

(ii) High concentrations or large volumes of etiologic agents are used.

(8) Laboratory coats, gowns, smocks, or uniforms will be removed before leaving the animal facility or laboratory area.

(b) Additional animal requirements.

(1) Cages must be decontaminated, preferably by autoclaving, before they are cleaned and washed.

(2) Approved molded masks are worn by all personnel entering animal rooms housing nonhuman primates.

(3) If floor drains are provided, the drain traps will be kept filled with water or a suitable disinfectant.

§ 627.15 Biosafety level 3.

(a) *Additional requirements.* In addition to the requirements stated in §§ 627.13 and 627.14, the following requirements apply—

(1) Approved molded masks or respirators with HEPA filters are worn by all personnel in rooms housing infected animals.

(2) Protective clothing worn in a laboratory or animal room will be removed before exiting the laboratory or animal room.

(3) Clothing worn in laboratories and animal areas to protect street clothing will be decontaminated before being laundered.

(b) *Additional laboratory requirements.*

(1) Laboratory doors will be kept closed.

(2) All activities involving etiologic agents will be conducted in biological safety cabinets (Class I, II, or III) or other physical containment devices within the containment module. No work in open vessels is conducted outside a biological safety cabinet.

(3) The work surfaces of biological safety cabinets and other containment equipment will be decontaminated after work with etiologic agents. Plastic-backed paper toweling should be used on nonperforated work surfaces within biological safety cabinets to facilitate clean-up.

(c) *Additional animal requirements.* (1) Cages are autoclaved before bedding is removed and before they are cleaned and washed.

(2) Gloves are removed aseptically and autoclaved with other wastes before being disposed of or reused.

(3) Boots, shoe covers, or other protective footwear and disinfectant foot baths must be available and used when indicated.

(4) Personal protective clothing and equipment and other physical containment devices are used for all procedures and manipulations of etiologic agents or infected animals. The risk of infectious aerosols from infected animals or their bedding shall be reduced by housing animals in partial containment caging systems as described in § 627.56.

(d) *Work with BL-3 etiologic agents that require additional secondary containment.* Facilities in which work with certain viruses, for example, Rift Valley fever, yellow fever, and Venezuelan equine encephalitis, is conducted require HEPA filtration of Xallexhaust air prior to discharge from the laboratory. All persons working with those agents for which a vaccine is available should be immunized.

§ 627.16 Biosafety level 4.

Laboratory work at BL-4 must follow the requirements stated in §§ 627.13, 627.14 and 627.15 as well as the following:

(a) All activities are conducted in Class III biological safety cabinets or in Class I or II biological safety cabinets in conjunction with a one-piece positive pressure personnel suit ventilated by a life-support system.

(b) Biological materials to be removed from the Class III cabinet or from the maximum containment laboratory in a viable or intact state must be transferred to a sealed nonbreakable primary container, enclosed in a nonbreakable sealed secondary container, and removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.

(c) No materials, except for biological materials that are to remain in a viable or intact state, are removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or material which might be damaged by

high temperature or steam is decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

(d) Personnel may enter and leave the facility only through the clothing change and shower rooms. Personnel must shower each time they leave the facility. Personnel may use the airlocks to enter or leave the laboratory only in an emergency.

(e) Street clothing must be removed in the outer clothing change room and kept there. Complete laboratory clothing, including undergarments, pants and shirts or jumpsuits, shoes, and gloves, will be provided and must be used by all personnel entering the facility. Head covers are provided for personnel who do not wash their hair during the shower. When leaving the laboratory and before proceeding into the shower area, personnel must remove their laboratory clothing and store it in a locker or hamper in the inner change room.

(f) When etiologic agents or infected animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biohazard symbol must be posted on all access doors. The sign must identify the agent, list the name of the commander or institute director or other responsible person(s), and indicate any special requirements for entering the area (for example, the need for immunizations or respirators).

(g) Supplies and materials needed in the facility are brought in by way of the double-doored autoclave, fumigation chamber, or airlock which is appropriately decontaminated after each use. After securing the outer doors, personnel within the facility retrieve materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. These doors are secured after materials are brought into the facility.

(h) Materials (for example, animals and clothing) not related to the experiment being conducted are not permitted in the facility.

(i) Whenever possible, avoid using any glass items.

§ 627.17 Toxins.

The laboratory facilities, equipment, and procedures appropriate for work with toxins of biological origin must reflect the intrinsic level of hazard posed by a particular toxin as well as the potential risks inherent in the operations performed. All toxins must be considered to pose a hazard in an aerosol form. However, most toxins exert their effects only after parenteral exposure or ingestion, and a few toxins present a dermal hazard. In general, toxins of biological origin are not intrinsically volatile. Thus, the laboratory safety precautions appropriate for handling these materials closely parallel those for handling infectious organisms. The requirements in this section for the laboratory use of toxins of biological origin include the requirements in § 627.12(a) and the following:

(a) *Vacuum lines.* When vacuum lines are used with systems containing toxins, they will be protected with a HEPA filter to prevent entry of toxins into the lines (or sink drains when water aspirators are used).

(b) *Preparation of concentrated stock solutions and handling closed primary containers of dry toxins.* Preparation of primary containers of toxin stock solutions and manipulations of closed primary containers of dry forms of toxins will be conducted—

(1) In a chemical fume hood, a glove box, or a biological safety cabinet or equivalent containment system approved by the safety officer.

(2) While wearing eye protection if using an open-fronted containment system.

(3) Ensuring that gloves worn when handling toxins will be disposed of as toxin waste, with decontamination if required.

(4) With the room door closed and posted with a universal biohazard sign, or other sign, indicating that toxin work is in progress. Extraneous personnel shall not be permitted in the room during operations.

(5) Ensuring that toxins removed from hoods or biological safety cabinets are double-contained during transport.

(6) After verification of hood or biological safety cabinet inward airflow is