

Public Health Service, HHS

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.

§ 73.12 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 agent or toxin, given its intended use. 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:

(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories", including all appendices. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250-7954 or from the CDC Web site at <http://www.cdc.gov/>. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.

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

(3) The "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia, 30333 or from the CDC Web site at <http://www.cdc.gov/>. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.

(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

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reviewed and revised, as necessary, after any drill or exercise and after any incident.

§ 73.13 Restricted experiments.

(a) An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. 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 conditions prescribed by the HHS Secretary, after consultation with Administrator.

(b) Restricted experiments:

(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.

(c) The HHS Secretary may revoke approval to conduct any of the experiments in paragraph (b) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(d) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.