

(2) Letter from special Assistant Attorney General for the State of Wyoming to Assistant Regional Counsel, EPA Region VIII, May 13, 1982;

(3) Letter from special Assistant Attorney General for the State of Wyoming to Assistant Regional Counsel, EPA Region VIII, July 1, 1982.

(d) *Program Description.* The Program Description and other material submitted as part of the application or amendments thereto, including the memorandum to the National UIC Branch reporting on Improvement to the Wyoming Oil and Gas 1425 program, dated April 28, 1989.

c. By revising § 147.2553(a) to read as follows:

§ 147.2553 EPA-administered program—Indian lands.

(a) *Contents.* The UIC program for all classes of wells on Indian lands in the State of Wyoming is administered by EPA. This program consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and any additional requirements set forth in the remainder of this subpart. Injection well owners and operators, and EPA shall comply with these requirements.

51. In Subpart AAA—Guam, by revising § 147.2601(a) to read as follows:

§ 147.2601 EPA-administered program—Indian lands.

(a) *Contents.* The UIC program for Indian lands in the territory of Guam is administered by EPA. This program consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and any additional requirements set forth in the remainder of this subpart. Injection well owners and operators, and EPA shall comply with these requirements.

52. In Subpart BBB—Puerto Rico, by revising § 147.2651(a) to read as follows:

§ 147.2651 EPA-administered program.

(a) *Contents.* The UIC program for Puerto Rico, including all Indian lands, is administered by EPA. This program consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and any additional requirements set forth in the remainder of this subpart. Injection well owners

and operators, and EPA shall comply with these requirements.

53. In Subpart CCC—Virgin Islands, by revising § 147.2701(a) to read as follows:

§ 147.2701 EPA-administered program.

(a) *Contents.* The UIC program for the Virgin Islands, including all Indian lands, is administered by EPA. This program consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and any additional requirements set forth in the remainder of this subpart. Injection well owners and operators, and EPA shall comply with these requirements.

54. In Subpart DDD—American Samoa, by revising § 147.2751 (a) to read as follows:

§ 147.2751 EPA-administered program.

(a) *Contents.* The UIC program for American Samoa, including all Indian lands, is administered by EPA. This program consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and any additional requirements set forth in the remainder of this subpart. Injection well owners and operators, and EPA shall comply with these requirements.

55. In Subpart EEE—Commonwealth of the Northern Mariana Islands, by revising § 147.2801(a) to read as follows:

§ 147.2801 EPA-administered program—Indian lands.

(a) *Contents.* The UIC program for Indian lands in the Commonwealth of the Northern Mariana Islands is administered by EPA. This program consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and any additional requirements set forth in the remainder of this subpart. Injection well owners and operators, and EPA shall comply with these requirements.

56. In Subpart FFF—Trust Territory of the Pacific Islands, by revising § 147.2851(a) to read as follows:

§ 147.2851 EPA-administered program.

(a) *Contents.* The UIC program for Trust Territory of the Pacific Islands, including all Indian lands, is administered by EPA. This program

consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and any additional requirements set forth in the remainder of this subpart. Injection well owners and operators, and EPA shall comply with these requirements.

57. In Subpart HHH—Lands of the Navajo, Ute Mountain Ute, and All Other New Mexico Tribes, by revising § 147.3000(a) to read as follows:

§ 147.3000 EPA-administered program.

(a) *Contents.* The UIC program for the Indian lands of the Navajo, the Ute Mountain Ute (Class II wells only on Ute Mountain Ute lands in Colorado and all wells on Ute Mountain Ute lands in Utah and New Mexico), and all wells on other Indian lands in New Mexico is administered by EPA. (The term "Indian lands" is defined at 40 CFR 144.3.) The Navajo Indian lands are in the States of Arizona, New Mexico, and Utah; and the Ute Mountain Ute lands are in Colorado, New Mexico and Utah. This program consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and additional requirements set forth in the remainder of this subpart. The additions and modifications of this subpart apply only to the Indian lands described above. Injection well owners and operators, and EPA shall comply with these requirements.

58. In Subpart III—Lands of Certain Oklahoma Indian Tribes, by revising § 147.3100(a) to read as follows:

§ 147.3100 EPA-administered program.

(a) *Contents.* The UIC program for the Indian lands in Oklahoma, except for that covering the Class II wells of the Five Civilized Tribes, is administered by EPA. The UIC program for all wells on Indian lands in Oklahoma, except Class II wells on the Osage Mineral Reserve (found at 40 CFR part 147, Subpart GGG) and the Class II program for the Five Civilized Tribes, consists of the UIC program requirements of 40 CFR parts 124, 144, 146, 148, and additional requirements set forth in the remainder of this subpart. Injection well owners and operators, and EPA shall comply with these requirements.

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Part III

Department of Defense

Department of the Army

32 CFR Part 627

**The Biological Defense Safety Program—
(Technical Safety Requirements)—DA
Pamphlet 385-69; Final Rule**

DEPARTMENT OF DEFENSE**Department of the Army****32 CFR Part 627****Biological Defense Safety Program
(Technical Safety Requirements) (DA
Pamphlet 385-69)****AGENCY:** Department of the Army, DOD.**ACTION:** Final rule.

SUMMARY: The Department of the Army (DA) acting as executive agent for the Department of Defense announces the Technical Safety Requirements of the Army Biological Defense Safety Program contained in 32 CFR part 626 and in Department of the Army Pamphlet 385-69. This rule prescribes the technical safety requirements for the use, handling, shipment, storage and disposal of etiologic agents used in research, development, test, and evaluation (RDT&E) for the Biological Defense Program (BDP).

EFFECTIVE DATE: April 5, 1991.**FOR FURTHER INFORMATION CONTACT:**

If you wish to comment or obtain further information concerning this publication contact: HQDA(DACS-SF), Mr. William Wortley, room 2C717, Pentagon, Washington, DC 20310-0200, (703) 695-7291.

SUPPLEMENTARY INFORMATION: The U.S. Army BDP, on behalf of the Department of Defense, supports RDT&E efforts to maintain and develop defensive measures and materiel to meet potential biological warfare threats. The program's objectives are to develop measures for identification, detection, treatment, protection, and decontamination of these threats. To meet the program objectives, it is necessary to use etiologic agents in the conduct of the necessary RDT&E. This document contains information on the safe use, handling, storage, shipment and disposal of etiologic agents and describes requirements based on the Centers for Disease Control Guidelines, Biosafety in Microbiological and Biomedical Laboratories, and establishes guidelines for toxins. This document was developed in coordination with the biological defense community and fully staffed and coordinated with subject matter experts, the Army Staff, and applicable major commands. Army-wide implementation of this program is authorized based on the policies and standards contained in the cited authority and references.

Executive Order 12291

This final rule has been reviewed under Executive Order 12291 and the

Secretary of the Army has classified this action as nonmajor. The effect of the final rule on the economy will be less than \$100 million.

Regulatory Flexibility Act

This final rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 and the Secretary of the Army has certified that this action does not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

This final rule does not contain reporting or recordkeeping requirements subject to approval by the Office of Management and Budget under the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

List of Subjects in 32 CFR Part 627

Safety, Occupational safety and health, Biological, Defense.

Accordingly, 32 CFR part 627 is added to read as follows:

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

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Appendix A to Part 627—References

Appendix B to Part 627—Resource List for Immunoprophylaxis of Personnel at Risk

Appendix C to Part 627—Laboratory Safety Inspection Check List

Appendix D to Part 627—Packaging and Labeling Requirements for Shipment of Etiologic Agents

Appendix E to Part 627—Permits for Importation and Shipment of Etiologic Agents

Appendix F to Part 627—Glossary

Authority: 5 U.S.C. 102, 21 U.S.C. 111, 151-158; 42 U.S.C. 216; sec. 361, 58 Stat. 703 and 264; 49 U.S.C. App. 1803, 1804, 1807 and 1808; 50 U.S.C. 1431, 29 CFR part 1910, section 1450(e) and Pub. L. 101-510.

Subpart A—Introduction**§ 627.1 Purpose.**

This pamphlet prescribes the technical safety requirements for the use, handling, shipment, storage and disposal of etiologic agents used in research, development, test, and evaluation (RDT&E) for the Biological Defense Program (BDP).

§ 627.2 Background.

The U.S. Army BDP, on behalf of the Department of Defense, supports RDT&E efforts to maintain and develop defensive measures and materiel to

meet potential biological warfare threats. The program's objectives are to develop measures for identification, detection, treatment, protection, and decontamination of these threats. To meet the program objectives, it is necessary to use etiologic agents in the conduct of the necessary RDT&E. This pamphlet contains information on the safe use, handling, storage, shipment and disposal of etiologic agents. This pamphlet describes requirements based on the Centers for Disease Control (CDC-NIH) guidelines, Biosafety in Microbiological and Biomedical Laboratories, and establishes guidelines for toxins.

§ 627.3 Scopes.

The requirements stated in this pamphlet apply to all elements of the Army to include the ARNG and the USAR and its contractors and subcontractors who use, produce, store, handle or ship etiologic agents in support of the BDP, regardless of the source of the agent(s).

§ 627.4 References.

A listing of references is contained in appendix A to part 627.

§ 627.5 Abbreviations and terms.

Abbreviations and special terms used in this pamphlet are explained in appendix F to part 627.

Subpart E—Administration

§ 627.6 Safety administration.

Each BDP institution must have a safety program that complies with AR 385-10, AR 385-69, and this pamphlet. In addition, the safety program must be designed to ensure compliance with Occupational Safety and Health Administration (OSHA) requirements for health and safety; Environmental Protection Agency (EPA) regulations designed to implement the Resource Conservation and Recovery Act (RCRA) and/or the National Environmental Policy Act (NEPA); Nuclear Regulatory Commission (NRC) requirements for safe handling of radioactive isotopes (when applicable); NIH Guidelines for Research Involving Recombinant DNA Molecules; relevant national, state and local regulations; and any requirements of applicable accrediting bodies.

(a) *Goals of a Laboratory Safety Program.* The goals of the laboratory safety program are to protect those working in the laboratory, others who may potentially be exposed to hazards in the laboratory, and the environment. In addition, a laboratory safety program should ensure that hazardous materials will be handled and disposed of in such a way that people, other living

organisms, and the environment are protected from harm. Safety awareness must be a part of everyone's habits, and can only be achieved if all senior and responsible staff have a sincere, visible, and continuing interest in the prevention of injuries and occupational illnesses. Laboratory personnel, for their part, must accept responsibility for carrying out their work in a way that protects themselves and their fellow workers.

(b) *Responsibility for Laboratory Safety.* Responsibilities for the safety program are as stated in AR 385-69. Additionally, the program will contain the following elements:

(1) The ultimate responsibility for safety within an institution lies with the Commander or Institute Director, who, along with all personnel, must have a continuing, observable and known commitment to the safety program.

(2) An effective Institutional Safety Program requires a Safety Officer appropriately trained in relevant safety technology. This individual, besides supplying advice and recommendations, will ensure that records are kept showing that the institution's physical facilities and safety rules are internally consistent and compatible with potential risks, as well as in compliance with all applicable laws, regulations, and guidelines.

(3) The responsibility for safety in a department or other equivalent administrative unit of the institution lies with its commander. Similarly, safety responsibilities are an integral function of each level of management through the first line supervisor. The Safety Office staff must work closely with administrators and investigators to develop and implement written policies and practices that promote safe laboratory work. Collectively, this group routinely must monitor current operations and practices, see that appropriate audits are maintained, and continue to seek ways to improve the safety program.

(4) Safety is a critical job element for each member of the scientific and technical staff. Each individual working in the laboratory is responsible for performing their job in a manner consistent with safety policy and training.

(5) If laboratory goals dictate operations or substances not suited to the existing facilities or equipment, it is the responsibility of the laboratory supervisor, assisted by the Safety Officer, to advise and assist the laboratory worker in developing or obtaining adequate facilities or equipment, and designing appropriate work procedures.

(6) The responsibility for authorization of a specific operation, delineation of appropriate safety procedures, and instruction of those who will carry out the operation lies with the supervisor.

(7) Potential hazards will be identified prior to initiation of work with etiologic agents, and actions necessary to avoid accidents and illnesses will be implemented. This practice, called a job safety analysis, consists of breaking a job down into its logical steps, analyzing each for its hazard potential, and deciding the safe procedures to use. The process will be designed by a project director with input from employees, and each step with potential for exposure or other incidents must be described in writing in a Standing Operating Procedures (SOP). All such SOPs will be approved by, at a minimum, the Commander or Institute Director and the Safety Officer.

(B) The job safety analysis will include a consideration of health hazards identified in AR 40-10 and of maximum credible events as described in paragraph 2-8, AR 385-69.

(c) *Safety Plans.* Clearly defined, published safety rules and monitoring procedures for compliance must be established. These rules will be readily available, in writing, for all involved in laboratory operations. This goal may be accomplished by preparing or modifying a Facility Safety Plan, Laboratory Safety Manual, Occupational Safety and Health Program Document, or equivalent. This plan will:

(1) Be coordinated with institutional and Federal, State and local emergency services.

(2) Be practiced with the emergency groups whose services are part of that plan prior to any need for their services, so that they can become familiar with any potential problem areas that may be encountered when they are called upon for assistance.

(3) Describe the method of rapid communication (e.g., telephone, alarms, etc.) that will be used in the event of an emergency.

(4) Describe the institution's etiologic agent labeling system.

(5) Describe the institution's requirements for testing of engineering controls (e.g., biological safety cabinets and high efficiency particulate air (HEPA) filters) and essential safety equipment (e.g., autoclaves) that are used to conduct RDT&E funded by the BDP.

(6) Appoint and train personnel responsible for handling an emergency.

(7) Require that emergency telephone numbers be posted, so that emergency

service personnel know whom to contact at all times of the day or night.

(8) Describe the institution's rules that have been established and are practiced to limit access to the facilities where etiologic agents under the sponsorship of the BDRP are handled. The rules will include the following requirements:

(i) Access to BL-1 and BL-1 LS laboratories is limited or restricted at the discretion of the Commander or Institute Director when experiments are in progress.

(ii) Access to areas classified as BL-2, BL-2 LS, or where work with toxins is conducted, is limited by the Commander or Institute Director when work with etiologic agents is in progress.

Individuals who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory. Only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) enter the individual laboratory or animal rooms. The Commander or Institute Director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

(iii) Access to areas classified as BL-3 or BL-3 LS is limited as stated in 2-1.c.(8)(b) above, and is restricted to those persons whose presence in the facility or individual laboratory rooms is required for program or support purposes. Individuals under 18 years of age will not be permitted to enter the controlled area.

(iv) Access to BL-4 facilities is limited as stated in paragraph (c)(8)(ii) and (iii) of this section as well as: Access to the facility is limited by means of secure, locked doors; access is controlled by the Commander or Institute Director, Safety Officer, or other person responsible for the physical security of the facility. Before entry all persons will be advised as to the appropriate safeguards for ensuring their safety. Authorized persons must comply with these instructions and all other applicable entry and exit procedures. A logbook will be maintained for all personnel to indicate the date and time of each entry and exit. A card-key activated computer record (or other electronic entry device) may be used if it indicates the date and time of both entry and exit.

(9) Describe the system that is developed and is operational for the reporting of accidents and exposures, employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses.

(d) *Safety Meetings and Safety Committees.* In effective safety programs, everyone associated with the

laboratory becomes involved. This involvement will be accomplished by ensuring maximum participation in planning and by conducting group safety meetings.

(1) A staff safety committee, consisting of the Commander or Institute Director or his designated representative, research supervisors, managers, medical personnel, employees, and the Safety Officer, will be established. The primary purpose of this group is to lead the safety effort, review mishaps, and recommend changes in policies, safety program, or equipment as needed to improve safety.

(2) Safety committees will meet at least quarterly and minutes will be prepared and maintained for at least 3 years.

(3) When work with recombinant DNA molecules is undertaken, an Institutional Biosafety Committee (IBC) for review of such work will be established and will function as stated in the NIH Guidelines for Research Involving Recombinant DNA Molecules (see reference appendix A to part 627).

(e) *Standing Operating Procedures (SOPs).* Besides the documented safety program that will be in effect, each institution will require that an SOP be established for each unique biological defense RDT&E operation. The SOPs will meet the criteria stated in AR 385-69, be reviewed and updated annually, and a copy of the SOP will be maintained in the work area. In addition, SOPs will address the following issues:

(1) The unique hazards introduced by the activity in the work area.

(2) The methods of controlling these hazards.

(3) Any unique procedures and requirements needed that are not described as universally required in the Safety Plan (e.g., signs, waste disposal, immunizations, emergency procedures, and personnel monitoring).

(4) Specialized orientation or training of personnel beyond that which is required in the Safety Plan.

(5) Ways of ensuring that the unique procedures are followed.

(6) Emergency procedures.

(f) *Safety Communications.* Safety communications alert people to newly recognized hazards, remind them of basic biological safety principles, and instill positive attitudes toward safety. A system of communication will be established to:

(1) Implement a biological safety training program for all personnel working with hazardous biological or chemical materials.

(2) Publish information addressing useful biological safety advice and

accounts of laboratory accidents, along with the lessons to be learned from them.

(3) Make reference books and regulations concerning laboratory hazards, occupational health, and proper laboratory practices readily available.

(4) Assure that Material Safety Data Sheets (MSDS) for hazardous chemicals used in the laboratory are readily available to all employees.

(5) Training requirements are also found in § 627.9(b).

(g) *Safety Audits.* One of the essential elements of a good safety program is the conduct of periodic audits of the safety performance in a laboratory. Observations of individual safety practices, operability of safety equipment, and compliance with safety rules must be part of the audit.

(1) An individual and an alternate will be appointed as the individuals responsible for each laboratory or room where BDP work is conducted. He/she will be responsible on a daily basis for ensuring that the conduct of personnel within their room(s) and maintenance of the room complies with the safety program and SOPs.

(2) Supervisors will ensure that their projects comply with applicable safety requirements and will audit their areas on at least a weekly basis to ensure compliance.

(3) The Safety Officer or his/her qualified designee will inspect the Institution's BL-1, BL-2 and toxin laboratories quarterly. BL-3 and BL-4 laboratories, and those in which dry forms of highly potent toxins are handled will be inspected monthly by safety and health professionals. These inspections will be unannounced, and included coverage of general safety practices as well as features specific to a particular biosafety level.

(i) Reports of deficiencies or procedures that create a potentially life-threatening situation will be made directly to supervisory personnel and the Commander or Institute Director and actions will be taken immediately to correct the situation. The operation will not continue until such a deficiency is corrected.

(ii) Reports of deficiencies for other than life-threatening situations will be made as soon as possible to the appropriate supervisor, with copies furnished to the Commander or Institute Director. If a problem is widespread, all affected personnel will be notified.

(4) Supervisory personnel notified of safety deficiencies by the Safety Officer will ensure that the people directly concerned are contacted and that the

deficiencies are remedied by corrective measures before operations are resumed.

(5) Malfunctioning equipment must be reported to the appropriate individuals, labeled to indicate that it should not be used, and repaired promptly.

(6) As a minimum, the audits conducted by the Safety Officer or his/her qualified designee will cover the items listed in appendix C to part 627.

(h) *Documentation.* Records, documenting the following items, will be maintained for 3 years:

(1) Safety audits and the corrective measures.

(2) Risk assessments for new laboratory procedures proposed.

(3) Annual reviews of established SOPs.

(4) Training.

(5) Engineering controls and protective equipment certifications and tests.

(6) Safety committee meeting minutes and recommendations.

(7) Any outside auditor comments and responses.

§ 627.7 Occupational health.

An occupational health program will be implemented per AR 40-5, chapter 5, for all employees whose employment requires that they conduct duties in a BDP etiologic agent area. Essential elements of the program will include policies for:

(a) *Medical Surveillance*

Examinations. Medical examinations by a licensed medical doctor will be given prior to employment, at least every three years thereafter, and upon termination of duties requiring access to laboratories where etiologic agents are used. When full medical examinations are not given annually, health professionals will perform annual health screening. Safety and health professionals will ensure that medical examiners are made aware of all hazardous substances each employee works with at the time of the medical examination. The physician's findings will include assessment of whether an employee has any health condition that would preclude work with etiologic agents. If any of the findings obtained during the examination are outside of the normal range, the employee's supervisor and employee will be notified and counseled on the courses of action available. In addition, a safety and health audit will be conducted to identify any potential occupational causes for the abnormalities, and corrective measures will be taken if applicable.

(b) *Serum Samples.* When appropriate and considering the agent(s) handled, baseline serum samples for laboratory

and other at-risk personnel will be collected and stored for their biologically useful lifetime, but not longer than 40 years. Additional serum specimens will be collected periodically, based upon the agents handled, or as required by participation in a Special Immunizations Program. SOPs will be written detailing the collection procedures and periods if serum sampling is deemed necessary.

(c) *Assignment of Personnel.* Personnel assigned duties in work areas where etiologic agents are used will be evaluated to determine their suitability for their assigned tasks by the installation medical authority. Only personnel who are physically and mentally capable of working in biocontainment areas (BL-3 and BL-4) or with toxins will be assigned to these duties.

(d) *Immunization of at-risk personnel.* The guidelines for immunizations in the latest edition of the American College of Physicians' Guide for Adult Immunizations and recommendations of HHS in publication number (NIH) 88-8395 shall be followed. A resource list for available immunizations for personnel at risk is given in appendix B to part 627.

(e) *Exposures.* Spills and mishaps which result in observable, known or potential exposures to etiologic agents will be immediately reported to the supervisor, Safety Officer, the responsible medical personnel, and the Commander. Appropriate medical evaluation, surveillance, and treatment will be provided and written records of these occurrences will be maintained for 40 years. A Med-16 report will be initiated (see AR 40-400).

(f) *Quarantine.* When etiologic agents designated as BL-4 by the CDC-NIH in HHS publication no. (NIH) 88-8395, (or most recent edition) are handled, a facility for the quarantine, isolation, and medical care of personnel with potential or known laboratory-associated exposures will be available.

§ 627.8 Medical records.

Army Activities will maintain medical records in accordance with AR 40-66 and FMP 293-31 for all military and Department of Army civilian employees who work with etiologic agents under sponsorship of the BDP.

Subpart C—Operational Requirements

§ 627.9 Personnel Prerequisites.

(a) *Medical.* Prior to assignment to work with etiologic agents, personnel will be evaluated by the appropriate medical personnel with respect to their assignment and will be evaluated in the

medical surveillance program as described in § 627.7.

(b) *Training.* All personnel directly or indirectly involved with containment or handling of known and potentially biohazardous material shall receive instruction that adequately prepares them for their assigned duties. Training will be given by occupationally qualified personnel as determined by the commander. This training will be documented and will include:

(1) General training:

(i) Personal hygiene related to laboratory work.

(ii) Laboratory practices.

(iii) Personal protective equipment.

(iv) Effective use of engineering controls.

(v) Packaging, transportation, and shipment of etiologic agents (when applicable).

(vi) Hazardous and infectious waste disposal, handling and minimization procedures.

(2) Training conducted specifically for the facilities that the individual will be working in, including:

(i) Procedures for the facility.

(ii) Reporting incidents and accidents.

(iii) Labeling and posting of signs.

(iv) Biohazardous waste handling, approaches to minimization of the volume of waste, decontamination, packaging, and disposal.

(v) Emergency Procedures.

(3) Additional general training required for work in facilities where viable etiologic agents are present.

(i) Aseptic technique and procedures to include hands on instruction and demonstration of proficiency.

(ii) Concept and definition of biosafety levels.

(iii) Disinfection and sterilization.

(iv) Safe use of workplace equipment, for example autoclave and centrifuge.

(v) Monitoring and auditing requirements.

(vi) Precautions for handling blood, tissues and body fluids (when applicable).

(vii) The infectivity, pathogenicity, mode(s) of transmission and medical surveillance requirements of specific agents.

(viii) Training for all new employees will include a period of supervised orientation in the facilities by a scientist or technician with specific training in the procedures and properties of the etiologic agents in use. During the training period, new laboratory personnel will be under the constant supervision of appropriately trained personnel.

(ix) Personnel who are assigned tasks in BL-2, BL-3, or BL-4 facilities will also

have specific training in handling pathogens.

(x) Personnel assigned duties in a BL-4 facility will also have specific and thorough training in handling extremely hazardous infectious agents, the primary and secondary containment functions of standard and special practices, use of personal protective equipment, containment equipment, and laboratory design characteristics.

(4) Additional general training for handline toxins will include relevant items from 3-1b. (3) plus:

(i) The availability of reference material on the hazards and safe handling of toxic substances.

(ii) The biological effects of the toxin(s) in use.

§ 627.10 Operational prerequisites.

(a) *Evaluation of the Risks.* The risk assessment of laboratory activities involving the use of etiologic agents is ultimately a subjective process. Those risks associated with the agent, as well as with any adjunct elements of the activity to be conducted, (chemicals, radioisotopes, end-products, etc) must be considered in the assessment. Selection of an appropriate biosafety level for work with a particular agent or animal study depends on the virulence, pathogenicity, biological stability, route of transmission, and communicability of the agent; the nature of the laboratory; the procedures and manipulations to be used; the quantity and concentration of the agent; and the availability of effective vaccines or therapeutic measures. The characteristics of etiologic agents, primary laboratory hazards of working with the agent, and recommended biosafety levels are described by CDC-NIH (HHS publication No. (NIH) 88-8395), the considerations for recombinant DNA molecules are described by NIH, and those for oncogenic viruses are described by NCI-NIH (sources listed below). The Commander or Institute Director shall be responsible for the assignment of work with given etiologic agents to the appropriate biosafety level. A risk assessment should take into account not only the NIH Guidelines for Research Involving Recombinant DNA Molecules, but also potential hazards associated with the organism and product of the experimentation.

(1) When established guidelines exist, these will be followed. The primary source guidelines are:

(i) HHS Publication No. (NIH) 88-8395—Biosafety in Microbiological and Biomedical Laboratories, as amended, and updates published in Morbidity and Mortality Weekly Report.

(ii) NIH—Guidelines for Research Involving Recombinant DNA Molecules (FR 51: 16958-16985 and updates).

(iii) The publication by the American Committee on Arthropod-Borne Viruses Subcommittee on Arbovirus Laboratory Safety (SALS) entitled Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates in the American Journal of Tropical Medicine and Hygiene, 29(6), 1980, pp. 1359-1381.

(iv) The DHEW Publication No. (NIH) 76-1165 by the National Cancer Institute (NCI) entitled Biological Safety Manual for Research Involving Oncogenic Viruses.

(2) When samples with unidentified viable agents are obtained, the risks will be evaluated by a knowledgeable and qualified scientist who will make recommendations to the Safety Officer, who will add recommendations for review and approval by the Commander or Institute Director. When guidelines for a specific organism are not established, in addition to these steps, the Centers for Disease Control and/or SALS will be consulted. Their recommendations will be documented and provided to the Commander or Institute Director before approval.

(b) *Selection of Facilities.* The facility requirements identified by the risk assessment will be adhered to. Any variations and compensatory measures will be approved by the IBC (when recombinant DNA molecules are involved), the Safety Officer, and the Commander or Institute Director before a request for an exception or waiver is submitted as stated in AR 385-69.

(c) *Policies and Procedures.* Policies in the form of a Laboratory Safety Manual, Regulations, Memoranda, or Standing Operating Procedures (SOPs) are required for work with etiologic agents in the BDP. Before beginning a new procedure, the policies and procedures will be reviewed to ascertain that the intended operations are described and to determine the requirements that apply to the operation. If procedures exist for the intended operation, personnel will be trained to follow them; if procedures do not exist, then a detailed SOP will be written, reviewed, and approved before beginning the operation. SOPs will conform to the requirements as stated in 2-1.e., and be signed by all personnel who are required to follow the procedures, thus acknowledging that they have read and understand the contents. All SOPs that pertain to a specific area (room, laboratory, or suite) will be available at the worksite.

§ 627.11 General laboratory techniques.

The general requirements for use of etiologic agents are composed of two sets of requirements, with the requirements for toxins being a sub-set of the requirements for handling viable etiologic agents. These requirements are as follows:

(a) *General Techniques Applicable to Etiologic Agents.* (1) A fully fastened long-sleeved laboratory coat, gown, uniform, or coveralls will be worn in laboratories or animal rooms.

(2) Eating, drinking, smoking, and application of cosmetics are not permitted in the work areas.

(3) Personnel wash their hands after they handle etiologic agents or animals, and before leaving the laboratory area.

(4) Mouth pipetting is strictly prohibited. Mechanical pipetting aids must be used.

(5) Gloves:

(i) Will be worn when manipulating etiologic agents and handling containers of etiologic agents. Gloves are not required when materials are packaged appropriately for shipment.

(ii) Will be selected based on the hazards.

(iii) Will be changed frequently (or decontaminated frequently), and will be decontaminated and/or discarded into a labeled biohazardous container after each use and immediately upon observable direct contact with an etiologic agent.

(iv) Will be removed at the workspace (workbench or hood) after handling etiologic agents to ensure that doorknobs and other surfaces are not contaminated.

(6) Good housekeeping will be maintained. This includes:

(i) Work areas free of clutter.

(ii) Work environment free of tripping hazards, with adequate access to exits, emergency equipment, controls, and such.

(iii) Benches and general work areas will be cleaned regularly using a wet sponge or similar method with disinfectant as appropriate. Methods that stir up dusts such as sweeping or use of ordinary vacuum cleaners, will not be used (except for HEPA-filtered vacuum cleaners).

(iv) Specific work areas will be cleaned and decontaminated immediately following each use of an etiologic agent (at least once a day) and after any spill of viable material.

(v) Hallways and stairways will not be used for storage.

(7) All solutions, reagents and chemicals will be labeled.

(8) All contaminated liquid or solid wastes will be inactivated before disposal.

(9) Work will be conducted over spill trays or plastic-backed absorbent paper. The paper will be removed, decontaminated or disinfected, and the general area wiped with decontaminant at the end of each work day or at the end of the experiment, whichever occurs first.

(10) Etiologic agents will be kept in closed containers when not in use. Cultures, solutions, or dried etiologic agents in glass vessels transported or incubated within a room or suite will be handled in non-breakable, leak-proof pans, trays, pails, carboys, or other secondary containers large enough to contain all the material, in case of leakage or breakage of the glass vessel. Etiologic agents removed from a room or suite for transport to another approved area within the same building will be placed in a closed unbreakable secondary container before removal from the laboratory. The secondary container will be labeled on the exterior with a biohazard symbol and identification of the contents, including the required biosafety level, the scientific name, the concentration (if applicable), and the responsible individual. The secondary containers will be wiped with suitable disinfectant before removal from the laboratory/area.

(11) Working stocks of etiologic agents will be stored in double containers. The primary and secondary containers will provide a positive seal and the secondary container will be unbreakable. The secondary container will be labeled as stated in paragraph (a)(1) of this section and with the date stored.

(12) Storage units (e.g., freezers, refrigerators, cabinets, and hoods) will be labeled with the universal biohazard sign and indicate the classes of etiologic agents contained in them. Storage units will be secured when not in use.

(13) All contaminated materials, containers, spills, and solutions will be decontaminated or disinfected by approved methods before disposal.

(14) After injection of an etiologic agent into animals, the site of injection will be swabbed with a decontaminant.

(15) Syringes.

(i) Reusable or disposable syringes will be of the fixed needle or LUER-LOK type (or equivalent) to assure that the needle cannot separate during use.

(ii) After use, non-disposable glass syringes with attached needles contaminated with etiologic agents will be submerged in a container of decontaminant. Disposable syringes will

be discarded with needles attached in puncture-proof rigid containers. Needles will not be recapped after use.

(iii) Sterilized or decontaminated containers marked "SYRINGES AND/OR NEEDLES" may be disposed of in appropriate refuse containers after proper packaging and destruction of the contents.

Note: Many states, especially those on the Eastern seaboard, have implemented strict requirements for the disposal of medical wastes. For example, the State of Maryland has designated all waste from a microbiological laboratory as hazardous waste with licensing requirements for disposal. There are rigid documentation requirements for generators of 50 kg/month or more of waste, while all medical waste released for transport off-site must be manifested to a State licensed medical waste hauler with the destination specified. Additionally, in some cases, the local government (e.g., city) regulates the disposal of these wastes. These requirements will be identified and followed.

Needles/syringes may not be destroyed by clipping. A mechanical shear may be used to smash or sheer needles after or concurrently with sterilization or decontamination.

(16) Refrigerators, deep freezers, and dry ice chests should be checked, cleaned out, and defrosted periodically to remove any ampules, tubes, etc., containing etiologic agents that may have broken during storage. Rubber gloves and respiratory protection appropriate to the materials in storage are recommended during cleaning. Do not store flammable solutions in non-explosion proof refrigerators.

(b) *Additional Techniques Applicable to Work with Viable Etiologic Agents.* The major objective of these techniques is to assist in protection against laboratory acquired infections. Air sampling studies have shown that aerosols are generated from most of the manipulations of bacterial and viral cultures common to research laboratories. The generation of aerosols during routine laboratory manipulations must be considered when evaluating the individual degree of risk, keeping in mind the four main factors governing infection: dosage, virulence of the organism, route of infection (e.g., skin, eyes, mouth, lungs), and host susceptibility (e.g., state of health, natural resistance, previous infection, response to vaccines and toxoids). The requirements stated below are minimum handling requirements to prevent accidental infection created by incidental aerosols.

(1) All procedures are performed carefully to minimize the creation of aerosols.

(2) No infectious mixtures will be prepared by bubbling air through a liquid.

(3) Pipettes.

(i) No infectious material will be forcibly ejected from pipettes. Only TD (to deliver) pipettes will be used.

(ii) Pipettes used with infectious or toxic materials will be plugged with cotton except where pipettes are used exclusively in a gas-tight cabinet system.

(iii) Contaminated pipettes will be placed horizontally in a rigid container containing enough disinfectant for complete immersion. Cylinders used for vertical discard are not recommended. The container and pipettes must be autoclaved as a unit and replaced by a clean container containing fresh disinfectant.

(iv) Pipetting devices must be used. Under no circumstances is mouth pipetting permitted.

(4) Syringes.

(i) The use of syringes and needles for making dilutions of etiologic agents is not recommended.

(ii) When removing a syringe and needle from a rubber stoppered bottle containing viable etiologic agents, an alcohol soaked pledget around the stopper and needle will be used.

(iii) Excess fluid and bubbles should be expelled from syringes vertically into a cotton pledget soaked with disinfectant, or into a small bottle containing disinfectant-soaked cotton.

(iv) The site of injection of an animal will be swabbed with a disinfectant before and after injection.

(v) After use, syringes contaminated with residual infectious fluid will be submerged in a container of disinfectant in a safety cabinet prior to removal for autoclaving. To minimize accidental injection of infectious material, the removable needles should remain on such syringes until after autoclaving. When possible, syringes with attached needles should be placed in a pan separate from that holding other discarded materials.

(vi) Caps will not be placed over needles until after disinfection. During recapping, procedures to prevent personnel injuries will be used.

(5) Centrifuges and Shakers.

(i) Before centrifuging, tubes, rotors, seals and gaskets will be checked for cleanliness and integrity. In low speed clinical-type centrifuges, a germicidal solution may be added between the tube and trunnion cup to disinfect the outer surfaces of both and to provide cushion against shocks that might otherwise break the tube. Metal or plastic tubes (other than nitro-cellulose) will be used.

(ii) Decanting from centrifuge tubes will be avoided. If decanting is necessary, the outer rim will be wiped with a disinfectant after decanting so that material on the lip cannot spin off as an aerosol. Centrifuge tubes will not be filled beyond the level recommended by the manufacturer.

(iii) Broth cultures will be shaken in a manner that avoids wetting the plug or cap.

(6) Water baths in which viable etiologic agents are incubated must contain a disinfectant. For cold water baths, 70 percent propylene glycol is recommended. The disinfectant should be changed frequently.

(7) When laboratory vacuum is used to manipulate viable etiologic agents, a secondary reservoir containing disinfectant and a HEPA filter must be employed to insure that the laboratory vacuum lines do not become contaminated.

(8) Test tubes:

(i) Tubes containing viable etiologic agents should be manipulated with extreme care. Studies have shown that simple procedures, such as removing a tube cap or transferring an inoculum, can create a potentially hazardous aerosol.

(ii) Manipulation of biohazardous test tubes will be conducted in biological safety cabinets. Tubes and racks of tubes containing biohazardous material should be clearly marked. It is the responsibility of the individual employee to insure that tubes containing biohazardous material are properly sterilized prior to disposal or glassware washing. Safety test tube trays should be used in place of conventional test tube racks to minimize spillage that might arise from broken tubes. When safety test tube trays are not used, the conventional test tube racks will be placed in a tray large enough to contain any potential spill. A safety test tube tray is one having a solid bottom and sides deep enough to hold all liquids, should a test tube break.

(9) Care should be exercised when using membrane filters to obtain sterile filtrates of viable etiologic agents. Due to the fragility of the membranes and other factors, such filtrates cannot be considered noninfectious until laboratory culture or other tests have proven their sterility.

(10) The preparation, handling, and use of dry powders of viable etiologic agents in open containers presents hazards of an unusual nature. The slightest manipulation of such powders can result in the generation of aerosols containing a high concentration of etiologic agents. Therefore, work with dry powders of etiologic agents in open

containers should be carried out in gas-tight biological safety cabinets.

§ 627.12 Biosafety level 1.

(a) *General.* BL-1 operations follow the general techniques described in § 627.11 (a) and (b).

(b) *Additional Laboratory Requirement.* Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory. Examples of suitable containers are metal tubs with lids or plastic bags that are sealed and then placed inside a rigid container for transport.

(c) *Additional Animal Requirements.*

(1) Bedding materials from animal cages will be removed in such a manner as to minimize the creation of aerosols and disposed of in compliance with applicable institutional or local requirements.

(2) Cages are washed manually or in a cagewasher. Temperature of final rinse water will be a minimum of 180 °F.

(3) Laboratory coats, gowns, or uniforms worn in animal rooms shall not be worn in other areas.

§ 627.13 Biosafety level 2.

(a) *General.* In addition to the general microbiological techniques stated in § 627.12, BL-2 operations include the following requirements:

(1) When etiologic agents are in use, a hazard warning sign incorporating the universal biohazard symbol is posted on the access door of the work area. The hazard warning sign identifies the etiologic agent, lists the name and telephone number of the Institute Director or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.

(2) Animals not involved in the work being performed are not permitted in the laboratory.

(3) Special care is taken to avoid skin contamination with the etiologic agents; gloves will be worn when handling etiologic agents or infected animals.

(4) All wastes from laboratories and animal rooms are decontaminated before disposal.

(5) Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles.

(6) Spills and accidents which result in a potential exposure to etiologic agents will be reported immediately to the Biosafety officer, the project leader and the Institute Director.

(7) Biological safety cabinets (Class I or II) will be used when:

(i) Procedures with a high potential for creating infectious aerosols are conducted.

(ii) High concentrations or large volumes of etiologic agents are used.

(8) Laboratory coats, gowns, smocks, or uniforms will be removed before leaving the animal facility or laboratory area.

(b) *Additional Animal Requirements.*

(1) Cages must be decontaminated, preferably by autoclaving, before they are cleaned and washed.

(2) Approved molded masks are worn by all personnel entering animal rooms housing nonhuman primates.

(3) If floor drains are provided, the drain traps will be kept filled with water or a suitable disinfectant.

§ 627.14 Biosafety level 3.

(a) *General.* In addition to the requirements stated in §§ 627.12 and 627.13, the following requirements apply:

(1) Approved molded masks or respirators with HEPA filters are worn by all personnel in rooms housing infected animals.

(2) Protective clothing worn in a laboratory or animal room will be removed before exiting the laboratory or animal room.

(3) Clothing worn in laboratories and animal areas to protect street clothing will be decontaminated before being laundered.

(b) *Additional laboratory requirements:* (1) Laboratory doors will be kept closed.

(2) All activities involving etiologic agents will be conducted in biological safety cabinets (Class I, II, or III) or other physical containment devices within the containment module. No work in open vessels is conducted outside a biological safety cabinet.

(3) The work surfaces of biological safety cabinets and other containment equipment will be decontaminated when work with etiologic agents is finished. It is recommended that plastic-backed paper toweling be used on nonperforated work surfaces within biological safety cabinets to facilitate clean-up.

(c) *Additional Animal Requirements.*

(1) Cages are autoclaved before bedding is removed and before they are cleaned and washed.

(2) Gloves are removed aseptically and autoclaved with other wastes before being disposed of or reused.

(3) Boots, shoe covers, or other protective footwear and disinfectant foot baths must be available and used when indicated.

(4) Personal protective clothing and equipment and/or other physical

containment devices are used for all procedures and manipulations of etiologic agents or infected animals. The risk of infectious aerosols from infected animals or their bedding shall be reduced by housing animals in partial containment caging systems as described in § 627.55.

(d) *Work with Biosafety Level 3*

Etiologic Agents that Require Additional Secondary Containment.

Facilities in which work with certain viruses, for example, Rift Valley fever, yellow fever, and Venezuelan equine encephalitis, is conducted require HEPA filtration of all exhaust air prior to discharge from the laboratory. All persons working with those agents for which a vaccine is available should be immunized.

§ 627.15 Biosafety level 4.

Laboratory work at BL-4 must follow the requirements stated in §§ 627.12, 627.13 and 627.14 as well as the following:

(a) All activities are conducted in Class III biological safety cabinets or in Class I or II biological safety cabinets in conjunction with a one-piece positive pressure personnel suit ventilated by a life support system.

(b) Biological materials to be removed from the Class III cabinet or from the maximum containment laboratory in a viable or intact state must be transferred to a sealed non-breakable primary container, enclosed in a nonbreakable sealed secondary container, and removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.

(c) No materials, except for biological materials that are to remain in a viable or intact state, are removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or material which might be damaged by high temperature or steam is decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

(d) Personnel may enter and leave the facility only through the clothing change and shower rooms. Personnel must shower each time they leave the facility. Personnel may use the airlocks to enter or leave the laboratory only in an emergency.

(e) Street clothing must be removed in the outer clothing change room and kept there. Complete laboratory clothing, including under-garments, pants and shirts or jumpsuits, shoes, and gloves, will be provided and must be used by all personnel entering the facility. Head covers are provided for personnel who

do not wash their hair during the exit shower. When leaving the laboratory and before proceeding into the shower area, personnel must remove their laboratory clothing and store it in a locker or hamper in the inner change room.

(f) When etiologic agents or infected animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biohazard symbol must be posted on all access doors. The sign must identify the agent, list the name of the Commander or Institute Director or other responsible person(s), and indicate any special requirements for entering the area (e.g., the need for immunizations or respirators).

(g) Supplies and materials needed in the facility are brought in by way of the double-doored autoclave, fumigation chamber, or airlock which is appropriately decontaminated between each use. After securing the outer doors, personnel within the facility retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. These doors are secured after materials are brought into the facility.

(h) Materials (e.g., animals and clothing) not related to the experiment being conducted are not permitted in the facility.

(i) Whenever possible, the use of any glass items should be avoided.

§ 627.16 Toxins.

The laboratory facilities, equipment and procedures appropriate for work with toxins of biological origin must reflect the intrinsic level of hazard posed by a particular toxin as well as the potential risks inherent in the operations performed. All toxins must be considered to pose a hazard in an aerosol form. However, most toxins exert their effects only after parenteral exposure or ingestion, and a few toxins present a dermal hazard. In general, toxins of biological origin are not intrinsically volatile. Thus, the laboratory safety precautions appropriate for handling these materials closely parallel those described for handling infectious organisms. The requirements in this section for the laboratory use of toxins of biological origin include the requirements in § 627.11(a) and the following:

(a) Vacuum lines. When vacuum lines are used with systems containing toxins, they will be protected with a HEPA filter to prevent entry of toxins into the lines (or sink drains when water aspirators are used).

(b) Preparation of concentrated stock solutions and handling closed primary containers of dry toxins. Preparation of

primary containers of toxin stock solutions and manipulations of closed primary containers of dry forms of toxins will be conducted:

(1) In a chemical fume hood, a glove box, or a biological safety cabinet or equivalent containment system approved by the Safety Officer.

(2) While wearing eye protection if using an open-fronted containment system.

(3) Ensuring that gloves worn when handling toxins will be disposed of as toxin waste, with decontamination if required.

(4) With the room door closed and posted with a universal biohazard sign, or other sign indicating that toxin work is in progress. Extraneous personnel shall not be permitted in the room during operations.

(5) Ensuring that toxins removed from hoods or biological safety cabinets are double-contained during transport.

(6) After verification of hood or biological safety cabinet inward airflow is made by the user before initiating work.

(7) Within the operationally effective zone of the hood or biological safety cabinet.

(8) Ensuring that non-disposable laboratory clothing is decontaminated before release for laundering.

(9) Ensuring that all individuals who handle toxins wash their hands upon each exit from the laboratory.

(10) With two knowledgeable individuals present whenever more than an estimated human lethal dose is handled in a syringe with a needle. Each must be familiar with the applicable procedures, maintain visual contact with each other, and be ready to render assistance in the event of an accident.

(c) Manipulations with open containers of dry forms of toxins. Handling of dry forms of toxins in uncovered containers (e.g. during weighing) will be performed following the requirements stated in §§ 627.11(a), and 627.16(b) and (b) and the following:

(1) Manipulations will be conducted in a HEPA filtered chemical fume hood, glove box or biological safety cabinet. The exhaust may additionally be charcoal filtered if the material is volatile.

(2) When using an open-fronted fume hood or biological safety cabinet, protective clothing, including gloves and a disposable long-sleeved body covering (gown, laboratory coat, smock, coverall, etc) will be worn in such a manner that hands and arms are completely covered. Eye and approved respiratory protection is also required. The protective clothing will not be worn outside of the

laboratory and will be disposed of as solid toxin waste.

(3) Before containers are removed from the hood, cabinet or glove box, the exterior of the closed primary container will be decontaminated and placed in a clean secondary container.

(4) When toxins are in use, the room will be posted to indicate "Toxins in Use—Authorized Personnel Only". Any special entry requirements will be posted on the entrance(s) to the room.

(5) All operations will be conducted with two knowledgeable individuals present. Each must be familiar with the applicable procedures, maintain visual contact with each other and be ready to render assistance in the event of an accident.

(6) Individuals handling toxins will wash their hands upon exit from the laboratory.

(d) Additional considerations of specific toxin properties. The following requirements are in addition to the requirements stated in the paragraphs above. Determine whether the material fits paragraph (b) or (c) of this section, and comply with the appropriate section and the following when applicable:

(1) When handling dry forms of toxins that are electrostatic.

(i) Gloves that facilitate the generation of static electricity (such as latex) will not be worn when handling dry forms of these toxins.

(ii) A glove bag within a hood or biological safety cabinet, a glove box, or a class III biological safety cabinet will be utilized when handling these materials.

(2) When handling toxins that are percutaneous hazards (irritants, necrotic to tissue or exhibit extreme toxicity by the dermal route of exposure).

(i) Gloves will be selected that are known to be impervious to the toxin and the diluent (when applicable) for the duration of the manipulations.

(ii) Disposable laboratory clothing will be worn, left in the laboratory upon exit, and disposed of as solid toxin waste.

(e) Aerosol exposures. The requirements found in paragraphs (a) and (b) of this section will be complied with plus the following:

(1) Chambers, nose-only exposure apparatus, and generation system must be placed inside a fume hood, glove box, or a Class III biological safety cabinet. Glove boxes and Class III biological safety cabinets will have HEPA filters on both inlet and outlet air ports.

(2) The atmosphere from within the exposure chamber will be HEPA filtered before release inside the hood, glove box or cabinet.

(3) All items inside the hood, glove box, or Class III biological safety

cabinet will be decontaminated upon removal. Materials such as experimental samples that cannot be decontaminated directly will be placed in a closed secondary container, the exterior of which will be decontaminated and labeled appropriately. Animals will have any areas exposed to toxin wiped clean after removal from the exposure apparatus.

(4) The interior of the hood, glove box, or cabinet containing the chamber and all items will be decontaminated periodically, for example, at the end of a series of related experiments. Until decontaminated, the hood, box or cabinet will be posted to indicate that toxins are in use, and access to the equipment and apparatus restricted to necessary, authorized personnel.

§ 627.17 Emergencies.

(a) *Introduction.* All laboratories will establish specific emergency plans for their facilities. Plans will include liaison through proper channels with local emergency groups and with community officials. These plans will include both the building and the individual laboratories. For the building, the plan must describe evacuation routes, facilities for medical treatment, and procedures for reporting accidents and emergencies. The plans will be reinforced by drills. Emergency groups and community officials must be informed of emergency plans in advance of any call for assistance. See AR 385-69.

(b) *General Emergency Procedures.* The following emergency procedures will be followed for laboratory accidents or incidents.

(1) Using appropriate personal protection, render assistance to persons involved, remove contaminated clothing if necessary, decontaminate affected areas, and remove them from exposure to further injury if necessary; do not move an injured person not in danger of further harm. Render immediate first aid if necessary.

(2) Warn personnel in adjacent areas of any potential hazards to their safety.

(3) In case of fire or explosion, call the fire department or community fire brigade immediately. Follow local rules for dealing with incipient fire. Portable fire extinguishers will be made available with instructions for their use. Fire fighters responding to the fire scene will be advised to wear a self-contained positive pressure breathing apparatus to protect themselves from toxic combustion by-products.

(4) Laboratories must be prepared for problems resulting from severe weather or loss of a utility service. In the event of the latter, most ventilation systems not

supplied with emergency power will become inoperative. All potentially hazardous laboratory work must stop until service has been restored and appropriate action has been taken to prevent personnel exposure to etiologic agents.

(5) In a medical emergency, summon medical help immediately. Laboratories without a medical staff must have personnel trained in first aid available during working hours.

(6) For small-scale laboratory accidents, secure the laboratory, leave the area, and call for assistance.

(7) When handling mixed hazards (e.g., a substance or mixture that may be infectious and radioactive, or infectious and chemically toxic), respond with procedures addressing the greater hazard first, and then follow through with those for the lesser hazards to ensure that all appropriate steps have been taken.

(c) *Evacuation Procedures.* Building and laboratory evacuation procedures will be established and communicated to all personnel.

(1) Emergency alarm system.

(i) There will be a system to alert personnel of an emergency that requires evacuation of the laboratory or building. Laboratory personnel must be familiar with the location and operation of alarm equipment.

(ii) Isolated areas (e.g., cold, warm, or sterile rooms) will be equipped with an alarm or communication system that can be used to alert others outside to the presence of a worker inside, or to warn workers inside of the existence of an emergency that requires evacuation.

(2) Evacuation routes will be established and an outside assembly area for evacuated personnel must be designated. All individuals should be accounted for.

(3) Shut-down/Start-up procedures.

(i) Guidelines for shutting down operations during an emergency evacuation will be available in writing. Those guidelines will include procedures for handling and power failure emergency.

(ii) Written procedures will also be provided to ensure that personnel do not return to the laboratory until the emergency is ended. Those procedures must also contain start-up operations for the laboratory.

(iii) All shut-down/start-up procedures will be available to personnel and reviewed semi-annually.

(4) All aspects of the building evacuation procedure will be tested semi-annually through the use of drills.

(d) *Spills.*

(1) All areas where work with etiologic agents is performed will have designated personnel to respond to a spill and provide protective apparel, safety equipment, and materials necessary to contain and clean up a spill. Protective clothing requirements are described in § 627.30. Also, there will be supplies on hand to deal with the spill consistent with the hazard and quantities of the spilled substance.

(2) The Safety Officer will be notified immediately of all spills. The first line supervisor will ensure that proper clean-up techniques are employed.

(3) Etiologic agents.

(i) A program for responding to spills of etiologic agents will be developed and implemented. This program will contain emergency response procedures for a biological spill, which will be tailored to the potential hazard of the material being used, the associated laboratory reagents involved, the volume of material, and the location of the materials within the laboratory. Generally, the spill should be confined to a small area while minimizing aerosolization of the substance. The spill will be chemically decontaminated or neutralized, followed by a cleanup with careful disposal of the residue. If the spilled material is volatile and noninfectious, it may be allowed to evaporate but must be exhausted by a chemical hood or ventilation system.

(ii) When a mishap occurs that may generate an aerosol of etiologic agents requiring BL-2 (or higher) containment, the room must be evacuated immediately, the doors closed, and all clothing decontaminated, unless the spill occurs in a class II or class III biological safety cabinet. Sufficient time must be allowed for the droplets to settle and the aerosols to be reduced by the air changes of the ventilation system before decontaminating the area. The area will then be decontaminated to prevent exposure to the infectious agents or toxic substances. Reentry procedures to perform the decontamination will conform to § 627.17(e).

(iii) A spill of biohazardous material within a biological safety cabinet requires a special response and cleanup procedure. Cleanup will be initiated while the cabinet continues to operate, using an effective chemical decontaminating agent. Aerosol generation during decontamination, and the escape of contaminants from the cabinet, must be prevented. Caution must be exercised in the choice of decontaminant, keeping in mind that fumes from flammable organic solvents, such as alcohol, can reach dangerous concentrations within a biological safety cabinet.

(4) Combined radioactive/biological spills.

(i) Both the Radiation Protection Officer (RPO) and the Safety Officer must be notified immediately whenever there is a spill of radioactive biological material, regardless of its size. Laboratory personnel may be expected to clean up the spill. The RPO will direct the cleanup, in accordance with the Nuclear Regulatory Commission (NRC) license for the facility.

(ii) The spill will be cleaned up in a way that minimizes the generation of aerosols and spread of contamination. All items used in cleaning up the spill must be disposed of as radioactive waste.

(iii) Following cleanup, the area, affected protective clothing, and all affected equipment and supplies must be surveyed for residual radioactive contamination. All potentially affected areas and items that are not disposable will be wipe-tested to verify that unfixed radioactive contamination has been removed. If fixed contamination is found, the RPO will determine the requirements for additional cleanup.

(e) *Reentry Procedures.* This section applies when reentry is necessary to clean up a spill outside of a hood or biological safety cabinet, or to decontaminate or service engineering controls that failed or malfunctioned such that they do not provide the required containment.

(1) When agent(s) requiring BL-1 or BL-1 LS containment are involved, the clothing requirements stated in § 627.29 (a) or (b) as appropriate will be followed. Individuals will remove the required protective clothing when finished and wash their hands before proceeding to other tasks.

(2) When agent(s) requiring BL-2, BL-2 LS, or toxin procedures and containment are involved, personnel will be required to wear the clothing stated in § 627.29 (c) or (d) as appropriate. Outer protective clothing will be removed and left in the room before exiting and personnel will wash their hands before proceeding on to other activities.

(3) When agent(s) requiring BL-3, or BL-3 LS containment are involved, containers for sealing up inner protective clothing and decontaminant will be placed at the room exit before entering the room or suite. Personnel will be required to wear the clothing stated in § 627.29(e). When exiting the area after decontamination procedures, individuals will remove their outer layer of protective clothing just before exiting the room. Once outside the room the inner layer of protective clothing (e.g., coverall) will be removed and placed in

the container and the inner gloves will be decontaminated before being removed and placed in the container. Personnel will proceed directly to the shower facility to take a complete shower before exiting the facility.

(4) When agents requiring BL-4 containment are involved, the following applies as appropriate to the type of BL-4 facility:

(i) When a spill requiring clean-up is in an area designed for use with personal positive pressure suits, the entry and exit procedures will be as normally required for entrance and exit from the area.

(ii) When entering a non-suit area where a spill of etiologic agent has occurred outside the containment of a Class III biological safety cabinet, personnel will wear the clothing as stated in § 627.29(f). Before entry, decontamination areas will be established. To accomplish this, two step-in decontamination pans with the appropriate disinfectant will be set up [one just inside the room (where the contamination exists) and the second immediately outside the room]. Immediately outside the room, there will also be a sealable container suitable for sealing up the suit and any air lines (if used). When exiting the room, suited individuals will place all equipment and other items in autoclaves or disinfectant, step into the disinfectant pan and wash down the exterior of their suits with appropriate disinfectant. When completed, the door to the room will be opened and the individual will step through the doorway into the second disinfectant pan. The suit will be thoroughly rinsed with disinfectant again before moving toward the exit from the facility. The suit (but not the respirator) will be placed in the provided container. The individual will proceed through another doorway before removing the respirator and placing it in a closed container for decontamination. The individual will then proceed directly to the shower area and take a full shower before exiting the area. In case they are needed, personnel will be standing by ready to render assistance. Suited individuals will be visually observed, if possible. When visual observation is not possible, a communications system is required.

(f) *Mishap Reports and Investigations.*

(1) Each institution must have a defined system for reporting laboratory injuries, illnesses and mishaps, as well as for investigating them. These events will be documented and reported to the appropriate safety, supervisory and occupational health personnel. Those organizations subject to the regulations

promulgated by the Occupational Safety and Health Administration (OSHA) will follow the specific requirements for reporting injuries in the work place contained in those regulations. The requirements stated in AR 385-69, State, and local government requirements for similar reporting will be followed.

(2) Form(s) for recording mishaps will be available and completed for all laboratory mishaps. Those reports must include a description of the mishap and any factors contributing to the mishap. In addition, a description of any first aid or other health care given to the employee will be included. Responsibility for completing these forms must be clearly defined in the Facility Safety Manual. Mishaps will be reviewed periodically by the Safety Officer, the safety committee, the employee health unit, or other appropriate personnel. Individual reports or a summary must be sent, along with recommended changes in laboratory procedure or policy, to the Commander or Institute Director. Policy or procedural changes must be implemented if deemed necessary by the Commander or Institute Director.

(3) Any mishaps with etiologic agents used under sponsorship of the BDP that result in sero-conversion or a laboratory-acquired illness will be reported.

§ 627.16 Large scale operations.

(a) *Large Scale.* In addition to the requirements stated in § 627.12 the following applies to research or production activities involving viable etiologic agents in quantities greater than 10 liters:

(1) All large-scale operations will be conducted in facilities described in the appropriate part of section 627.46.

(2) Cultures will be handled in a closed system.

(3) Sample collection, the addition of materials, and the transfer of culture fluids shall be done in a manner which minimizes the release of aerosols or contamination of exposed surfaces.

(4) A closed system or other primary containment equipment that has contained viable organisms shall not be opened for maintenance or other purposes unless it has been sterilized.

(5) Standing operating procedures (SOPs) will include a section describing and requiring a validation of the process equipment's proper function.

(6) Scientists, technicians, equipment workers, and support personnel with access to the large-scale production area when it is in operation will be included in the medical surveillance program.

(b) *Biosafety Level 2—Large Scale.* In addition to the requirements stated in

§§ 627.18(a) and 627.13, the following procedures will be employed for Biosafety Level 2—Large Scale:

(1) Rotating seals and other mechanical devices directly associated with closed system used for the propagation and growth of viable organisms shall be designed to prevent leakage or shall be fully enclosed in vented housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through other equivalent treatment devices.

(2) A closed system used for the propagation and growth of viable organisms and other primary containment equipment used to contain operations involving viable organisms shall include monitoring or sensing devices that monitor the integrity of containment during operations.

(3) Systems used for the propagation and growth of viable organisms shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to the use of this equipment.

(c) *Biosafety Level 3—Large Scale.* In addition to the requirements stated in §§ 627.18(b) and 627.14., the following procedures apply:

(1) Personnel entry into the controlled area shall be through the entry area specified in § 627.46(c)(1).

(2) Persons entering the controlled area shall exchange or cover their personal clothing with work garments such as jumpsuits, long sleeved laboratory coats, pants and shirts, head cover, and shoes or shoe covers. On exit from the controlled area the work clothing may be stored in a locker separate from that used for personal clothing, or discarded for laundering. Clothing shall be decontaminated before laundering.

(3) Entry into the controlled area during periods when work is in progress shall be restricted to those persons required to meet program support needs.

(4) Prior to entry all persons shall be informed of the operating practices, emergency procedures, and the nature of the work conducted.

(5) The universal biohazard sign shall be posted on entry doors to the controlled area and all internal doors. The sign posted on the entry doors to the controlled area shall include a statement of agents in use and personnel authorized to enter.

(6) Equipment and materials required for the management of accidents involving viable organisms shall be available in the controlled area.

(d) *Biosafety Level 4—Large Scale.* Guidelines for these operations are not established. If these are needed, they

must be established by the U.S. Army Surgeon General or the National Institutes of Health on an individual basis.

§ 627.19 Operations with radioactive material.

Operations that combine etiologic agents with radiolabeled material present unique problems. When this is the case, the following apply:

(a) *Radiation Program.* A radiation program meeting the requirements of AR 385-11 and NRC licensure that allows the particular isotope and use are required. The requirements for acquisition, handling procedures, labeling, storage, training, monitoring, and disposal will be described in an organization policy document.

(b) *Procedure Approval.* In addition to the required approvals for work with etiologic agents, the RPO will approve all SOPs involving the use of radioactive materials. Laboratory operators must be fully trained, with annual training updates as required by the existing license.

(c) *Special Situations.* (1) Special attention must be paid to the laboratory waste because it must be segregated as radioactive waste and disposed of as such after it has been decontaminated. Do not mix non-radioactive waste with radioactive waste as the disposal of radioactive waste is much more complex and expensive. When RCRA-listed chemicals are mixed with radioactive waste it becomes "mixed waste" for which there is currently no means of disposal.

(2) Activities conducted with radioisotopes should be confined to the smallest number of areas/rooms consistent with requirements.

(3) Decontamination methods specific for etiologic agents will not always remove radioactivity. Other methods, such as specialized detergents and solvents designed for this use, should be employed to remove residual radioactivity.

Subpart D—Personal Protective Equipment

§ 627.20 Introduction.

Personal protective equipment (PPE) includes clothing and equipment used to protect the laboratory worker from contact with infectious, toxic, and corrosive agents, as well as excessive heat, fire, and other physical hazards. The appropriate PPE for any activity is dependent upon the proposed operations and the potential hazards associated with them. While PPE are important items of personal protection,

they are to be used with the understanding that they serve as a secondary line of protection against hazards in the workplace. Engineering controls (chapter B), combined with common sense, good laboratory techniques and adherence to SOP's, are the primary barriers to exposure. There are some situations, however, in which it is either impractical or impossible to rely exclusively on engineering controls. In these cases, PPE may form the primary barrier between personnel and the hazards or infectious materials.

§ 627.21 Minimum laboratory attire for use of etiologic agents.

Individuals required to wear PPE will be trained in their proper use. The PPE listed below are the minimum required when etiologic agents are handled at any Biosafety Level. Research with etiologic agents usually involves hazards other than those presented by the agents themselves. When selection of PPE is made, the hazards presented by these other factors must be considered regardless of the Biosafety Level used. For example, toxic chemicals are commonly used in research involving etiologic agents, the processes may expose personnel to physical hazards, such as heat or animal bites, and the decontamination process may involve the handling of toxic or corrosive materials. When the PPE required to mitigate these hazards exceeds that of the minimum requirements, the necessary PPE will be selected considering all of the hazards. Information regarding the additional appropriate PPE worn to protect against these hazards will be available from one of the following sources: Material Safety Data Sheets (MSDS), SOP for the operation, or the Safety Officer. Deviations from the standards stated in approved SOPs must be approved by the Safety Officer. All laboratory coats when worn for purposes of protection of the individual should be left in the laboratory when an individual leaves the laboratory. In each case, the minimum attire will be:

(a) *Laboratory Workers.* Street attire is permissible in the laboratory, but must include closed-toe shoes. A full-length, long sleeved, fully fastened laboratory coat, gown, or smock will be worn over the street attire in the laboratory at all times. The laboratory clothing will be removed and left in the laboratory when leaving to enter non-laboratory use areas.

(b) *Animal Caretakers.* In addition to the clothing requirements in paragraph (a) of this section, animal handlers will be provided with safety shoes or safety

boots. The requirements of § 627.23(b) should also apply.

(c) *Non-human Primate Rooms.* Personnel entering rooms housing nonhumans primates will wear the clothing stated in paragraph (a) of this section and if applicable paragraph (b) of this section in addition to a molded mask or HEPA filtered respirator, latex or vinyl gloves, and eye protection.

§ 627.22 Biosafety level 1.

This level requires only the minimum attire described in § 627.21.

§ 627.23 Biosafety level 2.

This level requires the following additions to the minimum clothing specified in § 627.21:

(a) *Laboratory.* Gloves (type dependent on the application) will be worn when handling etiologic agents or containers of etiologic agents and when handling infected animals.

(b) *Animal Rooms.* (1) Protective clothing will be changed completely on a daily basis. One- or two-piece laboratory suits or solid-front gowns and wrap-around smocks are preferable. Full-length, long sleeved, fully fastened laboratory coats are allowed.

(2) Eye protection must be worn when handling non-human primates.

(3) Appropriate gloves must be worn.

(4) Molded masks or HEPA filtered respirators will be worn in rooms housing non-human primates.

§ 627.24 Biosafety level 3.

Because it is imperative that the outer clothing worn in these facilities not be worn outside the facility, color-coded clothing that is worn only in the facility is recommended to assist in precluding individuals from wearing this clothing outside the facility. The minimum clothing includes:

(a) *Laboratory.* (1) Long-sleeved, solid front, or wrap-around gowns, scrub suits, or coveralls over street attire which includes closed-toe shoes. Dedicated shoes, boots or shoe covers will be worn in the facility.

(2) Appropriate gloves.

(b) *Animal Rooms.* (1) A complete change of protective clothing on a daily basis. Long-sleeved one- or two-piece solid front uniforms, solid-front gown, wrap-around smocks, or solid front coveralls.

(2) Eye protection must be worn when handling non-human primates.

(3) Molded masks or HEPA filtered respirators will be worn in rooms housing infected animals.

(4) Shoe covers will be worn and removed before exiting the room; alternatively, disinfectant footbaths will

be used for each exit from the room when infected animals are present.

§ 627.25 Biosafety level 4.

Street clothing must be removed in an outer clothing change room and kept there. Clothing worn in the facility will be removed in an inner change room and a shower taken before replacing the street clothing. Two distinct PPE requirements exist for BL-4 operations:

(a) *Class III Biological Safety Cabinet Containment.* Clothing requirements when all etiologic agents and infected animals are housed and manipulated in Class III biological safety cabinets will include:

(1) Complete change of clothing and wet shower upon exit. This includes undergarments, pants and shirts or jump-suits, and shoes. While it is preferred that the shower include washing the hair, head covers will be worn by those who do not wash their hair on each exit.

(2) Appropriate inner gloves. The inner gloves will be donned in the change room.

(b) *Class I or II Biological Safety Cabinet Containment.* Clothing requirements for this level when etiologic agents are contained in Class I or II biological safety cabinets or equivalent partial-containment caging systems (for infected animals) (See §§ 627.55 and 627.56) include:

(1) Complete change of clothing and wet shower upon exit. This includes undergarments, pants and shirts or jump-suits, and shoes. While it is preferred that the shower include washing the hair, head covers will be worn by those who do not wash their hair on each exit.

(2) Appropriate inner gloves will be donned in the change room.

(3) A one piece positive pressure suit described in § 627.30(g).

(4) Impervious boots fitted over the suit.

§ 627.26 Large Scale (LS) Operations.

The clothing requirements for these are the same as for the corresponding biosafety levels for laboratory operations.

§ 627.27 Solutions of toxins and dry forms of toxins in closed containers.

In addition to the minimum clothing specified in § 627.21 above, disposable gloves or gloves designed to be protective against the diluent will be worn when handling these materials.

§ 627.28 Dry forms of toxins handled in open containers.

In addition to the requirements stated in § 627.27 above, the requirements stated in § 627.16(c) apply.

§ 627.29 Situations specified in § 9627.17(e).

The clothing requirements for this section are for the emergency procedures specified in § 627.17(c). When these situations occur and there is no feasible or available means to adequately mitigate the potential hazard by engineering controls, the clothing requirements exceed those required for a properly conducted laboratory operation at an equivalent Biosafety Level. The protective equipment required will be selected based upon an assessment of the potential hazards that could be encountered. As a guide, the following clothing requirements are given. The selection of PPE will be based upon the highest possible level of contamination that could exist in the room. This will be based upon what is known about the operations that were conducted in the room during and prior to the current incident. In each situation, allowance will be made for the any aerosols to dissipate or settle before entry (approximately 30 min.). The following clothing requirements apply to these situations:

- (a) *Biosafety Level 1.* (1) Gloves.
- (2) Outer complete covering such as a pair of coveralls.
- (3) Shoe covers, provided shoes, or safety shoes or boots.
- (4) Eye protection (maintenance only).
- (b) *Biosafety Level 1 Large Scale.* The same as described in § 627.29(a) with the following additions:
 - (1) An impervious apron.
 - (2) Impervious boots.
- (c) *Biosafety Level 2 and toxins.* (1) Gloves.
- (2) Full outer covering such as a coverall.
- (3) Shoe covers, provided shoes, or safety shoes or boots (maintenance).
- (4) An Approved half-face or full-face respirator with HEPA filters (worn).
- (5) Eye protection.
- (6) An impervious apron (not required for entry only).
- (d) *Biosafety Level 2 Large Scale.* The same as § 627.29(c) with the addition of impervious boots.
- (e) *Biosafety Level 3 and Biosafety Level 3 Large Scale.* (1) A complete change of clothing.
- (2) Gloves.
- (3) An approved full-face HEPA or HEPA plus charcoal filtered respirator.
- (4) An impervious apron (not required for entry only).
- (5) Impervious boots.

(6) Head cover.

(f) *Biosafety Level 4.* (1) A full change of inner clothing.

(2) An inner pair of gloves.

(3) A one piece positive pressure suit as described in § 627.30(g), or a one piece suit with an approved positive pressure self contained breathing apparatus (SCBA) and/or a supplied-air respirator (SAR) (see § 627.30(f)).

(4) Appropriate gloves fitted to the suit.

(5) Impervious boots fitted over the suit.

§ 627.30 Specific requirements for individual PPE items.

(a) *Aprons.* Simple plastic or rubber aprons.

(b) *Boots.* When boots are required to be worn with an apron, the apron should cover the boot tops sufficiently so that liquids splashed on the apron will not run into the boots.

(c) *Eye and Face Protection.* Eye protection will meet or exceed the requirements of OSHA found in the Code of Federal Regulations title 29 part 1910.133 and will be worn at all times when required. Special eye wear may be required around UV light source.

(d) Gloves.

(1) No one glove can be expected to be satisfactory for all applications. Gloves are fabricated in a wide assortment of materials. The type of glove selected will be dependent upon the specific activity. The various activities in biocontainment facilities call for gloves to protect against etiologic agents in situations where micro-manipulations are required and excellent tactile feed-back through gloves is important, gloves for handling hot glassware and cryogenic materials, and gloves to protect against animal bites, toxic substances, chemical carcinogens, solvents, acids, and caustics. Many of these requirements call for gloves distinctly different from gloves suitable for the other hazards. As a result, the SOP for each operation should address these hazards and specify the appropriate glove required for each operation. MSDSs, manufacturer glove charts, and the Safety Officer can serve as excellent resources to determine the correct glove type needed.

(2) Before donning a pair of gloves, the gloves should be examined closely to ascertain that they are in serviceable condition. Check for rips and pin holes. Gloves should overwrap the cuff and lower sleeve of the laboratory garment.

(3) Operations in open-front biological safety cabinets should be planned so that once gloved hands have been inserted into the cabinet, the operator

does not have to withdraw them from the cabinet until the work has been completed. If gloves become visibly contaminated, they will be removed and decontaminated. Additional gloves should be available so that work can continue. When wearing gloves for an extended period, they should be changed periodically or decontaminated. Individual SOPs will designate this periodicity based upon the hazards.

(4) Gloves will be removed before going from one level of containment to another (remove gloves in a safety cabinet before removing your hands from the cabinet). Care will be taken to ensure that skin is not touched with the outer surface of contaminated or potentially contaminated gloves when they are removed. Gloves will be placed in suitable decontaminant when they are removed. Disposable gloves will be placed in a covered container for decontamination/disposal.

(5) Gloves that are a part of a biological safety cabinet system will be examined initially, after each sterilization of the biological safety cabinet system, and at least annually for leaks using the soap bubble test, followed by the halo-carbon test. Gloves will be tested while still attached to the cabinet.

(6) Sterilization of non-disposable gloves either before use or before reuse is usually done with ethylene oxide or formaldehyde gas. Sterilized gloves must be aerated in flowing sterile (filtered) air at 21°C or higher for a minimum of 24 hours prior to use to prevent skin burns and irritation from residual decontaminants.

(e) *Laboratory Clothing.* Clothing will be checked by the users before it is worn, to ensure that it is free from defects that would compromise its usefulness. Laboratory clothing (except BL-1) will be decontaminated before being released for laundering by untrained or unprotected personnel. Protective laboratory clothing that requires the personnel to pull it over the head will not be used. Laboratory clothing will meet OSHA requirements found in the title 29 Code of Federal Regulations (CFR) part 1910.132.

(f) *One-Piece Suits.* One-piece suits with a respirator under the suit are not used to any great extent except in certain emergencies. The respirators used with these are supplied air by an approved positive pressure SCBA, or SAR. Respirators will be of the pressure-demand or constant flow type. The air provided will meet OSHA requirements found in the Code of Federal Regulations title 29 part CFR 1910.134,

the requirements of Grade D breathing air as specified in the Compressed Gas Association pamphlet G-7.1 and ANSI Z86.1-1973. When used in an area that does not have a chemical shower to decontaminate the suit, a decontamination station will be set up for this purpose. Suits maintained for emergency use will be inspected at least quarterly and respiratory equipment will be inspected monthly.

(g) *One-Piece Positive Pressure Suits.* A life-support system will be provided with alarms and emergency backup breathing tanks. The air provided will be HEPA-filtered meeting OSHA requirements found in the CFR title 29 part 1910.134, the requirements of Grade D breathing air as specified in the Compressed Gas Association pamphlet G-7.1 and ANSI Z86.1-1973. A HEPA-filter will be in-line between the disconnect on the suit and the breathing space in the suit. When these are used in other than an emergency situation, a chemical shower must be provided to decontaminate the surfaces of the suit as the worker leaves the containment area. Suits will be inspected before each use to check for indications of significant wear or leakage. The suits will be worn with impervious boots over the foot area of the suit and the outer gloves will be attached over the hand portion.

(h) *Respiratory Protection Equipment.* (1) Respirators and their use will be approved by the Safety Officer. The selection will be made with knowledge of the conditions of the activities and the risks involved. In general, NIOSH-approved respirators that use aerosol filters for dusts and fumes having a Threshold Limit Value (TLV) of less than 0.05 mg/m³ have been found acceptable for use in microbiological laboratories. Alternatively, the Army M-17 or M-9 masks may be used. Air-supplied hoods are used in situations where greater respiratory protection is required without the need for body protection. One-piece suits are used when total body and respiratory protection are required.

(2) When respirators are used, a respirator protection program will be established that conforms to AR 11-34 and OSHA standards in the CFR title 29 part 1910.134. In general, the wearers will be approved to wear them by a medical authority, respirators will be fitted to individuals trained in their use and limitations, and these individuals will be responsible for the proper storage and regular inspection of their assigned respirators. Air-purifying respirators will not be worn in oxygen deficient environments.

(3) Reusable respirators that have been worn in a contaminated area will be decontaminated before reuse. At the end of each work day when a respirator has been worn in an area where it was required, personnel will wipe down their respirator with an appropriate liquid decontaminant. A damp cloth soaked in the decontaminant, with the excess liquid squeezed out, will be used for the wipe-down process, taking care to ensure that all crevices are reached. The respirator will be rinsed with clean, warm water. Visibly contaminated respirators will be decontaminated and discarded.

(4) Respirator programs will comply with AR 385-10 and AR 11-34.

(i) *Shoes.* All shoes specially issued for use in controlled access areas should be identified so that they can be segregated from other areas. Safety shoes or boots meeting OSHA requirements stated in the CFR title 29 part 1910.134 will be issued wherever heavy items or corrosive chemicals are handled. These will be sterilized appropriately after visible contamination. In certain situations (excluding BL-4 operations), it is desirable to wear disposable booties over street shoes, especially when product protection is required.

(j) *Deluge showers and eye.*

Subpart E—Decontamination and Disposal

§ 627.31 Introduction.

All material or equipment that is potentially contaminated with etiologic agents must be rendered nonhazardous before disposal. This chapter describes the acceptable physical and chemical decontamination methods and the general applicability of each. In general, all infectious materials and all contaminated equipment or apparatus will be sterilized before being washed and stored, or discarded.

§ 627.32 Methods of decontamination.

(a) *Autoclave.* The use of wet heat is the most dependable procedure for the destruction of all forms of microbial life. An autoclave employs saturated steam under a pressure of approximately 15 psi to achieve a chamber temperature of at least 121 °C for a minimum of 15 minutes. The time is measured after the temperature of the material being sterilized reaches 121 °C. Other combinations of temperature and pressure (some of which are dependent of the equipment used) can be used to accomplish sterilization provided that the efficacy of sterilization is validated as described below. The most critical factor in ensuring the reliability of this

sterilization method, other than proper temperature, is the prevention of entrapment of air that is not replaced by steam. Material to be autoclaved must come in contact with steam and heat and as a result, it may be necessary to add water to a load of waste to aid in the formation and penetration of steam. Autoclaves use either a steam-activated exhaust valve that remains open during the replacement of air by live steam until the steam triggers the valve to close, or a precycle vacuum to remove air prior to steam introduction.

(b) Sterilization will be verified through the use of biological indicators (e.g., *Bacillus stearothermophilus* spores) at locations throughout the autoclave, to include placement in the center of test loads, when the autoclave is first put into service, and after any maintenance or repairs. The primary means of verifying routine sterilization will be through the use of chemical indicators (e.g., autoclave tape or labels) at locations throughout the autoclave. In addition each autoclave will be equipped with a means to permanently record time and the temperature of each operational event as a means of ensuring sterilization. The type of materials being handled must be reviewed and standard conditions for sterilization of each established. As a guide, the manufacturer's manual for the autoclaves will be consulted as a starting point in establishing these conditions. Treatment conditions to achieve sterility will vary in relation to the volume of material treated, the contamination level, the moisture content and other factors that should be considered and which may be cause to lengthen the times. In each case the conditions will be established based on tests which verify that the conditions selected are effective. In addition to being effective for viable agents, autoclaving effectively inactivates most protein toxins.

(c) *Dry Heat.* Dry heat requires longer times and/or higher temperatures than wet heat. If used, the specific sterilization times and temperatures must be determined for each type of material being sterilized. In general, sterilization by dry heat can be accomplished at 169–170 °C for periods of 2–4 hours. Higher temperatures reduce the time requirements. The heat transfer properties and spatial relation or arrangement of materials in the load are critical in ensuring effective sterilization.

(d) *Liquid Disinfectants.* Liquid disinfectants may be used in surface treatment, in dip tanks, and, at sufficient concentration, as sterilants of liquid

waste for final disposal. If liquid disinfectants are used, they must have been shown to be effective against the organisms present. Important considerations include: temperature; time of contact, pH; concentration and state of dispersion; penetrability; and reactivity of organic material at the site of application. Small variations in these factors may make large differences in the effectiveness of disinfection, so complete reliance should not be placed on liquid disinfectants when the end result must be sterility. If evidence of efficacy under the proposed has not been reported previously, preliminary studies to verify the efficacy of liquid disinfectants must be conducted. Such studies may include attempts to recover and quantitate the agent in question from liquid or swab samples, or sealed patches, by animal inoculation, plaque assay, agar or broth cultivation, etc., following controlled decontamination under the same experimental conditions envisioned for the proposed studies.

(1) *Alcohol*. Ethyl or isopropyl alcohol at a concentration of 70–85% by weight will denature proteins but is slow in its germicidal action. Alcohols are effective disinfectants for lipid-containing viruses. These alcohols exhibit no activity against bacterial spores.

(2) *Phenolic Compounds*. These are effective disinfectants against vegetative bacteria, including *Mycobacterium tuberculosis*, fungi and lipid-containing viruses. The phenolics are not effective against bacterial spores or non-lipid-containing viruses. The concentrations used will be in accordance with the manufacturer's recommendations.

(3) *Formaldehyde Solutions*. Formaldehyde in solution at a concentration of 8 percent (formalin) is effective against vegetative bacteria, spores, and viruses. It loses considerable disinfectant activity below room temperature. Due to the toxic properties of formaldehyde, the use of formalin is restricted to surfaces or materials that are contained within appropriate engineering controls.

(4) *Quaternary Ammonium Compounds*. These cationic detergents are strongly surface-active. They lose effectiveness in the presence of proteins and are neutralized by anionic detergents, such as soap. At low concentrations, they are bacteriostatic, tuberculostatic, sporostatic, fungistatic, and algistatic. At medium concentration, they are bactericidal, fungicidal, algicidal, and virucidal against lipophilic viruses. They are not tuberculocidal, sporicidal, or virucidal against hydrophilic viruses, even at high

concentrations. The manufacturer's recommended dilution will be used.

(5) *Chlorine*. Sodium hypochlorite is normally used as a base for chlorine disinfectants. Free available chlorine is the active ingredient and, at concentrations of at least 2,500 ppm (0.25 percent), is a disinfectant that is active against most microorganisms and bacterial spores. Chlorine solutions at 2.5% free available chlorine are effective against most toxins. Chlorine solutions lose strength if exposed to air, so fresh solutions must be prepared whenever the free chlorine content falls below desired minimums.

(6) *Iodine*. The characteristics of chlorine and iodine are similar. Iodophor compounds with 1,600 ppm free available iodine provide a relatively rapid inactivation of all microorganisms, including some bacterial spores. A commonly available iodophor is Wescodyne. The manufacturer of Wescodyne recommends a range of dilution from 1–3 ounces per 5 gallons of water, giving a solution containing from 25–75 ppm of free iodine. At these concentrations, available iodine may be rapidly taken up by any extraneous protein present and will not be an effective sporicide. A solution providing 1,600 ppm iodine is recommended for hand washing or for use as a sporicide.

(7) *Mercurials*. Although the mercurials exhibit good activity against viruses, they are toxic and are not recommended for general use. They have poor activity against vegetative bacteria and are totally ineffective sporicides. The dilution recommendations stated by the manufacturer will be followed.

(e) *Vapors and Gases*. Formaldehyde, ethylene oxide, peracetic acid, beta-propiolactone, methyl bromide, and glutaraldehyde have all been used successfully as space sterilants where they can be employed in closed systems and with controlled conditions of temperature and humidity. Of these, methyl bromide, beta-propiolactone, and glutaraldehyde are not recommended because of their toxic properties. Peracetic acid can readily decompose with explosive violence in a concentrated state and must be used only in a diluted state and with extreme care. Formaldehyde and ethylene oxide are both regulated by OSHA for their potential human carcinogenicity, but do have permissible exposure levels (unlike beta-propiolactone, for example) and can be used safely under controlled conditions.

(1) *Formaldehyde*. Formaldehyde gas is, in general, the chemical of choice for space disinfection. Biological safety

cabinets and associated effluent air-handling systems and air filters, incubators, laboratory rooms, buildings, or other enclosed spaces can be disinfected with formaldehyde. The procedures found in appendix E of the National Sanitation Foundation Standard Number 49 will be followed for the disinfection of biological safety cabinets. Other enclosures or areas will be disinfected by following the same principles. To disinfect rooms, the generation of formaldehyde gas from heating powdered or flake paraformaldehyde is the preferred method. When area decontamination is performed, use 0.3 grams of paraformaldehyde for each cubic foot of space to be treated. The room or area must be above 70 °F, the relative humidity above 70%, and the exposure time at least two hours (overnight is preferred). After the required time for disinfection, the room must be cleared of the formaldehyde gas (a small room with nonporous surfaces and no materials or equipment in the room can be cleared of all detectable formaldehyde by aeration for one hour, while larger areas with equipment in them may take a full day). Before formaldehyde is used as a space disinfectant, the area to be treated must be surveyed to ensure that there are no open containers of any acidic solution containing chloride ion in order to prevent the possible formation of bis(chloromethyl)ether, a human carcinogen. Specific OSHA requirements for posting of rooms and equipment, personnel protection, and other requirements are found in 29 CFR 1910.1048.

(2) *Ethylene oxide*. Ethylene oxide (EtO) sterilization will only be conducted in a sterilizer designed for that purpose and designed to maintain potential exposure levels below the current OSHA standard. EtO is effective against all microorganisms, including spores, molds, pathogenic fungi, and highly resistant thermophilic bacteria. All materials to be used in contact with human skin (e.g., clothing, shoes, masks, adhesive tape) must be aerated for at least 24 hours after sterilization and prior to use. Concentrations of 500–1000 ppm are required for sterilization. Specific OSHA requirements for the use of ethylene oxide are found in 29 CFR 1910.1047.

(f) *Ultraviolet Radiation*. Ultraviolet (UV) radiation at a wave length of 253.7 nanometers is a practical method for inactivating airborne viruses, mycoplasma, bacteria, and fungi. The usefulness of UV radiation on exposed surfaces is limited by its low penetrating

power. UV radiation shall only be relied upon for the sterilization of surfaces when conventional methods, such as autoclaving or the use of liquid disinfectants, would make the product unusable. An example is data sheets that must be brought out of a biocontainment facility. The UV intensity must be at least 40 microwatts/cm² on the surface to be treated. Single sheets of paper may be treated by exposing them to this radiation for a minimum of 15 minutes. A calibrated photoelectric UV intensity meter, capable of measuring UV radiation at a wave length of 253.7 nanometers, will be used whenever a new UV source is installed, and quarterly thereafter, to ensure the UV source is providing at least 40 microwatts/cm² at the work surface. Routine cleaning of bulbs to remove any accumulated dust is recommended to prolong bulb performance and assure proper energy output. Protective eye wear and clothing may be necessary when working around UV radiation.

§ 627.33 Disposal.

Inactivation is the first step in the disposal of etiologic agents or materials that are potentially contaminated with them. All contaminated or potentially contaminated materials must be effectively disinfected or sterilized by an approved procedure discussed in § 627.32. After decontamination, reusable items, such as clothing or glassware, may be washed with other non-contaminated or decontaminated items.

(a) *Combustible Items.* Combustible disposable items should be bagged and incinerated in an appropriate approved incinerator or otherwise disposed of in accordance with state and local regulations.

(b) *Non-combustible disposable items.* Items will be packaged as stated in paragraph (e) of this section and disposed of by a licensed waste hauler.

(c) *Equipment.* Equipment that cannot be autoclaved will be decontaminated by gaseous sterilization or with a suitable liquid disinfectant. Such equipment will be certified as decontaminated by the safety officer.

(d) *Waste.* Materials generated, such as solvents, acids, chemical carcinogens, radioactive isotopes, medical waste, or dead animals must be decontaminated, packaged, and then disposed of in accordance with EPA, NRC, local, state and Federal regulations.

(e) *Mixed Waste.* When two or more hazardous materials are mixed together, the mixture will be decontaminated and disposed of in accordance with EPA, NRC, state and Federal regulations for

the mixture, or for the most hazardous material.

(f) *Packaging.* Solid waste will be placed in cans, sturdy bags or boxes. Rigid, puncture-resistant, sealable containers will be used for packaging "sharps". When wet materials are packaged for disposal, the materials will be placed in a leak-proof container. Heavy waste will be placed in rigid containers ensuring that the burst strength of the container is not exceeded.

(g) *Labeling.* A method of verifying that all items prepared for disposal have been decontaminated will be established for etiologic agent wastes. Mixed waste will be labeled as appropriate to indicate the hazards that must be addressed after decontamination.

(h) *Record keeping.* Manifest will be initiated and maintained, where required, to record the disposition and transfer of waste. Applicable Federal, state, and local ordinance will be followed.

Subpart F—Importation, Shipment, and Transport of Etiologic Agents

§ 627.34 Introduction.

The Centers for Disease Control (CDC) of the Public Health Service (PHS), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Department of Transportation (DOT), the United States Postal Service and the International Air Transport Association (IATA), regulate the importation, shipment, and transportation of etiologic agents. This chapter outlines the minimum administrative requirements the Commander or Institute Director are to follow and gives resources for information on the requirements for importation, packaging, labeling, and shipment of etiologic agents.

§ 627.35 Administration.

The Commander or Institute Director will establish the following controls to ensure that etiologic agents are transported with proper authorization, controls, and procedures:

(a) Institute policies will be established in writing to ensure that before etiologic agents are acquired or shipped:

(1) The Division chief responsible for the area where work with etiologic agents is to be conducted approves all acquisitions or shipments.

(2) The Safety Officer is informed in writing of the type and amount of any BL-4 or USDA-restricted etiologic agent (listed in HHS publication No. (NIH) 88-

8395 or current edition) being received, and the estimated date of arrival.

(3) The recipient of all etiologic agents shipped from an institute will be documented.

(4) The Commander or Institute Director approves all acquisitions and shipments of BL-4 or USDA-restricted etiologic agents.

(5) The Commander or Institute Director approves all requests for shipments to or from foreign countries and to individuals not affiliated with an institution or agency (e.g., physicians in private practice).

(6) The Office of The Surgeon General U.S. Army or the Commander, Army Material Command (AMC) approves the initial acquisition and use of all reference stocks of etiologic agents and transfers between Army RDT&E activities in accordance with AR 70-65.

(7) There is full compliance with the regulatory requirements referenced in §§ 627.35, 627.36, 627.37 and 627.38.

(8) The following information will be kept on file for 10 years, regarding the recipient and the intended use of BL-4 and USDA-restricted animal pathogens. This information will also be kept for all shipments to or from foreign countries and to individuals not affiliated with an institution or agency (e.g., physicians in private practice).

(i) The requester's name and address.

(ii) The type and amount of the etiologic agent to be sent.

(iii) The qualifications of the recipient of the etiologic agent.

(iv) The intended use of the etiologic agent.

(v) A statement indicating that the agent is not for human use.

(b) Etiologic agents assigned to Biosafety level 1, 2, or 3 approved for shipment and properly labeled and packaged may be shipped by commercial cargo carriers.

(c) All etiologic agents assigned to BL-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.

§ 627.36 Importation directives.

Importation of etiologic agents is subject to the Public Health Service Foreign Quarantine Regulations (42 CFR, part 71, § 71.156). Permits authorizing the importation or receipt of regulated materials and specifying conditions under which the etiologic agent is

shipped, handled, and used are contained in appendix E to this part.

§ 627.37 Shipment directives.

Shipping unmarked and unidentified etiologic agents is prohibited. Etiologic agents will be packaged, labeled, and shipped according to the requirements found in the Interstate Shipment of Etiologic Agents (42 CFR, part 72) and its amendments. The USDA regulations in 9 CFR, parts 102-104, and part 122 and the FDA regulations in 21 CFR, parts 312 and 600-680 will also be followed as applicable. Packaging and labeling requirements for interstate shipment of etiologic agents are summarized and illustrated in appendix D. Permits authorizing the shipment of regulated materials and specifying conditions under which the etiologic agent is shipped, handled, and used are contained in appendix E to this part.

§ 627.38 Transportation directives.

The packaging and labeling requirements cited above must be followed for the local transport of etiologic agents and diagnostic specimens by courier or by other delivery services. Similar requirements and restrictions applicable to the transport of etiologic agents, diagnostic specimens, and biological products by all modes of transportation (i.e., air, motor, rail, and water) are imposed by the Department of Transportation (49 CFR part 173), IATA "Dangerous Goods Regulations", the Air Transport Association "Restricted Articles Tariff 6-D", the International Civil Aviation Organization (ICAO), Postal Bulletin No. 21246 "International Mail-Hazardous Materials", 39 CFR and, the Domestic Mail Manual. When shipments exceed 4 liters, the requirements found in AR 740-32 will be followed.

§ 627.39 Additional requirements.

Additional requirements for importation, shipment, and transportation of infectious agents and hazardous materials that must be followed are contained in the following directives:

(a) AR 40-12, Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces.

(b) AR 70-65, Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities.

§ 627.40 Sources for further information on shipment of etiologic agents.

(a) Guide for Transportation of Hazardous Materials, Vol. 4(1). February 10, 1975. Copies are obtained from the Office of Research Grants Inquiries, NIH, Department of Health, Education, and Welfare, 5333 Westbard Avenue, Bethesda, MD 20205.

(b) The Centers for Disease Control, Office of Biosafety, 1600 Clifton Road NE., Atlanta, Georgia 30333. Telephone (404) 639-3883, or FTS: 236-3883.

(c) The American Type Culture Collection (ATCC), Packaging and Shipping of Biological Materials at ATCC. Copies are obtainable from the ATCC, 12301 Parklawn Drive, Rockville, MD. 20852. Phone (301) 881-2600.

(d) National Committee for Clinical Laboratory Standards (NCCLS), Procedures for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents (H5-A2), Second edition, Vol. 5, No. 1. Copies are obtained from the NCCLS, 771 East Lancaster Avenue, Villanova, PA 19085.

Subpart G—Facilities

§ 627.41 Introduction.

The design of the facility is important in providing a secondary barrier to protect individuals inside and outside the facility. Because the hazards presented by various organisms and materials vary, the requirements for the facility varies accordingly. These minimum facility requirements are described below for the various biosafety levels and toxins. The biosafety levels correspond to those described in the HHS Publication *Biosafety in Microbiological and Biomedical Laboratories* (HHS No. (NIH) 88-8395), while the large scale biosafety levels were adapted from those described in the NIH *Guidelines for Research Involving Recombinant DNA Molecules*.

§ 627.42 Biosafety level 1.

(a) *Laboratories*. Each laboratory used for this level will, as a minimum, have the following features:

- (1) A sink for handwashing.
- (2) Work surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- (3) Fly screens on any windows that can be opened.
- (4) Furnishings and surfaces that are sturdy and designed to be easily cleaned.
- (5) Spaces between furnishings and equipment will be accessible for cleaning.

(b) *Animal facilities*. Each room will have the following features:

- (1) Designed and constructed to facilitate cleaning and housekeeping.
- (2) A sink for handwashing within the facility.
- (3) Fly screens on any windows that can be opened.
- (4) Ventilation designed so that the direction of airflow in the animal facility is inward, with the exhausted air discharged to the outside without being recirculated.
- (5) Self-closing doors that open inward.

§ 627.43 Biosafety level 2.

(a) *Laboratories*. Each laboratory used for this level of hazard will have, in addition to the requirements stated in § 627.42(a), the following:

- (1) An autoclave available.
- (2) Containment equipment necessary for the operations unless the Biosafety Officer approves the use of a compensatory level of personal protective equipment.
- (3) An eyewash available near the laboratory.

(b) *Animal Facilities*. In addition to the requirements stated in § 627.42(b), facilities will include:

- (1) A sink for handwashing in each room where animals are housed.
- (2) An autoclave available in the building.
- (3) Appropriate containment equipment unless the Biosafety Officer approves the use of a compensatory level of personal protective equipment.

§ 627.44 Biosafety level 3.

(a) *General Requirements*. Each suite used as a laboratory or in which infected animals are housed will, as a minimum, have the following features:

- (1) Physical separation from areas which are open to unrestricted traffic.
- (2) All entrances to each laboratory or animal room from the non-laboratory access corridors will be through two sets of doors. A change room or airlock may be incorporated between the doors.
- (3) The interior surfaces of walls, floors, and ceilings will be water resistant so that they may be easily cleaned.
- (4) All penetrations into the walls, floors, and ceilings should be sealed or capable of being sealed to facilitate decontamination.
- (5) A foot, elbow, or automatically operated sink will be located near the exit door to each laboratory or animal room.
- (6) An autoclave should be in each laboratory or animal room and will be available to the facility.
- (7) A ventilation system that will:

(i) Create directional airflow that draws air into the laboratory through the entry areas.

(ii) Not recirculate laboratory air.

(iii) Discharge the exhaust air from the laboratory to the outside and will disperse the exhaust air away from occupied areas and air intakes.

(iv) Exhaust the HEPA-filtered air from Class I or II biological safety cabinets or other primary containment devices directly to the exterior of the laboratory or through the building exhaust system. Exhaust air from the cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months. If the filtered cabinet exhaust is discharged through the building exhaust system, it will be connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or the building exhaust system.

(8) All windows to the facility will be sealed shut.

(9) Appropriate biological safety cabinets and/or other specialized containment equipment will be provided.

(10) Any vacuum line in the facility will have a HEPA filter and liquid disinfectant trap.

(11) Bench tops that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(12) Furnishings that are sturdy and spaces between benches, cabinets, and equipment that are accessible for cleaning.

(13) An eyewash available in or near the laboratory.

(b) *Additional Animal Facility Requirements.* In addition to the requirements given above in §§ 627.43(b) and 627.44(a), all doors to the animal rooms will open inward and be self-closing.

§ 627.45 Biosafety level 4.

The engineering controls within the facility must provide absolute biological containment. All procedures with etiologic agents requiring this biosafety level of facilities, equipment and procedures must be conducted either in Class III biological safety cabinets, or in a facility that is designed for the use of a personal positive pressure suit as described in paragraph (b) of this section in conjunction with Class I or II biological safety cabinets.

(a) *General Requirements.* The facility will have the following features:

(1) A separate building or a clearly demarcated and isolated area within a building which incorporates positive personnel control for access.

(2) All entrances from access corridors incorporate an inner and outer change room.

(3) Inner and outer change rooms separated by a shower facility.

(4) A double-doored autoclave, fumigation chamber, or ventilated airlock for passage of all items which do not enter the facility through the change room.

(3) Interior surfaces of walls, floors, and ceilings resistant to water and chemicals to facilitate cleaning and disinfecting.

(4) Walls, floors, and ceilings of the facility constructed to form a sealed internal shell which facilitates fumigation and is animal and insect proof.

(5) All penetrations into the walls, floors, and ceilings sealed.

(6) All liquid drains in the facility connected directly to a liquid waste decontamination system.

(i) Holding tanks collecting waste from sinks, biological safety cabinets, floors, and autoclave chambers provide decontamination by heat treatment.

(ii) Holding tanks collecting waste from shower rooms and toilets provide decontamination by heat or chemical disinfectant methods.

(7) Sewer and other ventilation vents contain in-line HEPA filters.

(8) Internal facility appurtenances (e.g., light fixtures, air ducts, and utility pipes) arranged to minimize the horizontal surface area on which dust can settle.

(9) A foot, elbow, or automatically operated handwashing sink located near the exit door to each laboratory or animal room.

(10) Self-closing and lockable access doors.

(11) A ventilation system that:
(i) Is dedicated to the facility and provided fresh air meeting ASHRAE Standard 62.

(ii) Maintains a negative pressure differential and assures flow inward from areas outside of the facility toward areas of highest potential risk.

(iii) Has manometers or magnehelic gages to provide, sense, and display pressure differentials between adjacent areas maintained at different pressure levels. An alarm will sound when the pressures fall below acceptable levels.

(iv) Has the air supply and exhaust interlocked to ensure that exhaust failure or reduction will not allow the air pressure in the area to become positive to the adjacent areas.

(v) Does not recirculate exhaust air.

(vi) Is HEPA-filtered and discharged to the outside, dispersing the exhaust air away from occupied areas and air intakes. Has the HEPA filters on the

exhaust located as near to the rooms as is practicable.

(vii) Has the filter chambers designed to allow in-place decontamination before the filters are removed and to facilitate certification testing.

(ix) Contains pre-filters and HEPA filters in the air supply system to protect the air supply system should air pressures become unbalanced.

(x) Exhausts the HEPA-filtered air from Class I or II biological safety cabinets directly into the laboratory or to the exterior of the building. If the HEPA-filtered exhaust from these cabinets is recirculated, the cabinets are tested and certified every 6 months. If the filtered cabinet exhaust is discharged through the building exhaust system, it will be connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or the building exhaust system.

(xi) Passes the treated exhaust air from Class III biological safety cabinets through two sets of HEPA filters in series to the exterior of the facility through the laboratory exhaust air system.

(12) Windows (if present) sealed shut and breakage resistant.

(13) Has a double-doored autoclave for decontaminating materials passing out of the facility. The autoclave door that opens to the area external to the facility is sealed to the outer wall and automatically controlled so that it can only be opened after the autoclave sterilization cycle has been completed.

(14) Has a pass-through dunk tank, fumigation chamber, or an equivalent decontamination method for materials and equipment that cannot be autoclaved.

(15) Has central vacuum systems (if present) that:

(i) Do not serve areas outside the facility.

(ii) Have an in-line HEPA filter placed as near as practicable to each use point or service cock.

(iii) Have filters designed to allow in-place decontamination and replacement.

(16) Liquid and gas service to the facility provided with protective devices that prevent backflow.

(b) *Additional Requirements for Personal Positive Pressure Suit Areas.* If personal positive pressure suits are worn in lieu of using Class III biological safety cabinets for containment, a special suit area will be provided. The suit area will provide the following, in addition to the requirements stated in paragraph (a) of this section:

(1) An exhaust system dedicated to that area that provides filtration by two

sets of HEPA filters installed in series. This system will be backed up by a duplicate filtration unit, exhaust fan, and an automatically starting emergency power source. The ventilation system will maintain the suit area under negative pressure relative to the surrounding areas.

(2) An entry area consisting of an airlock fitted with airtight doors.

(3) A chemical shower to decontaminate the surface of the personal positive pressure suit upon exit.

(4) An air supply and distribution system to support the life support system of the personal positive pressure suits.

(5) Emergency lighting and communications systems.

(6) Sealed penetrations into the internal shell of the area.

(7) A double-doored autoclave to decontaminate waste materials to be removed from the suit area.

(c) *Additional Laboratory Requirements.* In addition to those given in § 627.44, if water fountains are provided, they will be foot operated and located in the facility corridors outside the laboratory.

(d) *Additional Animal Facility Requirements.* In addition to those requirements given in § 627.44, all animal facility external doors will be self-locking.

§ 627.45 Large scale facilities.

The following requirements apply to facilities in which an individual culture of viable etiologic agents exceeds 10 liters:

(a) *Biosafety Level 1 Large Scale.* In addition to the laboratory requirements stated in § 627.42(a), the exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to HEPA filters or by other equivalent procedures (e.g., incineration) to minimize the release of viable organisms.

(b) *Biosafety Level 2 Large Scale.* In addition to the requirements stated in § 627.43(a) and paragraph (a) of this section:

(1) Rotating seals and other mechanical devices directly associated with a closed system used to contain viable organisms shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through equivalent treatment devices.

(2) A closed system used for the propagation and growth of viable organisms shall include monitoring or sensing devices that monitor the

integrity of containment during operations.

(3) Closed systems used for the propagation and growth of viable organisms shall be tested operationally for integrity of the containment features. The containment will be rechecked following modification or replacement of essential containment features. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.

(c) *Biosafety Level 3 Large Scale.* The requirements stated in § 627.45 and paragraph (b) of this section apply, and all closed systems and other primary containment equipment used in handling cultures of viable organisms shall be located within a controlled area which meets the requirements of a BL-3 facility plus the following requirements:

(1) All utilities and service or process piping or wiring entering the controlled area shall be protected against contamination.

(2) A shower facility shall be provided. This facility shall be located in close proximity to the controlled area.

(3) The controlled area shall be designed to preclude release of culture fluids outside the controlled area in the event of an accidental spill or release from the closed systems or other primary containment equipment.

(4) The controlled area shall have a ventilation system that is capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential. If the ventilation system provides positive pressure supply air, the system shall operate in a manner that prevents the reversal of air movement or shall be equipped with an alarm that would be actuated in the event that reversal in the direction of air movement were to occur. The exhaust air from the controlled area shall not be recirculated to other areas of the facility. The exhaust air from the controlled area may be discharged to the outdoors after filtration or other means of effectively reducing an accidental aerosol burden, and dispersed clear of occupied buildings and air intakes.

§ 627.47 Toxins.

(a) General requirements for all facilities in which toxins are used are as follows. Such facilities will:

(1) Have a ventilation system that provides three to six air changes per hour, and that provides a directional airflow inward relative to the access halls.

(2) Have a sink for handwashing.

(3) Have an eyewash available.

(4) Have bench tops that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(5) Have furniture, furnishings, and surfaces that are sturdy and designed to be easily cleaned.

(6) Be arranged so that items are accessible for cleaning.

(7) Have a quick-drench shower available within the facility.

(8) A fume hood, biological safety cabinet, glove box, or equivalent engineering control equipped with HEPA filters and with charcoal filters if volatile materials are being used.

Subpart H—Engineering Controls

§ 627.48 Introduction.

As required by the Occupational Safety and Health Administration (OSHA) and recommended by the American Industrial Hygiene Association (AIHA) and the Centers for Disease Control (CDC), engineering controls and proper microbiological techniques are the primary means of protecting personnel who work with potentially hazardous biological materials. In situations of potentially higher hazard, these engineering controls are supplemented by personal protective clothing and equipment. Thus, the engineering controls discussed in this chapter will be the primary means of personnel and environmental protection when working with etiologic agents. Because of the importance of these engineering controls, this chapter contains not only requirements for the engineering and construction of these controls, but also requirements for the certification and continuous satisfactory performance of these controls. These will be described for each engineering control.

§ 627.49 Class I Biological Safety Cabinet.

(a) *Description.* The Class I biological safety cabinet (see Footnote ¹) is a ventilated cabinet for personnel protection only. The cabinet provides an uncirculated inward flow of air away from the operator. The exhaust is passed through a HEPA filter. The exhaust may be discharged into the laboratory or vented out of the laboratory and dispersed away from occupied spaces or air intakes. When the exhaust is recirculated in a BL-2 or

¹ A line drawing of the Class I Biological Safety Cabinet is not included in this part but may be obtained from HQDA (DAC9-SF), Mr. Wortley, room 2C717, Pentagon, Washington, DC 20310-0200 (703) 695-7291.

BL-3 facility, the cabinet must be tested and certified annually. In a BL-4 facility, if the exhaust is recirculated, the cabinet must be tested and certified semi-annually.

(b) *Uses.* These cabinets are used in situations where personnel protection against the micro-organisms is required; for modest quantities of volatile, toxic, or radioactive chemicals (in concentrations and quantities associated with biological systems) if vented to the outside; and when sterility is not required. They are commonly used for housing tabletop centrifuges, in the necropsy of small animals, and for changing animal bedding.

(c) *Prohibitions.* This class of cabinet is not to be used when sterility must be maintained. In addition, volatile, toxic, or radioactive materials can not be used in this class of cabinet when the exhaust air is not exhausted to the exterior.

(d) *Certifications and requirements.*

(1) The inward air velocity on these cabinets will be an average of 100 ± 20 linear feet per minute (lfpm). Each cabinet must be certified before use and semiannually thereafter by a face velocity test. Additionally, smoke tests will be performed annually to verify containment.

(2) The exhaust system will have a HEPA filter, which will be tested initially upon installation, after repair or replacement, and every two years thereafter (except when required more often). Filters will be certified to be 99.97 percent effective in capturing particulate matter by a leakage test using mineral oil or other appropriate aerosol dispersed as 0.3 micron droplets.

§ 627.50 Class II Biological Safety Cabinets.

All Class II biological safety cabinets (See Footnote ²) are ventilated cabinets for personnel and product protection, having an open front with inward air flow for personnel protection.

(a) *General.* (1) All of these cabinets must conform and be certified to meet NSF Standard No. 49 revised, June 1987, for the applicable type of cabinet.

(2) After installation and before use, and annually thereafter, the cabinets will be tested in accordance with NSF Standard No. 49 (latest revision June 1987) as follows:

Primary (Required) Tests:

- (i) Velocity Profile Test.
- (ii) Work access opening airflow (Face Velocity) test.
- (iii) HEPA filter leak test.

(iv) Cabinet integrity test (soap bubble test) for cabinets with positive pressure internal plenums.

Secondary (Optional) Tests:

- (v) Vibration test.
- (vi) Electrical leakage and ground circuit resistance tests.

(vii) Noise level test.

(viii) Lighting intensity test.

(ix) UV light intensity test.

(3) After repairs or alterations to the cabinetry or ventilation system that affect the cabinet, the tests listed in paragraph (a)(2) of this section will be performed for the relevant parameters.

(4) The work access opening airflow (face velocity) test, as specified in NSF Standard No. 49 (latest revision June 1987), will be performed to check that the cabinet is within specifications on an annual basis for Biosafety Levels 1 and 2 and toxin use. This test will be performed semi-annually on cabinets used for Biosafety Levels 3 and 4 as well as for work with dry forms of toxins.

(5) When the exhaust is recirculated in a BL-4 facility, the cabinet must be tested and certified semi-annually.

(b) *Class IIA Biological Safety Cabinets—(1) Description.* A Class IIA biological safety cabinet is one in which typically 70% of the air is recirculated within the cabinet and the exhaust passes through a HEPA filter before discharge. The exhaust may be exhausted into the room and positive-pressure contaminated ducts and plenums within the cabinet are allowed. Type A cabinets shall have a minimum calculated face velocity of 75 fpm.

(2) *Uses.* These cabinets are for working with low-to-moderate risk biological samples and for protection of the personnel against biological material while providing a sterile atmosphere in which to handle the material.

(3) *Prohibitions.* Materials that are toxic or volatile must not be used in these cabinets.

(c) *Class IIB₁ Biological Safety Cabinets—(1) Description.* A Class IIB₁ biological safety cabinet is one that maintains a minimum average inflow of air of 100 ± 20 lfpm and in which typically 30 percent of the air is recirculated. All recirculated and exhausted air passes through two HEPA filters in series. All contaminated internal ducts and plenums are under negative pressure. Type B cabinets shall have a minimum calculated face velocity of 100 fpm.

(2) *Uses.* When ultra-sterility is needed, these are the cabinets of choice. The double filtration achieves a cleaner atmosphere. Minute quantities of volatile, toxic, or volatile radioactive materials coincidental to use in

biological systems may also be used in these cabinets.

(3) *Prohibitions.* More than minute quantities of toxic, volatile, or radioactive materials must not be used in these cabinets.

(4) *Additional Certifications or Requirements:* None.

(d) *Class IIB₂ Biological Safety Cabinets—(1) Description.* A Class IIB₂ biological safety cabinet is one that maintains a minimum average of 100 ± 20 lfpm inward flow and in which all air is exhausted directly from the cabinet through a HEPA filter without recirculation within the cabinet. All contaminated ducts and plenums are under negative pressure. Type B cabinets shall have a minimum calculated face velocity of 100 fpm.

(2) *Uses.* These cabinets are recommended when small quantities of volatile, flammable, or toxic chemicals must be used coincidental with items requiring sterility.

(3) *Prohibitions.* While these cabinets do offer the greatest degree of safety for volatile, toxic, and flammable chemical handling in a sterile environment, they are not to be used in place of a fume hood for preparation of stock solutions of hazardous chemicals.

(e) *Class IIB₃ Biological Safety Cabinets—(1) Description.* A Class IIB₃ biological safety cabinet is one that meets all of the requirements of a Class IIB biological safety cabinet except that it recirculates most (typically 70 percent) of the air inside the cabinet. Type B cabinets shall have a minimum calculated face velocity of 100 fpm.

(2) *Uses.* Minute amounts of non-flammable chemicals can be used coincidental with the use of low-to-moderate risk biological agents.

(3) *Prohibitions.* Flammable materials and more than minute amounts of toxic, radioactive, or volatile chemicals must not be used in these cabinets.

(4) *Additional Certifications or Requirements:* None.

§ 627.51 Class III Biological Safety Cabinets.

(a) *Description.* These cabinets (See Footnote ³) are totally enclosed, ventilated cabinets of gas-tight construction. Operations are conducted through attached rubber gloves. The supply air is drawn into the cabinet through HEPA filters. The exhaust air is treated by double HEPA filtration, or by HEPA filtration followed by

² A line drawing of the Class II Biological Safety Cabinet is not included in this part but may be obtained from HQDA (DACS-SF), Mr. Wortley, room 2C717, Pentagon, Washington, DC 20310-0200 (703) 695-7291.

³ A line drawing of the Class III Biological Safety Cabinet is not included in this part but may be obtained from HQDA (DACS-SF), Mr. Wortley, room 2C727, Pentagon, Washington, DC 20310-0200 (703) 695-7291.

incineration, and is not allowed to recirculate within the room.

(b) *Uses.* These cabinets provide the ultimate protection for personnel. These cabinets are suitable for low, moderate, and high risk etiologic agents.

(c) *Prohibitions.* More than minute amounts of flammables must not be used in these cabinets.

(d) *Certifications and Requirements.*

(1) These cabinets will have a manometer or magnehelic gauge that indicates the negative pressure that is maintained inside the cabinet. The pressure inside the cabinet should be a minimum of 0.5 inches water gauge negative to the surrounding room.

(2) These cabinets will be pressure tested by the soap bubble/halogen leak test as prescribed in NSF Standard No. 49, Appendix B1 (latest revision June 1987), and certified, when the HEPA filter units are serviced.

§ 627.52 Fume hood.

Fume hoods in which etiologic agents are handled must use proven technologies to provide optimal containment. Fume hood placement, design, and capture testing requirements for use in the design of new laboratories can be found in the latest edition of *Industrial Ventilation, A Manual of Recommended Practice*, published by the American Conference of Governmental Industrial Hygienists.

(a) *Description.* Fume hoods are common chemical laboratory furnishings designed to capture fumes from chemicals that are used within them. Air is drawn through the opening and vented to the exterior without recirculation.

(b) *Uses.* Fume hoods provide excellent containment for handling hazardous chemicals.

(c) *Prohibitions.* Moderate risk biologicals and open containers of dry forms of toxins must not be used in a fume hood without HEPA filtration. Fume hoods should never be used when sterility is required.

(d) *Certifications and requirements.*

(1) Inward air flow will be an average of 100 ± 20 lpm as measured at the face of the fume hood. Proper function of laboratory hoods is not only a function of face velocity. An evaluation of the total operating environment is necessary.

(2) When filters are required, they will be certified by the mineral oil droplet (HEPA) or Freon (Charcoal) leak test as appropriate. Leakage through the filters will be less than 0.05 percent for Freon and 0.03% for oil droplets when initially installed.

(3) Fume hoods will be provided with indicator devices to give a warning

should the ventilation system fail or if the hood face velocity falls below an average of 80 lpm.

(4) Hood air flow will be certified when installed, when maintenance is performed on the ventilation system, and semiannually thereafter.

§ 627.53 Glove box.

(a) *Description.* A glove box is an enclosure that provides a positive barrier from liquids, solids, and chemical vapors. A glove box has viewing ports and glove ports for access. The box maintains personnel protection through solid barriers and maintenance of a negative pressure relative to its surroundings.

(b) *Uses.* Glove boxes are used when extreme containment is needed for highly toxic chemicals, especially for dry chemicals that can be swept out of containers by the airflow in hoods.

(c) *Prohibitions.* Unventilated boxes must not be used with volatile flammable materials and should not be used with volatile toxic materials unless dilution ventilation is provided.

(d) *Additional Certifications and Requirements.* (1) The glove box will be maintained at a pressure of at least 0.25 inches water gauge less than its surroundings.

(2) The pressure differential will be indicated by a manometer or magnehelic gauge. Indicator devices will display a loss of pressure below 0.25 inches water gauge.

(3) Gloves will be changed at appropriate intervals (dependent on the box contents) that will insure they provide the protection needed.

(4) Inlets that provide dilution air will be protected by HEPA filters.

§ 627.54 Ventilated balance enclosures.

(a) *Description.* A ventilated balance enclosure is a box that surrounds a balance and has a small open area for access and handling material in the front. Air is exhausted out the rear of the enclosure.

(b) *Uses.* A ventilated balance enclosure is used when containment of a balance is required for the weighing of hazardous materials that have a low vapor pressure (such as toxins). These enclosures are also used when it is desirable to utilize the balance in other than a fume hood (due to the turbulence and vibration) and when biological safety cabinets or glove boxes are inappropriate or unavailable. Dry forms of toxins may be weighed in these enclosures.

(c) *Prohibitions.* Very volatile or highly toxic volatile materials must not be handled in ventilated balance enclosures unless they are placed in

closed containers in a properly functioning fume hood before being transferred to the balance enclosure.

(d) *Additional Certifications or Requirements.* (1) The flow through the openings in the enclosure will be at least 60 lpm and must average between 60 and 80 lpm.

(2) Containment will be certified prior to first use and annually thereafter by smoke tubes.

(3) The air flow will be certified initially and semi-annually by averaging readings taken from the face of the opening.

§ 627.55 Ventilated cage enclosures.

There are a number of cage-ventilated enclosures in which infected animals may be housed at levels corresponding to the various classes of biological safety cabinets. A brief description of four different types of animal ventilated cages is given below. This is not a complete description of all the different animal ventilated cages available. The proper functioning of these will be made initially, upon each connection to exhaust sources and at least annually. The inward flow rates on the partial containment systems and pressure checks on the total containment cages will be performed. Prior to selecting such equipment, an evaluation of the function and the equipment should be made, and the methods for testing and decontamination should be analyzed and documented.

(a) *Filter-top cages.* Small laboratory animal polystyrene or polycarbonate cage bottoms are fitted with a dome shaped glass fiber or polyester filter cage cover. The dome shaped filters help reduce the dissemination of aerosols, and the spread of infectious agents. Adequate ventilation around cages fitted with a dome shaped filter is essential since they may contain elevated ammonia and carbon dioxide levels, and high temperature and humidity. Ventilation recommendations in the NIH publication 86-23, 1985 Guide for the Care and Use of Laboratory Animals will be followed.

(b) *Forced ventilation cages.* This is a small HEPA-filtered animal cage connected to a centralized exhaust system. A minimum airflow of $0.03 \text{ m}^3/\text{min}$ per cage is required. Ventilation rates may vary with the size of the cage, and the number and type of animals being housed.

(c) *Cubicle-type isolation cage.* This is a partial containment unit which holds several animal cages. This unit is a negative pressure HEPA-filtered stainless steel cage. A minimum airflow of $0.3 \text{ m}^3/\text{min}$ per cage is required for a

0.24 m³ unit. Ventilation rates may vary with the size of the cage, and the number and type of animals being housed.

(d) *Total containment cage.* This unit is a negative pressure or positive pressure HEPA-filtered stainless steel cage which has the filters incorporated into the design. It is halogen gas-leak tight and can be considered a Class III biological safety cabinet. A minimum airflow of 0.3 m³/min per cage is required for a 0.24 m³ unit. Ventilation rates may vary with the size of the cage, and the number and type of animals being housed.

§ 627.56 Ventilated cage areas.

Ventilated cage areas are areas within a room that are solid-walled and bottomed areas for containing multiple cages housing infected animals. The containment for these areas is equivalent to the Class I biological safety cabinet. For testing purposes they will be treated the same as a Class I biological safety cabinet.

Appendix A to Part 627—References

Required Publications

Executive Order 12196
Safety and Health Programs for Federal Employees, 26 February 1980
9 CFR 102-104, 122
Animals and Animal Products
10 CFR Chapter 1
Nuclear Regulatory Commission
21 CFR 312, 600-680
Food and Drugs
29 CFR 1910
Occupational Health and Safety
Administration Safety and Health Standards
39 CFR 111
Postal Service
40 CFR 1500-1508
Protection of Environment
42 CFR 71-72
Public Health Service Foreign Quarantine Regulations
49 CFR 172-173
The Department of Transportation.
AR 11-34
Army Respiratory Protection Program
AR 40-5
Medical Surveillance Program
AR 40-12

Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces.

AR 40-14

Control and Recording Procedures for Exposure to Ionizing Radiation and Radioactive Materials

AR 40-66

Medical Record and Quality Assurance Administration

AR 70-65

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

AR 385-10

Army Safety Program

AR 385-40

Accident Reporting and Records

AR 385-BIO

Biological Defense Safety Program

AR 740-32

Responsibilities for Technical Escort of Dangerous Materials.

ASHRAE Standard 62

HHS Publication No. (NIH) 88-8395

Biosafety in Microbiological and Biomedical Laboratories

NIH Guidelines for Research Involving Recombinant DNA Molecules

Federal Register 51: 7 May 1986

Postal Bulletin No. 21246

International Mail-Hazardous Materials Dangerous Goods Regulations

International Air Transport Association (IATA), Publications Section, 2000 Peel Street, Montreal, Quebec, Canada H3A 2R4, Tel (514) 844-6311.

Guide for Adult Immunizations

Published by the American College of Physicians

Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates

The American Journal of Tropical Medicine and Hygiene, 29:1359-1381, 1980.

NSF Standard #49

National Sanitation Foundation Standard Number 49, Class II (Laminar Flow)

Biohazard Cabinetry

Restricted Articles Tariff 6-D

Air Transport Association

Technical Instructions for the Safe Transport of Dangerous Goods by Air

International Civil Aviation Organization (ICAO) Intereg Group, 5724 Pulaski Road, Chicago, IL 60646, Tel. (312) 478-0900.

Additional References

ANSI Z86.1-1973

Breathing Air

Biohazards Reference Manual

American Industrial Hygiene Association, 1985

Bacterial Toxins: A Table of Lethal Amounts
Gill, D.M., Microbiological Reviews, Volume 46, Number 1; March 1982, pages 86-94.

Clinical Medicine Branch, Division of Host Factors, Center for Infectious Disease, Centers for Disease Control, Atlanta, GA 30333, telephone: (404) 639-3356

Compressed Gas Association Pamphlet G-7.1
Grade D Breathing Air

DHEW Pub. No. (NIH) 76-1165

Biological Safety Manual for Research

Involving Oncogenic Viruses Guide for Transportation of Hazardous Materials,

Vol. 4(1), February 10, 1975. Copies are obtained from the Office of Research

Grants Inquiries, NIH, Department of Health, Education, and Welfare, 5333

Westbard Avenue, Bethesda, MD 20205.

Guidelines for Laboratory Design, Health and Safety Considerations

L. DiBerardinis, et. al., John Wiley and Sons, 1987

Guidelines for Prevention of Herpesvirus Simiae (B Virus) Infection in Monkey

Handlers

Kaplan, J.E., et. al., Mortality and Morbidity Weekly Report, Volume 36, Number 41;

October 23, 1987, pages 680-689.

Industrial Ventilation, A Manual of Recommended Practice, Published by the

American Conference of Governmental Industrial Hygienists.

NIH publication 86-23

Guide for the Care and Use of Laboratory Animals, Packaging and Shipping of

Biological Materials at ATCC

The American Type Culture Collection (ATCC), Copies are obtained from the

ATCC, 12301 Parklawn Drive, Rockville, MD. 20852. Phone (301) 881-2600.

Procedures for the Domestic Handling and Transport of Diagnostic Specimens and

Etiologic Agents

National Committee for Clinical Laboratory Standards (NCCLS), (H5-A2), Second

edition, Vol. 5, No. 1. Copies are obtained from the NCCLS, 771 East Lancaster

Avenue, Villanova, PA 19085.

The Centers for Disease Control, Office of Biosafety, 1600 Clifton Road N.E., Atlanta,

Georgia 30333. Telephone (404) 639-3883, or FTS: 236-3883.

Appendix B to Part 627—Resource List for Immunoprophylaxis of Personnel at Risk

B-1.—RECOMMENDATIONS FOR IMMUNOPROPHYLAXIS OF PERSONNEL AT RISK

Description of disease	Recommended product	Source for use in	Of product
Anthrax	Inactivated vaccine	Personnel working regularly with cultures, diagnostic materials, or infected animals.	USAMRIID. ¹
Botulism	Pentavalent toxoid (A,B,C,D,E) (IND). ²	Personnel working regularly with cultures or toxin....	CDC. ³
Cholera	Inactivated vaccine	Personnel working regularly with large volumes or high concentrations of infectious materials.	Commercially available.
Diphtheria Tetanus (Adult)	Combined toxoid.....	All laboratory and animal care personnel irrespective of agents handled.	Commercially available.
Eastern equine encephalitis (EEE)....	Inactivated vaccine (IND) ²	Personnel who work directly and regularly with EEE in the laboratory.	USAMRIID. ¹

B-1.—RECOMMENDATIONS FOR IMMUNOPROPHYLAXIS OF PERSONNEL AT RISK—Continued

Description of disease	Recommended product	Source for use in	Of product
Hepatitis A.....	Immune Serum Globulin [ISG (Human)].	Animal care personnel working directly with chimpanzees naturally or experimentally infected with Hepatitis A virus.	Commercially available.
Hepatitis B.....	Serum-derived or recombinant vaccine.	Personnel working regularly with human blood and blood components.	Commercially available.
Influenza.....	Inactivated vaccine.....	(Vaccines prepared from earlier isolate strains may be of little value in personnel working with recent isolates from humans or animals).	Commercially available.
Japanese Encephalitis.....	Inactivated vaccine (IND) ²	Personnel who work directly and regularly with JE virus in the laboratory.	CDC. ³
Measles.....	Live attenuated virus vaccine.....	Measles-susceptible personnel working with the agent or potentially infectious clinical materials.	Commercially available.
Meningococcal Meningitis.....	Purified polysaccharide vaccine.....	Personnel working regularly with large volumes or high concentrations of infectious materials (Does not protect against infection with group B meningococcus).	Commercially available.
Plague.....	Inactivated vaccine.....	Personnel working regularly with cultures or <i>Yersinia pestis</i> , or infected rodents or fleas.	Commercially available.
Poliomyelitis.....	Inactivated (IPV) and live attenuated (OPV) vaccines.	Polio-susceptible personnel working with the virus or entering laboratories or animal rooms where the virus is in use.	Commercially available.
Pox viruses (Vaccinia, Cowpox, or Monkey Pox viruses).	Live (lyophilized vaccinia virus).....	Personnel working with orthopox viruses transmissible to humans, with animals infected with these agents, and persons entering areas where these viruses are in use.	CDC. ³
Q Fever (Phase II) vaccine.....	Inactivated (IND) ²	Personnel who have no demonstrable sensitivity to Q fever antigen and who are at high risk of exposure to infectious materials or animals.	USAMRIID. ¹
Rabies.....	Human diploid line cell inactivated vaccine.	Personnel working with <i>all strains</i> of rabies virus, with infected animals, or persons entering areas where these activities are conducted.	Commercially available.
Rift Valley Fever.....	Inactivated virus vaccine (IND) ²	All laboratory and animal care personnel working with the agent or infected animals and all personnel entering laboratories or animal rooms when the agent is in use.	USAMRIID. ¹
Rubella.....	Live attenuated virus vaccine.....	Rubella-susceptible personnel, especially women, working with "wild" strains or in areas where these viruses are in use.	Commercially available.
Tuberculosis.....	Live, attenuated (BCG) bacterial vaccine.	BCG vaccine ordinarily is not used in laboratory personnel in the U.S.	Commercially available.
Tularemia.....	Live attenuated bacterial vaccine (IND). ²	Personnel working regularly with cultures or infected animals or persons entering areas where the agent or infected animals are in use.	USAMRIID. ¹
Typhoid.....	Inactivated vaccine.....	Personnel who have no demonstrated sensitivity to the vaccine and who work regularly with cultures.	Commercially available.
Venezuelan equine (VEE) encephalitis.	Live attenuated (TC83) viral vaccine (IND). ²	Personnel working with VEE and the Equine Cabassou, Everglades, Mucambo and Tonate viruses, or who enter areas where these viruses are in use.	USAMRIID. ¹
Western equine encephalitis (WEE).	Inactivated vaccine (IND) ² with WEE virus.	Personnel who work directly and regularly in the laboratory.	USAMRIID. ¹
Yellow Fever.....	Live attenuated (17D) virus vaccine.	Personnel working with virulent and avirulent strains of Yellow Fever virus.	Commercially available.

¹ For information, contact: U.S. Army Medical Materiel Development Activity, Fort Detrick, Frederick, MD 21701, telephone: (301) 663-7661.

² Investigational New Drug.

³ Clinical Medicine Branch, Division of Host Factors, Center for Infectious Disease, Centers for Disease Control, Atlanta, GA 30333, telephone: (404) 639-3356.

Source: Adapted from recommendations of the PHS Immunization Practices Advisory Committee and Biosafety in Microbiological and Biomedical Laboratories.

Appendix C to Part 627—Laboratory Safety Inspection

Check List

C-1. The check list that follows is not an exhaustive list of the items that should be considered when inspecting facilities where etiologic agents are used; however, it does provide some basic guidelines that can be useful in reminding safety and non-safety professionals of the things that need to be considered in laboratories that they are responsible for. The check lists are designed to be used as follows: All areas should be inspected using the general list in C-2. Certain items are optional, such as radiation safety; if no radioactive material is present in

the room, then this would not be applicable. For BL-1 facilities the list in C-2 is adequate, while BL-2, BL-3, and BL-4 facilities must use the list in C-2 together with the appropriate list in C-3 to C-5.

C-2. Basic Checklist.

a. Housekeeping

- (1) Is the room free of clutter?
- (2) Are all aisles from the work areas to the available exits maintained clear of obstructions?
- (3) Are all safety equipment items unobstructed and ready for use?
- (4) Is the room clean?

b. Fire Safety

- (1) Is the fire extinguisher hung in its proper place, ready for use and unobstructed?
- (2) Is there an excess of flammables located outside NFPA approved cabinetry?
- (3) Are all IA flammables that are in breakable containers in pint or smaller containers?
- (4) Are all IB flammables that are in breakable containers in liter or smaller containers?

c. Chemical Safety

- (1) Are the chemicals stored with compatible materials?
- (2) Have the chemical fume hoods been certified in the last 6 months?

(3) Are the eyewash and deluge shower unobstructed and ready for use?

(4) Is the eyewash and deluge shower tested regularly to document proper operation?

(5) Is the organic waste container maintained in a closed position?

(6) Are all reagents and solutions properly labeled?

(7) Is a spill kit within a reasonable distance from the work areas?

(8) Is appropriate protective clothing available for the chemical hazards present?

(9) Is there a written hazard communication program?

(10) Have the personnel in the laboratory been trained in the provisions and principles of the hazard communication program?

(11) Are MSDS's located where they are available to the laboratory workers?

(12) Is there a written chemical hygiene plan?

(d) Radiation Safety

(1) Are the radioactive materials stored double-contained?

(2) Is the containment for the radiation waste container adequate to preclude spread of radiation?

(3) Are all containers appropriately labeled with radiation labels?

(4) Are all entrances to the room appropriately labeled?

(e) Electrical Safety

(1) Are excess extension cords being utilized?

(2) Are there any frayed cords in the room?

(3) Are there any cords on the floor across normal traffic patterns in the room?

(f) General Laboratory Safety

(1) Are sharps discarded and destroyed in a safe manner?

(2) Are work surfaces decontaminated daily and after a spill?

(3) Is the appropriate attire worn by everyone in the room?

(4) Is there evidence that personnel eat, drink, smoke, or store items for such in the room?

(5) Was mouth pipetting observed?

(6) Are all gas cylinders secured and all cylinders that are not in use capped?

(7) Are cylinders of oxidizers stored at least 20 feet from cylinders of flammable gases in the same room?

(8) Are the cylinders clearly labeled as to the contents?

(9) Are the cylinders transported on appropriate dollies or hand trucks?

(10) Is there a written respiratory protection program where respirators are used?

(g) Etiologic Agents

(1) Are all containers of etiologic agents appropriately labeled?

(i) Are freezers, refrigerators and similar storage units labeled with the biohazard warning sign?

(ii) Are the storage and shipping containers adequate and properly labeled?

(2) Have all personnel been adequately trained in general microbiological techniques?

(3) Are laboratory doors kept closed when experiments are in progress?

(4) Are all operations conducted over plastic-backed absorbent paper or spill trays?
C-3. Biosafety Level 2 supplemental checklist.

(a) Are all floor drains filled with water or suitable disinfectant?

(b) Is the Standing Operating Procedure for an etiologic agent spill signed by all personnel who work with etiologic agents in the room?

(c) If biological safety cabinets are used, have they been certified within the last year?

(d) Are the appropriate decontaminants available?

(e) Are all entrances to the laboratory posted with:

(1) The appropriate special provisions for entry?

(2) The universal biohazard symbol?

(3) The name and phone number of the laboratory director or other responsible person?

(f) Is entry limited and restricted?

(g) Were gloves being worn when handling infected animals or infectious or toxic materials?

(h) Is eye and respiratory protection being worn in rooms where non-human primates are present?

(i) If materials are being transported off-site for decontamination, is the containment adequate?

C-4. Biosafety Level 3 supplemental checklist.

(a) Is laboratory clothing decontaminated before being sent to the laundry?

(b) Are all windows and penetrations through the walls and ceilings sealed?

(c) If biological safety cabinets are used, have they been certified within the last year?

(d) Are the appropriate decontaminants available?

(e) Are all entrances to the facility posted with:

(1) The appropriate special provisions for entry?

(2) The universal biohazard symbol?

(3) The name and phone number of the laboratory director or other responsible person?

(f) Is entry limited and restricted?

(g) Were gloves being worn when handling infected animals or infectious or toxic materials?

(h) Is eye and respiratory protection being worn in rooms where non-human primates are present?

(i) Do the monitors indicate that the room is under negative pressure relative to all entrances?

(j) Are all vacuum lines protected with HEPA filters and liquid disinfectant traps?

(k) Is the autoclave being properly maintained and certified?

(l) Is the foot, elbow, or automatic handwash sink operating properly?

(m) Are all operations with etiologic agents being conducted inside of biological safety cabinets or other approved engineering controls?

(n) Are all infected animals housed using appropriate primary containment systems?

(o) Do all personnel who enter rooms housing infected animals wear appropriate respiratory protection?

(p) Do personnel who exit rooms having infected animals leave their protective clothing in the animal and laboratory rooms?

(q) If available, has the UV pass box output been certified within the last 3 months?

C-5. Biosafety Level 4 supplemental inspection checklist.

(a) General.

(1) Are all penetrations through the walls and ceilings sealed?

(2) Are the appropriate decontaminants available and used properly?

(3) Are all entrances to the facility posted with:

(i) The appropriate special provisions for entry?

(ii) The universal biohazard symbol?

(iii) The name and phone number of the laboratory director or other responsible person?

(4) Is access to the laboratory controlled strictly and documented?

(5) Do the monitors indicate that the room is under negative pressure relative to all entrances?

(6) Are all vacuum lines protected with HEPA filters and liquid disinfectant traps?

(7) Is the autoclave being properly maintained and certified?

(8) Is the foot, elbow, or automatic handwash sink operating properly?

(9) Do the self-closing doors to the facility operate properly?

(10) Do personnel completely exchange street clothing for laboratory clothing before entry, and shower upon exiting?

(11) Is the dunk tank disinfectant fresh and appropriate for the agents in use?

(b) Suit Areas.

(1) Are all operations with etiologic agents conducted in Class I or II biological safety cabinets?

(2) Do the procedures in place ensure that, as much as possible, the contamination remains inside the cabinets [such as ensuring that everything removed from within the cabinets, such as gloves being worn, instruments, glassware, etc., are decontaminated or properly packaged first]?

(3) Were the Class I or II cabinets in the facility certified within 6 months?

(4) Does the suit decontamination shower have adequate appropriate decontaminant available?

(5) Has the suit decontamination shower been used or tested in the last month?

(6) Is the ventilated suit air supply and emergency air supply adequate and working properly?

(7) Is the emergency alarm system working properly?

(8) Are all of the one-piece positive pressure suits available for use in serviceable condition?

(9) Are infected animals housed in appropriate primary containment systems?

(10) Is the static pressure in the suit area negative to all surrounding areas?

(c) Non-Suit Areas.

(1) Are all operations with etiologic agents conducted inside of Class III biological safety cabinets?

(2) Were the Class III biological safety cabinets certified before initiating the current operation?

(3) Are all infected animals housed in Class III cabinet containment caging systems?

Appendix D to Part 627—Packaging and Labeling Requirements for Shipment of Etiologic Agents

D-1. Packaging and Labeling of Etiologic Agents, from HHS publication No. (NIH) 88-8395.

D-2. Guidelines for the Air Shipment of Diagnostic Specimens, from the Air Transport Association of America, Cargo Services Division, 1709 New York Ave. NW., Washington, DC 20006.

Appendix E to Part 627—Permits for Importation and Shipment of Etiologic Agents

E-1. Permit Application to Import or Transport Agents or Vectors of Human Disease. Department of Health, Education, and Welfare, PHS, CDC, Office of Biosafety, Atlanta, Georgia 30333.

E-2. Permit Application to Import Controlled Material; Import or Transport Organisms or Vectors. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Federal Building, Hyattsville, Maryland 20782.

Appendix F to Part 627—Glossary

Part I—Abbreviations

AIHA
American Industrial Hygiene Association
AMC
Army Materiel Command
AR
Army Regulation
ATCC
American Type Culture Collection
ASHRAE
American Society of Heating, Refrigerating and Air Condition Engineers, Inc.
BDP
Biological Defense Program
BL
Biosafety Level
CDC
Centers for Disease Control
CFR
Code of Federal Regulations
DA PAM
Department of Army Pamphlet
DOT
Department of Transportation
DNA
Deoxyribonucleic Acid
EPA
Environmental Protection Agency
EtO
Ethylene Oxide
FDA
Food and Drug Administration
HEPA
High Efficiency Particulate Air
HHS
Health and Human Services
IATA
International Air Transport Association
IBC
Institutional Biosafety Committee
ICAO
International Civil Aviation Organization

lfpm
Linear Feet Per Minute
m
Meter
min
Minute
MSDS
Material Safety Data Sheets
MSHA
Mine Safety and Health Administration
NCCLS
National Committee for Clinical Laboratory Standards
NCI
National Cancer Institute
NEPA
National Environmental Policy Act
NIH
National Institutes of Health
NIOSH
National Institute for Occupational Safety and Health
NRC
Nuclear Regulatory Commission
NSF
National Sanitation Foundation
OSHA
Occupational Safety and Health Administration
pH
The negative logarithm of Hydrogen Ion Concentration
PHS
Public Health Service
PPE
Personnel Protective Equipment
RCRA-Listed
Resource Conservation Recovery Act of 1976
Listed Hazardous Waste
RDT&E
Research, Development, Test, and Evaluation
RPO
Radiation Protection Officer
SALS
Subcommittee on Arbovirus Laboratory Safety
SAR
Supplied-Air Respirator
SCBA
Self Contained Breathing Apparatus
SOP
Standard Operating Procedure
TLV
Threshold Limit Value
USDA
United States Department of Agriculture
UV
Ultraviolet

Section II—Terms

Approved respiratory protection

Tested and listed as satisfactory according to standards established by a competent authority (such as NIOSH, MSHA, or host country agency) to provide respiratory protection against the particular hazard for which it is designed. For military agent protection, DA and DOD are the approval authorities. (Approval authority may be specified by law.)

Biocontainment area

An area which meets the requirements for a Biosafety Level 3 or 4 facility. The area may be an entire building or a single room within a building. See Subpart G for details.

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. The various classes of cabinets are described in detail in Subpart H.

Biosafety Level 1

The facilities, equipment and procedure 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, and 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.

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, other physical containment devices, or by personnel wearing appropriate personnel protective clothing and 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 Institute Director; (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 Level.

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.

Etiologic Agents

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 agent of biological origin that poses a degree of hazard similar to those agents.

Facility

An area within a building that provides the barriers appropriate to protect persons working in the facility and the environment external to the facility, and outside of the building.

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%. While the filters remove particulate matter with great efficiency, vapors and gases (e.g. from volatile

chemicals) are passed through without restriction. HEPA filters are used as the primary means of removing infectious agents from air exhausted from engineering controls and facilities.

Human Lethal Dose

The estimated quantity of a toxin that is a minimum lethal dose for a 70 kilogram individual based upon published data or upon estimates extrapolated from animal toxicity data.

Commander or Institute Director

The commander or Institute Director of an Army activity conducting RDT&E with BDP etiologic agents, or the equivalent at a research organization under contract to the BDP.

Institution

An organization such as an Army RDT&E activity (Institute, Agency, Center, etc.) or a contract organization such as a School of Medicine, or Research Institute that conducts RDT&E with BDP etiologic agents.

Laboratory

An individual room or rooms within a facility that provide space in which work with etiologic agents can be performed. It contains all of the appropriate engineering features and equipment required at a given Biosafety Level to protect personnel working in the lab and the environment external to the facility.

Large Scale Operations

Research or production involving viable etiologic agents in quantities greater than 10 liters of culture.

Maximum Containment Area

An area which meets the requirements for a Biosafety Level 4 facility. The area may be an entire building or a single room within the building. See chapter 7 for details.

Molded Masks

Formed masks that fit snugly around the mouth and nose and are designed to protect against non-toxic nuisance level dusts and

powders. These do not require approval by NIOSH/MSHA. Masks made of gauze do not qualify.

Potential Accidental Exposure

Any accident in which there was reason to believe that anyone working with a BDRP agent may have been exposed to that agent, 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, respiratory tract, broken skin or circulatory system as a direct result of the accident, injury or incident.

Resource Conservation Recovery Act of 1976 Listed Hazardous Waste

The waste materials listed by EPA 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.

Suite

An area consisting of more than one room, and designed to be a functional unit in which entire operations can be facilitated. Suites may contain a combination of laboratories and/or animal holding rooms 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 etiologic origin that has been isolated from the parent organism ⁴.

Kenneth L. Denton,

Alternate Army Federal Register Liaison Officer.

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BILLING CODE 3710-08-M

⁴ The publication "Bacterial Toxins: a Table of Lethal Amounts." (Gill, D.M. (1982) Microbiological Reviews, 46:86-94) contains a useful table of mammalian toxicities of numerous toxins.

Registered Federal

**Wednesday
March 6, 1991**

Part IV

Federal Emergency Management Agency

44 CFR Part 353

**Fee for Services in Support, Review and
Approval of State and Local Government
or Licensee Radiological Emergency
Plans and Preparedness; Final rule**

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 353

RIN 3067-AB49

Fee for Services in Support, Review and Approval of State and Local Government or Licensee Radiological Emergency Plans and Preparedness

AGENCY: Federal Emergency
Management Agency.

ACTION: Final rule

SUMMARY: This rule adopts in final form part 353 of title 44 CFR, Emergency Management and Assistance, chapter 1, Federal Emergency Management Agency (FEMA), subchapter E, Preparedness. This Part establishes a fee charged to nuclear power plant licensees for services that FEMA contributes to site-specific radiological emergency preparedness activities for commercial nuclear power plants. FEMA's services contribute to the fulfillment of emergency preparedness requirements needed for the Nuclear Regulatory Commission's (NRC) licensing purposes under the Atomic Energy Act of 1954, as amended. This rule implements Title V of the Independent Offices Appropriations Act (IOAA) of 1952, 31 U.S.C. 9701, which authorizes the Federal Emergency Management Agency to recover to the fullest extent possible costs attributable to services to identifiable recipients.

EFFECTIVE DATE: This rule is effective April 8, 1991.

FOR FURTHER INFORMATION CONTACT: Vernon Wingert, Chief, Program Development Branch, Technological Hazards Division, FEMA, Washington, DC 20472; 202-646-2872.

SUPPLEMENTARY INFORMATION:

Background

On June 29, 1989, FEMA published in the Federal Register (54 FR 27390-27396) a proposed rule to establish a fee system for the services provided by the agency to recipient licensees for services to support site-specific offsite radiological emergency preparedness for commercial nuclear power plants. The fees are based on site-specific costs incurred under FEMA's Radiological Emergency Preparedness (REP) Program in support of the Nuclear Regulatory Commission's (NRC) licensing process under the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011, *et seq.* These services are provided in support of a Memorandum of Understanding between NRC and FEMA (50 FR 15485, April 18, 1985) and regulations issued by both FEMA (44

CFR parts 350, 351 and 352) and NRC (10 CFR part 50). Emergency response plans and exercises are evaluated under joint FEMA-NRC criteria, NUREG-0654/FEMA-REP-1, Revision 1 and Supplement 1. When State and local governments do not participate in the development of an emergency plan, the licensee can submit a utility plan to the NRC (see 10 CFR part 50). FEMA, if requested by the NRC through the MOU, can make an assessment, finding and determination on such utility developed plans and exercises, that will be evaluated under the joint FEMA-NRC criteria.

After careful consideration, FEMA has prepared a final rule somewhat more narrow in scope than the proposed rule. The fees in this rulemaking are applicable only to services directly related to the obtaining and maintaining of an operating license. The primary differences between the proposed and final rule are the narrowing of activities eligible for reimbursement to the United States Treasury, including deletion of user fee charges for activities performed by FEMA in connection with continued review of State plans under 44 CFR part 350 once an operating license has been granted or the application has been denied or withdrawn. Licensees continue to be identified as recipients and payors of fees assessed for FEMA services due to the benefit of regulatory compliance with NRC requirements. The fee is based on Title V of the Independent Offices Appropriation Act (IOAA) of 1952, 31 U.S.C. 9701, which authorizes Federal agencies to recover to the fullest extent possible costs attributable to services to identifiable recipients.

Fee Development

A. Radiological Emergency Plans and Preparedness

Under the Radiological Emergency Preparedness (REP) Program, FEMA is responsible for processing applications for the review and approval of offsite radiological emergency plans and preparedness requested directly by a State under 44 CFR part 350 or by the NRC under the MOU (50 FR 15485, April 18, 1985) on behalf of the licensee. The REP Program also has responsibility for processing a licensee's certification when a request is made under Executive Order (E.O.) 12657 for Federal assistance and for providing such assistance, if warranted under 44 CFR part 352.

In identifying the site-specific services FEMA renders to licensees, it was determined that only those elements of the agency that provide such services

benefitting licensees would be considered in the calculation of fees. These units are the Office of Natural and Technological Hazards/State and Local Programs and Support Directorate, the FEMA Regional Offices/Natural and Technological Hazards Divisions and the Office of General Counsel.

An estimate of the program's professional staff time is necessary to calculate the fee for site-specific offsite radiological emergency plans and preparedness services provided by FEMA. The costs of personnel who provide these services are included in the calculation of an average cost per work-year rate to maintain a professional employee who provides site-specific services that are billable for radiological emergency planning and preparedness activities. This rate has been developed by using: (1) The program's cost of personnel compensation (salaries) for professional REP and legal staff, (2) personnel benefits for the professional REP and legal staff, (3) administrative support (e.g., clerical salaries and benefits and printing), (4) travel and (5) overhead support (e.g., rent and utilities). This rate will be applied for site-specific services provided for licensees on a professional staff hourly rate basis of \$39.00 per hour for FY 91, by FEMA staff. This rate will be revised on a fiscal year basis using the most current fiscal data available and the revised hourly rate will be published as a notice in the Federal Register for each fiscal year if the rate increases or decreases.

The professional staff hourly rate will be charged when any FEMA professional staff member works on a site-specific project that contributes to a licensee's compliance with the NRC's regulatory requirements. No charge will be made for work not related to a site-specific project.

Additional costs incurred by FEMA in the use of contractual services will be charged to the licensee by FEMA, at the rate and cost incurred.

Discussion of Comments on Proposed Rule

FEMA requested that comments on the proposed rule be submitted by August 28, 1989, followed by an extension to September 11, 1989. Thirty-one (31) written communications were received and placed in the Docket. These comments were received from eight (8) States, seventeen (17) utilities, two (2) utility associations, one (1) regulatory utility commissioners association, the Tennessee Valley Authority (TVA), one (1) city bar association and two (2) attorneys

representing twenty-five (25) utilities and two (2) citizens.

A number of the comments were general in nature addressing FEMA's basic authority for promulgation of the regulation and the role of FEMA in the planning process. A general comment was directed to the question of the identification of the licensee as the ultimate beneficiary of FEMA's services and thus, responsible for the payment of fees. There were also a number of comments directed to specific sections of the regulation. These specific comments will be related to the applicable section discussed and the agency's response noted with supporting comments.

A. General Comments

The Role and Authority of FEMA in the Regulatory Process

Several commenters expressed the concern that FEMA's role is not that of a regulatory agency and, therefore, is not authorized to recover costs under Title V of the IOAA. However, FEMA's role as the lead agency for review and assessment of the adequacy of offsite emergency plans developed by State and local governments or licensees and their capability to implement such plans is an inherent and necessary part of the regulatory process (FEMA/NRC MOU). Pursuant to 10 CFR 50.47(a) (1) and (2), the NRC will not issue an operating license for a nuclear power plant unless a finding by FEMA is made that there exists reasonable assurance that adequate protective measures can be taken in the event of a radiological emergency. Therefore, FEMA's services convey the benefit of regulatory compliance for the licensee. Further, the IOAA does not explicitly state that only regulatory agencies may assess user fees pursuant to its authorities. It is used by many agencies, including FEMA, to charge for a number of services provided.

The authority for FEMA to assess user fees based on the IOAA was further questioned based on the assertion that FEMA's offsite preparedness activities provide benefits to the general public, as well as State and local governments, rather than to licensees. It is FEMA's intent to assess user fees only for site-specific activities which provide a direct benefit to the licensee. While there will be an offsite benefit to State and local governments in the increased level of preparedness, the ultimate benefit remains with the utility in complying with NRC licensing requirements. Indeed, the REP program and its attendant requirements and regulations would not exist were it not for the

existence of commercial nuclear power plants and special safeguards necessary for protection of public health and safety. The aspect of separation of services where there is some public benefit is addressed in *Mississippi Power and Light v. United States Nuclear Regulatory Commission*, 601 F.2d 223 (5th Cir. 1979). The Court held that the NRC "is not required to segregate public and private benefits and that it may recover the full cost of providing a service to a private beneficiary, regardless of whether that service may also benefit the public."

Several commenters contended that FEMA cannot assess user fees where the licensees do not make requests directly to FEMA for its services based on the interpretations of the IOAA stating that user fee assessments must be incident to a voluntary act, i.e., at the request of the recipient. However, when utilities seek to obtain or maintain a license with the NRC, such requests are implicitly made of FEMA due to the necessity of FEMA assessments, findings and determinations in the NRC licensing process.

Some commenters asserted that in providing services incident to the FEMA/NRC MOU that FEMA's activities primarily benefit the NRC rather than the licensee. While FEMA is an integral part of the NRC's licensing process, that relationship does not change the fact that the ultimate beneficiaries of FEMA's activities are the utilities seeking to obtain and maintain an operating license. Further, concerns that user fees collected by FEMA in conjunction with NRC licensing activities will exceed the 45% limitation imposed by 42 U.S.C. 2213(b)(1)(a) are not applicable as the cited statute only limits user fee collections by the NRC.

There appears to be a general concern that FEMA's position as a fair and unbiased participant in the planning process may be jeopardized by the collection of fees and that FEMA would be compelled to concur in offsite planning activities to keep nuclear generating facilities in operation and, in turn, assess more user fees in the future. The precedent for collection of fees from licensees for services provided in support of commercial nuclear power plant licensing and other regulatory services is established in NRC regulation, 10 CFR part 170. Both in the circumstances set forth under 10 CFR part 170 and in this rule, fees collected are, in fact, remanded to the U.S. Treasury and are not available to the agency. FEMA will continue to receive appropriated funds for radiological

emergency preparedness activities. Concerns were expressed that the agency will attempt to generate revenues by charging excessively for services. As FEMA will not benefit directly from the collection of fees, no incentive is present to bill for other than reasonable services provided.

Relationship to Executive Order 12657

On November 18, 1988, the President issued Executive Order 12657 (3 CFR 1988 comp. p. 611) "Federal Emergency Management Agency Assistance in Emergency Preparedness Planning at Commercial Nuclear Power Plants." This Order was issued to ensure that adequate offsite radiological emergency planning and preparedness exist at commercial nuclear power plants for "decline and fail" situations, in order to satisfy the emergency planning requirements of the NRC for the issuance or retention of operating licenses.

Several comments were made with respect to the relation of this proposal to E.O. 12657. E.O. 12657 applies only to situations where a State or local government declines or fails to prepare adequate offsite radiological emergency plans or fails to participate adequately in demonstrating, testing, exercising or the using of such plans. The suggestion was made that this rulemaking should have been applied solely to the limited purpose of E.O. 12657.

While the procedures and costs established under this rule will also apply in the circumstances presented under Executive Order 12657, the establishment of fees for services within this rule has a much broader purpose. It is intended to apply to those situations where FEMA provides services that are of benefit to commercial nuclear power plant licensees in order to fulfill the broader Presidential initiative of recovering the cost of services provided by a Federal agency, as authorized under the IOAA.

Response to Section-Specific Comments

Section 353.4

Comment: A number of commenters expressed a concern that adequate accounting measures be developed to assure that procedures for the determination of costs incurred by FEMA and attributable to specific licensees provide a sufficient degree of accountability to ensure the reasonableness of fees to be assessed. Specifically, the provision of a fee ceiling or annual cap was suggested.

Discussion: FEMA's position in not establishing a ceiling on fees is

consistent with the NRC revision of fee schedules (10 CFR part 170) where the NRC fee ceiling was removed based on the concept that fees should be consistent with expenditures. Time-keeping procedures developed by the agency will track all site-specific FEMA services.

Response: No change.

Comment: FEMA site-specific cost estimates were requested to allow licensees to adequately project budget needs.

Discussion: It is estimated that the total cost recovery to the U.S. Treasury will be approximately \$4 million to \$6 million during the next year. The estimated fee that each licensee can expect to be charged will be based on the work performed at a specific site and will vary due to the complexity of the work accomplished.

Response: No change.

Comment: Several commenters were concerned that the proposed rule did not specify provisions for resolving disputed assessments where a licensee might question FEMA expenses.

Discussion: Disputed bills for services will be processed in accordance with FEMA Regulation, 44 CFR part 11, subpart C and procedures regarding debt collection in FEMA Manual 2610.1 (November, 1988). See § 353.7.

Response: No change.

Section 353.5

Comment: Several commenters suggested that the computation of hourly professional charges by combining the FEMA staff cost and contractual staff cost results in a duplicative charge.

Discussion: It is agreed that a more equitable system results from the computation of the hourly rate based on costs directly attributable to FEMA personnel. Contractual support will be charged separately at the rate and cost incurred.

Response: The fee schedule has been revised to implement a more equitable system of site-specific charges for FEMA and FEMA contract support services. See § 353.6.

Section 353.6

Comment: One State questioned whether the fee assessment would apply to exercises conducted for continued FEMA approval as defined in 44 CFR 350.9(c) (1) through (4).

Discussion: It is the intent of the agency for fees to apply to services required on a site-specific basis to assure that appropriate protective measures can be implemented in the event of a radiological emergency. This would include, but not be limited to the preparation, conduct and evaluation of

all exercises and drills (including medical drills and remedial exercises) and review of plan revisions required by exercise-identified inadequacies.

Response: This has been clarified in the rule. See § 353.6(a).

Comment: Several commenters representing utilities expressed the concern that licensees are not the identifiable beneficiaries for certain categories of services contained in the rule because these services are not directly required for a utility's NRC license. Specifically, the recovery of fees for "formal review and approval" of State and local offsite plans developed pursuant to 44 CFR part 350 was questioned based on the position that formal part 350 approval is not required for issuance and maintenance of a nuclear power plant license.

Discussion: FEMA has accepted the view that, once an operating license has been granted or the application denied or withdrawn, continued review of State plans under 44 CFR part 350 will generally not have a direct impact on the license except insofar as it is necessary to support biennial exercises under 10 CFR part 50, appendix F. Because FEMA recognizes that there is some difficulty in distinguishing plan review activities which support such exercises from those that do not, FEMA has decided not to charge user fees for continued review of State plans under 44 CFR part 350 once an operating license has been granted or the application denied or withdrawn, except as noted in the next paragraph.

However, FEMA believes that activities that are directly related to biennial exercises of State and local plans are of benefit to the licensee because of the direct relationship between results of exercise activities and the maintenance of the license. Therefore, FEMA has decided to charge user fees for activities that are directly related to biennial exercises of State and local plans, or any other drill or exercise upon which maintenance of a license may be predicated, including but not limited to the following:

Development of exercise objectives and scenarios, preexercise logistics, exercise conduct and participation, evaluation, and post-exercise meetings and reports; review and approval of plan revisions that are exercise inadequacy-related; remedial exercise and medical drill preparation, review, conduct, participation, evaluation, meetings and reports and technical assistance that are exercise inadequacy-related.

Response: The rule has been revised to delete charges for formal reviews under 44 CFR part 350 once an operating license has been granted or the

application denied or withdrawn, except as is necessary to support exercise related activities. See § 353.6.

Comment: Several commenters questioned whether it is appropriate for FEMA to charge the licensee for participation in site-specific adjudicatory proceedings, particularly where contested hearings are involved.

Discussion: FEMA recognizes that the NRC has adopted a policy of not charging user fees for contested hearings. However, FEMA views that policy as being within the NRC's discretion and not mandated by law. FEMA's participation in contested hearings related to site-specific concerns has a direct impact on receipt or retention of an operating license. FEMA, therefore, adopts a policy of imposing user fees for such participation.

Response: No change.

Comment: One commenter questioned the equity of charging a licensee for the FEMA investigation of third party allegations, particularly where the allegations are unfounded.

Discussion: The circumstances under which FEMA would be called upon to investigate a third party allegation are quite limited. FEMA does not intend to charge a user fee for such activities.

Response: The rule has been revised to make this clear. See § 353.6.

Comment: Several commenters questioned whether technical assistance to State and local governments should be an eligible cost if it is not a requirement for NRC licensing.

Discussion: There are some circumstances where technical assistance directly impacts the issuance and maintenance of a license and others where it does not. FEMA intends to impose user fees for technical assistance only where: (a) It is requested by a utility, or (b) it is requested by a State or local government in order to correct an inadequacy identified as a result of a biennial exercise or any other drill or exercise upon which maintenance of a license may be predicated.

Response: The rule has been changed to specify those circumstances under which technical assistance would be billed to the licensee. See § 353.6.

Comment: Two commenters noted that while the proposed rule specifically states that FEMA will not charge for services by another Federal agency to benefit a licensee, § 353.6(a) indicates that plan review by the Regional Assistance Committee is an eligible cost item.

Discussion: Fees for services in this rulemaking will apply only to FEMA personnel and FEMA contractors.

Response: Section 353.6(a) has been revised to remove language reflecting charges for other Federal agencies.

Comment: Charging fees for FEMA's response to an actual radiological emergency was questioned, because such a response was viewed as performing a fundamental government service not specific to the licensee, and, therefore, not properly the subject of the assessment of fees under the IOAA.

Discussion: FEMA, in response to the comments received, has determined not to include in its regulation user fees for FEMA's response to an actual radiological emergency. However, should such an event take place, FEMA will evaluate it on a case-by-case basis and reserves the option to consider and utilize whatever legal remedies may be available to secure compensation for its costs incurred in responding to a radiological emergency.

Response: Charges for this service have been deleted from § 353.6.

Regulatory Flexibility Certification

This rule will not have a significant economic impact on a substantial number of small entities and, hence, has not undergone regulatory flexibility analysis.

Environmental Assessment and Finding of No Significant Environmental Impact

The Director has determined under the National Environmental Policy Act of 1969 and FEMA Regulation, 44 CFR part 10, "Environmental Considerations," that this rule is not a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required. In support of this finding, an environmental assessment has been prepared which is available for inspection and copying for a fee in the Rules Docket. The changes made in the final rule do not require any modification to the prior "Environmental Assessment and Finding of No Significant Environmental Impact."

Regulatory Analysis

This rule is not a "major rule" as the term is used in Executive Order 12291 and implementing OMB guidance. It will not have an annual effect on the economy of \$100 million or more, will not result in a major increase in costs or prices to consumers, individual industries, Federal, State or local agencies or geographic regions, and will not have a significant adverse impact on competition, employment, investment, productivity, innovation or the ability of United States based enterprises to compete with foreign based enterprises

in domestic or export markets. Therefore, no Regulatory Analysis is required.

Paper Work Reduction Act

This rule does not contain collection of information requirements and is not subject, therefore, to the Paper Work Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*).

Federalism Executive Order

A Federalism assessment under E.O. 12612 has been prepared and a copy is available for inspection and copying for a fee at the Rules Docket.

List of Subjects in 44 CFR Part 353

Nuclear power plants and reactors, Radiation protection, Intergovernmental relations and Federal assistance.

Accordingly, subchapter E chapter 1, title 44 Code of Federal Regulations is amended by adding part 353.

PART 353—FEE FOR SERVICES IN SUPPORT, REVIEW AND APPROVAL OF STATE AND LOCAL GOVERNMENT OR LICENSEE RADIOLOGICAL EMERGENCY PLANS AND PREPAREDNESS

Sec.

- 353.1 Purpose.
- 353.2 Scope.
- 353.3 Definitions.
- 353.4 Payment of fees.
- 353.5 Average cost per FEMA professional staff-hour.
- 353.6 Schedule of services.
- 353.7 Failure to pay.

Appendix A to Part 353—Memorandum of Understanding Between Federal Emergency Management Agency and Nuclear Regulatory Commission

Authority: 31 U.S.C. 9701; E.O. 12657 and E.O. 12148.

§ 353.1 Purpose.

This part sets out fees charged for site-specific radiological emergency planning and preparedness services rendered by the Federal Emergency Management Agency, as authorized by 31 U.S.C. 9701.

§ 353.2 Scope.

The regulation in this part applies to all licensees who have applied for or have received a license from the Nuclear Regulatory Commission to operate a commercial nuclear power plant.

§ 353.3 Definitions.

As used in this part, the following terms and concepts are defined:

(a) *FEMA* means the Federal Emergency Management Agency.

(b) *NRC* means the Nuclear Regulatory Commission.

(c) *Certification* means the written justification by a licensee of the need for Federal compensatory assistance, as authorized in 44 CFR part 352 and E.O. 12657.

(d) *Technical assistance* means services provided by FEMA to facilitate offsite radiological emergency planning and preparedness such as provision of support for the preparation of offsite radiological emergency response plans and procedures; provision of advice and recommendations for specific aspects of preparedness such as alert and notification and emergency public information.

(e) *Licensee* means the utility which has applied for or has received a license from the NRC to operate a commercial nuclear power plant.

(f) *Governor* means the Governor of a State or his/her designee.

(g) *RAC* means Regional Assistance Committee chaired by FEMA with representatives from the Nuclear Regulatory Commission, Environmental Protection Agency, Department of Health and Human Services, Department of Energy, Department of Agriculture, Department of Transportation, Department of Commerce and other Federal Departments and agencies as appropriate.

(h) *REP* means FEMA's Radiological Emergency Preparedness Program.

(i) *Fiscal Year* means Federal fiscal year commencing on the first day of October through the thirtieth day of September.

(j) *Federal Radiological Preparedness Coordinating Committee* is the national level committee chaired by FEMA with representatives from the Nuclear Regulatory Commission, Environmental Protection Agency, Department of Health and Human Services, Department of Interior, Department of Energy, Department of Transportation, United States Department of Agriculture, Department of Commerce and other Federal Departments and agencies as appropriate.

§ 353.4 Payment of fees.

Fees for site-specific offsite radiological emergency plans and preparedness services and related site-specific legal services are payable upon notification by FEMA. FEMA services will be billed at 6-month intervals for all accumulated costs on a site-specific basis. Each bill will identify the costs related to services for each nuclear power plant site.

§ 353.5 Average cost per FEMA professional staff-hour.

Fees for FEMA services rendered will be calculated based upon the costs for such services using a professional staff rate per hour equivalent to the sum of the average cost to the agency of maintaining a professional staff member performing site-specific services related to the Radiological Emergency Preparedness Program, including salary, benefits, administrative support, travel and overhead. This rate will be charged when FEMA performs such services as: Development of exercise objectives and scenarios, pre-exercise logistics, exercise conduct and participation, evaluation, meetings and reports; review and approval of Plan revisions that are utility-requested or exercise inadequacy related; remedial exercise, medical drill or any other exercise or drill upon which a license is predicated, with regard to preparation, review, conduct, participation, evaluation, meetings and reports; the issuance of interim findings pursuant to the FEMA/NRC Memorandum of Understanding (MOU) (App. A of this part); review of utility plan submissions through the NRC under the MOU; utility certification submission review under 44 CFR part 352 and follow-on activities; site-specific adjudicatory proceedings and any other site-specific legal costs and technical assistance that is utility requested or exercise inadequacy related. The professional staff rate for FY 91 is \$39.00 per hour. The referenced FEMA/NRC MOU is provided in this rule as appendix A. The professional staff rate for the REP Program and related legal services will be revised on a fiscal year basis using the most current fiscal data available and the revised hourly rate will be published as a notice in the *Federal Register* for each fiscal year if the rate increases or decreases.

§ 353.6 Schedule of services.

Recipients shall be charged the full cost of site-specific services based upon the appropriate professional hourly staff rate for the FEMA services described in this Section and for related contractual services which will be charged to the licensee by FEMA, at the rate and cost incurred.

(a) When a State seeks formal review and approval by FEMA of the State's radiological emergency response plan pursuant to 44 CFR part 350 (Review and Approval Process of State and Local Radiological Emergency Plans and Preparedness), FEMA shall provide the services as described in 44 CFR part 350 in regard to that request and fees will be charged for such services to the licensee, which is the ultimate

beneficiary of FEMA services. This provision does not apply where an operating license has been granted or the application denied or withdrawn, except as necessary to support biennial exercises and related activities. Fees will be charged for all FEMA, but not other Federal agency activities related to such services, including but not limited to the following:

- (1) Development of exercise objectives and scenarios, preexercise logistics, exercise conduct and participation, evaluation, meetings and reports.
 - (2) Review of plan revisions that are exercise-inadequacy related;
 - (3) Technical assistance that is exercise-inadequacy related;
 - (4) Remedial exercise, medical drill, or any other exercise or drill upon which maintenance of a license is predicated, with regard to preparation, review, conduct, participation, evaluation, meetings and reports.
- (b) Interim findings. Where the NRC seeks from FEMA under the FEMA/NRC MOU an interim finding of the status of radiological emergency planning and preparedness at a particular time for a nuclear power plant, FEMA shall assess a fee to the licensee for providing this service. The provision of this service consists of making a determination whether the plans are adequate to protect the health and safety of the public living in the vicinity of the nuclear power facility by providing reasonable assurance that appropriate protective measures can be taken offsite in the event of a radiological emergency and that such plans are capable of being implemented.

(c) NRC utility plan submissions. Fees will be charged for all FEMA but not other Federal agency activities related to such services, including but not limited to the following:

- (1) Development of exercise objectives and scenarios, preexercise logistics, exercise conduct and participation, evaluation and post-exercise meetings and reports.
- (2) Notice and conduct of public meeting.
- (3) Regional finding and determination of adequacy of plans and preparedness followed by review by FEMA Headquarters resulting in final FEMA determination of adequacy of plans and preparedness.
- (4) Remedial exercise, medical drill, or any other exercise or drill upon which maintenance of a license is predicated, with regard to preparation, review, conduct, participation, evaluation, meetings and reports.

(d) Utility certification submission review. When a licensee seeks Federal assistance within the framework of 44 CFR part 352 due to the decline or failure of a State or local government to adequately prepare an emergency plan, FEMA shall process the licensee's certification and make the determination whether a decline or fail situation exists. Fees will be charged for services rendered in making the determination. Upon the determination that a decline or fail situation does exist, any services provided or secured by FEMA consisting of assistance to the licensee, as described in 44 CFR part 352, will have a fee charged for such services.

(e) FEMA participation in site-specific NRC adjudicatory proceedings and any other site-specific legal costs. Where FEMA participates in NRC licensing proceedings and any related court actions to support FEMA findings as a result of its review and approval of offsite emergency plans and preparedness, or provides legal support for any other site specific FEMA activities comprised in this rule, fees will be charged to the licensee for such participation.

(f) Rendering technical assistance. Where FEMA is requested by a licensee to provide any technical assistance, or where a State or local government requests technical assistance in order to correct an inadequacy identified as a result of a biennial exercise or any other drill or exercise upon which maintenance of a license is predicated, FEMA will charge such assistance to the licensee for the provision of such service.

§ 353.7 Failure to pay.

In any case where there is a dispute over the FEMA bill or where FEMA finds that a licensee has failed to pay a prescribed fee required under this part, procedures will be implemented in accordance with 44 CFR part 11 subpart C to effectuate collections under the Debt Collection Act of 1982 (31 U.S.C. 3711 *et seq.*).

Appendix A to Part 353—Memorandum of Understanding Between Federal Emergency Management Agency and Nuclear Regulatory Commission

The Federal Emergency Management Agency (FEMA) and the Nuclear Regulatory Commission (NRC) have entered into a new Memorandum of Understanding (MOU) Relating to Radiological Emergency Planning and Preparedness. This supersedes a memorandum entered into on November 1, 1980 (published December 16, 1980, 45

FR 82713). The substantive changes in the new MOU deal principally with the FEMA handling of NRC requests for findings and determinations concerning offsite planning and preparedness. The basis and conditions for interim findings in support of licensing are defined, as well as provisions for status reports when plans are not complete. The text of the MOU is set out below except that an attachment is not included. This attachment concerns membership on a steering committee.

Memorandum of Understanding Between NRC and FEMA Relating to Radiological Emergency Planning and Preparedness

I. Background and Purposes

This Memorandum of Understanding (MOU) establishes a framework of cooperation between the Federal Emergency Management Agency (FEMA) and the U.S. Nuclear Regulatory Commission (NRC) in radiological emergency response planning matters, so that their mutual efforts will be directed toward more effective plans and related preparedness measures at and in the vicinity of nuclear reactors and fuel cycle facilities which are subject to 10 CFR part 50, appendix E, and certain other fuel cycle and materials licensees which have potential for significant accidental offsite radiological releases. The memorandum is responsive to the President's decision of December 7, 1979, that FEMA will take the lead in offsite planning and response, his request that NRC assist FEMA in carrying out this role, and the NRC's continuing statutory responsibility for the radiological health and safety of the public.

On January 14, 1980, the two agencies entered into a "Memorandum of Understanding Between NRC and FEMA to Accomplish a Prompt Improvement in Radiological Emergency Preparedness," that was responsive to the President's December 7, 1979, statement. A revised and updated memorandum of understanding became effective November 1, 1980. This MOU is a further revision to reflect the evolving relationship between NRC and FEMA and the experience gained in carrying out the provisions of the January and November 1980 MOU's. This MOU supersedes these two earlier versions of the MOU.

The general principles, agreed to in the previous MOU's and reaffirmed in this MOU, are as follows: FEMA coordinates all Federal planning for the offsite impact of radiological emergency

response plans¹ and preparedness, makes findings and determinations as to the adequacy and capability of implementing offsite plans and communicates those findings and determinations to the NRC. The NRC reviews those FEMA findings and determinations in conjunction with the NRC onsite findings for the purpose of making determinations on the overall state of emergency preparedness. These overall findings and determinations are used by NRC to make radiological health and safety decisions in the issuance of licenses and the continued operation of licensed plants to include taking enforcement actions as notices of violations, civil penalties, orders, or shutdown of operating reactors. This delineation of responsibilities avoids duplicative efforts by the NRC staff in offsite preparedness matters.

A separate MOU dated October 22, 1980, deals with NRC/FEMA cooperation and responsibilities in response to an actual or potential radiological emergency. Operations Response Procedures have been developed that implement the provisions of the Incident Response MOU. These documents are intended to be consistent with the Federal Radiological Emergency Response Plan which describes the relationships, roles, and responsibilities of Federal agencies for responding to accidents involving peacetime nuclear emergencies.

II. Authorities and Responsibilities

FEMA—Executive Order 12148 charges the Director, FEMA, with the responsibility to " * * * establish Federal policies for, and coordinate, all civil defense and civil emergency planning, management, mitigation, and assistance functions of Executive agencies" (Section 2-101) and " * * * represent the President in working with State and local governments and the private sector to stimulate vigorous participation in civil emergency preparedness, mitigation, response, and recovery programs." (Section 2-104.)

On December 7, 1979, the President in response to the recommendations of the Kemeny Commission on the Accident at Three Mile Island, directed that FEMA assume lead responsibility for all offsite nuclear emergency planning and response.

Specifically, the FEMA responsibilities with respect to

radiological emergency preparedness as they relate to NRC are:

1. To take the lead in offsite emergency planning and to review and assess offsite emergency plans and preparedness for adequacy.
2. To make findings and determinations as to whether offsite emergency plans are adequate and can be implemented (e.g., adequacy and maintenance of procedures, training, resources staffing levels and qualifications, and equipment adequacy). Notwithstanding the procedures which are set forth in 44 CFR part 350 for requesting and reaching a FEMA administrative approval of State and local plans, findings and determinations on the current status of emergency planning and preparedness around particular sites, referred to as interim findings, will be provided by FEMA for use as needed in the NRC licensing process. Such findings will be provided by FEMA on mutually agreed to schedules or on specific NRC request. The request and findings will normally be by written communications between the co-chairs of the NRC/FEMA Steering Committee. An interim finding provided under this arrangement will be an extension of FEMA's procedures for review and approval of offsite radiological emergency plans and preparedness set forth in 44 CFR part 350. It will be based on the review of currently available plans and, if appropriate, joint exercise results related to a specific nuclear power plant site.

An interim finding based only on the review of currently available offsite plans will include an assessment as to whether these plans are adequate when measured against the standards and criteria of NUREG-0654/FEMA-REP-1, and, pending a demonstration through an exercise, whether there is reasonable assurance that the plans can be implemented. The finding will indicate one of the following conditions: (1) Plans are adequate and there is reasonable assurance that they can be implemented with only limited or no corrections needed; (2) plans are adequate, but before a determination can be made as to whether they can be implemented, corrections must be made to the plans or supporting measures must be demonstrated (e.g., adequacy and maintenance of procedures, training, resources, staffing levels and qualifications, and equipment adequacy); or (3) plans are adequate and cannot be implemented until they are revised to correct deficiencies noted in the Federal review.

¹ Assessments of offsite plans may be based on State and local government plans submitted to FEMA under its rule (44 CFR part 350), and as noted in 44 CFR 350.3(f) may also be based on plans currently available to FEMA or furnished to FEMA through the NRC/FEMA Steering Committee.

If in FEMA's view the plans that are available are not completed or are not ready for review, FEMA will provide NRC with a status report delineating milestones for preparation of the plan by the offsite authorities as well as FEMA's actions to assist in timely development and review of the plans.

An interim finding on preparedness will be based on review of currently available plans and joint exercise results and will include an assessment as to (1) whether offsite emergency plans are adequate as measured against the standards and criteria of NUREG-0654/FEMA-REP-1, Revision 1 and Supplement 1, and (2) whether the exercise(s) demonstrated that there is reasonable assurance that the plans can be implemented.

An interim finding on preparedness will indicate one of the following conditions: (1) There is reasonable assurance that the plans are adequate and can be implemented as demonstrated in an exercise; (2) there are deficiencies that may adversely affect public health and safety that must be corrected in order to provide reasonable assurance that the plans can be implemented; or (3) FEMA is undecided and will provide a schedule of actions leading to a decision.

3. To assume responsibility, as a supplement to State and local, and utility efforts, for radiological emergency preparedness training of State and local officials.

4. To develop and issue an updated series of interagency assignments which delineate respective agency capabilities and responsibilities and define procedures for coordination and direction for emergency planning and response. [Current assignments are in 44 CFR part 351, March 11, 1982 (47 FR 10758).]

NRC—The Atomic Energy Act of 1954, as amended, requires that the NRC grant licenses only if the health and safety of the public is adequately protected. While the Atomic Energy Act does not specifically require emergency plans and related preparedness measures, the NRC requires consideration of overall emergency preparedness as a part of the licensing process. The NRC rules (10 CFR 50.33, 50.34, 50.47, 50.54, and appendix E to 10 CFR part 50) include requirements for the licensee's emergency plans.

Specifically, the NRC responsibilities for radiological emergency preparedness are:

1. To assess licensee emergency plans for adequacy. This review will include organizations with whom licensees have written agreements to provide onsite

support services under emergency conditions.

2. To verify that licensee emergency plans are adequately implemented (e.g., adequacy and maintenance of procedures, training, resources, staffing levels and qualifications, and equipment).

3. To review the FEMA findings and determinations as to whether offsite plans are adequate and can be implemented.

4. To make radiological health and safety decisions with regard to the overall state of emergency preparedness (i.e., integration of emergency preparedness onsite as determined by the NRC and offsite as determined by FEMA and reviewed by NRC) such as assurance for continued operation, for issuance of operating licenses, or for taking enforcement actions, such as notices of violations, civil penalties, orders, or shutdown of operating reactors.

III. Areas of Cooperation

A. NRC Licensing Reviews. FEMA will provide support to the NRC for licensing reviews related to reactors, fuel facilities, and materials licensees with regard to the assessment of the adequacy of offsite radiological emergency response plans and preparedness. This will include timely submittal of an evaluation suitable for inclusion in NRC safety evaluation reports.

Substantially prior to the time that a FEMA evaluation is required with regard to fuel facility or materials license review, NRC will identify those fuel and materials licensees with potential for significant accidental offsite radiological releases and transmit a request for review to FEMA as the emergency plans are completed.

FEMA routine support will include providing assessments, findings and determinations (interim and final) on offsite plans and preparedness related to reactor license reviews. To support its findings and determinations, FEMA will make expert witnesses available before the Commission, the NRC Advisory Committee on Reactor Safeguards, NRC hearings boards and administrative law judges, for any court actions, and during any related discovery proceedings.

FEMA will appear in NRC licensing proceedings as part of the presentation of the NRC staff. FEMA counsel will normally present FEMA witnesses and be permitted, at the discretion of the NRC licensing board, to cross-examine the witnesses of parties, other than the NRC witnesses, on matters involving FEMA findings and determinations, policies, or operations; however, FEMA

will not be asked to testify on status reports. FEMA is not a party to NRC proceedings and, therefore, is not subject to formal discovery requirements placed upon parties to NRC proceedings. Consistent with available resources, however, FEMA will respond informally to discovery requests by parties. Specific assignment of professional responsibilities between NRC and FEMA counsel will be primarily the responsibility of the attorneys assigned to a particular case. In situations where questions of professional responsibility cannot be resolved by the attorneys assigned, resolution of any differences will be made by the General Counsel of FEMA and the Executive Legal Director of the NRC or their designees. NRC will request the presiding Board to place FEMA on the service list for all litigation in which it is expected to participate.

Nothing in this document shall be construed in any way to diminish NRC's responsibility for protecting the radiological health and safety of the public.

B. FEMA Review of Offsite Plans and Preparedness. NRC will assist in the development and review of offsite plans and preparedness through its membership on the Regional Assistance Committees (RAC). FEMA will chair the Regional Assistance Committees. Consistent with NRC's statutory responsibility, NRC will recognize FEMA as the interface with State and local governments for interpreting offsite radiological emergency planning and preparedness criteria as they affect those governments and for reporting to those governments the results of any evaluation of their radiological emergency plans and preparedness.

Where questions arise concerning the interpretation of the criteria, such questions will continue to be referred to FEMA Headquarters, and when appropriate, to the NRC/FEMA Steering Committee to assure uniform interpretation.

C. Preparation for and Evaluation of Joint Exercises. FEMA and NRC will cooperate in determining exercise requirements for licensees, and State and local governments. They will also jointly observe and evaluate exercises. NRC and FEMA will institute procedures to enhance the review of objectives and scenarios for joint exercises. This review is to assure that both the onsite considerations of NRC and the offsite considerations of FEMA are adequately addressed and integrated in a manner that will provide for a technically sound exercise upon which an assessment of preparedness

capabilities can be based. The NRC/FEMA procedures will provide for the availability of exercise objectives and scenarios sufficiently in advance of scheduled exercises to allow enough time for adequate review by NRC and FEMA and correction of any deficiencies by the licensee. The failure of a licensee to develop a scenario that adequately addresses both onsite and offsite considerations may result in NRC taking enforcement actions.

The FEMA reports will be a part of an interim finding on emergency preparedness; or will be the result of an exercise conducted pursuant to FEMA's review and approval procedures under 44 CFR Part 350. Exercise evaluations will identify one of the following conditions: (1) There is reasonable assurance that the plans are adequate and can be implemented as demonstrated in the exercise; (2) there are deficiencies that may adversely impact public health and safety that must be corrected by the affected State and local governments in order to provide reasonable assurance that the plan can be implemented; or (3) FEMA is undecided and will provide a schedule of actions leading to a decision. Within 30 days of the exercise, a draft exercise report will be sent to the State, with a copy to the Regional Assistance Committee, requesting comments and a schedule of corrective actions, as appropriate, from the State in 30 days. When there are deficiencies of the types noted in 2 above, and when there is a potential for a remedial exercise, FEMA Headquarters will promptly discuss these with NRC Headquarters. Within 90 days of the exercise, the FEMA report will be forwarded to the NRC Headquarters. Within 15 days of receipt of the FEMA report, NRC will notify FEMA in writing of action taken with the licensee relative to FEMA initiatives with State and local governments to correct deficiencies identified in the exercise.

D. Emergency Planning and Preparedness Guidance. NRC has lead responsibility for the development of emergency planning and preparedness guidance for licensees. FEMA has lead responsibility for the development of radiological emergency planning and

preparedness guidance for State and local agencies. NRC and FEMA recognize the need for an integrated, coordinated approach to radiological emergency planning and preparedness by NRC licensees and State and local governments. NRC and FEMA will each, therefore, provide opportunity for the other agency to review and comment on such guidance (including interpretations of agreed joint guidance) prior to adoption as formal agency guidance.

E. Support for Document Management System. FEMA and NRC will each provide the other with continued access to those automatic data processing support systems which contain relevant emergency preparedness data.

At NRC this includes Document Management System support to the extent that it does not affect duplication or records retention. At FEMA, this includes technical support to the Radiological Emergency Preparedness Management Information System. This agreement is not intended to include the automated information retrieval support for the national level emergency response facilities.

F. Ongoing NRC Research and Development Programs. Ongoing NRC and FEMA research and development programs that are related to State and local radiological emergency planning and preparedness will be coordinated. NRC and FEMA will each provide opportunity for the other agency to review and comment on relevant research and development programs prior to implementing them.

G. Public Information, and Education Programs. FEMA will take the lead in developing public information and educational programs. NRC will assist FEMA by reviewing for accuracy educational materials concerning radiation, and its hazards and information regarding appropriate actions to be taken by the general public in the event of an accident involving radioactive materials.

IV. NRC/FEMA Steering Committee

The NRC/FEMA Steering Committee on Emergency Preparedness will continue to be the focal point for coordination of emergency planning, preparedness, and response activities

between the two agencies. The Steering Committee will consist of an equal number of members to represent each agency with one vote per agency. When the Steering Committee cannot agree on the resolution of an issue, the issue will be referred to NRC and FEMA management. The NRC members will have lead responsibility for licensee planning and preparedness and the FEMA members will have lead responsibility for offsite planning and preparedness. The Steering Committee will assure coordination of plans and preparedness evaluation activities and revise, as necessary, acceptance criteria for licensee, State and local radiological emergency planning and preparedness. NRC and FEMA will then consider and adopt criteria as appropriate in their respective jurisdictions.

V. Working Arrangements

A. The normal point of contact for implementation of the points in this MOU will be the NRC/FEMA Steering Committee.

B. The Steering Committee will establish the day-to-day procedures for assuring that the arrangements of this MOU are carried out.

VI. Memorandum of Understanding

A. This MOU shall be effective as of date of signature and shall continue in effect unless terminated by either party upon 30 days notice in writing.

B. Amendments or modifications to this MOU may be made upon written agreement by both parties.

Approved for the U.S. Nuclear Regulatory Commission.

Dated: April 3, 1985.

William J. Dircks,

Executive Director for Operations.

Approved for the Federal Emergency Management Agency.

Dated: April 3, 1985.

Samuel W. Speck,

Associate Director, State and Local Programs and Support.

Dated: January 25, 1991.

Wallace E. Stickney,

Director of FEMA.

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