

§ 73.9

Secretary's review process for an individual upon a showing of good cause (e.g., public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher). To apply for an expedited review, an entity must submit a request in writing in accordance with § 73.21 to the HHS Secretary establishing the need for such action. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

§ 73.9 Responsible Official.

(a) As a condition of conducting activities regulated under this part, an entity must identify and authorize an individual as the Responsible Official. The Responsible Official may identify one or more individuals, any of whom may serve as the Alternate Responsible Official when the Responsible Official is unavailable. The Responsible Official and all individuals identified to serve as the Alternate Responsible Official must meet all of the qualifications for a Responsible Official. The Responsible Official and all Alternate Responsible Officials must:

- (1) Be approved under § 73.8;
 - (2) Be familiar with the requirements of this part; and
 - (3) Have authority and responsibility to ensure that the requirements of this part are met, on behalf of the entity.
- (b) For purposes of this part, the Alternate Responsible Official acting in the absence of the Responsible Official may conduct all of those activities required under this part to be performed by the Responsible Official.

(c) The Responsible Official is responsible for ensuring compliance with the regulations, including:

- (1) Developing and implementing safety, security and emergency response plans in accordance with § 73.10—§ 73.12;
- (2) Allowing only approved individuals to have access to select agents or toxins in accordance with § 73.8 and § 73.11;
- (3) Providing appropriate training for safety, security and emergency response in accordance with § 73.13;
- (4) Transferring select agents or toxins in accordance with § 73.14;

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(5) Providing timely notice of any theft, loss, or release of a select agent or toxin in accordance with § 73.13;

(6) Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins in accordance with § 73.15.

(7) The reporting of the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing in accordance with § 73.6.

§ 73.10 Safety.

(a) An entity subject to the provisions of this part, must develop and implement a safety plan. In developing a safety plan, an entity should consider:

(1) The biosafety standards and requirements for BSL 2, 3, or 4 operations, as they pertain to the respective select agents, that are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," including all appendices except Appendix F. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, 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 acquire 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;

(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