

Army Regulation 385-69

Safety

Biological Defense Safety Program

Headquarters
Department of the Army
Washington, DC
31 December 1993

Unclassified

SUMMARY of CHANGE

AR 385-69

Biological Defense Safety Program

This regulation--

- o Prescribes policies and procedures for the Army Biological Defense Program.
- o Provides responsibilities for establishing and conducting a safe biological defense research program (para 1-4).
- o Establishes Biological Defense Safety Program requirements for maintaining safe operations (chap 2).
- o Contains approval authority and procedures for requesting and granting waivers and exemptions from program requirements (para 2-10).
- o Contains requirements for overseeing contractor operations(chap 3).
- o Contains requirements for overseeing biological safety studies and reviews (chap 4).

Safety

Biological Defense Safety Program

By Order of the Secretary of the Army:

GORDON R. SULLIVAN
General, United States Army
Chief of Staff

Official:


MILTON H. HAMILTON
Administrative Assistant to the
Secretary of the Army

History. This UPDATE printing publishes a new Army regulation. This publication has been reorganized to make it compatible with the Army electronic publishing database. No content has been changed.

Summary. This regulation implements DODD 5160.5. It establishes the Army Safety Program for all aspects of the Biological Defense Program. It provides new Department of the Army policy on the management of the Biological Defense Safety Program. This regulation implements the Centers for Disease Control—National Institutes of Health Guidelines on Laboratory

Biosafety, Department of Defense and Department of the Army policy statements, and other Federal regulations. It assigns responsibility for safety studies and reviews of biological defense research, development, test and evaluation projects, and prescribes safety precautions and procedures applicable to contractor operations.

Applicability. This regulation applies to Active Army, Army National Guard, U.S. Army Reserve, Army civilian employees, Army contractors with a responsibility for biological defense research, development, test and evaluation operations, and other Federal agencies engaged in biological defense operations for the Department of the Army.

Proponent and exception authority. The proponent of this regulation is the Director of the Army Staff(DAS). The DAS has the authority to approve exceptions to this regulation that are consistent with controlling law and regulation. The DAS may delegate this approval authority, in writing, to a division chief under their supervision within the proponent agency in the grade of colonel or the civilian equivalent.

Army management control process.

This regulation is not subject to the requirements of AR 11-2. It does not contain internal control provisions.

Supplementation. Supplementation of this regulation and establishment of command and local forms are prohibited without prior approval from Army Safety Office (DACS-SF), Chief of Staff, 200 Army Pentagon, Washington DC 20310-0200.

Interim changes. Interim changes to this regulation are not official unless they are authenticated by the Administrative Assistant to the Secretary of the Army. Users will destroy interim changes on their expiration dates unless sooner superseded or rescinded.

Suggested improvements. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to Army Safety Office (DACS-SF), Chief of Staff, 200 Army Pentagon, Washington DC 20310-0200.

Distribution. Distribution of this publication is made in accordance with the special distribution list provided by the proponent, intended for command level D for the Active Army, the Army National Guard, and the U. S. Army Reserve.

Contents (Listed by paragraph and page number)

Chapter 1

Introduction, page 1

Purpose • 1-1, page 1

References • 1-2, page 1

Explanation of abbreviations and terms • 1-3, page 1

Responsibilities • 1-4, page 1

Chapter 2

Biological Defense Safety Policy and Procedures, page 1

Policy • 2-1, page 1

Mishap reporting and investigation • 2-2, page 1

Administrative and work practice controls • 2-3, page 2

Etiologic agent containment • 2-4, page 2

Inspections • 2-5, page 2

Transportation of BDP etiologic agents • 2-6, page 3

General construction plans • 2-7, page 3

Maximum credible event • 2-8, page 3

Controls • 2-9, page 3

Waivers and exemptions • 2-10, page 3

Chapter 3

Biological Defense Program Contractors, page 4

Written procedures for contractor review • 3-1, page 4

Contracting agencies • 3-2, page 4

Contractor changes • 3-3, page 4

BDP contract requirements • 3-4, page 4

Chapter 4

Biological Defense Program Safety Studies and Reviews, page 5

Assuring maximum safety • 4-1, page 5

Special studies • 4-2, page 5

Appendix A. References, page 6

Glossary

Index

RESERVED

Chapter 1 Introduction

1-1. Purpose

a. This regulation prescribes Department of the Army (DA) safety policy, responsibilities, and procedures for biological defense research, development, test, and evaluation (RDTE) operations.

b. DA Pam 385-69 provides the minimum safety criteria and technical requirements for the Army biological defense safety program and will be used together with this regulation to establish and implement the Biological Defense Safety Program.

1-2. References

Required and related publications and prescribed and referenced forms are listed in appendix A.

1-3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

1-4. Responsibilities

a. The Assistant Secretary of the Army (Installations, Logistics, and Environment) (ASA(IL&E)) establishes overall Army occupational safety and health policy and maintains oversight of the following:

(1) All aspects of environment, safety, and occupational health statutory compliance.

(2) Safe biological defense RDTE operations.

b. The Assistant Secretary of the Army (Research, Development, and Acquisition) (ASA(RDA)) establishes overall Army RDA policy and will—

(1) Integrate, coordinate, and manage Army efforts to increase effectiveness of biological defense technologies, materiel research, and the development and acquisition program.

(2) Review and validate all future biological defense RDTE facility construction or renovation requirements before any organization initiates these construction or renovation programs.

c. The Director of Army Safety (DASAF), Office of the Chief of Staff, U.S. Army (OCSA), administers and directs the Army Safety Program as specified in AR 385-10. The DASAF will—

(1) Manage Army-wide safety policy and guidance for biological defense RDTE programs as a part of the Army Safety Program.

(2) Approve all actions that imply or establish a DA safety position for biological defense RDTE covered by this regulation.

(3) Represent DA on all biological defense RDTE safety studies and reviews.

(4) Develop safety policy and standards for biological defense RDTE operations.

(5) Develop Army level safety program guidance.

(6) Conduct an annual management review of the biological defense safety and health occupational programs of commands with Biological Defense Program (BDP) operations and responsibilities, to ensure consistency with DA policy.

(7) Conduct biological defense safety evaluation visits and advise the Army Staff (ARSTAF) of concerns, trends, and needed corrective actions.

(8) Develop policies and provide guidance for executing the Biological Defense Safety Program.

(9) Conduct the review of general construction plans for biological defense RDTE facilities.

(10) Establish procedures to investigate biological defense related mishaps, referenced in AR 385-40.

(11) Serve as proponent for Army biological safety training.

d. The Commanding General, U. S. Army Corps of Engineers, (CG, USACE) will establish procedures to ensure that biological defense RDTE facilities are designed, constructed, and acquired in accordance with current Federal, State, Department of Defense (DOD), and DA regulatory standards.

e. The Surgeon General (TSG) will—

(1) Develop occupational health standards and medical support policies for the BDP.

(2) Provide advice and guidance for health hazard assessments and medical surveillance in accordance with current directives and policies.

(3) Provide medical guidance for selecting appropriate protective equipment for use in the BDP.

(4) Provide a representative to each BDP special safety study group.

(5) Provide occupational health support to the DASAF for conduct of annual management reviews (para c(6) above).

f. The Commander, U. S. Army Medical Research and Development Command (USAMRDC), in addition to major Army commands (MACOMs) responsibilities, will—

(1) Conduct safety site assistance visits at BDP Army research facilities, on a periodic basis as determined necessary by the DASAF, and advise the ARSTAF of findings and recommendations.

(2) Provide a group member for all other studies and reviews.

(3) Assist Headquarters, Department of the Army (HQDA) in its oversight role of monitoring biological defense RDTE activities throughout the Army and advise HQDA on concerns, trends, and corrective actions required.

(4) Assist the DASAF in performing biological defense safety program mishap investigations.

(5) Assist the DASAF in developing biological defense safety policy and recommend changes to policies and procedures.

(6) Serve as the proponent for the BDP Special Immunization Program.

g. Commanders of MACOMs with a BDP mission will—

(1) Establish and operate an effective safety program.

(2) Publish a command program to implement HQDA biological safety standards and to identify responsibilities for all subordinate organizations that maintain, store, handle, use, transport, or dispose of etiologic agents used in the BDP.

(3) Supervise subordinate organizations to ensure that an effective safety program, which complies with this regulation, DA Pam 385-69, and AR 385-10 is implemented and maintained.

(4) Ensure that biological defense safety programs comply with the provisions of this regulation and DA Pam 385-69.

(5) Appoint a safety and occupational health manager per AR 385-10, who is occupationally qualified under Office of Personnel Management standards and has special knowledge of biological safety and health requirements. This safety and occupational health manager should be the single point of contact for all aspects of the BDP Safety Program.

(6) Review standing operating procedures (SOPs) for biological defense RDTE operations.

(7) Develop and submit general construction plans for approval through command channels to Army Safety Office (DACS-SF), Chief of Staff, 200 Army Pentagon, Washington DC 20310-0200.

(8) Approve or disapprove individual access to etiologic agent restricted areas.

(9) Implement a Chemical Hygiene Plan, as appropriate, which meets the requirement of section 1910, part 1450, title 29 Code of Federal Regulations.

Chapter 2 Biological Defense Safety Policy and Procedures

2-1. 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 385-69.

2-2. Mishap reporting and investigation

Biological defense RDTE related mishaps will be reported and investigated per AR 385-40 and AR 40-400. Follow procedures in

AR 40–400 for completing the Med 16 Report. This report will be used to report only personnel exposure or illness related to the BDP.

2–3. Administrative and work practice controls

a. Minimizing exposure. 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. Open air testing under the BDP is restricted to use of simulated etiologic agents only, unless the Secretary of Defense determines that testing is necessary for national security in accordance with Title 50, U.S. Code section 1512. 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 conducted in appropriate biosafety level containment laboratories.

c. Hazard analysis. 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. Required SOP. 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 effects, 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 will 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

will receive specialized training on the 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 DA Pam 385–69, chap 5.)

(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.

2–4. 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.

2–5. Inspections

a. Biological 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 occupational 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, that 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 will inspect work areas frequently (at least weekly) and take corrective actions promptly.

2-6. Transportation of BDP etiologic agents

a. Etiologic agents utilized in the BDP will be packed, labeled, marked, prepared for shipment, and shipped in accordance with applicable Federal, State, and local laws and regulations, to include Title 42, Code of Federal Regulations (CFR) Part 72, "Interstate Shipment of Etiologic Agents," 49 CFR 172 and 173 (Department of Transportation), 9 CFR 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 DA Pam 385-69, para 6-4.)

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. All etiologic agents assigned to biosafety level 4 or USDA-restricted animal pathogens approved for shipment and properly packaged will be accompanied by a designated courier, or under close supervision of a responsible party who will monitor aspects of the shipment, ensuring 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 will 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 agents shipped and received.

2-7. 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 Army Safety Office (DACS-SF), Chief of Staff, 200 Army Pentagon, Washington DC 20310-0200, for safety review and approval. Plans for new construction or major modifications of facilities used in the BDP will be forwarded. The facility system safety requirements of AR 385-16 and AR 415-15 will be followed. Simultaneously, RDTE requirements that necessitate such renovation, modification, or construction will be submitted through the chain of command to Asst Secy Army Research Development Acquisition, 103 Army Pentagon, Washington DC 20310-0200.

2-8. Maximum credible event

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. Maximum credible event (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 analyses and general construction plans mentioned in paragraph 2-7 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 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.

2-9. 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.

2-10. Waivers and exemptions

a. *Compensatory measures.* The goal of the biological defense safety program is strict adherence to safety standards and the elimination of all waivers and exemptions. Compensatory measures will be applied, commensurate with risk, to each waiver or exemption in effect.

b. *Waiver authority.*

(1) The 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—

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

(b) 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. Command safety offices will submit waiver requests for independent technical review and provide an accept or reject recommendation to their commander. When such waivers affect other commands, initiating activities will coordinate requests with those commands.

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

(a) 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 etiologic agents required.

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

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

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

(e) 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.

(f) 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 Army Safety Office (DACS-SF), Chief of Staff, 200 Army Pentagon, Washington 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.

(a) Waivers are normally limited to 1 year or less, and will be considered rescinded after 1 year, unless reviewed. The activity or installation commander forwarding a request for waiver will allow time to permit investigation, evaluation, and reply.

(b) Waivers may be renewed each year by the commander originally granting the waiver for a waiver period not to exceed 5 years. Prior to renewal, commanders will review the need for the waiver to ensure that circumstances requiring the waiver have not changed. Results of this review (and a progress report regarding milestones that have been completed) will be forwarded through command channels to the commander originally granting the waiver.

(c) A request for amendment will be initiated when factors or circumstances requiring a change to the original waiver are identified.

(d) When factors or circumstances prevent correction of the waiver condition within 5 years of the initial approval of the waiver, such condition becomes a candidate for an exemption.

d. Exemptions.

(1) Exemptions are relatively long-term exceptions to otherwise mandatory standards. Exemptions will be granted only under the following conditions:

(a) If corrective measures are impractical.

(b) If impairment of the overall defense posture would result.

(c) If positive programs to eliminate the need for the exemption are being pursued.

(2) Exemptions can be approved only by the Secretary of the Army.

(a) Requests for exemptions will be sent through command channels to Army Safety Office (DACs-SF), Chief of Staff, 200 Army Pentagon, Washington DC 20310-0200.

(b) Exemption requests will include the information required in (2) above.

(c) Copies of exemption requests will be maintained at the installation and MACOM or USAMRDC safety offices.

Chapter 3 Biological Defense Program Contractors

3-1. Written procedures for contractor review

The contracting agency will prepare written procedures for reviewing contractor capability to perform BDP work with etiologic agents safely. 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.

3-2. 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 biosafety level 3 or 4 (BL-3 or BL-4) agents. Inspections will be conducted by safety and occupational 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, the need for major corrective measures is noted, 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 semiannual inspections 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 occupational 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 occupational health professionals or contracting agency representatives who are trained in biological safety inspection techniques. The safety inspection checklist in DA Pam 385-69, appendix B, will be used.

c. Inspections of contractor laboratories outside of the continental United States (OCONUS) will be based on published safety standards of the country in which studies are proposed or conducted. In the absence of such standards, a checklist will be used which is based on guidelines published by the World Health Organization (Laboratory Safety Manual) for laboratory containment appropriate to the risk group level associated with the work being done. The risk group level assignment will be based on such factors as the pathogenicity of the agent, modes of transmission and host range, concentration of agent, procedures to be performed, individual risk including availability of preventive measures and treatment, and community risk in the geographic area in which the laboratory is located.

d. The contracting agency will require each BDP contractor whose contract requires the use of etiologic 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 paragraph 2-3e. 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 will 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(s).

(7) For MCE scenarios that ensure that all realistic threats are considered at contractor sites, see paragraph 2-8.

3-3. 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.

3-4. 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 will 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 will be required to review the plan annually and consult external agencies if there is an agreement for them to provide assistance. This plan will be sent to the contracting agency.

b. Not used.

Chapter 4 Biological Defense Program Safety Studies and Reviews

4-1. Assuring maximum safety

a. Safety studies and reviews are conducted to assure that maximum safety and occupational health measures are being taken to prevent mishaps involving BDP etiologic agents in any amount or under any conditions that may cause incapacitation, illness, or death to any person, or adverse effects on the public or to the environment.

b. The system safety requirements of AR 385-16 will be followed during all BDP safety studies and reviews.

4-2. Special studies

Any HQDA agency may recommend a special study or review of an etiologic agent or system when it becomes necessary to investigate the condition or changes described below. The responsible HQDA agency will determine the scope and conduct the study or review. Special study activities will be coordinated with Army Safety Office (DACS-SF), Chief of Staff, 200 Army Pentagon, Washington DC 20310-0200.

a. Conditions or practices which may affect safety.

b. Major system modifications including both design and physical configuration changes.

c. Significant changes to safety, health, and environmental protection standards and requirements that affect BDP operations.

Appendix A References

Section I Required Publications

AR 40-5

Preventive Medicine. (Cited in para 2-3f.)

AR 40-400

Patient Administration. (Cited in para 2-2.)

AR 385-10

Army Safety Program. (Cited in paras 1-4c, 1-4g(3), and 1-4g(5).)

AR 385-16

System Safety Engineering and Management. (Cited in paras 2-7a and 4-1b.)

AR 385-40

Accident Reporting and Records. (Cited in paras 1-4c(10) and 2-2.)

AR 415-15

Military Construction, Army (MCA) Program Development. (Cited in para 2-7.)

DA Pam 385-69

Biological Defense Safety Program. (Cited in paras 1-1b, 1-4g(3), 1-4g(4), 2-1b, 2-3h(1), 2-3i, 2-3i(1), 2-3k, 2-4b, 2-6b, and 3-2b.)

World Health Organization Laboratory Biosafety Manual, Geneva 1983. (Cited in para 3-2c.) (This manual is available from the World Health Organization Publications Center, 49 Sheridan Avenue, Albany, NY 12210.)

Section II Related Publications

A related publication is merely a source of additional information. The user does not have to read it to understand this publication.

AR 40-10

Health Hazard Assessment Program in Support of the Army Materiel Acquisition Decision Process

AR 70-1

Systems Acquisition Policy and Procedures

AR 70-10

Test and Evaluation During Development and Acquisition of Materiel

AR 70-18

The Use of Animals in DOD Programs

AR 70-25

Use of Volunteers as Subjects of Research

AR 70-65

Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities

AR 200-1

Environmental Protection and Enhancement

AR 200-2

Environmental Effects of Army Actions

AR 405-90

Disposal of Real Estate

Department of Health and Human Services Publication No. (NIH)88-8395, May 1988, Biosafety in Microbiological and Biomedical Laboratories. (This publication is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC.20402.)

Section III Prescribed Forms

This section contains no entries.

Section IV Referenced Forms

This section contains no entries.

Glossary

Section I Abbreviations

ARSTAF

Army Staff

ASA (IL&E)

Assistant Secretary of the Army (Installations, Logistics, and Environment)

ASA (RDA)

Assistant Secretary of the Army (Research, Development, and Acquisition)

CG

commanding general

CSA

Chief of Staff, U. S. Army

DA

Department of the Army

DAS

Director of the Army Staff

DOD

Department of Defense

HQDA

Headquarters, Department of Army

MACOM

major Army command

OCONUS

outside of the continental United States

OCSA

Office of the Chief of Staff, U. S. Army

RDTE

research, development, test, and evaluation

SOP

standing operating procedure

TSG

The Surgeon General

USACE

U. S. Army Corps of Engineers

Section II

Terms

Biological defense mishap

An event in which the failure of laboratory facilities, equipment, or procedures appropriate to the level of potential pathogenicity or toxicity of a given etiologic agent (organism or toxin) may allow the unintentional, potential exposure of humans or the laboratory environment to that agent. Mishaps can be categorized into those resulting in confirmed exposures and those resulting in potential exposures. A confirmed accidental exposure is any mishap in which there was direct evidence of an exposure, such as a measurable rise in specific antibody titer to the etiologic

agent in question, or a confirmed diagnosis of intoxication or disease. A potential exposure is any mishap in which there was reason to believe that anyone working with an etiologic agent may have been exposed to that agent, yet no measurable rise in specific antibody titer or diagnosis of illness or disease can be found. However, there is reason to believe in such a case that the possibility existed for introduction of an etiologic agent through mucous membranes, the respiratory tract, broken skin, or the circulatory system as a direct result of the incident or injury.

Biocontainment area

An area which meets the requirements for a BL-3 or BL-4 facility. The area may be an entire building, a suite of rooms, a single room within a building, or a biological safety cabinet.

Biological safety cabinets

Engineering controls designed to enable laboratory workers to handle infectious etiologic agents and to provide primary containment of any resultant aerosol. There are three major classes of cabinets (I, II, and III) and several subclasses of class II cabinets. Each type of cabinet provides a different degree of protection to personnel and to the products handled inside them.

Biosafety level

A combination of facilities, equipment, and procedures used in handling etiologic agents to protect the worker, environment, and the community. This combination is proportional to the potential hazard of the etiologic agent in question.

Biosafety level 1

The facilities, equipment, and procedures suitable for work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment.

Biosafety level 2

The facilities, equipment, and procedures applicable to clinical, diagnostic, or teaching laboratories, suitable for work involving indigenous agents of moderate potential hazard to personnel and the environment. It differs from BL-1 in that—*a.* The laboratory personnel have specific training in handling pathogenic agents, *b.* The laboratory is directed by scientists with experience in the handling of specific agents, *c.* Access to the laboratory is limited when work is being conducted, and *d.* Certain procedures in which infectious aerosols could be created are conducted in biological safety cabinets or other physical containment equipment. Personnel must be trained. Strict adherence to recommended practices is as important in attaining the maximum containment capability as is the mechanical performance of the equipment itself.

Biosafety level 3

The facilities, equipment, and procedures applicable to clinical, diagnostic, research, or

production facilities in which work is performed with indigenous or exotic agents where there is potential for infection by aerosol and the disease may have serious or lethal consequences. It differs from BL-2 in that—*a.* More extensive training in handling pathogenic and potentially lethal agents is necessary for laboratory personnel, *b.* All procedures involving the manipulation of infectious material are conducted within biological safety cabinets, or by other physical containment devices, *c.* The laboratory has special engineering and design features, including access zones, sealed penetrations, and directional airflow, and *d.* Any modification of BL-3 recommendations must be made only by the commander or director.

Biosafety level 4

The facilities, equipment, and procedures required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. It differs from BL-3 in that—*a.* Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents, *b.* Laboratory personnel understand the primary and secondary containment functions of the standard and special practices, containment equipment, and laboratory design characteristics, *c.* Access to the laboratory is strictly controlled by the commander or director, *d.* The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building, *e.* A specific facility operations manual is prepared or adopted, *f.* Within work areas of the facility, all activities are confined to Class III biological safety cabinets or Class I or Class II biological safety cabinets used together with one-piece positive pressure personnel suits ventilated by a life support system, and *g.* The maximum containment laboratory has special engineering and design features to prevent microorganisms from being disseminated to the environment.

Building

A structure that contains the requisite components necessary to support a facility that is designed according to the required biosafety level. The building can contain one or more facilities conforming to one or more biosafety levels.

Confirmed exposure

Any mishap with a BDP agent in which there was direct evidence of an actual exposure such as a measurable rise in antibody titer to the agent, or a confirmed diagnosis of intoxication or disease.

Decontamination

The physical or chemical processes by which an object or area, contaminated with a harmful or potentially harmful etiologic agent, is made safe for handling or use. Such processes include physical removal of all

contaminants, thermal destruction of biological activity (sterilization), chemical inactivation (biocidal process), or a combination of these methods.

Etiologic agent

A viable microorganism, or its toxin which causes or may cause human disease, and includes those agents listed in 42 CFR 72.3 of the Department of Health and Human Services regulations, and any material of biological origin that poses a degree of hazard similar to those organisms.

Exemption

A permanent written exemption approved by HQDA from a requirement imposed by this regulation. An exemption is based on a determination that conformity to the established standard is impossible, highly impracticable, unnecessary, or not in the best interest of the United States Government.

First aid

Any onetime treatment, and any follow-up visit for observation of minor scratches, cuts, burns, splinters, and so forth, which do not ordinarily require medical care. Such one-time treatment and follow-up visit for observation is considered first aid, even though provided by a physician or registered medical professional personnel.

High efficiency particulate air (HEPA) filter

A filter which removes particulate matter down to sub-micron sized particles from the air passed through it with a minimum efficiency of 99.97 percent. HEPA filters remove particulate matter with great efficiency while vapors and gases (for example from volatile chemicals) are not removed and pass through unrestricted. HEPA filters are used as the primary means of removing infectious agents from air exhausted from engineering controls and facilities.

Institute director

The commander of an Army activity conducting RDTE with BDP etiologic agents, or the equivalent at a research organization under contract to the BDP.

Institution

An organization such as an Army RDTE activity (institute, agency, center, or similar facility), or a contract organization such as a school of medicine or research institute, that conducts RDTE with BDP etiologic agents.

Laboratory

An individual room or rooms within a facility that provides space in which work with etiologic agents may be performed. It contains all of the appropriate engineering features and equipment required at a given biosafety level to protect personnel working in the laboratory and the environment external to the facility.

Potential accidental exposure

Any mishap in which a high probability existed for introduction of an agent through mucous membranes, ingestion, respiratory tract, broken skin, or circulatory system as a direct result of the accident, injury, or incident.

Resource Conservation Recovery Act (RCRA) Listed Hazardous Waste

The waste materials listed by the Environmental Protection Agency under authority of the RCRA for which the disposal is regulated by the Environmental Protection Agency. A description and listing of these wastes is located in Title 40, Code of Federal Regulations, Part 261.

Sterilization

The complete destruction of all forms of microbial life.

Suite

An area consisting of more than one room, and designed to be a functional unit in which laboratory operations can be conducted. Suites may contain a combination of laboratories and animal holding rooms or both and associated support areas within a facility that are designed to conform to a particular biosafety level. There may be one or more suites within a facility.

Toxin

Toxic material of biologic origin that has been isolated from the parent organism. The toxic material of plants, animals, or microorganisms.

Waiver

A temporary (1 year or less) written relief from a requirement imposed by this regulation, pending accomplishment of actions or programs which will result in conformance to the required standards. Waivers will not be extended beyond 5 years.

Section III Special Abbreviations and Terms

BDP

Biological Defense Program

BL

Biosafety level

DASAF

Director of Army Safety

MCE

maximum credible event

USAMDRC

U.S. Army Medical Research and Development Command

Index

This index is organized alphabetically by topic and by subtopic within a topic. Topics and subtopics are identified by paragraph number.

Administrative controls, 2-3

Aerosols, 2-8

Assistant Secretary of the Army (Installations, Logistics and Environment)(ASA(IL&E)), 1-4

Assistant Secretary of the Army (Research, Development, and Acquisition)(ASA(RDA)), 1-4, 2-7

Audit trails, 2-6

BDP studies and reviews, 4-1

Construction, 1-4, 2-7

Plan Approval, 2-7

Plans, 2-7

Contracting, 3-1, 3-2

Agency oversight, 3-2

BDP contract requirements, 3-4

Pre-award surveys, 3-2

Controls

Access, 2-9

Engineering 2-4, 2-8

Work practice 2-3, 2-4

Director of Army Safety (DASAF), 1-4

Disposal, 2-3, 3-2

Emergency preparedness, 2-3

Etiologic agent containment, 3-2,3-4

Exemptions, 2-10

Health assessments, 2-3

Immunizations, 2-3

Inspections, 2-5, 3-2

Labeling hazards, 2-3

Maintenance, 2-3

Maximum credible event, 2-8

Medical officer training, 2-3

Medical surveillance, 1-4, 2-3,3-4

Posting hazards, 2-3

Protective equipment, 1-4, 2-3,2-4

References, 1-2

Safety analysis, 2-3

Shipping, 2-6

Signs,

Exposure of, 2-3

Hazard, 2-3

SOP, 1-4, 2-3, 2-4,3-2

Special studies, 4-2

System safety, 2-7, 4-1

Surgeon General (TSG), 1-4

Training, 2-3, 2-5, 3-2,3-4

Transportation, 2-6

United States Army Corps of Engineers, 1-4

United States Army Medical Research and Development Command(USAMRDC), 1-4, 2-10,

Waivers

Authority, 2-10

Limitations, 2-10

Requests, 2-10

Work practice controls, 2-3

Unclassified

PIN 071616-000

USAPA

ELECTRONIC PUBLISHING SYSTEM
TEXT FORMATTER ... Version 2.63

PIN: 071616-000

DATE: 08-11-99

TIME: 11:59:43

PAGES SET: 13

DATA FILE: ar385-69.fil

DOCUMENT: AR 385-69

DOC STATUS: NEW PUBLICATION