

§ 627.27

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 jumpsuits, and shoes. While the shower should include washing the hair, head covers will be worn by those who do not wash their hair on each exit.

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

(3) A one-piece positive pressure suit described in § 627.31(g).

(4) Impervious boots fitted over the suit.

§ 627.27 Large-scale (LS) operations.

The clothing requirements for these are the same as for the corresponding biosafety levels for laboratory operations.

§ 627.28 Solutions of toxins and dry forms of toxins in closed containers.

In addition to the minimum clothing specified in § 627.22, disposable gloves or gloves designed to protect against the diluent will be worn when handling these materials.

§ 627.29 Dry forms of toxins handled in open containers.

In addition to the requirements stated in § 627.28, the requirements stated in § 627.18(c) apply.

§ 627.30 Situations specified in § 627.18(e).

The clothing requirements for this section are for the emergency procedures specified in § 627.18(e). Because situations can occur and there is no feasible or available means to mitigate the potential hazard adequately by engineering controls, the clothing requirements exceed those required for a properly conducted laboratory operation at an equivalent biosafety level. The protective equipment required will be selected based upon an assessment of the potential hazards that could be encountered. The following clothing requirements are given as a guide. The selection of PPE will be based upon the highest possible level of contamination that could exist in the room. This will be based upon what is known about the operations that were conducted in the

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room during and prior to the current incident. In each situation, the aerosols will be allowed to dissipate or settle before entry (approximately 30 minutes). The following clothing requirements apply to these situations:

(a) *BL-1*. (1) Gloves.

(2) Outer complete covering such as a pair of coveralls.

(3) Shoe covers, provided shoes, or safety shoes or boots.

(4) Eye protection (maintenance only).

(b) *BL-1 LS*. The same as described in section 627.30(a) with the following additions:

(1) An impervious apron.

(2) Impervious boots.

(c) *BL-2 and toxins*. (1) Gloves.

(2) Full outer covering such as a coverall.

(3) Shoe covers, provided shoes, or safety shoes or boots (maintenance).

(4) An approved half-face or full-face respirator with HEPA filters (worn).

(5) Eye protection.

(6) An impervious apron (not required for entry only).

(d) *BL-2 LS*. The same as § 627.30(c) with the addition of impervious boots.

(e) *BL-3 and BL-3 LS*. (1) A complete change of clothing.

(2) Gloves.

(3) An approved full-face HEPA or HEPA plus charcoal filtered respirator.

(4) An impervious apron (not required for entry only).

(5) Impervious boots.

(6) Head cover.

(f) *BL-4*.

(1) A full change of inner clothing.

(2) An inner pair of gloves.

(3) A one-piece positive pressure suit as described in § 627.31(g), or a one-piece Xsuit with an approved positive pressure self-contained breathing apparatus (SCBA) and a supplied-air respirator (SAR) or both (see § 627.31(f)).

(4) Appropriate gloves fitted to the suit.

(5) Impervious boots fitted over the suit.

§ 627.31 Specific requirements for individual PPE items.

(a) *Aprons*. Simple plastic or rubber aprons.

(b) *Boots*. When boots must be worn with an apron, the apron should cover

the boot tops sufficiently so that liquids splashed on the apron will not run into the boots.

(c) *Eye and face protection.* Eye protection will meet or exceed the requirements of OSHA found in the 29 CFR 1910.133 and will be worn at all times when required. Special eye wear may be required around ultraviolet (UV) light source.

(d) *Gloves.* (1) No one glove will be satisfactory for all applications. Gloves are fabricated in a wide assortment of materials. The type of glove selected will depend upon the specific activity. The various activities in biocontainment facilities call for gloves to protect against etiologic agents in situations where micro-manipulations are required and excellent tactile feedback through gloves is important, gloves for handling hot glassware and cryogenic materials, and gloves to protect against animal bites, toxic substances, chemical carcinogens, solvents, acids, and caustics. Many of these requirements call for gloves distinctly different from gloves suitable for the other hazards. As a result, the SOP for each operation should address these hazards and specify the appropriate glove required for each operation. Consult MSDSs, manufacturer glove charts, and the safety officer to determine the correct glove type needed.

(2) Before donning a pair of gloves, examine them closely to ascertain that they are in serviceable condition. Check for rips and pin holes. Gloves should over-wrap the cuff and lower sleeve of the laboratory garment.

(3) Operations in open-front biological safety cabinets should be planned so that once the operator has inserted gloved hands into the cabinet, he or she does not have to withdraw them from the cabinet until the work has been completed. If gloves become visibly contaminated, they will be removed and decontaminated. Additional gloves should be available so that work can continue. When wearing gloves for an extended period, change them periodically or decontaminate them. Individual SOPs will designate the appropriate period based upon the hazards.

(4) Gloves will be removed before going from one level of containment to

another (remove gloves in a safety cabinet before removing your hands from the cabinet). Take care to ensure that skin is not touched with the outer surface of contaminated or potentially contaminated gloves when they are removed. Gloves will be placed in suitable decontaminant when they are removed. Disposable gloves will be placed in a covered container for decontamination or disposal.

(5) Gloves that are a part of a biological safety cabinet system will be examined initially, after each sterilization of the biological safety cabinet system, and at least annually for leaks using the soap bubble test, followed by the halo-carbon test. Gloves will be tested while still attached to the cabinet.

(6) Sterilization of nondisposable gloves either before use or before reuse is usually done with ethylene oxide or formaldehyde gas. Sterilized gloves must be aerated in flowing sterile (filtered) air at 21 ° C or higher for a minimum of 24 hours prior to use to prevent skin burns and irritation from residual decontaminants.

(e) *Laboratory clothing.* Users will check clothing before wearing it, to ensure that it is free from defects that would compromise its usefulness. Laboratory clothing (except BL-1) will be decontaminated before being released for laundering by untrained or unprotected personnel. Protective laboratory clothing that requires the wearer to pull it over the head will not be used. Laboratory clothing will meet OSHA requirements found in the 29 CFR 1910.132.

(f) *One-piece suits.* One-piece suits with a respirator under the suit are not used to any great extent except in certain emergencies. The respirators used with these are supplied air by an approved positive pressure SCBA or SAR. Respirators will be of the pressure-demand or constant flow type. The air provided will meet OSHA requirements found in the 29 CFR 1910.134, the requirements of Grade D breathing air as specified in the Compressed Gas Association pamphlet G-7.1 and American National Standards Institute (ANSI) Z86.1-1973. When used in an area that

does not have a chemical shower to decontaminate the suit, a decontamination station will be set up for this purpose. Suits maintained for emergency use will be inspected at least quarterly and respiratory equipment will be inspected monthly.

(g) *One-piece positive pressure suits.* A life-support system will be provided with alarms and emergency backup breathing tanks. The air provided will be HEPA-filtered meeting OSHA requirements found in the 29 CFR 1910.134, the requirements of Grade D breathing air as specified in the Compressed Gas Association pamphlet G-7.1 and ANSI Z86.1-1973. A HEPA-filter will be in-line between the disconnect on the suit and the breathing space in the suit. When these are used in other than an emergency situation, a chemical shower must be provided to decontaminate the surfaces of the suit as the worker leaves the containment area. Suits will be inspected before each use to check for indications of significant wear or leakage. The suits will be worn with impervious boots over the foot area of the suit and the outer gloves will be attached over the hand portion.

(h) *Respiratory protection equipment.* (1) Respirators and their use will be approved by the safety officer. The selection will be based on the conditions of the activities and the risks involved. In general, National Institute for Occupational Safety and Health (NIOSH) approved respirators that use aerosol filters for dusts and fumes having a Threshold Limit Value (TLV) of less than 0.05 mg/m³ have been found acceptable for use in microbiological laboratories. Alternatively, the Army M-17 or M-9 masks may be used. Air-supplied hoods are used in situations where greater respiratory protection is required without the need for body protection. One-piece suits are used when total body and respiratory protection are required.

(2) When respirators are used, a respirator protection program will be established that conforms to AR 11-34 and OSHA standards in the 29 CFR 1910.134. In general, a medical authority will designate who is to wear respirators, they will be fitted by individuals trained in their use and limitations, and wearers will be responsible

for the proper storage and regular inspection of their assigned respirators. Air-purifying respirators will not be worn in oxygen deficient environments.

(3) Reusable respirators that have been worn in a contaminated area will be decontaminated before reuse. At the end of each workday when a respirator has been worn in an area where it was required, the wearer will wipe it down with an appropriate liquid decontaminant. A damp cloth soaked in the decontaminant, with the excess liquid squeezed out, will be used for the wipe-down process, taking care to ensure that all crevices are reached. The respirator will be rinsed with clean, warm water. Visibly contaminated respirators will be decontaminated and discarded.

(4) Respirator programs will comply with AR 385-10 and AR 11-34.

(i) *Shoes.* All shoes specially issued for use in controlled access areas should be identified so that they can be segregated from other areas. Safety shoes or boots meeting OSHA requirements stated in the 29 CFR 1910.134 will be issued wherever heavy items or corrosive chemicals are handled. These will be sterilized appropriately after visible contamination. In certain situations (excluding BL-4 operations), it is desirable to wear disposable booties over street shoes, especially when product protection is required.

Subpart E—Decontamination and Disposal

§ 627.32 Introduction.

All material or equipment that is potentially contaminated with etiologic agents must be rendered nonhazardous before disposal. This chapter describes the acceptable physical and chemical decontamination methods and the general applicability of each. In general, all infectious materials and all contaminated equipment or apparatus will be sterilized before being washed and stored or discarded.

§ 627.33 Methods of decontamination.

(a) *Autoclave.* The use of wet heat is the most dependable procedure for destroying all forms of microbial life. An autoclave employs saturated steam under a pressure of approximately 15