

after any drill or exercise and after any incident.

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

§ 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 recombinant 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.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. 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, 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.

(d) 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;

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.

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(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.

(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.

(f) 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; 77 FR 61080, Oct. 5, 2012]

§ 121.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. 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; and

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator

before that individual enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.

(c) Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.

(d) The responsible official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

[77 FR 61081, Oct. 5, 2012]

§ 121.16 Transfers.

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by APHIS or CDC prior to the transfer.¹²

(b) In addition to any permit required under part 122 of this subchapter, a transfer may be authorized if:

(1) The sender:

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all the requirements of this part;

¹²The requirements of this section do not apply to transfers within a registered entity (*i.e.*, the sender and the recipient are covered by the same certificate of registration).