

General or the NIH on an individual basis.

§ 627.20 Operations with radioactive material.

Operations that combine etiologic agents with radioactive material present unique problems. When this is the case, the following apply:

(a) *Radiation program.* A radiation program meeting the requirements of AR 385-11 and NRC licensing that allows the particular isotope and its use are required. The requirements for acquisition, handling procedures, labeling, storage, training, monitoring, and disposal will be described in an organization policy document.

(b) *Procedure approval.* In addition to the required approvals for work with etiologic agents, the RPO will approve all SOPs involving the use of radioactive materials. Laboratory operators must be fully trained, with annual training updates as required by the existing license.

(c) *Special situations.* (1) The laboratory waste must be segregated as radioactive waste and disposed of as such after it has been decontaminated. Do not mix nonradioactive waste with radioactive waste as the disposal of radioactive waste is much more complex and expensive. When RCRA-listed chemicals are mixed with radioactive waste, it becomes "mixed waste" for which there is currently no means of disposal.

(2) Activities conducted with radioisotopes should be confined to the smallest number of areas or rooms consistent with requirements.

(3) Decontamination methods specific to etiologic agents will not always remove radioactivity. Other methods, such as specialized detergents and solvents designed for this use, should be employed to remove residual radioactivity.

Subpart D—Personal Protective Equipment

§ 627.21 Introduction.

Personal protective equipment (PPE) includes clothing and equipment used to protect the laboratory worker from contact with infectious, toxic, and corrosive agents, as well as excessive heat,

fire, and other physical hazards. The appropriate PPE for any activity depends upon the proposed operations and the potential hazards associated with them. While PPE is an important item of personal protection, it serves as only a secondary line of protection against hazards in the workplace. Engineering controls (subpart H), combined with common sense, good laboratory techniques, and adherence to SOPs, are the primary barriers to exposure. There are some situations, however, in which it is either impractical or impossible to rely exclusively on engineering controls. In these cases, PPE may form the primary barrier between personnel and the hazardous or infectious materials.

§ 627.22 Minimum laboratory attire for use of etiologic agents.

Individuals required to wear PPE will be trained in its proper use. The PPE listed below is the minimum required when etiologic agents are handled at any biosafety level. Research with etiologic agents usually involves hazards other than those presented by the agents themselves. When PPE is selected, the hazards presented by these other factors must be considered regardless of the biosafety level used. For example, toxic chemicals are commonly used in research involving etiologic agents. The processes may expose personnel to physical hazards, such as heat or animal bites, and the decontamination process may involve the handling of toxic or corrosive materials. When the PPE required to mitigate these hazards exceeds that of the minimum requirements, the necessary PPE will be selected considering all the hazards. Information regarding the additional appropriate PPE worn to protect against these hazards will be available from one of the following sources: MSDS, SOP for the operation, or the safety officer. Deviations from the standards stated in approved SOPs must be approved by the safety officer. All laboratory coats worn to protect the individual should be left in the laboratory when that individual leaves. In each case, the minimum attire will be—

(a) *Laboratory workers.* Street attire is permissible in the laboratory, but

must include closed-toe shoes. A full-length, long sleeved, fully fastened laboratory coat, gown, or smock will be worn over the street attire in the laboratory at all times. The laboratory clothing will be removed and left in the laboratory when leaving to enter non-laboratory use areas.

(b) *Animal caretakers.* In addition to the clothing requirements in §627.22(a), animal handlers will be provided with safety shoes or safety boots. The requirements of §627.22(b) should also apply.

(c) *Nonhuman primate rooms.* Personnel entering rooms housing nonhuman primates will wear the clothing stated in §627.22(a) and, if applicable, §627.22(b) in addition to a molded mask or HEPA filtered respirator, latex or vinyl gloves, and eye protection.

§ 627.23 Biosafety level 1.

This level requires only the minimum attire described in §626.22.

§ 627.24 Biosafety level 2.

This level requires the following additions to the minimum clothing specified in §627.22:

(a) *Laboratory.* Gloves (type dependent on the application) will be worn when handling etiologic agents or containers of etiologic agents and when handling infected animals.

(b) *Animal rooms.* (1) Protective clothing will be changed completely every day. One- or two-piece laboratory suits or solid-front gowns and wrap-around smocks are preferable. Full-length, long-sleeved, fully fastened laboratory coats are allowed.

(2) Eye protection must be worn when handling nonhuman primates.

(3) Appropriate gloves must be worn.

(4) Molded masks or HEPA filtered respirators will be worn in rooms housing nonhuman primates.

§ 627.25 Biosafety level 3.

The outer clothing worn in these facilities must never be worn outside the facility. Color-coded clothing that is worn only in the facility is recommended to remind individuals not to wear it outside. The minimum clothing includes—

(a) *Laboratory.* (1) Long-sleeved, solid front, or wraparound gowns, scrub

suits, or coveralls over street attire which includes closed-toe shoes. Dedicated shoes, boots, or shoe covers will be worn in the facility.

(2) Appropriate gloves.

(b) *Animal rooms.* (1) A complete change of protective clothing on a daily basis. Long-sleeved one- or two-piece solid front uniforms, solid-front gown, wrap-around smocks, or solid front coveralls.

(2) Eye protection must be worn when handling nonhuman primates.

(3) Molded masks or HEPA filtered respirators will be worn in rooms housing infected animals.

(4) Shoe covers will be worn and removed before exiting the room; alternatively, disinfectant footbaths will be used for each exit from the room when infected animals are present.

§ 627.26 Biosafety level 4.

Street clothing must be removed in an outer clothing change room and kept there. Clothing worn in the facility will be removed in an inner change room and a shower taken before replacing the street clothing. Two distinct PPE requirements exist for BL-4 operations:

(a) *Class III biological safety cabinet containment.* Clothing requirements when all etiologic agents and infected animals are housed and manipulated in Class III biological safety cabinets will include—

(1) Complete change of clothing and wet shower upon exit. This includes undergarments, pants and shirts or jumpsuits, and shoes. While it is preferred that the shower include washing the hair, head covers will be worn by those who do not wash their hair on each exit.

(2) Appropriate inner gloves. The inner gloves will be donned in the change room.

(b) *Class I or II biological safety cabinet containment.* Clothing requirements for this level when etiologic agents are contained in Class I or II biological safety cabinets of equivalent partial-containment caging systems (for infected animals) (See §§627.56 and 627.57) include—

(1) Complete change of clothing and wet shower upon exit. This includes undergarments, pants and shirts or jump-