(h) A fume hood, biological safety cabinet, glove box, or equivalent engineering control equipped with HEPA filters and with charcoal filters if volatile materials are being used.

Subpart H—Engineering Controls

§ 627.49 Introduction.

As required by the OSHA and recommended by the American Industrial Hygiene Association (AIHA) and the CDC, engineering controls and proper microbiological techniques are the primary means of protecting personnel who work with potentially hazardous biological materials. In situations of potentially higher hazard, these engineering controls are supplemented by personal protective clothing and equipment. Thus, the engineering controls discussed in this chapter will be the primary means of personnel and environmental protection when working with etiologic agents. Because of the importance of these engineering controls, this chapter contains not only requirements for the engineering and construction of these controls, but also requirements for their certification and continuous satisfactory performance. These will be described for each engineering control.

§ 627.50 Class I biological safety cabinet.

(a) *Description.* The Class I biological safety cabinet (figure H–I in appendix F to this part) is a ventilated cabinet for personnel protection only. The cabinet provides an uncirculated inward flow of air away from the operator. The exhaust is passed through a HEPA filter. It may be discharged into the laboratory or vented out of the laboratory and dispersed away from occupied spaces or air intakes. When the exhaust is recirculated in a BL–2 or BL–3 facility, the cabinet must be tested and certified annually. In a BL–4 facility, if the exhaust is recirculated, the cabinet must be tested and certified semiannually.

(b) *Uses.* These cabinets are used if personnel protection against the microorganisms is required; for modest quantities of volatile, toxic, or radioactive chemicals (in concentrations and quantities associated with biological systems) if vented to the outside; and when sterility is not required. They are commonly used for housing tabletop centrifuges, in the necropsy of small animals, and for changing animal bedding.

(c) *Prohibitions.* This class of cabinet is not to be used when sterility must be maintained. In addition, volatile, toxic, or radioactive materials can not be used in this class of cabinet when the exhaust air is not exhausted to the exterior.

(d) *Certifications and requirements.* (1) The inward air velocity on these cabinets will be an average of 100 plus or minus 20 linear feet per minute (lfpm). Each cabinet must be certified before use and semiannually thereafter by a face velocity test. Additionally, smoke tests will be performed annually to verify containment.

(2) The exhaust system will have a HEPA filter, which will be tested initially upon installation, after repair or replacement, and every 2 years thereafter (except when required more often). Filters will be certified to be 99.97 percent effective in capturing particulate matter by a leakage test using mineral oil or other appropriate aerosol dispersed as 0.3 micron droplets.

§ 627.51 Class II biological safety cabinet.

All Class II biological safety cabinets (figure H–II in appendix F to this part) are ventilated cabinets for personnel and product protection, having an open front with inward air flow for personnel protection.

(a) *Operating standards.* (1) All of these cabinets must conform and be certified to meet National Sanitation Foundation (NSF) Standard No. 49 revised, June 1987, for the applicable type of cabinet.

(2) After installation and before use, and annually thereafter, the cabinets will be tested in accordance with NSF Standard No. 49 (latest revision June 1987) as follows:

(i) Primary (required) tests—

(A) Velocity profile test.

(B) Work access opening airflow (face velocity) test.

(C) HEPA filter leak test.

(D) Cabinet integrity test (soap bubble test) for cabinets with positive pressure internal plenums.

(ii) Secondary (optional) tests—

(A) Vibration test.

(B) Electrical leakage and ground circuit resistance tests.

(C) Noise level test.

(D) Lighting intensity test.

(E) UV light intensity test.

(3) After repairs or alterations to the cabinetry or ventilation system that affect the cabinet, the tests listed in §627.51(a)(2) will be performed for the relevant parameters.

(4) The work access opening airflow (face velocity) test, as specified in NSF Standard No. 49 (latest revision, June 1987), will be performed to check that the cabinet is within specifications on an annual basis for BL–1 and BL–2 and toxin use. This test will be performed semiannually on cabinets used for BL–3 and BL–4 as well as for work with dry forms of toxins.

(5) When the exhaust is recirculated in a BL–4 facility, the cabinet must be tested and certified semiannually.

(b) *Class IIA biological safety cabinets.*—(1) *Description.* A Class IIA biological safety cabinet is one in which typically 70 percent of the air is recirculated within the cabinet and the exhaust passes through a HEPA filter before discharge. The exhaust may be exhausted into the room and positive-pressure contaminated ducts and plenums within the cabinet are allowed. Type A cabinets shall have a minimum calculated face velocity of 75 feet per minute (fmp).

(2) *Uses.* These cabinets are for working with low-to-moderate risk biological samples and for protecting personnel against biological material while providing a sterile atmosphere in which to handle the material.

(3) *Prohibitions.* Materials that are toxic or volatile must not be used in these cabinets.

(c) *Class IIB_1 biological safety cabinets.*—(1) *Description.* A Class IIB_1 biological safety cabinet is one that maintains a minimum average inflow of air of 100 plus or minus 20 lfpm and in which typically 30 percent of the air is recirculated. All recirculated and exhausted air passes through two HEPA filters in series. All contaminated internal ducts and plenums are under negative pressure. Type B cabinets shall have a minimum calculated face velocity of 100 fpm.

(2) *Uses.* When ultra-sterility is needed, these are the cabinets of choice. The double filtration achieves a cleaner atmosphere. Minute quantities of volatile, toxic, or volatile radioactive materials coincidental to use in biological systems may also be used in these cabinets.

(3) *Prohibitions.* More than minute quantities of toxic, volatile, or radioactive materials must not be used in these cabinets.

(4) *Additional certifications or requirements.* None.

(d) *Class IIB_2 biological safety cabinets.*—(1) *Description.* A Class IIB_2 biological safety cabinet is one that maintains a minimum average of 100 plus or minus 20 lfpm inward flow and in which all air is exhausted directly from the cabinet through a HEPA filter without recirculation within the cabinet. All contaminated ducts and plenums are under negative pressure. Type B cabinets shall have a minimum calculated face velocity of 100 fpm.

(2) *Uses.* These cabinets are recommended when small quantities of volatile, flammable, or toxic chemicals must be used coincidentally with items requiring sterility.

(3) *Prohibitions.* While these cabinets do offer the greatest degree of safety for volatile, toxic, and flammable chemical handling in a sterile environment, they are not to be used in place of a fume hood to prepare stock solutions of hazardous chemicals.

(e) *Class IIB_3 biological safety cabinets.*—(1) *Description.* A Class IIB_3 biological safety cabinet is one that meets all of the requirements of a Class IIB_2 biological safety cabinet except that it recirculates most (typically 70 percent) of the air inside the cabinet. Type B cabinets shall have a minimum calculated face velocity of 100 fpm.

(2) *Uses.* Minute amounts of nonflammable chemicals can be used coincidentally with low-to-moderate risk biological agents.

(3) *Prohibitions.* Flammable materials and more than minute amounts of toxic, radioactive, or volatile chemicals must not be used in these cabinets.

(4) *Additional certifications or requirements.* None.

§ 627.52 Class III biological safety cabinet.

(a) *Description.* These cabinets (figure H–III in appendix F to this part) are totally enclosed, ventilated cabinets of gas-tight construction. Operations are conducted through attached rubber gloves. The supply of air is drawn into the cabinet through HEPA filters. The exhaust air is treated by double HEPA filtration, or by HEPA filtration followed by incineration, and is not allowed to recirculate within the room.

(b) *Uses.* These cabinets provide the ultimate protection for personnel. They are suitable for low, moderate, and high-risk etiologic agents.

(c) *Prohibitions.* More than minute amounts of flammables must not be used in these cabinets.

(d) *Certifications and requirements.* (1) These cabinets will have a manometer or magnehelic gauge that indicates the negative pressure that is maintained inside the cabinet. The pressure inside the cabinet should be a minimum of 0.5 inches water gauge negative to the surrounding room.

(2) These cabinets will be pressure tested by the soap bubble or halogen leak test as prescribed in NSF Standard No. 49, appendix B1 (latest revision, June 1987), and certified, when the HEPA filter units are serviced.

§ 627.53 Fume hood.

Fume hoods in which etiologic agents are handled must use proven technologies to provide optimal containment. Fume hood placement, design, and capture testing requirements for use in designing new laboratories can be found in the latest edition of Industrial Ventilation, A Manual of Recommended Practices, published by the American Conference of Governmental Industrial Hygienists.

(a) *Description.* Fume hoods are common chemical laboratory furnishings designed to capture fumes from chemicals that are used within them. Air is drawn through the opening and vented to the exterior without recirculation.

(b) *Uses.* Fume hoods provide excellent containment for handling hazardous chemicals.

(c) *Prohibitions.* Moderate risk biologicals and open containers of dry forms of toxins must not be used in a fume hood without HEPA filtration. Fume hoods should never be used when sterility is required.

(d) *Certification and requirements.* (1) Inward air flow will be an average of 100 plus or minus 20 lfpm as measured at the face of the fume hood. Proper function of laboratory hoods is not only a function of face velocity. An evaluation of the total operating environment is necessary.

(2) When filters are required, they will be certified by the mineral oil droplet (HEPA) or Freon (Charcoal) leak test as appropriate. Leakage through the filters will be less than 0.05 percent for Freon and 0.03 percent for oil droplets when initially installed.

(3) Fume hoods will be provided with indicator devices to give a warning should the ventilation system fail or if the hood face velocity falls below an average of 80 lfpm

(4) Hood air flow will be certified when installed, when maintenance is performed on the ventilation system, and semiannually thereafter.

§ 627.54 Glove box.

(a) *Description.* A glove box is an enclosure that provides a positive barrier from liquids, solids, and chemical vapors. A glove box has viewing ports and glove ports for access. The box maintains personnel protection through solid barriers and maintenance of a negative pressure relative to its surroundings.

(b) *Uses.* Glove boxes are used when extreme containment is needed for highly toxic chemicals, especially for dry chemicals that can be swept out of containers by the airflow in hoods.

(c) *Prohibitions.* Unventilated boxes must not be used with volatile flammable materials and should be used with volatile toxic materials unless dilution ventilation is provided.

(d) *Additional certifications and requirements.* (1) The glove box will be maintained at a pressure of at least 0.25 inches water guage less than its surroundings.

(2) The pressure differential will be indicated by a manometer or magnehelic guage. Indicator devices