

Safety and health professionals will ensure that medical examiners are made aware of all hazardous substances each employee works with at the time of the medical examination. The physician's findings will include assessment of whether an employee has any health condition that would preclude work with etiologic agents. If any of the findings obtained during the examination are outside the normal range, the employee's supervisor and the employee will be notified and counseled on the courses of action available. In addition, a safety and health audit will be conducted to identify any potential occupational causes for the abnormalities, and corrective measures will be taken if applicable.

(b) *Serum samples.* When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel will be collected and stored for their biologically useful lifetime, but not longer than 40 years. Additional serum specimens will be collected periodically, based upon the agents handled, or as required by participation in a special immunizations program. SOPs will be written detailing the collection procedures and periods if serum sampling is deemed necessary.

(c) *Assignment of personnel.* Personnel assigned duties in work areas where etiologic agents are used will be evaluated to determine their suitability for their assigned tasks by the installation medical authority. Only personnel who are physically and mentally capable of working in biocontainment areas (BL-3 and BL-4) or with toxins will be assigned to these duties.

(d) *Immunization of at-risk personnel.* The guidelines for immunizations in the latest edition of the American College of Physicians' Guide for Adult Immunizations and recommendations of Health and Human Services (HHS) in publication number (NIH) 88-8395 shall be followed. A resource list for available immunizations for personnel at risk is given in appendix B of this part.

(e) *Reporting exposures.* Spills and mishaps which result in observable, known or potential exposures to etiologic agents will be immediately reported to the supervisor, the safety officer, the responsible medical per-

sonnel, and the commander. Appropriate medical evaluation, surveillance, and treatment will be provided and written records of these occurrences will be maintained for 40 years. A Med-16 report will be initiated (see AR 40-400).

(f) *Quarantine.* When etiologic agents designated as BL-4 by the CDC-NIH in HHS publication no. (NIH) 88-8395, (or most recent edition) are handled, a facility for the quarantine, isolation, and medical care of personnel with potential or known laboratory-associated exposures will be available.

§ 627.9 Medical records.

Army activities will maintain medical records in accordance with AR 40-66 and FPM 293-31 for all military and Department of the Army (DA) civilian employees who work with etiologic agents under sponsorship of the BDP.

Subpart C—Operational Requirements

§ 627.10 Personnel prerequisites.

(a) *Medical.* Before to assignment to work with etiologic agents, personnel will be evaluated by the appropriate medical personnel with respect to their assignment and will be evaluated in the medical surveillance program described in § 627.8.

(b) *Training.* All personnel directly or indirectly involved with containment or handling of known and potentially biohazardous material shall receive instruction that adequately prepares them for their assigned duties. Training will be given by occupationally qualified personnel as determined by the commander. This training will be documented and will include—

(1) General training—

(i) Personal hygiene related to laboratory work.

(ii) Laboratory practices.

(iii) Personal protective equipment.

(iv) Effective use of engineering controls.

(v) Packaging, transportation, and shipment of etiologic agents (when applicable).

(vi) Hazardous and infectious waste disposal, handling, and minimization procedures.

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(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).