

§ 121.9

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for each select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 121.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

§ 121.9 Responsible official.

(a) An individual or entity required to register under this part must designate an individual to be the responsible official. The responsible official must:

(1) Be approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General;

(2) Be familiar with the requirements of this part;

(3) Have authority and responsibility to act on behalf of the entity;

(4) Ensure compliance with the requirements of this part;

(5) Have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan; and

(6) Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

(b) An entity may designate one or more individuals to serve as an alternate responsible official who acts for the responsible official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official.

(c) The responsible official must report the identification and final disposition of any select agent or toxin

contained in a specimen presented for diagnosis or verification.

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or email: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), *Bacillus anthracis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, classical swine fever virus, foot-and-mouth disease virus, virulent Newcastle disease virus, rinderpest virus, and swine vesicular disease virus. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(2) To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(3) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(d) The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61332, Oct. 16, 2008; 77 FR 61078, Oct. 5, 2012]

§ 121.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the