

§ 331.13

7 CFR Ch. III (1–1–13 Edition)

toxin, given its intended use.⁴ The biocontainment plan must contain sufficient information and documentation to describe the containment procedures.

(b) The biocontainment 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 biocontainment 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

(2) “A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes” (Patricia L. Traynor ed., 2001).

(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.

EFFECTIVE DATE NOTE: At 77 FR 61076, Oct. 5, 2012, § 331.12 was amended by revising paragraph (a), redesignating paragraph (d) as paragraph (e); and by adding reserved paragraph (d), effective Apr. 3, 2013. For the convenience of the user, the revised text is set forth as follows:

§ 331.12 Biocontainment.

(a) An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use.⁴ The biocontainment plan must contain sufficient information and documentation to describe the containment procedures for the select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

§ 331.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accord-

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ance with the conditions prescribed by the Administrator:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

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

(b) The Administrator may revoke approval to conduct any of the experiments in paragraph (a) 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.

(c) 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 to the Administrator. A written decision granting or denying the request will be issued.

[70 FR 13278, Mar. 18, 2005, as amended at 77 FR 61076, Oct. 5, 2012]

§ 331.14 Incident response.⁶

(a) An individual or entity required to register under this part must develop and implement a written incident response plan.⁷ 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

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

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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.

EFFECTIVE DATE NOTE: At 77 FR 61076, Oct. 5, 2012, §331.14 was amended in the section heading, by redesignating footnote 6 as footnote 5, revising the first sentence in paragraph (a), redesignating footnote 7 as footnote 6, revising paragraph (b), redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively; and adding new paragraphs (c) and reserved (e), effective Apr. 3, 2013. For the convenience of the user, the added and revised text is set forth as follows:

§ 331.14 Incident response.⁵

(a) An individual or entity required to register under this part must develop and implement a written incident response plan⁶ based upon a site specific risk assessment. * * *

(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, and other natural and man-made events.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

§ 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 before he/she works in or visits areas where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.

(b) Refresher training must be provided annually.

(c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of training, a description of the training provided, and the means used to verify that the employee understood the training.

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