

(2) Training conducted specifically for the facilities that the individual will be working in, including—

- (i) Procedures for the facility.
- (ii) Reporting incidents and accidents.
- (iii) Labeling and posting of signs.
- (iv) Biohazardous waste handling, approaches to minimizing the volume of waste, decontamination, packaging, and disposal.
- (v) Emergency procedures.

(3) Additional general training required for work in facilities where viable etiologic agents are present.

(i) Aseptic technique and procedures to include hands-on instruction and demonstration of proficiency.

(ii) Concept and definition of biosafety levels.

(iii) Disinfection and sterilization.

(iv) Safe use of workplace equipment, for example autoclave and centrifuge.

(v) Monitoring and auditing requirements.

(vi) Precautions for handling blood, tissues, and body fluids (when applicable).

(vii) The infectivity, pathogenicity, mode(s) of transmission, and medical surveillance requirements of specific agents.

(viii) Training for all new employees will include a period of supervised orientation in the facilities by a scientist or technician with specific training in the procedures and properties of the etiologic agents in use. During the training period, new laboratory personnel will be under the constant supervision of appropriately trained personnel.

(ix) Personnel who are assigned tasks in BL-2, BL-3, or BL-4 facilities will also have specific training in handling pathogens.

(x) Personnel assigned duties in a BL-4 facility will also have specific and thorough training in handling extremely hazardous infectious agents, the primary and secondary containment functions of standard and special practices, use of personal protective equipment, containment equipment, and laboratory design characteristics.

(4) Additional general training for handling toxins will include relevant items from § 627.10 plus—

(i) The availability of reference material on the hazards and safe handling of toxic substances.

(ii) The biological effects of the toxin(s) in use.

#### § 627.11 Operational prerequisites.

(a) Evaluation of the risks. The risk assessment of laboratory activities involving the use of etiologic agents is ultimately a subjective process. Those risks associated with the agent, as well as with any adjunct elements of the activity to be conducted, (chemicals, radioisotopes, end-products, and so forth) must be considered in the assessment. The appropriate biosafety level for work with a particular agent or animal study depends on the virulence, pathogenicity, biological stability, route of transmission, and communicability of the agent; the nature of the laboratory; the procedures and manipulations to be used; the quantity and concentration of the agent; and the availability of effective vaccines or therapeutic measures.

(b) The characteristics of etiologic agents, primary laboratory hazards of working with the agent, and recommended biosafety levels are described by CDC-NIH (HHS publication No. (NIH) 88-8395), the considerations for recombinant DNA molecules are described by NIH, and those for oncogenic viruses are described by NCI-NIH (sources listed below). The commander or institute director will assign work with given etiologic agents to the appropriate biosafety level. A risk assessment should take into account not only the NIH Guidelines for Research Involving Recombinant DNA Molecules, but also potential hazards associated with the organism and the product of the experimentation.

(1) When established guidelines exist, these will be followed. The primary source guidelines are—

(i) HHS Publication No. (NIH) 88-8395, Biosafety in Microbiological and Biomedical Laboratories, as amended, and updates published in Morbidity and Mortality Weekly Report.

(ii) NIH Guidelines for Research Involving Recombinant DNA Molecules (FR 51: 16958-16985 and updates).

(iii) The publication by the American Committee on Arthropod-Borne Viruses Subcommittee on Arbovirus Laboratory Safety (SALS) entitled Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates in the American Journal of Tropical Medicine and Hygiene, 29(6), 1980, pp. 1359–1381.

(iv) The Department of Health and Human Services Publication No. (NIH) 76-1165 by the National Cancer Institute (NCI) entitled Biological Safety Manual for Research Involving Oncogenic Viruses.

(2) When samples with unidentified viable agents are obtained, a knowledgeable and qualified scientist will evaluate the risks and make recommendations to the safety officer, who will add recommendations for review and approval by the commander or institute director. When guidelines for a specific organism are not established, in addition to these steps, the CDC or SALS or both will be consulted. Their recommendations will be documented and provided to the commander or institute director before approval.

(c) *Selection of facilities.* The facility requirements identified by the risk assessment will be adhered to. Any variations and compensatory measures will be approved by the IBC (when recombinant DNA molecules are involved), the safety officer, and the commander or institute director before a request for an exception or waiver is submitted as stated in AR 385–69.

(d) *Policies and procedures.* Policies in the form of a laboratory safety manual, regulations, memorandums, or SOPs are required for work with etiologic agents in the BDP. Before beginning a new procedure, the policies and procedures will be reviewed to ascertain that the intended operations are described and to determine the requirements that apply to the operation. If procedures exist for the intended operation, personnel will be trained to follow them; if procedures do not exist, then a detailed SOP will be written, reviewed, and approved before beginning the operation. SOPs will conform to the requirements stated in § 627.7(d), and be signed by all personnel who are required to follow the procedures, thus acknowledging that they have read and

understood the contents. All SOPs that pertain to a specific area (room, laboratory, or suite) will be available at the worksite.

#### **§ 627.12 General laboratory techniques.**

The general requirements for use of etiologic agents are composed of two sets of requirements, with the requirements for toxins being a subset of the requirements for handling viable etiologic agents. These requirements are as follows—

(a) *General techniques applicable to etiologic agents.*

(1) A fully fastened long-sleeved laboratory coat, gown, uniform, or coveralls will be worn in laboratories or animal rooms.

(2) Eating, drinking, smoking, and applying cosmetics are not permitted in the work areas.

(3) Personnel must wash their hands after they handle etiologic agents or animals, and before leaving the laboratory area.

(4) Mouth pipetting is strictly prohibited. Mechanical pipetting aids must be used.

(5) Gloves—(i) Will be worn when manipulating etiologic agents and handling containers of etiologic agents. Gloves are not required when materials are packaged appropriately for shipment.

(ii) Will be selected based on the hazards.

(iii) Will be changed frequently (or decontaminated frequently), and will be decontaminated or discarded into a labeled biohazard container after each use and immediately upon observable direct contact with an etiologic agent.

(iv) Will be removed at the workspace (workbench or hood) after handling etiologic agents to ensure that doorknobs and other surfaces are not contaminated.

(6) Good housekeeping will be maintained. This includes—

(i) Work areas free of clutter.

(ii) Work environment free of tripping hazards, with adequate access to exits, emergency equipment, controls, and such.

(iii) Benches and general work areas will be cleaned regularly using a wet