

### Subpart D—BDP Studies and Reviews

#### § 626.19 Assuring maximum safety.

(a) Safety studies and reviews are conducted to assure that maximum safety and 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.

#### § 626.20 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 HQDA, DACS–SF, WASH 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 TO PART 626—REFERENCES

These publications can be obtained from the National Technical Information Services, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161.

#### REQUIRED PUBLICATIONS

- AR 40–5—Preventive Medicine. (Cited § 626.7(f) introductory text)
- AR 40–400—Patient Administration. (Cited in § 626.6)
- AR 385–10—Army Safety Program. (Cited in §§ 626.4(c) introductory text, 626.4(g)(3), and 626.4(g)(5))
- AR 385–16—System Safety Engineering and Management. (Cited in §§ 626.11, and 626.19)
- AR 385–40—Accident Reporting and Records. (Cited in §§ 626.4(c)(10) and 626.6)
- AR 415–15—Military Construction, Army (MCA) Program Development. (Cited in § 626.11)
- DA Pam 385–69—Biological Defense Safety Program. (Cited in §§ 626.1(b), 626.4(g)(3),

626.4(g)(4), 626.5(b), 626.7(h)(1), 626.7(i) intro text, 626.7(i)(1), 626.7(k), 626.8(b), 626.10(a), 626.10(b), and 626.16(b))  
Med 16 Report. (Cited in § 626.6)

#### RELATED PUBLICATIONS

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

- 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

#### APPENDIX B TO PART 626—GLOSSARY ABBREVIATIONS

- AMC—United States Army Materiel Command
- AR—Army regulation
- 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)
- BDP—Biological Defense Program
- BL—Biosafety level
- CG—commanding general
- CSA—Chief of Staff, United States Army
- DA—Department of the Army
- DA Pam—Department of the Army Pamphlet
- DASAF—Director of Army Safety
- DCSOPS—Deputy Chief of Staff for Operations and Plans
- DOD—Department of Defense
- HEPA—high efficiency particulate air
- HQDA—Headquarters, Department of Army
- IPR—in process reviews
- MACOM—major Army command
- MCA—Military Construction, Army
- MCE—maximum credible event
- OCSA—Office of the Chief of Staff, United States Army
- R&D—research and development
- RDTE—research, development, test, and evaluation
- RCRA—Resource Conservation Recovery Act

SOP—standing operating procedure  
 TSG—The Surgeon General, Army  
 USACE—United States Army Corps of Engineers  
 USAMRDC—United States Army Medical, Research and Development Command

## 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 sub-classes 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 (1) laboratory personnel have specific training in handling pathogenic agents, (2) the laboratory is directed by scientists with experience in the handling of specific agents, (3) access to the laboratory is limited when work is being conducted, and (4) 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 (1) more extensive training in handling pathogenic and potentially lethal agents is necessary for laboratory personnel, (2) all procedures involving the manipulation of infectious material are conducted within biological safety cabinets, or by other physical containment devices, (3) the laboratory has special engineering and design features, including access zones, sealed penetrations, and directional airflow, and (4) any modification of BL-3 recommendations must be made only by the commander.

*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 (1) members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents, (2) laboratory personnel understand the primary and secondary containment functions of the standard and special practices, containment equipment, and laboratory design characteristics, (3) access to the laboratory is strictly controlled by the commander, (4) 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, (5) a specific facility operations manual is prepared or adopted, (6) 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 in conjunction with one-piece positive pressure personnel suits ventilated by a life support system, and (7) 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 for 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 one-time treatment, and any follow-up visit for the purpose of 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 there was reason to believe that anyone working with a BDP material may have been exposed to that material, yet no measurable rise in antibody titer or diagnosis of intoxication or disease was made. However, the 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 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 40 CFR 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.

## **PART 627—THE BIOLOGICAL DEFENSE SAFETY PROGRAM, TECHNICAL SAFETY REQUIREMENTS (DA PAMPHLET 385-69)**

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