(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; and

(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 document entitled, "Security Guidance for Select Agent or Toxin Facilities." This document is available on the Internet at http://www.selectagents.gov/.

(h) 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.

§ 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.

(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 is available on the National Select Agent Registry at http://www.selectagents.gov/.

(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR 1910.1200 and 1910.1450. This document is available on the National Select Agent Registry at http://www.selectagents.gov/.

(3) The “NIH Guidelines for Research Involving Recombinant DNA Molecules.” This document is available on the Internet at http://www.selectagents.gov/.

(d) 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.

(e) 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.


§ 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.10
(a) An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment. 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, and other natural and man-made events.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

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

(1) The name and contact information (e.g., home and work) for the individual or entity (e.g., responsible official, alternate responsible official(s), biosafety officer, etc.);

(2) The name and contact information for the building owner and/or manager, where applicable;

(3) The name and contact information for tenant offices, where applicable;

(4) The name and contact information for the physical security official for the building, where applicable;

(5) Personnel roles and lines of authority and communication;

(6) Planning and coordination with local emergency responders;

10Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

11Technical assistance and guidance may be obtained by contacting APHIS.