(v) All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;
(vi) Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;
(vii) For powered access control systems, describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered space;
(viii) The entity must:
(A) Determine that the response time for security forces or local police will not exceed 15 minutes where the response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier or;
(B) Provide security barriers that are sufficient to delay unauthorized access until the response force arrives in order to safeguard the select agents and toxins from theft, intentional release, or unauthorized access. The response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier;
(5) Entities that possess foot-and-mouth disease virus and rinderpest virus must have the following additional security requirements:
(i) A minimum of four barriers, one of which must be a perimeter security fence or equivalent which is monitored 24 hours a day, 7 days a week (24/7) to detect the presence of unauthorized persons, vehicles, materials, or unauthorized activities;
(ii) Onsite 24/7 armed security response force with roving patrol. Response time must not exceed 5 minutes from the time of an intrusion alarm or report of a security incident;
(iii) CCTV surveillance with 24/7 monitoring and recording;
(iv) Transport vehicle with GPS tracking designed to serve as a containment vehicle.
(g) In developing a security plan, an individual or entity should consider the documentation to describe the biosafety and containment procedures. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.
(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).
(c) In developing a biosafety plan, an individual or entity should consider the following:
(1) The CDC/NIH publication, “Biosafety in Microbiological and Biomedical Laboratories.” This document may be obtained from the U.S. Government Printing Office. It is also available on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.
(d) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.
(70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008)

EFFECTIVE DATE NOTE: At 77 FR 61080, Oct. 5, 2012, §121.12 was amended by revising paragraphs (a) and (c)(1); adding a second sentence to paragraph (c)(2); in paragraph (c)(3), by removing the address “http://www.aphis.usda.gov/programs/ag_selectagent/index.html” and adding in its place “http://www.selectagents.gov/’’; by redesignating paragraph (d) as paragraph (e); and by adding a new paragraph (d), effective Apr. 3, 2013. For the convenience of the user, the added and revised text is set forth as follows:

§121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider the following:


§121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent.
or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

§ 121.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products (i.e., select agents that are not known to acquire a drug resistance trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50]<100 ng/kg body weight) resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:

(b) Restricted experiments: (1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50]<100 ng/kg body weight.

(c) The Administrator may revoke approval to conduct any of the experiments in paragraph (b) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(d) To apply for approval to conduct any of the experiments in paragraph (b) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

§ 121.14 Incident response.

(a) An individual or entity required to register under this part must develop and implement a written incident response plan. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity’s response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

(c) The incident response plan must also contain the following information:

9 Technical assistance and guidance may be obtained by contacting APHIS.

11 Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

12 Technical assistance and guidance may be obtained by contacting APHIS.