

agents to prepare a facility safety program plan based on the criteria below and submit the plan to the contracting agency for review prior to beginning BDP contract operations. The plan will describe the contractor organization, and procedures for meeting DOD, Army, and contracting Command safety requirements as specified in the contract.

(1) A safety training program for all individuals working with etiologic agents must be documented by the contractor and include, as a minimum, the requirements in §626.7(e). Appropriate safety training will be provided to scientists, other laboratory personnel, and unrelated personnel such as technicians, clerical, and maintenance workers. This training will be documented.

(2) The contractor must designate a qualified individual to be responsible for the entire safety program with full authority to develop and enforce contractor safety policies. Regular safety inspections will be conducted and inspection reports will be provided to the contracting agency upon request.

(3) Policies for storing, handling, and moving etiologic agents within the contractor facility shall be included in the plan.

(4) Policies and procedures for disposal of any etiologic agent waste must be identified. Disposal must comply with Federal, State, and local regulations as well as DOD and Army requirements.

(5) An SOP must be established for each area where BDP etiologic agents are stored, transferred, or used. In addition, an SOP must be prepared for operations unique to any specific contract. The contractor will provide the SOP to contracting agency personnel upon request for review.

(6) For contracts requiring BL-3 or BL-4, the contractor will provide (upon request) facility engineering drawings and specifications for the relevant etiologic agent containment areas, associated ventilation systems, and local approving authority. Also to be included is test data verifying that all systems adequately meet the DOD and Army safety requirements, as well as test methods for periodic recertification of the system.

(7) MCE scenarios that ensure that all realistic threats are considered at contractor sites, see §626.12 of this part.

§626.17 Contractor changes.

The contractor will submit proposed changes to the original safety documentation to the contracting agency for review prior to implementation. Requests will include justification and test data verifying that adequate safety will be maintained.

§626.18 BDP contract requirements.

(a) Contractors performing work with BL-3 and BL-4 material must prepare a plan detailing procedures for controlling laboratory mishaps involving etiologic agents.

(1) The contractor shall have the necessary equipment and trained personnel for controlling the mishap.

(2) In the event of an incidental release of a BDP etiologic agent from appropriate laboratory biocontainment that may result in personnel exposure, approved emergency procedures will be initiated immediately to effectively protect personnel and the environment and to constrain the spread of contamination. The affected areas will be decontaminated before normal operations are resumed.

(3) 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.

(4) Local emergency support 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 to provide effective emergency response. Agreements with external agencies must be formalized.

(5) The contractor shall be required to review the plan annually and consult external agencies if there is an agreement for them to provide assistance. This should be done in coordination with the contracting agency.

(b) [Reserved]