

the results of various MCEs. Those assumptions that yield the potential for more severe consequences, as opposed to assumptions that operational and safety controls will always perform as designed, will be used. The rule of reason will be applied to confine the MCE to realistic or believable occurrences.

(c) When considering an MCE, consider the redundancy of safety systems engineered into the facilities and the equipment used, depending on containment level required to make them as fail-safe as practical. The MCE for containment laboratories must be considered in terms of physical containment for both toxins and biological organisms. Therefore, both toxin and biological MCEs will be considered.

(d) Because aerosols of etiologic agents represent the most significant potential hazard for exposure of workers or the environment, a hazard analysis (to include MCE) of proposed BDP RDTE activities will be performed to determine the procedures, engineering controls, and facility design required to mitigate potential significant hazards.

§ 626.13 Controls.

(a) Personnel who are not needed to operate a BDP laboratory, will not be allowed to enter potentially hazardous areas.

(b) Written procedures to control access and ensure that personnel can be evacuated or protected from exposure may be used in place of absolute personnel exclusion.

§ 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 sub-delegated.

(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: (i) Waivers are normally limited to 1 year or less, and will be considered rescinded after 1 year, unless reviewed. The activity or