

conditions prescribed by the Administrator and the HHS Secretary.

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

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD₅₀ <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.¹¹ 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 ap-

propriate actions to contain such agent or toxin.

(c) 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;

(7) Procedures to be followed by employees performing rescue or medical duties;

(8) Emergency medical treatment and first aid;

(9) A list of personal protective and emergency equipment, and their locations;

(10) Site security and control;

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge; and

(12) Decontamination procedures.

(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.

§ 121.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the Administrator or the HHS Secretary before he/she has such access. In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access by the Administrator or the HHS Secretary before he/she works in or visits areas where select

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.