

(5) Any sign that inventory and use records for listed agents and toxins have been altered or otherwise compromised.

(3) *Incident response procedures.*¹⁴ The Biosafety and Security Plan must also include incident response plans for containment breach, security breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. The incident response plans must address personnel safety and health, containment, inventory control, and notification of managers and responders. The incident response plans must also address such events as bomb threats, severe weather (floods, hurricanes, tornadoes), earthquakes, power outages, and other natural disasters or emergencies.

(b) The Biosafety and Security Plan must be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident.

§ 121.13 Training.

(a) The responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to agents and toxins listed in § 121.3.

(b) The responsible official must provide information and training to an individual at the time the individual is assigned to work with a listed agent or toxin. The responsible official must provide refresher training annually.

§ 121.14 Transfer of biological agents and toxins.

Biological agents and toxins listed in § 121.3 may only be transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin. However, the sender of an agent or toxin may be an individual or entity that has a certificate of registration for the agent or toxin, an individual or entity that is exempt from the requirements of this part, or an individual or entity located outside of the United States. Biological agents or toxins may only be transferred under

the conditions of this section and must be authorized by APHIS or, for overlap agents or toxins, by APHIS or CDC, prior to the transfer.

(a) *Importation and interstate movement.* In addition to the permit required under part 122 of this subchapter, biological agents or toxins listed in § 121.3 may be imported or moved interstate only with the prior authorization of APHIS or, for overlap agents or toxins, APHIS or CDC. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with paragraph (c) of this section.

(b) *Intrastate movement.* Biological agents or toxins listed in § 121.3 may be moved intrastate only with the prior authorization of APHIS or, for overlap agents or toxins, APHIS or CDC. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with paragraph (c) of this section.

(c) *APHIS Form 2041; process and procedures.* (1) Prior to each transfer, the responsible official for the recipient and sender must complete APHIS Form 2041, and the sender must submit the form to APHIS or, for overlap agents or toxins, to APHIS or CDC.¹⁵

(2) APHIS or CDC will authorize the transfer based on a finding that the recipient has a certificate of registration covering the transfer of the listed agent or toxin.

(3) The responsible official for the recipient must notify the agency authorizing the transfer (either APHIS or CDC) and the sender upon receipt of the agent or toxin by mailing or faxing

¹⁵ APHIS Form 2041 may be obtained by calling APHIS at (301) 734-3277 or by calling CDC at (404) 498-2265. The form is also available on the Internet at <http://www.aphis.usda.gov/vs/ncie.bta.html> or <http://www.cdc.gov/od/ohs/lrsat.htm>. APHIS Form 2041 may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652. For overlap agents and toxins, it may be mailed to the above address or to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333; or faxed to (404) 498-2265.

¹⁴ The requirements in this paragraph do not supercede or preempt the enforcement of emergency response requirements imposed by other statutes or regulations.

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a completed APHIS Form 2041 to APHIS or CDC within 2 business days.

(4) The responsible official for the recipient must notify APHIS or CDC immediately if the agent or toxin has not been received within 48 hours after the expected delivery or if the package containing the agent or toxin is leaking or has been damaged.

(d) The sender must comply with all applicable laws governing packaging and shipping.

§ 121.15 Records.

(a) The responsible official must maintain complete, up-to-date records of information necessary to give an accounting of all of the activities related to agents or toxins listed in §121.3. Such records must include the following:

- (1) The Biosafety and Security Plan;
- (2) A current list of all individuals with access to agents or toxins listed in §121.3;
- (3) Training records for individuals with access to such agents or toxins;
- (4) Accurate and current inventory records (including source and characterization data);
- (5) Permits and transfer documents (APHIS Form 2041) issued by APHIS and CDC;
- (6) Security records (e.g., transactions from automated access control systems, testing and maintenance of security systems, visitor logs);
- (7) Biosafety, containment, and security incident reports.

(b) The responsible official must maintain such records for 3 years.

(c) All records must be produced upon request to APHIS or CDC inspectors, and appropriate Federal, State, or local law enforcement authorities.

§ 121.16 Inspections.

(a) To ensure compliance with the regulations, any APHIS or CDC inspector must be allowed, without previous notification, to enter and inspect the entire premises, all materials and equipment, and all records required to be maintained by this part.

(b) Prior to issuing a certificate of registration to an entity or individual, APHIS or CDC may inspect and evaluate the premises and records to ensure compliance with the regulations and

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the biosafety, containment, and security requirements.

§ 121.17 Notification in the event of theft, loss, or release of a biological agent or toxin.

(a) The responsible official must orally notify APHIS and appropriate Federal, State, or local law enforcement agencies immediately upon discovery of the theft or loss of agents or toxins listed in §121.3. The oral notification must be followed by a written report (APHIS Form 2043) within 7 days.

(b) The responsible official must orally notify APHIS immediately upon discovery that a release of an agent or toxin has occurred outside of the biocontainment area. The oral notification shall be followed by a written report (APHIS Form 2043) within 7 days. Upon notification and a finding that the release poses a threat to animal or plant health, or animal or plant products, APHIS will notify relevant Federal, State, and local authorities, and the public, if necessary. If the release involves an overlap agent or toxin, APHIS will also notify the Secretary of Health and Human Services.

(c) The responsible official must orally notify APHIS of a theft, loss, or release of an agent or toxin by calling (866) 994-5698. A copy of APHIS Form 2043 may be obtained by writing to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or by calling (301) 734-3277. The form is also available on the Internet at <http://www.aphis.usda.gov/vs/ncie.bta.html>. APHIS Form 2043 may be mailed to the same address or faxed to (301) 734-3652.

§ 121.18 Administrative review.

An individual or entity may appeal a denial or revocation of registration under this part. An individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins under this part may appeal that decision.¹⁶ The appeal must be in writing and submitted to the Administrator

¹⁶An entity may not appeal the denial or limitation of an individual's access to listed agents or toxins.