

§ 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. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review. The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

(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;

⁵Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

⁶Technical assistance and guidance may be obtained by contacting APHIS.

(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.

(e) [Reserved]

(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. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13278, Mar. 18, 2005, as amended at 77 FR 61076, Oct. 5, 2012; 82 FR 6206, Jan. 19, 2017]

§ 331.15 Training.

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

(1) Each individual with access approval from the Administrator or HHS Secretary. 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. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the Administrator or the HHS Secretary for access, whichever is earlier.

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

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under escort 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. The training must be accomplished prior to the individual's entry into 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.).

(b) [Reserved]

(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 biocontainment 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.

(e) The responsible official must ensure and document that individuals are provided the contact information of the USDA Office of Inspector General Hotline and the HHS Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

[77 FR 61076, Oct. 5, 2012, as amended at 82 FR 6206, Jan. 19, 2017]

§ 331.16 Transfers.

(a) Except as provided in paragraph (c) of this section, a select agent or toxin may only be transferred to an individual or entity 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.⁷

(b) 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;

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred; or

(iii) Is transferring the select agent or toxin from outside of the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) On a case-by-case basis, the Administrator may authorize a transfer of a select agent or toxin not otherwise eligible for transfer under this part under conditions prescribed by the Administrator.

(d) To obtain authorization for a transfer, APHIS/CDC Form 2 must be submitted.

(e) After authorization is provided by APHIS or CDC, the packaging of the select agent(s) and toxin(s) is performed by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins and is in compliance with all applicable laws concerning packaging.

(f) The sender must comply with all applicable laws governing shipping.

(g) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

(h) The recipient must submit a completed APHIS/CDC Form 2 within 2

⁷The 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).