

(1) Placement, periodic medical surveillance examinations, and termination examinations shall be conducted for each worker, to establish a baseline health record and to provide periodic job-related assessments of the worker's health status. Preassignment, periodic, and termination health assessments will include a work history, a medical history, physical examinations, indicated clinical laboratory studies and, when available, examinations or tests specific to the etiologic agent in question.

(2) Medical officers responsible for treating BDP etiologic agent exposures and conducting medical surveillance for BDP workers shall receive specialized training on the unique hazards of etiologic agents and recommended medical therapies.

(3) Special immunizations will be given to personnel handling specific etiologic agents as required.

(4) Records documenting the above will be maintained permanently.

(g) Emergency preparedness: (1) SOPs will address emergency procedures related to any mishap involving BDP etiologic agents. Notification and evacuation procedures will be covered in detail, as well as measures to contain the contamination.

(2) Local, regional, State, or Federal emergency support and coordinating agencies, such as law enforcement, fire departments, health departments, and governments will be informed of BDP activities and the appropriate support necessary, to include any equipment and training necessary, to provide effective emergency response and ensure compliance with community "right-to-know" statutes and regulations. Agreements with external agencies must be formalized.

(3) If a mishap with a BDP etiologic agent results in personnel exposure, approved emergency procedures will be immediately initiated to protect personnel and the environment and to constrain the spread of contamination. All personnel except those responsible for emergency operations will evacuate the immediate area.

(4) Special medical surveillance will be started as soon as possible for all workers present in the potentially affected area at the time of the mishap.

(h) Labeling and posting of hazards:

(1) Hazard warning signs which incorporate the universal biohazard symbol will be posted on the access door to the work area. (See DA PAM 385-69, para 3-5a(1).) The sign will be covered or removed if the organizational safety officer certifies that the area has been decontaminated.

(2) For areas irradiated with ultraviolet light, a caution sign reading "Ultraviolet Light, Wear Eye Protection" will be posted.

(i) Disposal controls. Etiologic agents used in the BDP must be decontaminated before disposal of infectious or hazardous wastes and must not violate any Army, Federal, State, local, or host nation environmental standards. Procedures for decontamination are described in DA Pam 385-69.

(1) The preferred methods of decontamination of etiologic agents are autoclaving or chemical inactivation with appropriate biocidal solutions. (See chap 5, DA Pam 385-69.)

(2) Etiologic agents awaiting decontamination will be contained at the appropriate biosafety level.

(j) Maintenance controls. A continuing program for equipment and facility maintenance will be implemented for each BDP operation.

(k) Protective equipment. Guidance concerning protective equipment is contained in DA Pam 385-69.

§ 626.8 Etiologic agent containment.

(a) Facility engineering controls and appropriate biocontainment equipment will be used, in conjunction with special practices and procedures, to minimize potential exposure of personnel and the environment to etiologic agents used in BDP operations. Engineering and equipment controls will be implemented to the maximum extent feasible and verified as effective. Protective clothing will not be used in lieu of engineering controls. Engineering controls will be the prime means of biocontainment. Personal protective equipment such as respirators are to be used only after feasible engineering controls have been shown unable to control the environment fully.

(b) Before beginning any etiologic agent operation, a determination will be made that the hazards associated

with the operation are under positive control as defined in the applicable SOP and that the operation complies with the criteria of this regulation and DA Pam 385-69.

§ 626.9 Inspections.

(a) Biosafety laboratories require periodic (at least quarterly for BL-1 and BL-2 and monthly for BL-3 and BL-4 laboratories), inspections by safety and health professionals. Safety officials will document the inspections, assure that deviations from safe practices are recorded, and that recommended corrective actions are taken. If deviations are life threatening, this area will be restricted until corrective actions are accomplished. New RDTE efforts involving etiologic agents will be evaluated and inspected prior to start-up to assure equipment, facilities, employee training, and procedures are in place and adequate for the introduction of BDP material. Safety officials will maintain such records for 3 years and will review the records at least annually for trends requiring corrective actions.

(b) Supervisors shall inspect work areas frequently (at least weekly) and take corrective actions promptly.

§ 626.10 Transportation of BDP etiologic agents.

(a) Etiologic agents utilized in the BDP shall be packed, labeled, marked, prepared for shipment, and shipped in accordance with applicable Federal, State, and local laws and regulations, to include 42 CFR part 72, "Interstate Shipment of Etiologic Agents," 49 CFR parts 172 and 173 (Department of Transportation), 9 CFR part 122 (USDA Restricted Animal Pathogens), and DA Pam 385-69.

(b) Etiologic agents shipped to support the BDP will use secondary shipping containers which are sealed with a crimped lid (see app D, DA Pam 385-69).

(c) BDP organizations and contractors who provide etiologic agents will ship all etiologic agents by private carrier. The United States Postal Service will not be used to transport etiologic agents required for the BDP.

(d) In addition to the above requirements, shipments of BL-4 etiologic agents will be hand carried by Govern-

ment courier or under the immediate supervision of a responsible party. This individual must be knowledgeable about the potential hazards of the materials and be able to monitor all aspects of the shipment to ensure that required transfers have been completed and documented and final receipt has been accomplished and acknowledged.

(e) Audit trails of all BDP etiologic agent shipments and receipts of such agents shall be established and maintained for at least 3 years. Such audit trails shall identify date of shipment, carrier, addresses of the shipper and recipient, and agent(s) shipped and received.

§ 626.11 General construction plans.

General construction plans for BDP facilities, as well as for changes in use of facilities, will be submitted through the chain of command to HQDA, Army Safety Office, DACS-SF, WASH DC 20310-0200 for safety review and approval. Plans shall be forwarded for new construction or major modifications of facilities used in the BDP. The facility system safety requirements of AR 385-16 and AR 415-15 shall be followed. Simultaneously, RDTE requirements that necessitate such renovation, modification, or construction shall be submitted through the chain of command to HQDA, OASA(RDA), SARD-ZT, WASH DC 20310-0103 for review and approval.

§ 626.12 Maximum credible event (MCE).

(a) Because of the complexity of the RDTE conducted in the BDP, the range of potential consequences that could be associated with a mishap must be considered. MCE is a risk analysis technique which provides a useful tool for estimating the effectiveness of existing safeguards. The potential for events must be carefully analyzed to determine the MCE that could occur and cause a mishap. All hazard analysis and general construction plans mentioned in § 626.11 will include a consideration of an MCE.

(b) The term MCE, as used herein, is analogous to a realistic worst-case analysis. The best available credible information will be applied to estimate