§ 73.12 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 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).

§ 73.13 Restricted experiments.

(a) An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator.

(b) Restricted experiments:

(1) Experiments utilizing recombinant DNA that involve the deliberate
§ 73.14 Incident response.

(a) An individual or entity required to register under this part must develop and implement a written incident response plan. 2 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, 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 and toxin and appropriate actions to contain such select 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.

§ 73.15 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 HHS Secretary or Administrator before he/she has such access. 3 In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select

2Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

3The training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard set forth at 29 CFR 1910.1030.