is also available on the CDC Web site at <http://www.cdc.gov>.

(2) The specific requirements for handling toxins found in 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories" and/or 29 CFR 1910.1200, "Hazard Communication," whichever applies and specific provisions for handling toxins found in Appendix I in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories,"

(3) For provisions of the safety plan relating to genetic elements, recombinant nucleic acids and recombinant organisms, the "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). This includes, among other things, provisions regarding risk assessment, physical containment, biological containment, and local review and applies to all recombinant DNA research, regardless of funding. Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia, 30333. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia. The "NIH Guidelines for Research Involving Recombinant DNA Molecules," is also available on the CDC Web site at <http://www.cdc.gov>.

(b) The Responsible Official or his or her designee must conduct regular inspections (at least annually) of the laboratory where select agents and toxins are stored or used to ensure compliance with all of the procedures and protocols of the safety plan. The results of these inspections must be documented, and any deficiencies identified during inspections must be corrected.

(c) An entity may not conduct the following experiments unless approved by the HHS Secretary after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to ac-

quire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

(d) [Reserved]

§ 73.11 Security.

(a) An entity must develop and implement a security plan establishing policy and procedures that ensure the security of areas containing select agents and toxins. The security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach.

(b) The plan must:

(1) Describe inventory control procedures, minimal education and experience criteria for those individuals with access to select agents or toxins, physical security, and cyber security;

(2) Contain provisions for routine cleaning, maintenance, and repairs; provisions for training personnel in security procedures; provisions for securing the area (*e.g.*, card access, key pads, locks) and protocols for changing access numbers or locks following staff changes;

(3) Describe procedures for loss or compromise of keys, passwords, combinations, etc.;

(4) Contain procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records;

(5) Contain provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons;

(6) Contain provisions for ensuring that all individuals with access, including workers and visitors, understand security requirements and are trained and equipped to follow established procedures;

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(7) Establish procedures for reporting and removing unauthorized persons; and

(8) Establish procedures for securing the area when individuals approved under § 73.8 are not present (e.g., card access system, key pads, locks), including protocols for changing access numbers or locks following staff changes.

(c) The security plan must be reviewed by the RO at least annually and after any incident.

(d) With respect to areas containing select agents and toxins, the entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(1) Allow unescorted access only to individuals who have been approved under § 73.8 and who are performing a specifically authorized function during hours required to perform the defined job (including delivery to an outside shipping agent for transportation in commerce);

(2) Allow individuals not approved under § 73.8 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by individuals approved under § 73.8;

(3) Provide for the control of access to containers where select agents and toxins are stored by requiring freezers, refrigerators, cabinets, and other containers where stocks of select agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of approved staff, and by using other monitoring measures as needed, such as video surveillance;

(4) Require the inspection of all packages upon entry to and exit from the area;

(5) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual approved under § 73.8;

(6) Require that each approved individual under § 73.8 does not share with any other person, his or her unique means (e.g., keycards or passwords) of

accessing the area or select agent or toxin;

(7) Require that each individual approved under § 73.8 report any of the following immediately to the Responsible Official:

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

(ii) Any suspicious persons or activities;

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

(iv) Any release of select agents or toxins; and

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

(e) The entity must separate areas where select agents and toxins are stored or used from the public areas of the buildings.

(f) Upon termination of the use, a select agent or toxin must be

(1) Securely stored in accordance with the requirements of this section;

(2) Transferred to another registered facility in accordance with § 73.14; or

(3) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

§ 73.12 Emergency response.

(a) An entity required to register under this part must develop and implement an emergency response plan that meets the requirements of OSHA Hazardous waste operations and emergency response standard at 29 CFR 1910.120. Nothing in this section is to supersede or preempt the enforcement of the emergency response requirements imposed by the other statute or regulation.

(b) The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies.

(c) The emergency response plan must address the following:

(1) The hazards associated with the use of the select agents and toxins;

(2) Any hazards associated with response actions that could lead to a spread of a select agent or toxin;