

or toxin, given its intended use.⁹ The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

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(c) * * *

(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories." This document is available on the National Select Agent Registry at <http://www.selectagents.gov/>.

(2) * * * This document is available on the National Select Agent Registry at <http://www.selectagents.gov/>.

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(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

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§ 121.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products (*i.e.*, select agents that are not known to acquire a drug resistance trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:

(b) *Restricted experiments:* (1) Experiments that involve the deliberate transfer of, or selection for, a drug 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 recom-

binant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50]<100 ng/kg body weight.

(c) The Administrator 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 (b) 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.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61080, Oct. 5, 2012]

§ 121.14 Incident response.¹¹

(a) An individual or entity required to register under this part must develop and implement a written incident response plan.¹² 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 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:

¹¹Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

¹²Technical assistance and guidance may be obtained by contacting APHIS.

⁹Technical assistance and guidance may be obtained by contacting APHIS.

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- (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.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

EFFECTIVE DATE NOTE: At 77 FR 61080, Oct. 5, 2012, §121.14 was amended in the section heading by redesignating footnote 11 as footnote 10; in paragraph (a), by redesignating footnote 12 as footnote 11 and revising the first sentence of the paragraph; by revising paragraph (b); by redesignating paragraphs (c) and (d) as paragraphs (d) and (f), respectively; and by adding new paragraphs (c) and (e), effective Apr. 3, 2013. For the convenience of the user, the added and revised text is set forth as follows:

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§ 121.14 Incident response.¹⁰

- (a) An individual or entity required to register under this part must develop and implement a written incident response plan¹¹ 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.

* * * * *

- (e) Entities with Tier 1 select agents and toxins must have the following additional incident response policies or procedures:
 - (1) The incident response plan must fully describe the entity’s response procedures for failure of intrusion detection or alarm system; and
 - (2) The incident response plan must describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins.

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§ 121.15 Training.

- (a) An individual or entity required to register under this part must provide information and training on biosafety 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 biosafety 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

¹⁰Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

¹¹Technical assistance and guidance may be obtained by contacting APHIS.