(c) Denial of an application for registration and revocation of registration may be appealed under § 73.20. 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.

§ 73.9 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 HHS Secretary or Administrator 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, and

(5) 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 be an alternate Responsible Official, who may act 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 e-mail: *Bacillus anthracis*, Botulinum neurotoxins, *Brucella melitensis*, *Francisella tularensis*, Ebola viruses, Hendra virus, Marburg virus, Lassa fever virus, Nipah virus, Rift Valley fever virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), Venezuelan equine encephalitis virus, or *Yersinia pestis*. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification. A copy of the completed form must be maintained for three years.

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

(3) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(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 three years.

§ 73.10 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 HHS Secretary or Administrator, 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 individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security