§ 626.5  
Subpart B—Biological Defense Safety Policy and Procedures

§ 626.5 Policy.
(a) This regulation applies to BDP RDTE operations involving etiologic agents being investigated by DA for biological defense purposes.
(b) Specific biological safety requirements and guidance are contained in DA Pam 365–69.

§ 626.6 Mishap reporting and investigation.
Biological defense RDTE related mishaps will be reported and investigated per AR 365–40 and AR 40–400. Med 16 Report will be used to report only personnel exposure or illness related to the BDP.

§ 626.7 Administrative and work practice controls.
(a) The cardinal principle for safety in BDP operations is to minimize the potential exposure of personnel to etiologic agents. In practice, this means conducting RDTE activities using the appropriate facilities, equipment, and procedures for the biosafety level (BL), and requiring only the minimum number of appropriately trained personnel, the minimum period of time, and minimum amount of the material, consistent with program objectives and safe operations.
(b) Open air testing under the BDP is restricted to use of simulants only, unless the Secretary of Defense determines that testing is necessary for national security in accordance with section 409, Public Law 91–121, 83 Stat. 204, signed November 18, 1967. Also, for RDTE involving protective equipment or detection devices, the least hazardous etiologic agent consistent with mission objectives will be employed. All testing of such equipment employing etiologic agents will be in appropriate biosafety level containment laboratories.
(c) A hazard analysis, to determine safety precautions, necessary personnel protection and engineering features, and procedures to prevent exposure, will be completed for—
(1) All BDP operations involving etiologic agents.
(2) A change in process or control measures that may increase potential contact or concentrations of biological material.
(d) An SOP is required for all biological defense RDTE operations. The SOP will—
(1) Describe in detail all necessary operational and safety requirements.
(2) Describe in detail actions to take in the event of mishap.
(3) Describe in detail the location of required emergency response equipment.
(4) Be available at the work site.
(5) Forbid concurrent unrelated work during biological defense RDTE operations within a laboratory area or suite.
(6) Be approved by the commander or the safety officer and signed by workers involved in the operation.
(7) Provide names and telephone numbers of responsible personnel.
(e) Training and information. All personnel who work directly with etiologic agents in the BDP, or who otherwise have a potential for exposure, will receive appropriate training to enable them to work safely and to understand the relative significance of agent exposures.
(1) This training will include signs and symptoms of etiologic agent exposure, information on sources of exposure, possible adverse health affects, and practices and controls used to limit exposures. The environmental and medical monitoring procedures in use, their purposes, worker responsibilities in health protection programs, and handling of laboratory mishaps will also be presented.
(2) Workers will be required to demonstrate proficiency before performing potentially hazardous operations. Refresher training will be repeated at least annually.
(3) Initial and refresher training will be documented and kept on file as a permanent record.
(f) Medical surveillance. A medical surveillance program (see AR 40–5) will be established for all personnel (military and civilian) who may be potentially exposed to etiologic agents.
(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.

(1) 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
§ 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 Government 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
§ 626.14 Waivers and exemptions.

(a) The goal of the biological defense safety program is strict adherence to safety standards and the elimination of all waivers and exemptions.

(b) Waiver authority. (1) The Chief of Staff, Army (CSA) is the controlling authority for granting waivers of biological defense safety standards. This authority is redelegated by this regulation to commanders of MACOMs and the commander of the USAMRDC.

(2) Waiver authority will not be subdelegated.

(3) Commanders with waiver authority will—

(i) Ensure the existence of necessary and compelling reasons before granting waivers.

(ii) Grant waivers to standards for installations and activities within their areas of authority.

(c) Waiver requests: (1) Commanders of installations and activities will submit a request for waiver when compliance with these standards cannot be achieved. When such waivers affect on other commands, initiating activities will coordinate requests with those commands.

(2) Requests for waivers will contain the following information:

(i) Description of conditions. State the mission requirements and compelling reasons which make the waiver essential and the impact if not approved, and describe all affected sites or facilities and the quantity and type of BDP required.

(ii) The safety regulations, including specific safety requirements or conditions cited by paragraph, from which the waiver is requested, and the reasons for the waiver.

(iii) Specific time period for which the waiver is requested.

(iv) A hazard analysis which identifies actual and potential hazards which can result from the waived requirements or conditions.

(v) A risk assessment that provides information on the risk being assumed because of the waiver. The assessment will include those safety precautions and compensatory measures in force during the waiver period.

(vi) A waiver abatement plan to include milestones, resources, and actions planned to eliminate the need for the waiver.

(3) Requests for waivers will be forwarded through command channels to the MACOM or CG, USAMRDC, as appropriate, for approval. MACOM or USAMRDC safety officials will forward a copy of approved waivers to HQDA, DACS–SF, WASH DC 20310–0200. Copies of all waivers will be maintained at the installation and MACOM or USAMRDC Safety Offices for up to 3 years after the waiver is terminated.

(4) Time limitations: (1) Waivers are normally limited to 1 year or less, and will be considered rescinded after 1 year, unless reviewed. The activity or
§ 626.15 Written procedures for contractor review.

The contracting agency will prepare written procedures for reviewing contractor capability to safely perform BDP work with etiologic agents. The written procedures will describe the criteria and guidelines for preparing the facilities description, safety requirements, special procedures and techniques, inspection procedures, and MCE scenarios. These written procedures will be submitted to the contracting agency MACOM for review and approval.

§ 626.16 Contracting agencies.

Contracting agencies, in coordination with their respective Command safety offices will monitor contractor performance in meeting safety requirements.

(a) The contracting agency will establish an inspection program and schedule for all BDP contractors who perform contract work with BL-3 or BL-4. Inspections will be conducted by safety and health personnel. The schedule will include, as a minimum, the following:

(1) A pre-award inspection on site, prior to contract award, for initial contracts for BDP work requiring BL-3 or BL-4 operations. If during a pre-award inspection, major corrective measures are required, a reinspection is required prior to the beginning of contract operations.

(2) A pre-award inspection of follow-on BL-3 and BL-4 contracts.

(3) A pre-operational inspection if a major change in procedures, facilities, or equipment is made after the pre-award survey.

(4) Annual inspection of BL-3 and semianual inspection of BL-4 contractor facilities, equipment, and operations.

(b) Pre-award surveys and annual inspections of contractors performing work requiring BL-3 or BL-4 will be conducted by safety and health professionals trained in BDP operational safety requirements. Pre-award surveys and annual inspections of BL-1 and BL-2 contractors will be conducted by safety and health professionals or contracting agency representatives who are trained in biological safety inspection techniques. The Safety Inspection Checklist in DA Pam 385–69 will be used.

(c) The contracting agency will require each BDP contractor whose contract requires the use of etiologic...