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or transfer agents or toxins listed in § 331.3; or

(4) The responsible official is an individual who handles or uses listed agents or toxins and he/she does not have the necessary training or skills to handle such agents or toxins; or

(5) The entity does not meet the containment and security requirements prescribed by the Administrator;[6] or

(6) There are egregious or repeated violations of the containment or security requirements; or

(7) The Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

(b) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraph (a) of this section.

(c) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(d) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 331.16.

§ 331.8 Registration; how to register.

(a) To apply for a certificate of registration, an individual or entity must submit all of the information and documentation required in the registration application package to APHIS, including the name, source, and characterization data for each agent or toxin to be registered.

(b) The registration application package may be obtained by calling (301) 734–5519 or faxing a request to (301) 734–8700. It is also available on the Internet at *http://www.aphis.usda.gov/ppq/permits.* The completed registration application package may be mailed to APHIS, Plant Protection and Quarantine, Biological and Technical Services, 4700 River Road Unit 133, Riverdale, MD 20737–1236; or faxed to (301) 734–8700. Assistance in completing the registration application may be requested by calling (301) 734–5519.

[6] If registration is denied for this reason, we may provide technical assistance and guidance.

§ 331.9 Responsibilities of the responsible official.

(a) The responsible official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing a Biocontainment and Security Plan in accordance with § 331.11;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 331.3 in accordance with § 331.10;

(3) Providing appropriate training in containment and security procedures for all personnel in accordance with § 331.12;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 331.13;

(5) Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;

(6) Notifying APHIS of changes in circumstances in accordance with § 331.6;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 331.16;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities related to agents or toxins listed in § 331.3 in accordance with § 331.14.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entity possessing, using, or transferring agents or toxins listed in § 331.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.[7] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

§ 331.10 Restricting access to biological agents and toxins.

(a) An individual may not have access to biological agents or toxins listed in § 331.3 unless approved by APHIS.

[7] A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734–5519.