

APHIS will grant, limit, or deny access of individuals to listed agents or toxins.

(b) The responsible official is responsible for ensuring that only approved individuals within the entity have access to any agents or toxins listed in §331.3. The responsible official must request such access for only those individuals who have a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins.

(c) The responsible official must provide appropriate training in containment and security procedures to all individuals with access to agents and toxins listed in §331.3, in accordance with §331.12.

(d) For each individual identified by the responsible official as having a legitimate need to handle or use listed agents or toxins, the responsible official must submit that individual's name and identifying information to APHIS and the Attorney General.

(e) In addition, the responsible official must submit information about the individual's training and skills to APHIS (*e.g.*, curriculum vitae for principal investigators and researchers, and a description of training completed by support personnel).

(f) APHIS may expedite the access approval process for individuals upon request by the responsible official and a showing of good cause (*e.g.*, agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher).

(g) APHIS will notify the responsible official if an individual is granted full or limited access, or denied access to listed agents or toxins. APHIS will also notify the individual if he/she is denied access or granted only limited access.

(h) APHIS may deny or limit access of an individual to listed agents or toxins if:

(1) The Attorney General identifies the individual as within any of the categories described in 18 U.S.C. 175b;

(2) The Attorney General identifies the individual as reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5);

knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801;

(3) The individual does not have a legitimate need to handle listed agents or toxins;

(4) The individual does not have the necessary training or skills to handle listed agents or toxins;

(5) The Administrator determines that such action is necessary to protect plant health or plant products.

(i) An individual may appeal the Administrator's decision to deny or limit access under §331.15.

(j) Access approval is valid for 5 years; thereafter, the responsible official shall request renewal of access approval every 5 years for as long as the individual needs access to agents or toxins listed in §331.3.

(k) The responsible official must immediately notify APHIS when an individual's access to listed agents or toxins is terminated by the entity and the reasons therefor.

#### §331.11 Biocontainment and security plan.

(a) As a condition of registration, an individual or entity must develop and implement a Biocontainment and Security Plan.<sup>8</sup> The Biocontainment and Security Plan must contain sufficient information and documentation to describe the containment procedures and the security systems and procedures. The plan must be commensurate with the risk of the agent or toxin, given its intended use.

(1) *Containment procedures.* The containment procedures must be sufficient to contain the agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards). At a minimum, the plan must address containment and inventory control.

<sup>8</sup>Technical assistance and guidance may be obtained by calling (301) 734-5519.

(2) *Security systems and procedures.*<sup>9</sup> The security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin.

(i) The site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified.

(ii) The security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs, and must mitigate the risks identified under paragraph (a)(2)(i) of this section.

(iii) The plan must describe inventory control procedures, personnel suitability for those individuals with access to agents or toxins listed in § 331.3, physical security, and cybersecurity. The plan must also contain provisions for securing the area (*e.g.*, card access, key pads, locks) and protocols for changing access numbers or locks following staff changes; procedures for loss or compromise of keys, passwords, combinations, etc.; procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records; provisions for the control of access to containers where listed agents and toxins are stored; provisions for routine cleaning, maintenance, and repairs; and procedures for reporting and removing unauthorized persons.

<sup>9</sup>For guidance, see the USDA Departmental Manual No. 9610-001, "USDA Security Policies and Procedures for Biosafety Level-3 Facilities" (August 30, 2002). The manual may be obtained by calling (301) 734-5519. The manual is also available on the Internet at <http://www.usda.gov/ocio/directives/DM/DM9610-001.htm>. See also Appendix F, "Biosafety in Microbiological and Biomedical Laboratories," in *Morbidity and Mortality Weekly Report* (2002). This document may be obtained by writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at <http://www.cdc.gov/mmwr>.

(iv) With respect to areas containing listed agents or toxins, an entity or individual must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(A) Allow unescorted access only to approved individuals who are performing a specifically authorized function during hours required to perform that job;

(B) Allow individuals not approved under § 331.10 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by approved individuals;

(C) Provide for the control of access to containers where listed agents and toxins are stored by requiring that such containers be locked when not in the direct view of an approved individual and by using other monitoring measures, as needed;

(D) Require the inspection of all packages upon entry and exit;

(E) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging and movement, is conducted under the supervision of an approved individual;

(F) Require that approved individuals do not share with any other person their unique means of accessing the area or listed agents or toxins; and

(G) Require that approved individuals immediately report any of the following to the responsible official:

(1) Any loss or compromise of keys, passwords, combinations, etc.;

(2) Any suspicious persons or activities;

(3) Any loss or theft of listed agents or toxins;

(4) Any release of a listed agent or toxin; and

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

(3) *Incident response procedures.*<sup>10</sup> The Biocontainment and Security Plan must also include incident response plans for containment breach, security

<sup>10</sup>The requirements in this paragraph do not supercede or preempt the enforcement of emergency response requirements imposed by other statutes or regulations.

breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. The incident response plans must address 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 Biocontainment and Security Plan must be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident.

#### § 331.12 Training.

(a) The responsible official must provide appropriate training in containment and security procedures to all individuals with access to agents and toxins listed in § 331.3.

(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.

#### § 331.13 Transfer of biological agents and toxins.

Biological agents and toxins listed in § 331.3 may only be transferred to an individual or entity 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 prior to the transfer.

(a) *Importation and interstate movement.* In addition to the permit required under part 330 of this chapter, biological agents or toxins listed in § 331.3 may be imported or moved interstate only with the prior authorization of APHIS. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to

APHIS, in accordance with paragraph (c) of this section.

(b) *Intrastate movement.* Biological agents or toxins listed in § 331.3 may be moved intrastate only with the prior authorization of APHIS. To obtain authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS prior to each transfer, in accordance with paragraph (c) of this section.

(c) *APHIS Form 2041; process and procedures.* (1) Prior to each transfer, the sender and the responsible official for the recipient must complete APHIS Form 2041, and the sender must submit the form to APHIS.<sup>11</sup>

(2) APHIS 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 entity must notify APHIS and the sender upon receipt of the agent or toxin by mailing or faxing a completed APHIS Form 2041 within 2 business days.

(4) The responsible official for the recipient must notify APHIS 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.

#### § 331.14 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 § 331.3. Such records must include the following:

(1) The Biocontainment and Security Plan;

<sup>11</sup> APHIS Form 2041 may be obtained by calling (301) 734-5519 or faxing a request to (301) 734-8700. The form is also available on the Internet at <http://www.aphis.usda.gov/ppq/permits>. APHIS Form 2041 may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700.