

various biosafety levels and toxins are described below. The biosafety levels correspond to those described in the HHS Publication Biosafety in Microbiological and Biomedical Laboratories (HHS No. (NIH) 88-8395), while the large-scale biosafety levels were adapted from those described in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

**§ 627.43 Biosafety level 1.**

(a) *Laboratories.* Each laboratory used for this level will, as a minimum, have the following features:

- (1) A sink for handwashing.
- (2) Work surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- (3) Fly screens on any windows that can be opened.
- (4) Furnishings and surfaces that are sturdy and designed to be easily cleaned.
- (5) Spaces between furnishings and equipment that are accessible for cleaning.

(b) *Animal facilities.* Each room will have the following features:

- (1) Design and construction to facilitate cleaning and housekeeping.
- (2) A sink for handwashing within the facility.
- (3) Fly screens on any windows that can be opened.
- (4) Ventilation designed so that the direction of airflow in the animal facility is inward, with the exhausted air discharged to the outside without being recirculated.
- (5) Self-closing doors that open inward.

**§ 627.44 Biosafety level 2.**

(a) *Laboratories.* Each laboratory used for this level of hazard will have, in addition to the requirements stated in § 627.43(a), the following:

- (1) An autoclave available.
- (2) Containment equipment necessary for the operations unless the safety officer approves the use of a compensatory level of personal protective equipment.
- (3) An eyewash available near the laboratory.

(b) *Animal facilities.* In addition to the requirements stated in § 627.43(b), facilities will include—

(1) A sink for handwashing in each room where animals are housed.

(2) An autoclave available in the building.

(3) Appropriate containment equipment unless the safety officer approves the use of a compensatory level of personal protective equipment.

**§ 627.45 Biosafety level 3.**

(a) *General requirements.* Each suite used as a laboratory or in which infected animals are housed will, as a minimum, have the following features:

(1) Physical separation from areas which are open to unrestricted traffic.

(2) All entrances to each laboratory or animal room from the nonlaboratory access corridors will be through two sets of doors. A change room or airlock may be incorporated between the doors.

(3) The interior surfaces of walls, floors, and ceilings will be water resistant so that they may be easily cleaned.

(4) All penetrations into the walls, floors, and ceilings should be sealed or capable of being sealed to facilitate decontamination.

(5) A foot, elbow, or automatically operated sink will be located near the exit door to each laboratory or animal room.

(6) An autoclave should be in each laboratory or animal room and will be available to the facility.

(7) A ventilation system that will—

(i) Create directional airflow that draws air into the laboratory through the entry areas.

(ii) Not recirculate laboratory air.

(iii) Discharge the exhaust air from the laboratory to the outside and disperse the exhaust air away from occupied areas and air intakes.

(iv) Exhaust the HEPA-filtered air from Class I or II biological safety cabinets or other primary containment devices directly to the exterior of the laboratory or through the building exhaust system. Exhaust air from the cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every 12 months. If the filtered cabinet exhaust is discharged through the building exhaust system, it will be connected to this system in a manner (for example, thimble unit connection) that avoids any

interference with the air balance of the cabinets or the building exhaust system.

(8) All windows to the facility will be sealed shut.

(9) Appropriate biological safety cabinets or other specialized containment equipment will be provided.

(10) Any vacuum line in the facility will have a HEPA filter and liquid disinfectant trap.

(11) Bench tops that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(12) Furnishings that are sturdy and spaces between benches, cabinets, and equipment that are accessible for cleaning.

(13) An eyewash available in or near the laboratory.

(b) *Additional animal facility requirements.* In addition to the requirements given in §627.44(b) and 627.45(a), all doors to the animal rooms will open inward and be self-closing.

#### § 627.46 Biosafety level 4.

The engineering controls within the facility must provide absolute biological containment. All procedures with etiologic agents requiring this biosafety level of facilities, equipment, and procedures must be conducted either in Class III biological safety cabinets, or in a facility that is designed for the use of a personal positive pressure suit as described in §627.46(b) in conjunction with Class I or II biological safety cabinets.

(a) *General requirements.* The facility will have the following features:

(1) A separate building or a clearly demarcated and isolated area within a building which incorporates positive personnel control for access.

(2) All entrances from access corridors incorporate an inner and outer change room.

(3) Inner and outer change rooms separated by a shower facility.

(4) A double-doored autoclave, fumigation chamber, or ventilated airlock for passage of all items which do not enter the facility through the change room.

(5) Interior surfaces of walls, floors, and ceilings resistant to water and chemicals to facilitate cleaning and disinfecting.

(6) Walls, floors, and ceilings of the facility constructed to form a sealed internal shell which facilitates fumigation and is animal and insect proof.

(7) All penetrations into the walls, floors, and ceilings sealed.

(8) All liquid drains in the facility connected directly to a liquid waste decontamination system.

(i) Holding tanks collecting waste from sinks, biological safety cabinets, floors, and autoclave chambers provide decontamination by heat treatment.

(ii) Holding tanks collecting waste from shower rooms and toilets provide decontamination by heat or chemical disinfectant methods.

(9) Sewer and other ventilation vents contain in-line HEPA filters.

(10) Internal facility appurtenances (for example, light fixtures, air ducts, and utility pipes) arranged to minimize the horizontal surface area on which dust can settle.

(11) A foot, elbow, or automatically operated handwashing sink located near the exit door to each laboratory or animal room.

(12) Self-closing and lockable access doors.

(13) A ventilation system that—

(i) Is dedicated to the facility and provides fresh air meeting American Society of Heating, Refrigerating, and Air Condition Engineers, Inc. (ASHRAE) Standard 62.

(ii) Maintains a negative pressure differential and assures flow inward from areas outside of the facility toward areas of highest potential risk.

(iii) Has manometers or magnehelic gauges to provide, sense, and display pressure differentials between adjacent areas maintained at different pressure levels. An alarm will sound when the pressures fall below acceptable levels.

(iv) Has the air supply and exhaust interlocked to ensure that exhaust failure or reduction will not allow the air pressure in the area to become positive to the adjacent areas.

(v) Does not recirculate exhaust air.

(vi) Is HEPA-filtered and discharged to the outside, dispersing the exhaust air away from occupied areas and air intakes.

(vii) Has the HEPA filters on the exhaust located as near to the rooms as is practicable.