Department of the Army
Pamphlet 385–69

Safety

Safety Standards for Microbiological and Biomedical Laboratories

Rapid Action Revision (RAR) Issue Date: 8 February 2013

Headquarters
Department of the Army
Washington, DC
6 May 2009

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SUMMARY of CHANGE

DA PAM 385–69
Safety Standards for Microbiological and Biomedical Laboratories

This rapid action revision, dated 8 February 2013--

- Corrects applicability statement for consistency with the purpose statement (title page).

- Identifies the usage of infectious agents and toxins in clinical tests (para 1-4).

- Updates requirements for safety committees to correspond with scope and complexity of mission (paras 3-1 and 3-2).

- Clarifies requirements for standing operating procedures (para 3-5).

- Directs that standing operating procedures need to be maintained in a centralized location for emergency responders (paras 3-5 a and 3-9 c).

- Clarifies biosafety officers qualification and training (para 3-8 a).

- Designates additional duty safety officer/collateral duty safety officer for each laboratory room or suite in research facilities or per clinical department for healthcare diagnostic laboratories (para 3-10 b).

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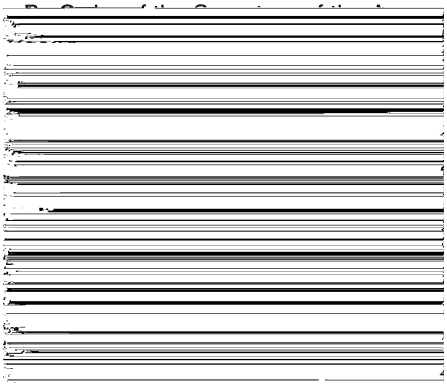

History. This publication is a rapid action revision (RAR). This RAR is effective 8

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Chapter 1
Introduction

1–1. Purpose
This pamphlet prescribes the technical safety requirements for the use, handling, transportation, transfer, storage, and disposal of infectious agents and toxins (IAT) rated at biosafety level 2 (BSL–2) and above used in microbiological activities in clinical laboratories, biomedical and biological research settings, microbiology teaching laboratories, and veterinary reference laboratories. This pamphlet requires the mandatory use of the latest edition of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health's (NIH) Biosafety in Microbiological and Biomedical Laboratories (BMBL). The requirements stated in the BMBL and this pamphlet apply to all U.S. Army activities and facilities in which IAT are used, produced, stored, handled, transported, transferred or disposed, to include the Army National Guard and the U.S. Army Reserve, and to contractors and consultants conducting microbiological and biomedical activities for the Army.

1–2. References
Required and related publications and prescribed and referenced forms are listed in appendix A.

1–3. Explanation of abbreviations and terms
Abbreviations and special terms used in this pamphlet are explained in the glossary.

1–4. Background
Microbiological and biomedical activities are conducted by the U.S. Army in developing measures to identify, detect, diagnose, treat, and protect against IAT. To meet these objectives, IAT are used when conducting the necessary research, development, test, and evaluation (RDT&E), sampling and analysis, and clinical tests. The U.S. Army needs clear standards to protect personnel and the environment from exposure to IAT. Since the BMBL has been recognized as the code of practice for biosafety, the U.S. Army has decided to make the BMBL mandatory for biological activities using IAT assessed at BSL–2 or above. This pamphlet contains requirements and resources in addition to the BMBL

tenant on an installation, that organization will coordinate their biological safety and occupational health program with the installation commander.

2–3. Mishap risk management

a. The mishap risk management process is the process of identifying and assessing hazards; determining their risk; developing, evaluating and selecting controls; making risk decisions; and implementing and managing those decisions to improve operational effectiveness and conserve Army resources. The mishap risk management process is also the process of providing recommendations on whether to accept or resolve potential consequences of hazards associated with a given activity.

b. The mishap risk management process consists of the following five steps:

(1) Identify hazards.

(2) Assess hazards to determine risk.

(3) Develop possible countermeasures and make risk decisions.

(4) Implement controls.

(5) Supervise and evaluate.

2–4. Biological risk assessment and determination of biosafety levels

Biological risk assessment (as opposed to risk assessment in general) is conducted to determine the BSL for handling a particular IAT. Procedures for defining BSL are contained in the BMBL. BSLs (the four ascending levels of containment, referred to as BSL–1 through BSL–4) describe the microbiological practices, safety equipment and facility safeguards for the corresponding level of risk associated with handling a particular IAT based on that IAT's infectivity, severity of disease, the availability of preventive measures and effective treatments for the disease, transmissibility, the nature of the work being conducted, and the origin of the agent (whether indigenous or exotic).

2–5. Safety controls

Safety controls will be identified through the risk management process as well as prescribed in statutory and regulatory requirements. Safety controls include the following – as further defined throughout this pamphlet – and will be documented in the agency/facility safety program, the laboratory specific biosafety manual, standing operating procedures (SOPs), and so forth.

a. Facility safety controls (for example, directional airflow, emergency backup power, continuity of seal between the floor and wall).

b. Safety equipment (for example, biological safety cabinets, glove boxes, laboratory chemical hoods).

c. Laboratory practices and safety requirements, including all applicable SOPs and special practices and requirements.

d. Personal protective equipment (PPE).

e. Access control and rosters.

f. Signage, labeling of containers, and safety communications.

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h. Access control (see para 3–7).
i. Engineering controls/safety equipment (selection, use, training, testing, and maintenance) (see chap 6).
j. Biosafety practices (see chap 7).
k. The PPE (selection, use, training, testing, and maintenance) (see chap 8).
l. Labeling and posting of hazards (see AR 385–10).
m. Chemical hygiene plan.
n. Personnel qualifications and training (see para 3–8).
o. Safety information (see para 3–9).
p. Inspections (see para 3–10).
q. Facility, utilities, and equipment continuing maintenance plan (see AR 385–10).
r. Pest management (see para 7–9).
s. Transportation and transfer of IAT (see chap 9).
t. Decontamination and disposal of IAT (see chap 10).
u. Emergency planning and response (see chap 11).
v. Mishap investigation and reporting (see para 3–11).
w. Select agent registration, if applicable.
x. Recombinant deoxyribonucleic acid (DNA), if applicable (see para 3–12).
y. Radiation safety, if applicable (see chaps 7, 10 and 11).
z. Animal safety, if applicable (see chaps 6 and 7).
aa. Contract activities, if applicable (see para 3–13).

3–2. Safety committee

a. Facilities, with the exception of clinical laboratories, conducting IAT activities will establish and charter a biological safety committee, or similar committee, consisting of representatives of the following: commander or institute director or designee, laboratory supervisors, biosafety officer, occupational health, industrial hygiene (IH), facility maintenance, safety, emergency response, and an employee representative. At a minimum, the safety committee will—

(1) Review proposed work activities and facility modifications.
(2) Assist in performing biological risk assessments.
(3) Discuss mishaps and near misses.
(4) Evaluate compliance and adequacy of established safety policy, training, engineering, and administrative controls, PPE, and safe work practices.
(5) Meet at least quarterly. Meeting minutes will be—
(a) Prepared and staffed through the institute commander/director.
(b) Available for review.
(c) Maintained for at least 3 years.

b. Clinical laboratories, BSL–3 and above, conducting IAT research or diagnosis will establish and charter a biological safety committee or similar committee consisting of representatives of the following: laboratory director, laboratory supervisors, biosafety officer, occupational health, IH, facility maintenance, emergency response, safety, and an employee representative. At a minimum, the safety committee will—

(1) Review proposed work activities and facility modifications.
(2) Assist in performing biological risk assessments.
(3) Discuss mishaps and near misses.
(4) Evaluate compliance and adequacy of established safety policy, training, engineering, and administrative controls, PPE, and safe work practices.
(5) Meet at least semiannually. Minutes will be—
(a) Prepared and staffed through the military treatment facility (MTF) commander.
(b) Available for review.
(c) Maintained for at least 3 years.

c.

assessments, risk management, biosafety controls, biological safety program management, SOPs, biosafety training, inspections, mishap notification, investigation and reporting, and emergency planning and response.

3–4. Risk assessment and management

a. A risk assessment will be conducted for every microbiological and biomedical laboratory activity or activity involving IAT. In assessing and managing risk, the activity will be broken down into subtasks, and for each subtask the hazards, initial risk level, recommended controls (personnel training and qualification, procedures, containment equipment, and facility design), residual risk level, and the means for implementing the recommended control will be identified. A sample risk assessment is at appendix D. It is recommended that risk assessments be documented on DA Form 7566 (Composite Risk Management Worksheet).

b. A risk assessment will be performed and documented for any deviation from a required or recommended procedure or safeguard. DA Pam 385–30 has a recommended risk acceptance matrix.

c. The principal investigator or immediate supervisor is responsible for conducting the risk assessment in close coordination with safety and occupational health subject matter experts and the safety committee to ensure compliance with established guidelines and regulations.

3–5. Standing operating procedures

a. An SOP will be established for each laboratory activity or activity involving IAT. A copy of the SOP will be maintained or available electronically in each work area in which the activity is conducted and designated individuals will maintain the SOP in a centralized location. SOPs will address the following:

(1) Any unique procedures and requirements needed that are not described as universally required in the biosafety program (for example, signs, waste disposal, building systems operation and maintenance, decontamination, immunizations, emergency procedures, and personnel monitoring).

(2) Specialized orientation or training of personnel beyond that required in the biosafety program.

(3) Emergency procedures.

b. If the laboratory uses external-agency standardized SOPs (for example, CDC SOPs for Laboratory Response Network laboratories), any of the above items that are not addressed in the SOP will be addressed in the laboratory-specific safety manual or in an addendum to the SOP.

c. SOPs will periodically be reviewed and updated. Each activity will establish a method for reviewing and revising SOPs based upon the complexity and hazardous nature of the process. The review cycle should not exceed 12 months for any SOP.

d. SOPs will limit personnel to the minimum number of appropriately qualified and trained personnel to engage in the activity, for the shortest period of time, and with the minimum amount of material (consistent with program objectives and safe operations), and maximize use of engineering and administrative controls to preclude or minimize the need for PPE.

e. SOPs (or the laboratory-specific safety manual or SOP addendum if the laboratory uses external-agency standardized SOPs) will be reviewed by personnel with specialized knowledge to assess safety and health of the process, to include facility and equipment aspects and emergency response. Examples include safety, occupational health, IH, facility maintenance, and fire and emergency services. Reviews are required at the initial development and when changes are made to the SOP that potentially impact safety or health. Reviews will evaluate accuracy, compliance with standards and regulations, and conformity with accepted practices. Reviewers will provide concurrence with the SOP prior to it being signed by the approving authority. The cover sheet with signatures of reviewers will be maintained as a permanent part of the SOP.

f. SOP cover sheets will contain the following information:

(1) Facility/activity name.

(2) Unique SOP number and name of process.

(3) Date of the SOP.

(4) Name of preparer, title, and phone number.

(5) Signatures and office titles of individuals responsible for reviewing and concurring with the SOP.

(6) Name and title of the approving authority and the date of approval.

g. Operators and others involved in the operation will read the SOP and sign a review sheet indicating that they have read the SOP and understand operations involved in the task; the supervisor or person in charge will sign indicating they have verified that operators are trained and understand the SOP and that the task can be executed in a safe and efficient manner:

(1) When first assigned to supervise the task.

(2) Beginning an operation that is intermittent and has not been performed for 90 days.

(3) When a change is made to the SOP.

(4) Following periodic reviews or updates as described in paragraph 3–5*c*.

h. Supervisors and safety and IH will evaluate SOP validity and compliance during routine inspections (observe employees performing work and validate that risks are identified, controls implemented, and procedures followed).

i. An index of all approved SOPs will be available and contain the following information:

(1) SOP number and title.

(2) Name of the office submitting the SOP.

(3) Date of approval.

(4) Next review date.

3–6. Facility design and commissioning

As required by AR 385–10, prior to initial use BSL–3 and BSL–4 laboratories are required to be validated for safe operation through a commissioning survey. Facility design and commissioning survey criteria are contained in appendix C.

3–7. Access control

a. Access to areas defined as BSL–2 and higher where work with IAT is in progress is limited in accordance with institutional policies. Only persons who have been advised of the potential hazard and meet specific entry requirements (for example, approval of Principle Investigator or supervisor, required PPE, training, medical screening) may enter the individual laboratory or animal rooms. The laboratory supervisor will enforce institutional policies that control access to the laboratory.

b. Access to areas defined as BSL–3 is limited in accordance with paragraph 3–7*a*. In addition is restricted to those persons whose presence in the facility or individual laboratory rooms is required for program or support purposes. Doors leading to these areas will have access restriction signs posted and be secured with locks (or equivalent means) to prevent unauthorized entry.

c. Access to BSL–4 facilities is limited as stated in paragraphs 3–7*a* and 3–7*b*. This is done with secure, locked doors with access controlled by the commander or institute director, safety or biosafety officer, or other person(s) 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 record will be maintained for all personnel to indicate the date and time of each entry and exit.

3–8. Personnel qualifications and training

a. Biosafety officers will meet the following qualifications:

(1) Bachelor's degree with background in science.

(2) One year of laboratory experience at equivalent BSL/animal BSL.

(3) A 3, 4, or 5 day Service-approved biosafety course.

(4) The Department of Defense (DOD) biosafety course.

(5) Training in Service-specific safety policy and standards and risk management.

b. Supervisors are responsible for understanding IAT operations and safety policy and standards for microbiological and biomedical activities.

c. Supervisors are responsible for ensuring that employees have received the training to enable them to safely execute the operation; and ensuring safety equipment and controls are available, safe, functioning, inspected, tested, and maintained.

d. Supervisors are responsible for ensuring that personnel entering a clinical or biomedical research laboratory meet applicable access control, medical, and safety and occupational health training requirements.

e. Prior to performing assigned duties, personnel working with IAT will be aware of the associated hazards, will receive instruction that adequately prepares them for their assigned duties, and will be proficient in microbiological practices and procedures. Training will be developed in coordination with the safety office and will be documented to include the date of the training session, the contents or a summary of the training, and employee's name. Training will include:

(1) Risk management principles and techniques.

(2) Concept and definition of BSLs.

(3) Modes of transmission, infectivity, time delay to onset of signs and symptoms, as well as the potential acute and chronic health effects and signs/symptoms associated with the IAT to which workers are potentially exposed.

(4) Facility safety controls.

(5) Selection and use of safety equipment (for example, biological safety cabinets, glove boxes, laboratory chemical hoods).

(6) Laboratory practices and safety requirements, including applicable SOPs and special practices and requirements.

(7) Bloodborne pathogens (per 29 CFR 1910.1030), hazard communication (per 29 CFR 1910.1200), and occupa-
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if revision of exposure prevention strategies is indicated. These documented inspections may be unannounced and will include coverage of general safety practices as well as requirements applicable to the laboratory's BSL. One of the semi-annual or quarterly inspections can be a Standard Army Safety and Occupational Health Inspection (SASOHI) as required by AR 385-10.

e. A qualified industrial hygienist (GS–0690 job series) will conduct an IH survey of research microbiology laboratories on an annual basis. Surveys will identify and document chemical, physical, biological and ergonomic hazards. Industrial hygienists will evaluate and assign a risk assessment code to each hazard and recommend appropriate hazard control (see DA Pam 40–503). Each visit is documented, and the work site supervisor is provided a written report. At a minimum, these evaluations should include hazardous material identification, type of engineering controls needed (if applicable), type of PPE required, and posting of appropriate signs needed (that is, noise-hazardous area or eye protection required). Appropriate entries should be made in the Defense Occupational and Environmental Health Readiness System-IH.

f. Deficiencies or procedures that create a potentially life-threatening situation will be immediately referred to supervisory personnel, the safety office, the commander or institute director, and, if the facility is a tenant on an installation, the garrison commander. The operation will be stopped, and corrective actions will be immediately implemented or the residual risk will be accepted at the appropriate level in accordance with Army Headquarters' (for example, U.S. Army Materiel Command, U.S. Army Medical Command (MEDCOM), and U.S. Army Test and Evaluation Command) risk acceptance policy.

g. 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 safety office. If a problem is widespread, all affected personnel will be notified.

3–11. Mishap notification, investigation, and reporting

a. Biological mishap reporting and investigation will be in accordance with requirements of this pamphlet, AR 50-1, AR 385-10, DA Pam 385-40, 7 CFR 331, 9 CFR 121, 42 CFR 73, and applicable Federal, State, and local requirements. Commanders will establish procedures to ensure initial notification, investigation, and reporting of a biological mishap is accomplished in accordance with the requirements of these documents as follows, as well as applicable State and local requirements. All biological mishaps will be investigated for the purpose of accident prevention.

b. The term "biological mishap" is defined as an event in which the failure of laboratory facilities, equipment, or procedures appropriate to the level of potential pathogenicity of an IAT may allow the unintentional, potential exposure of humans or the laboratory environment to that agent.

c. BSAT (including clinical, diagnostic, or proficiency test specimens of BSAT).

(1) In accordance with 7 CFR 331, 9 CFR 121, and 42 CFR 73, upon discovery of a release of a BSAT causing occupational exposure or release of a BSAT outside of the primary containment barriers (for example, biological safety cabinet, trunnion centrifuge cups, and aerosol-containing blenders) of the biocontainment area (including clinical or diagnostic laboratories and other entities that possess, use, or transfer BSAT contained in a specimen presented for diagnosis, verification, or proficiency testing), an individual or entity must immediately notify the CDC or the Animal and Plant Health Inspection Service (APHIS). The following information must be provided:

(a) The name of the BSAT and any identifying information (for example, strain or other characterizing information).

(b) An estimate of the quantity released.

(c) The date, time, and duration of release.

(d) The environment into which the release occurred (for example, in building or outside of building, waste system,

(b) Mishaps in which there was direct evidence of an exposure to BSAT, such as a measurable rise in specific antibody titer to the BSAT in question, or a confirmed diagnosis of intoxication or disease.

(5) A completed APHIS/CDC Form 3 must be submitted to the CDC or APHIS within 7 calendar days, with a copy forwarded through the first general officer in the chain of command to ODASAF.

(6) A closeout report will be submitted to ODASAF with copy furnished through normal command channels after the mishap investigation is complete.

d. Non-BSAT (IAT not characterized as BSAT).

(1) Upon discovery of a non-BSAT occupational exposure or release of a non-BSAT outside of the laboratory, an individual or entity must immediately notify the first general officer (or equivalent) in the mishap reporting chain. Reports will include the information required in paragraph 3(1). If the facility is a tenant on an installation, the mishap will also be reported to the garrison commander. The first general officer (or equivalent) receiving the report will forward it up the chain of command to the ODASAF. The entity should notify the appropriate local and State health agencies.

(2) A closeout report will be submitted to ODASAF with copy furnished through normal command channels after the mishap investigation is complete.

e. Class A-D accidents, as defined in AR 385–10, occurring during biological activities will be reported in accordance with requirements of AR 385–10.

f. All biological mishap investigation reports will be shared with the Department of the Army Biological Safety and Health Council in order to disseminate lessons learned to other Army organizations.

3–12. Recombinant deoxyribonucleic acid

a. When work with recombinant DNA is undertaken, an Institutional Biosafety Committee (IBC) will be established to review recombinant DNA activities and protocols. The IBC will function as stated in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

b. Activities funded by the NIH involving recombinant DNA will comply with all requirements of the NIH Guidelines for Research Involving Recombinant DNA Molecules and are subject to IBC approval. Facilities conducting work with recombinant DNA that are not funded by the NIH should adopt these guidelines as best practices.

3–13. Contract activities

a. Contracting agencies, or agencies performing safety and health oversight for a contracting agency, will develop and document procedures for reviewing contractors' capability to perform activities with IAT safely in accordance with AR 385–10 and this pamphlet.

b. Upon award, the contracting agency or agency performing safety and health oversight will conduct a survey of the contractor's biological safety program to determine if it meets the intent of paragraph 3–1. In addition, the laboratory facilities to be used for Army-contracted IAT activities will be inspected for compliance with safety and occupational health requirements, using the checklist in appendix B as a guide. For contract laboratory facilities working at BSL–3 or BSL–4, the contracting agency or agency performing safety and health oversight will reinspect the laboratory facilities on a 12-month basis. Surveys and inspections may be accomplished by a qualified, independent third party using contracting agency approved survey and inspection criteria. Survey and inspection reports will be provided to the contracting officer.

Chapter 4
Occupational Health

4–1. Occupational health program

a. The Army Occupational Health Program consists of capabilities and activities necessary to identify, assess, and control disease and injury risks to military and eligible civilian personnel from exposures to IAT encountered due to their occupation. These exposures may occur in a clinical laboratory or in a biomedical research setting.

b. The occupational health program is a part of the installation, MTF, or laboratory biological safety and health program, which encompasses many disciplines and may cut across different Army commands. The occupational health program should address the relevant requirements from AR 40–5, DA Pam 40–11, the occupational health and immunoprophylaxis section of the BMBL, and the other specific elements as his or her apply to the biological safety program. An occupational health program should be established to ensure that:

(4) The CMA informs the workers as to availability of medical support services, examinations, immunizations, and postexposure prophylaxes.

(5) The CMA provides licensed vaccines (when available and recommended based on risk assessment and medical opinion) for personnel whose duties may potentially expose them to etiologic agents (see latest recommendations from the Advisory Committee on Immunization Practices, Department of Health and Human Services, and the CDC).

(6) The CMA refers employees to the Special Immunization Program (SIP) when risk assessments indicate that the individual may be a candidate to receive investigational new drug (IND) vaccines for possible workplace exposures to IAT.

(7) The CMA conducts periodic workplace visits with biological safety professionals to laboratories with etiologic agents to identify potential workplace hazards.

(8) The CMA, with the assistance of biological safety professionals, annually reviews occupational illness and injury reports to determine if revision of exposure preventions strategies is indicated.

4–2. Competent medical authority qualifications

Medical officers responsible for treating IAT exposures and conducting medical surveillance for personnel working with IAT will receive specialized training on the hazards of IAT and recommended medical therapies, such as the Medical Management of Chemical and Biological Casualties course or the Fundamentals of Occupational Medicine course and may strongly consider the CDC's International Symposium on Laboratory Biological Safety ("Protecting Workers in Clinical Laboratories, Research, Animal Care, and Public Health Communities") based on processes and risk assessments. Medical professionals should have this training to be considered a CMA. A CMA is a physician, physician assistant, or nurse practitioner (military, civilian, or contract), appropriately trained and privileged to provide medical services or clinical evaluations in support of biosafety programs. Physician assistants must be supervised by licensed physicians. Nurse Practitioners must have a licensed physician available for consultation. DA Form 5440–53 (Delineation of Clinical Privileges – Occupational Medicine), Category I Clinical Privileges provides a strong framework for recommended requirements for physicians, which includes the Army Medical Department (AMEDD) Fundamental of Occupational Health Course, 6H–F20 or equivalent. See also definition of CMA in glossary.

4–3. Medical surveillance examinations

a. Preplacement examinations. Workers who may be exposed to human pathogens should receive a preplacement medical evaluation. The CMA should be cognizant of chemical, physical, and biological potential hazards encountered by the worker. The supervisor incorporates relevant portions of the risk assessment or job hazard analysis associated with the position, and completes an occupational health survey detailing the requirements for the position, the potential exposure hazards, and PPE requirements, and provides this to the CMA prior to the examination. The CMA should review the worker's previous and ongoing medical problems, current medications, allergies to medicines, animals, and other environmental proteins, and prior immunizations. With that information, the CMA determines the content of the medical surveillance examination and what medical services (for example, serologies, immunizations, and so forth) are indicated to permit the individual to safely assume the duties of the position. Occasionally, it may be useful to review preexisting medical records to address specific concerns regarding an individual's medical fitness to perform the duties of a specific position. The CMA should determine an individual's vulnerability to infection with specific agents that he or she may be working with as part of the preplacement medical surveillance examination. Some occupational exposures present substantially more hazard to identifiable subpopulations of workers. Immunodeficient workers or nonimmune pregnant female workers may experience devastating consequences from exposures that pose a chance o risk to pregnant women with prior immunity and other immunocompetent workers (for example, cytomegalovirus or toxoplasmosis). Where appropriate, the CMA should use serologic testing to document baseline vulnerability to specific infections to which the worker might be exposed, and nonimmune workers should be adequately informed about risks. In specific settings, serologic documentation that individual workers have preexisting immunity to specific infections also may be required for the protection of research animals. During the visit, the CMA should also inform the worker of potential health hazards in the work area and review steps that should be taken in the event of an accidental exposure, and conform to any relevant bloodborne pathogen program requirements described in DA Pam 385–10.

b. Periodic medical surveillance.

(1) The CMA should conduct periodic medical surveillance that includes updating the employee's medical and occupational history from the previous year, reviewing any changes in job activities or exposure hazards, and updating respirator clearances, as required. In special circumstances, it may be appropriate to offer booster immunizations, or periodic laboratory testing to workers with substantial risk of exposure to infectious agents to detect preclinical or subclinical evidence for an occupationally acquired infection. Before asymptomatic workers without specific exposures are tested for seroreactivity, the benefit of such testing should be justified, plans for further investigation of indeterminate test results should be delineated, and clearly defined criteria for interpretation of results should be developed.

(2) Workers and support personnel that have been designated or granted approval of facility access during etiological agent operations will be identified, and their risk assessment will be reviewed in conjunction with all occupational health examinations or screenings.

c. Termination examinations.

(1) Employees enrolled in medical surveillance from working in a BSL–3 or BSL–4 laboratory areas will suspend work in those laboratories 30 days prior to termination to ensure proper medical surveillance.

(2) The CMA performs a termination of employment examination or a termination of exposure examination on individuals within 30 days after the employee's removal from the exposure that requires the medical surveillance. The examination documents the employee's health status at the time of termination, particularly for organ systems that may have been affected by etiologic agent exposure.

(3) The supervisor ensures that a termination examination has been administered or offered to workers who have been enrolled in the medical surveillance program.

d. Postexposure examinations for occupational illnesses and injuries.

(1) In the event of injury, consultation between the CMA, employee, and the employee's supervisor is required for proper medical management and recordkeeping (mishap and Office of Workers Compensation Program reports and Occupational Safety and Health Administration (OSHA) logs). The supervisor and biological safety officer should report all occupational injuries, including exposures to human pathogens, to the CMA. Strategies for responding to biohazard exposures should be formulated in advance. The CMA should develop exposure-specific protocols that define appropriate first aid, potential postexposure prophylaxis options, recommended diagnostic tests, and sources of expert medical evaluation. These protocols should address how exposures that occur outside of regular work hours are handled and these protocols should be distributed to potential health care providers (for example, local hospital emergency departments) with whom the CMAs have developed external support agreements. The adequacy and timeliness of wound cleansing or other response after an exposure occurs may be the most critical determinant in preventing infection. The CMA should review and define appropriate first aid treatment, and promulgate this information through the appropriate safety or supervisory management chain. Laboratory SOPs should include a printed summary of the recommended medical response to specific exposures that can guide immediate response in the work place and that the injured worker can provide to the treating facility. The CMA's description of the injury should include:

(a) The potential infectious agent.

(b) The mechanism and route of exposure (percutaneous, splash to mucous membranes or skin, aerosol, and so forth).

(c) Time and place of the incident.

(d) The PPE used at the time of the injury.

(e) Prior first aid provided (for example, nature and duration of cleaning and other aid, time that lapsed from exposure to treatment).

(f) Aspects of the worker's personal medical history relevant to risk of infection or complications of treatment.

(2) In some instances, it may be possible to prevent or ameliorate illness through postexposure prophylaxis. The CMA should develop protocols in advance that clearly identify the situations in which postexposure prophylaxis are to be considered, the appropriate treatment, and the source of products and expert consultation within (and outside) the AMEDD. Postexposure regimens may involve off-label use of licensed products (for example, use of smallpox vaccine for workers exposed to monkey pox) in settings where there is insufficient experience to provide exact guidance on the safety or likely protective efficacy of the prophylactic regimen. Thus, protocols should exist that delineate the circumstances under which it would be appropriate to consider use of each product following exposure, as well as the limits of current understanding of the value of some postexposure interventions. In these cases, consultations with subject matter experts are especially useful. Appropriate postexposure prophylactic response is always pathogen- and exposure-dependent, may be host-factor dependent, and may also be influenced by immediate postexposure management. Before prophylactic treatment is undertaken, the CMA should confirm the likelihood that an exposure occurred, that prophylaxis is indicated and is not contraindicated by past medical history. Conveying this information to the injured worker requires clear, honest communication. The clinical risk assessment and treatment decision process, and the medical followup plan, should be carefully explained and documented in the medical record. Each incident should receive prompt reconsideration of the initial risk assessment and reevaluation of current strategies to reduce the possibility of future exposures.

e. Documentation of medical opinion. The CMA records a written opinion in the medical record for each medical surveillance examination. This opinion includes—

(1) The results of the medical examination and testing.

(2) A statement about any detected medical condition that would place the individual's health at an increased risk of impairment if exposed to etiologic agent.

(3) Any recommended limitations on the potential exposure to etiologic agent or on the use of PPE.

(4) A statement that the employee has been informed of the above.

4–4. Health hazard education

a. Supervisors. Supervisors will ensure that health care providers are made aware, at the time of the medical

examination, of all hazardous substances with which each employee works. The CMA'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 the normal range, the employee will be notified and counseled on the courses of action available. The employee's supervisor will be notified of any duty limitations. 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. Employee health education.

(1) Employee health training. The CMA should review and provide input on employee-training materials, local plans, policies or procedures dealing with the health effects or treatment aspects of etiologic agent exposure, patient or skin decontamination procedures, use of respiratory, ocular or dermal protective equipment to protect against etiologic agent exposure, and all first aid practices. The CMA should conduct and document (for example, memorandum for record) this review on an annual basis.

(2) Access to health education materials. The biosafety officer ensures that a copy of health education materials used in the employee training programs are readily available to all individuals with an exposure potential to etiologic agents. Consideration should be given to co-location of these documents with SDSs used in the laboratory.

4–5. Immunoprophylaxis

a. Immunoprophylaxis program. CMAs offering immunoprophylaxis as a means of personal protection will develop a written immunoprophylaxis program and SOPs. SOPs will address procedures for vaccine administration, follow up, and recordkeeping.

b. Program requirements. Written immunoprophylaxis programs will address the following:

(1) Identification of personnel responsible for development and administration of the program.

virus, Rift Valley fever virus, Venezuelan equine encephalitis virus (TC 83), and Venezuelan equine encephalitis virus (C 84).

(4) In order to avoid placing individuals at undue risk and to ensure the continued availability of SIP vaccines, individuals will not be enrolled in the SIP unless the following criteria are met:

(a) The hazard analysis/risk assessment (completed by the individual's supervisor and endorsed by the agency Safety Manager) of the activity presenting the potential exposure lists, as a hazard of the activity, one or more of the twelve etiological agents for which a SIP vaccine is available and justifies use of the SIP vaccine as an added level of protection.

(b) The individual has been informed by qualified medical personnel of the purpose, benefits, and risks (and possible side effects including those resulting from interaction of the vaccine with other drugs or treatments being administered to the individual) of the specific SIP vaccine and the individual consents to participation in the SIP.

(5) If an IND is to be used, the individual has been informed by qualified medical personnel that the vaccine is an IND and provided specific information on whether the IND is approved by the FDA and/or whether it is unapproved for its applied use.

(6) When requesting enrollment or reenrollment in SIP, documentation showing satisfaction of the above requirements, along with a copy of the applicable research protocols, will be provided to the SIP program coordinator at the U.S. Army Medical Research and Materiel Command. Medical records for individuals enrolled in SIP will accurately document the receipt of SIP vaccines and satisfaction of the above criteria. Medical records should be maintained for the duration of employment plus 30 years.

4–6. Illness and absence monitoring

a. Personnel enrolled in the medical surveillance program who have an unplanned absence from the workplace should be contacted by the supervisor that day to rule out an occupational-related concern. Personnel absent 3 or more work days due to a medical condition should be evaluated and cleared by occupational health prior to resumption of duties.

b. Personnel who are enrolled in the medical surveillance program may be required to report all illnesses, health care received, and medication use to the CMA, regardless of whether or not it led to absence from the workplace. The CMA will make recommendations to the supervisor on the disposition of the employee.

c. Supervisors, in coordination with safety and occupational health subject matter experts, should address in SOPs the need for "illness contact cards" based on the activity's risk assessment. If it is determined that employees will be issued "contact cards," the process will be described in the SOPs and cards made available for the employees.

d. Work with BSL–4 agents involves special challenges for occupational health. Infections of laboratory staff by such agents may be expected to result in serious or lethal disease for which limited treatment options exist. In addition, BSL–4 agents are frequently geographically exotic to the areas in which high containment labs are located but produce immediate public health concern if infections occur in laboratory staff. Potential (if unlikely) transmission from infected staff into the human or animal populations in the areas surrounding the laboratories may raise such concerns to higher levels. Thus, SOPs for BSL–4 settings require special attention to management of unexplained worker absence, including protocols for monitoring, medical evaluation, work-up, and follow-up of workers with unexplained non-specific illness. Advance planning for the provision of medical care to workers potentially infected with BSL–4 agents is a fundamental component of an occupational health program for a BSL–4 facility.

4–7. Fitness for duty

a. Supervisors will assure that employees are referred for required job-related medical surveillance.

b. The CMA should conduct or coordinate medical surveillance and health hazard training for military and civilian employees potentially exposed to work-related hazards, and evaluate employees in positions requiring specific standards of physical fitness.

c. Guidelines from DOD 6055.05–M C1.4.7 should be considered. Where promulgated medical standards may not

Chapter 5
Facility Safety Controls

5–1. Facility design (secondary barriers)

The design of the facility is important in providing a secondary barrier to protect individuals inside and outside the facility. Facility requirements for each BSL are outlined in the BMBL.

a. Prior to selecting facility equipment, an evaluation of the function of the equipment should be made, and the

pressure HEPA filtered stainless steel cage. A minimum airflow of 0.3 m^3/min per cage is required for a 0.24 cubic meter (m^3) unit. Ventilation rates may vary with the size of the cage and the number and type of animals being housed.

d. A total containment cage is a negative pressure or positive pressure HEPA filtered stainless steel cage that 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 m^3/min per cage is required for a 0.24 m^3 unit. Ventilation rates may vary with the size of the cage, and the number and type of animals being housed.

6–6. Ventilated cage areas

Ventilated cage areas are areas within a room that have solid walls for containing multiple cages housing infected or intoxicated animals. The containment for these areas is equivalent to the class I biological safety cabinet. Smoke tests will be performed annually to verify containment.

Chapter 7
Biosafety Practices

7–1. General practices for infectious agents and toxins

Biological facilities will develop or adopt a laboratory biosafety manual based on the recommendations found in the latest edition of the BMBL. The following are Army specific requirements that must be included in facility safety plans or biosafety manuals.

a. Hallways and stairways will not be used for storage.

b. Labeling.

(1) Chemicals. All solutions and reagents will be labeled in accordance with local policy. When working with chemicals, operators will be knowledgeable of their hazards.

(2) Infectious agents and toxins. All primary or secondary containers will be labeled with contents (for example, the rack containing 100 microfuge tubes with the same culture can be labeled instead of the individual tubes).

c. Storage.

(1) Equipment used to store IAT (for example, freezers and refrigerators) will be labeled with the universal biohazard sign and indicate the IAT identity and BSL contained in them.

(2) Refrigerators, deep freezers, and dry ice chests will be inspected periodically for integrity of any ampoules, tubes, or other vessels stored. Refrigerators and deep freezers will be defrosted and cleaned out in accordance with the manufacturer's recommendations and when broken ampules/tubes are found or spills visible.

(3) Flammable solutions, required to be kept cold, will be stored in approved laboratory safe refrigerators or freezers.

d. Emergency eyewash and shower equipment will be installed, used, inspected, tested and maintained in accordance with ANSI Z358.1, latest edition.

7–2. Additional techniques applicable to work with infectious agents and toxins

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 (for example, skin, eyes, mouth, lungs), and host susceptibility (for example, 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.

a. Centrifuges and shakers.

(1) Centrifuges will be on a preventive maintenance program as recommended by the manufacturer.

(2) Before centrifuging, tubes, rotors, seals, and gaskets will be checked for cleanliness and integrity. Tubes that show cracks of stress marks will not be used. Seals on safety buckets and rotors will be inspected prior to use.

c. Since disinfectants vary, instructions on water bath disinfection will be incorporated into the lab specific biosafety manual to identify appropriate antimicrobial disinfectants against the agent and change frequency.

d. Care should be exercised when using membrane filters to obtain sterile filtrates of viable IAT. 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.

e. Work with dry powders of IAT in open containers should be carried out in gas-tight (Class III) biological safety cabinets. Dry powders in open containers may also be manipulated in a glove bag within a BSC, in a BSC or chemical fume hood with proper respiratory protection, or in other ways as determined by a risk assessment.

7–3. Operations with radioactive material

Operations combining IAT with radioactive material present unique problems. When this is the case, the following apply.

a. A radiation program meeting the requirements of DA Pam 385-24 and Nuclear Regulatory Commission standards for the radionuclide 10 CFR Part 20 is required and will be implemented. The requirements for acquisition, handling procedures, labeling, storage, training, monitoring, and disposal will be described in an organizational policy document.

b. The radiation safety officer (RSO) 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) Radioactive waste must be segregated, labeled and disposed of as such after the etiological agent has been decontaminated. Radiological material must not be autoclaved. Do not mix nonradioactive waste with radioactive waste as the disposal of radioactive waste is much more complex and expensive. When Resource Conservation and Recovery Act listed chemicals are mixed with radioactive waste, it becomes “mixed waste” which must be disposed of in accordance Specia

a. Laboratory staff members are supervised by competent scientists who are trained and experienced in working with these agents.

b. All activities involving Risk Group 4 agents (see BMBL) will be 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 suits ventilated by a life-support system.

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. Supplies and materials entering or exiting maximum containment areas present unique hazards. Each institution must have an approved SOP detailing methods and procedures for the movement of various types of materials (paper, heavy equipment, cages, PPE, and so forth) in and out of maximum containment areas.

e. If water fountains are provided in a cabinet laboratory, they will be foot operated and located in the facility corridors outside the laboratory.

f. A ventilation system that is dedicated to the BSL–4 laboratory and provides fresh air meeting ASHRAE Standard 62.

g. The BSCs are tested and certified at the time of installation, at least annually thereafter, or whenever HEPA filters are damaged, maintenance repairs made to internal parts or the cabinet is moved. If the filtered cabinet exhaust is discharged through the building exhaust system, it will be connected to this system in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system. Note: class II Type B1 and B2 BSCs must be hard-ducted/directly connected to the exhaust system to function properly and cannot use a thimble unit.

h. The BSL–4 animal areas may be included as an integral part of BSL–4 cabinet laboratories or suit laboratories. The facility requirements for a BSL–4 laboratory should be used in conjunction with animal biosafety level 4 (ABSL–4) facility requirements listed in the BMBL.

7–8. Toxins

The following requirements in addition to those listed in the BMBL apply to the use of toxins of biological origin.

a. Two knowledgeable individuals will be present in the laboratory during high-risk operations involving dry forms of toxins, intentional aerosol formation, or the use of hollow-bore needles in conjunction with amounts of toxin estimated to be lethal for humans. One individual is to conduct the high-risk activity, the other to act as a safety observer and emergency responder in the event of an incident.

b. All facilities in which toxins are used will:

(1) Have a ventilation system that provides a negative pressure in the laboratory room (a directional airflow inward relative to the access halls).

(2) Have a quick-drench shower readily available within the facility and in accordance with the latest edition of ANSI Z358.1, American National Standard for Emergency Eyewash and Shower Equipment.

c. Glove box or class III BSC and toxin use .

(1) All items inside the glove box or class III BSC 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. Secondary containers will be labeled appropriately immediately upon removal from the glove box or class III.

(2) The interior of the glove box or cabinet and all items will be decontaminated periodically, for example, at the end of a series of related experiments. Until decontaminated, the 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.

d. It should be noted that laboratory safety precautions appropriate for handling toxins closely parallel those for handling nonvolatile hazardous chemicals.

7–9. Integrated pest management

Clinical laboratories and biomedical research facilities will institute an effective integrated pest management (IPM) program to identify and control the infestation by and harborage of animal or insect vectors or pests. See AR 40–5, AR 200–1, and DODI 4150.7.

Chapter 8
Personal Protective Equipment

8–1. General

a. 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

approved hazardous material shipper certification course and be appointed in writing by the activity or unit commander or designated representative stating the scope of authority and expiration date.

Chapter 10
Decontamination and Disposal of Infectious Agents and Toxins

10–1. General

All material or equipment that is potentially contaminated with IAT must be rendered nonhazardous before disposal. In general, all contaminated materials and equipment or apparatus will be decontaminated before being washed and stored or discarded.

a. Consult with installation legal counsel regarding local, federal, state or host country safety, health and environmental requirements for necessary approvals (for example, the use of formaldehyde may require a permit from the Environmental Protection Agency or a State agency).

b. Follow decontamination requirements listed in the latest version of the BMBL.

10–2. Methods of decontamination

a. Autoclave.

(1) General. Using wet heat and high pressure is the most dependable procedure for destroying all forms of microbial life. In addition to being effective for viable agents, autoclaving effectively inactivates most protein toxins.

(2) Validation. Sterilization will be verified using biological indicators (for example, Bacillus stearothermophilus (Geobacillus stearothermophilus) spores) at locations throughout the autoclave, to include placement in the center of test loads, when the autoclave is first put into service, after any maintenance or repairs, and on a quarterly basis (unless more frequent verification is warranted). Each autoclave sterilization operation will be verified through the use of chemical indicators (for example, autoclave tape, labels, or strips) at locations throughout the autoclave and an autoclave thermometer capable of indicating the maximum temperature of the operation. In addition, each autoclave will be equipped with a permanent means to record time and the temperature of each operational event as a means of ensuring sterilization. The type of materials, volume, contamination level, and other factors of materials being autoclaved must be reviewed and standard conditions for sterilization must be established. As a guide, the manufacturer's manual for the autoclaves will be consulted as a starting point in establishing these conditions. In each case, the conditions will be established based on tests, which verify that the conditions selected are effective.

b. Dry Heat. Dry heat requires longer times and/or higher temperatures than wet heat requires. 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 to170 degrees Celsius (°C) for periods of 2 to 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.

c. Liquids.

(1) If used as a disinfectant, liquids must be proven effective against the organism or toxin in use. Liquid disinfectants will be made up and used in accordance with the manufacturer's instructions and the BMBL.

(2) If used for sterilization there must be a validation method in place to ensure sterility.

d. Vapors and gases.

(1) Vapors and gases such as vaporized hydrogen peroxide, formaldehyde-paraformaldehyde, and chlorine dioxide

viruses, Mycoplasma, bacteria, and fungi on clean surfaces such as a laboratory bench. However, the usefulness of UV radiation on exposed surfaces is limited by its low penetrating power and will only be used to decontaminate surfaces when conventional methods, such as autoclaving or liquid disinfectants, would make the product unusable. An example is data sheets that must be brought out of a BSL–3 or BSL–4 laboratory. The UV intensity must be at least 40 microwatts per square centimeter ($\mu W/cm^2$) 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. If worker exposure to the UV lamp emissions is not avoidable, personal protective gear will be worn to prevent accidental overexposures. Examples of such gear include, but are not limited to, UV protective goggles and face shields to protect the eyes and face, clothing with tightly woven fabrics to protect the arms and neck, and work gloves or disposable nitrile gloves to protect the hands.

(2) Validation.

potentially hazardous laboratory work must stop until service has been restored and appropriate action has been taken to prevent personnel exposure to IAT.

(5) In a medical emergency, summon medical help immediately. Laboratories and facilities without access to a MTF or health care providers within ten minutes must have personnel trained in first aid available during working hours in accordance with 29 CFR 1910.151.

material, regardless of amount. Laboratory personnel may be expected to clean up the spill. The RSO will direct the cleanup, in accordance with the Nuclear Regulatory Commission license for the facility.

(2) 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.

(3) 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 RSO will determine the requirements for additional cleanup.

Appendix A
References

Section I
Required Publications

AR 11–34
The Army Respiratory Protection Program (Cited in para 8–2f.)

AR 40–5
Preventive Medicine (Cited in paras 4–1b, 4–5e(1), 7–9.)

AR 50–1
Biological Surety (Cited in para 3–11a.)

AR 200–1
Environmental Protection and Enhancement (Cited in para 7–9.)

AR 385–10

National Institutes of Health Publication 86–23
Guide for the Care and Use of Laboratory Animals (Cited in paras 6–5a, 7–5b(1).) (This publication is available from the Office of Laboratory Animal Welfare, NIH or the National Academy Press. It is also available at http://www.nap.edu/readingroom/books/labrats/.)

National Institutes of Health
Biosafety Level 3 Laboratory Certification Requirements (Cited in para C-1.) (This publication is available at http://orf.od.nih.gov/NR/rdonlyres/9EC84DBB–AC8D–409C–9783–025830F47D5A/15898/BSL3CertificationRequirements.pdf.)

American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 62
Ventilation for Acceptable Indoor Air Quality (Cited in para 7–7f.) (This publication is available through the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.)

American National Standards Institute
ANSI Z87.1, Occupational and Educational Personal Eye and Face Protection Devices (Cited in para 8–2a.) (This publication is available from the American National Standards Institute, 25 West 43rd Street, New York, NY 10036.)

American National Standards Institute
ANSI Z358.1, American National Standard for Emergency Eyewash and Shower Equipment (Cited in paras 7–1d, 7–8b(2).) (This publication is available from the American National Standards Institute, 25 West 43rd Street, New York, NY 10036.)

National Sanitation Foundation
NSF/ANSI 49, Class II (laminar flow) biosafety cabinetry (Cited in para 6–1a(3).) (This publication is available from the National Sanitation Foundation International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, Michigan, 48113–0140.)

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

AR 420–1
Army Facilities Management

DOD 6055.18–M
Safety Standards for Microbiological and Biomedical Laboratories (Available at http://www.dtic.mil/whs/directives/corres/pdf/605518m.pdf)

Occupational Health and Safety in the Care of Research Animals, Committee on Occupational Safety and Health in Research Animal Facilities, Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council
(Cited in para 5–5a.) (This publication is available from the National Academy Press.)

Laboratory Safety for Arboviruses and Certain other Viruses of Vertebrates, The Subcommittee on Arbovirus Laboratory Safety of the American Committee on Arthropod–Borne Viruses
(Cited in para 5–6.) (This publication is available from the American Journal of Tropical Medicine and Hygiene, 29 (6): 1359–1381.)

American National Standards Institute/American Society of Heating, Refrigerating, and Air Conditioning Engineers (ANSI/ASHRAE) 110
Method of Testing Performance of Laboratory Fume Hoods. (This publication is available through the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.)

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.

Title 9 Code of Federal Regulations, Parts 1–3, Subchapter A
Animal and Plant Health Inspection Service, Department of Agriculture (This publication is available at http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr1_08.htm.)

Title 10 Code of Federal Regulations, Part 20
Standards for Protection against Radiation (Cited in para 5–3 (Cited in para).) (This publication is available at http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr20_08.html)

Title 29 Code of Federal Regulations, Part 1910
Occupational safety and health standards (Cited in para 7–2a, 7–2e, 7–2f, 10–2a(5).) (This publication is available at http://www.access.gpo.gov/nara/cfr/waisidx_08/29cfrv5_08.html)

U.S. Department of Health and Human Services, Primary Containment for Biohazards
Selection, Installation and Use of Biological Safety Cabinets (This publication is available on the internet.)

Section III
Prescribed Forms
This section contains no entries.

Section IV
Referenced Forms
DA Forms are available on the Army Publishing Directorate Web site (http://www.apd.army.mil).

DA Form 2028
Recommended Changes to Publications and Blank Forms

DA Form 5440–53
Delineation of Clinical Privileges — Occupational Medicine

DA Form 7566
Composite Risk Management Worksheet

Appendix B
Laboratory Safety Inspection Checklist
The checklist that follows is not an exhaustive list of the items to consider when inspecting facilities where IAT are used. It does provide some basic guidelines to remind safety and nonsafety professionals of the specific requirements for biological laboratories.

B–1. Basic checklist for infectious agents and toxins laboratories (Biosafety level 2)

a. Laboratory supervisor enforces institutional policies that control access to the laboratory and personnel with access have been screened for or enrolled in appropriate medical surveillance program.

b. Personnel wash hands after ws icherpuvl ptgenitaly ohazariousmiatprilts andbe fohe eaviche the laboratorm.

l. Laboratory equipment is routinely decontaminated, as well as, after spills, splashes, or other potential contamination and before repair, maintenance or removal from the laboratory. Animals and plants not associated with the work being performed are not permitted in the laboratory.

m. Any procedure involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment device.

n. PPE worn when working with hazardous materials. PPE is removed before leaving for nonlaboratory areas.

o. Eye, face and respiratory protection used in rooms containing infected animals if required by risk assessment.

p. Laboratory doors should be self-closing and have locks in accordance with institutional policies.

q. Laboratories have a sink for hand washing. It should be located near the exit door.

r. The laboratory is designed so that it can be easily cleaned and decontaminated. There are no carpets and rugs.

s. Laboratory furniture is capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

t. Bench tops are impervious to water and resistant to heat, solvents, acids, and other chemicals.

u. Chairs used in laboratory work are covered with a nonporous material that can be easily decontaminated.

v. Laboratory windows that open to the exterior are fitted with screens.

w. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

x. Vacuum lines should be protected with HEPA filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.

y. An eyewash station is readily available.

z. BSCs are certified annually.

aa. There is a way to decontaminate all laboratory wastes (should be in the facility). For example, autoclave, chemical disinfection, incineration, or other validated decontamination method.

B–2. Biosafety level 3 supplemental checklist

a. All procedures involving the manipulation of infectious materials must be conducted within a BSC (preferably class II or class III), or other physical containment device.

b. The PPE with a solid front such as tieback or wraparound gowns, scrub suits, or coveralls are worn by workers in the laboratory. PPE is not worn outside of the laboratory.

c. Reusable clothing is decontaminated with appropriate disinfectant before being laundered.

d. q.

(a) The appropriate special provisions for entry.
(b) The universal biohazard symbol.
(c) The name and telephone number of the laboratory director or other responsible person.
(4) Access to the laboratory is controlled strictly and documented.
(5) Monitors indicate that the room is under negative pressure relative to all entrances.
(6) All vacuum lines are protected with HEPA filters and liquid disinfectant traps.
(7) The autoclave is properly maintained and certified.
(8) Foot, elbow, and automatic hand wash sinks operate properly.
(9) Self-closing doors to the facility operate properly.
(10) Personnel completely exchange street clothing for laboratory clothing before entry and shower upon exiting.
(11) The dunk tank disinfectant is fresh and appropriate for the agents in use.
b. Suit areas.
(1) All operations with IAT are conducted in class I or II biological safety cabinets.
(2) Procedures are in place ensure that, as much as possible, contamination remains inside the cabinets (such a ensuring that everything removed from the cabinets, such as gloves, instruments, glassware, or similar items, are first decontaminated and properly packaged first).
(3) Class I or II cabinets in the facility are certified every 6 months.
(4) The suit decontamination shower has adequate appropriate decontaminant available.
(5) The suit decontamination shower has been used or tested in the last month.
(6) The ventilated suit air supply and emergency air supply are adequate and working properly.
(7) The emergency alarm system is working properly.
(8) All of the one-piece positive pressure suits available for use are in serviceable condition.
(9) Infected animals are housed in appropriate primary containment systems.
(10) The static pressure in the suit area is negative to all surrounding areas.
c. Nonsuit areas.
(1) All operations with IAT are conducted inside class III biological safety cabinets.
(2) Class III biological safety cabinets were certified before personnel initiated the current operation.
(3) All infected animals are housed in class III cabinet containment caging systems.

Appendix C
Biosafety Level 3 and Biosafety Level 4 Facility Commissioning Criteria

C–1. Commissioning requirements

Prior to initial use, BSL–3 and BSL–4 laboratories are required to be validated for safe operation through a commissioning survey.

a. The National Institutes of Health Biosafety Level 3 Laboratory Certification Requirements and the following requirements will be used as criteria in commissioning BSL–3 and BSL–4 laboratories.

b. The criteria in table C–1 are segregated by method of primary control: laboratory siting; laboratory containment perimeter; air handling; decontamination, sterilization, and waste disposal systems; safety and health equipment utilities; and performance, verification, and testing. Compliance with all criteria in table C–1, as well National Institutes of Health Biosafety Level 3 Laboratory Certification Requirements for BSL–3 laboratories, is required for successfully complete the commissioning survey.

c. Organizations conducting commissioning surveys of BSL-3 and BSL-4 laboratories will have subject matter expertise (in-house or contracted) experienced in conducting commissioning surveys at the same, or higher, BSL of the laboratory to be commissioned and able to validate the design, construction, and operation of engineering and safety and occupational health controls outlined in table C-2. They will also have access to the materials and equipment necessary to review, test, and validate the engineering and safety controls outlined in table C-2.

Table C–1
Biosafety Level 3 and Biosafety Level 4 Facility Commissioning Criteria

BSL		Requirement
3	**4**	**Laboratory Siting**
O	X	Containment labs located away from outside building envelope walls
O	X	Containment labs located adjacent to or nearby mechanical rooms to minimize lengths of containment ducts
X	X	Office areas must be outside laboratory containment zone
3	**4**	**Laboratory Containment Perimeter**
O	X	Walls are reinforced structural masonry, reinforced non-load-bearing masonry, steel frame reinforced non-load-bearing masonry, or reinforced concrete
O	X	Entrance doors to be interlocked with manual overrides
3	**4**	**Air Handling**
O	X	Room air supply independent from adjoining laboratory zones
O	X	Room air supply HEPA-filtered or provided with bubble tight dampers
3	**4**	**Decontamination, Sterilization, and Waste Disposal Systems**
O	X	Provide refrigerated space for lockable, closed storage for biomedical waste which will be disposed of off site
3	**4**	**Safety and Health Equipment**
O	X	Eye/face wash facilities equipped with in-use audio/visual alarm (not applicable for positive pressure suit mode)
O	X	Clothing change area adjacent to containment area (0.5 m^2 per person)
O	X	Provide storage space for laboratory clothing in lab or adjacent change area (minimum 300 linear mm for each peg)
3	**4**	**Utilities**
	X	Equipped with bottled backup breathing air sufficient to provide 30 minutes per person
O	X	Equipped with positive-pressure hood respirators with compressed breathing air cylinders located in support area
3	**4**	**Performance, Verification, and Testing**
X		Construction of laboratory perimeter to be leak proof and able to withstand loading characteristics imposed by negative air pressure required in laboratory operation; integrity of seals demonstrated by visual inspection
	X	Construction of laboratory perimeter to be leak proof and able to withstand loading characteristics imposed by negative air pressure required in laboratory operation; integrity of room tightness demonstrated by physical testing (pressure decay 0.05 water gage (wg) loss/min) at 2" wg
O	X	All air supply and exhaust ductwork tested in situ to be leak tight by pressure decay: BSL 3 not > 0.2% duct vol/min at 2" wg (500 Pa); BSL 4 not > 0.1% duct vol/min at 2" wg (500 Pa)
X	X	All air supply and exhaust duct work verified to have back-draft protection
X	X	All HEPA filters tested to meet required specification after installation
O	X	All HEPA filter housings tested to be leak tight: not > 0.2% of vol/min at 10" wg (2500 Pa) and located outside of containment
X	X	Testing of BSCs meets required specifications after installation. All BSC must be equipped with a monitoring gauge
X	X	HEPA filters must be tested as installed and be accessible to facilitate decontamination
X	X	Testing of autoclaves to meet specified standards after installation by the use of 9ontaminatioc4uf located in

Table C–1
Biosafety Level 3 and Biosafety Level 4 Facility Commissioning Criteria—Continued

BSL		Requirement
X	X	Verification of fire alarm systems
O	X	Verification of communication systems between containment area and outside support areas
X	X	Testing of directional airflow demonstrated by field tests with visual smoke: verify elimination of "dead" zones within the laboratory
	X	Verification of integrity positive pressure suits
	X	Testing of breathing air as per CSA Standard Z180.1–M85
	X	Testing of regular and emergency air system
O	X	Ventilation, electrical, compressed gas cylinders, plumbing, and so forth are accessible from outside of the containment lab
X	X	Verification of operation of backflow preventers on air, gas, and water supply lines

Legend for Table C-1:
X - mandatory
O - optional

Table C–2
Microbiological Laboratory Engineering and Safety and Occupational Health Controls

Mechanical Engineering Controls
Construction of mechanical systems satisfies design intent
Design, construction, and operation of containment ducts meet requirements
Design, construction, and operation of room air supply/exhaust/filtration meet requirements; includes performance testing of air supply, exhaust, and filtration
Design, construction, and operation of breathing air supply systems meet requirements; includes testing of breathing air (BSL–4)
Design, construction, and operation of backflow preventers on air, gas, and water supply lines meet requirements
HVAC design parameters by performing HVAC system failure test
Condition of HVAC equipment through visual inspection
Operation of HVAC equipment within design parameters through testing
Proper operation of supply/exhaust interlock through testing
Proper placement of BSCs with respect to doors, traffic patterns, supply diffusers, and exhaust vents to minimize BSC airflow disturbance
Electrical Engineering Controls
Construction of electrical systems satisfies design intent
Electrical design parameters by performing electrical system failure test
A/E Controls
Design and construction of floors, walls, and ceilings meet requirements
Design, construction, and operation of doors, door interlocks, and automatic closers meet requirements; includes performance testing
Design and construction of laboratory perimeter meets requirements; includes pressure decay testing for ABSL–3 and BSL–4
Design, construction, and operation of alarm and fire detection systems meet requirements; includes performance testing
Design, construction, and operation of backup generators meet requirements; includes performance testing
Design, construction, and operation of communication systems meet requirements
Design, construction, and operation of emergency systems meet requirements
Safety and Occupational Health Controls
Biomedical waste storage meets requirements
Safety/health/emergency equipment meet requirements; includes performance testing
BSL–4 suit labs meet PPE and breathing air supply requirements; includes functionality check

Table C–2
Microbiological Laboratory Engineering and Safety and Occupational Health Controls—Continued

BSCs and fume hoods are certified and meet requirements

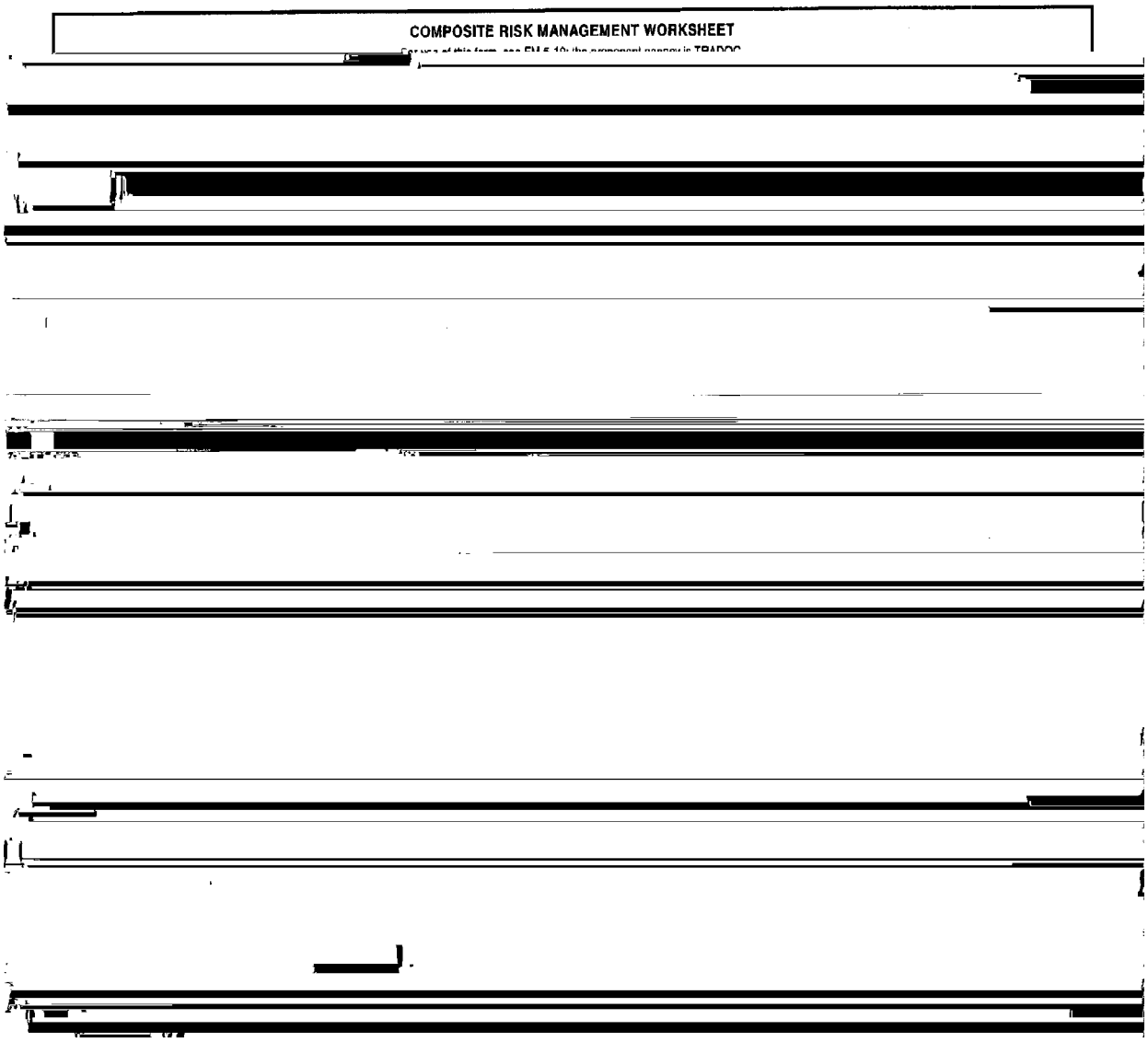

Figure D–1. Sample of Composite Risk Management Worksheet

Glossary

Section I
Abbreviations

ABSL
animal biosafety level

ADSO
additional duty safety officer

AMEDD
Army Medical Department

ANSI
American National Standards Institute

APHIS
Animal and Plant Health Inspection Service

AR
Army regulation

ASHRAE
American Society of Heating, Refrigerating, and Air Condition Engineers, Inc.

BMBL
Biosafety in Microbiological and Biomedical Laboratories

BSAT
biological select agents and toxins

BSC
biosafety cabinet

BSE
bovine spongiform encephalopathy

BSL
biosafety level

C
Celsius

CDC
Centers for Disease Control and Prevention

CDSO
collateral duty safety officer

CFR
Code of Federal Regulations

CJD
Cretuzfeldt-Jakob disease

CMA
competent medical authority

DA
Department of Army

RSO
radiation safety officer

SDS
safety data sheet

SIP
Special Immunization Program

SOP
standing operating procedures

UV
ultraviolet

vCJD
variant Cretuzfeldt-Jakob disease

wg
water gage

Section II
Terms

Aerosol
Particles of respirable size generated by both humans and environmental sources and that have the capability of remaining viable and airborne for extended periods in the indoor environment.

Airborne transmission
A means of spreading infection when airborne droplet nuclei (small particle residue of evaporated droplets <5 μm in size containing microorganisms that remain suspended in air for long periods of time) are inhaled by the susceptible host.

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

Biological mishap
A biological mishap is an event in which the failure of laboratory facilities, equipment, or procedures appropriate to the level of potential pathogenicity or toxicity of a given etiologic agent (organism or toxin) may allow the unintentional, potential exposure of humans or the laboratory environment to that agent.

Biomedical research/activity
The application of biological science in medical research, development, testing, and evaluation for the purpose of illness prevention and product development.

Biosafety level 2 (BSL–2)
Practices, equipment, and facility design and construction applicable to clinical, diagnostic, or teaching laboratories, in which work is being done with indigenous moderate risk agents that are present in the community and associated with human disease of varying severity. Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials. See BMBL (latest edition) for complete definition.

Biosafety level 3 (BSL–3)
Practices, equipment, and facility design and construction applicable to clinical, diagnostic, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission and which may cause serious or potential lethal infection. Primary hazards to personnel working with these agents relate to autoinoculation, ingestion, and exposure to infectious aerosols. See BMBL (latest edition) for complete definition.

Biosafety level 4 (BSL–4)
Practices, equipment, and facility design and construction applicable for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. The primary hazards are respiratory exposure to infectious aerosols, mucous membrane or broken skin exposure to infectious droplets, and autoinoculation. See BMBL (latest edition) for complete definition.

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

Cleaning
The removal of visible soil and organic contamination from a device or surface, using either the physical action of scrubbing with a surfactant or detergent and water, or an energy-based process (for example, ultrasonic cleaners) with appropriate chemical agents.

Competent
By way of training, experience, education, licensing, and/or certification (as appropriate), is knowledgeable of applicable principles, practices, and standards, is capable of identifying risks and hazards relating to the activity, is designated by the employer, and has authority to take appropriate actions.

Competent medical authority (CMA)
A physician, physician assistant, or nurse practitioner (military, civilian, or contractor) employed by or under contract or subcontract to the U.S. Government or a U.S. Government contractor. A CMA is someone who has been awarded clinical privileges for independent practice granted by the health care facility responsible for the provider's place of duty OR if not privileged for independent practice (for example, a physician assistant or nurse practitioner), then is

Infectious agents and toxins (IAT)
Fungi, virus, bacteria, prions, rickettsia, parasites, or a viable microorganism, or its toxin, or a prion that lacks nucleic acids, that causes or may cause disease, includes clinical cultures.

Institute director or commander
The institute director or commander of an Army activity conducting RDT&E, or sampling and analysis with IAT, or the equivalent at a research organization under contract to the biological defense program.

Institution
An organization such as an Army RDTE activity (institute, agency, center, and so forth) or a contract organization such as a school of medicine, or research institute that conducts RDT&E, or sampling and analysis with IAT.

Intermediate-level disinfection
A disinfection process that inactivates vegetative bacteria, most fungi, mycobacteria, and most viruses (particularly the enveloped viruses), but does not inactivate bacterial spores.

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

Large-scale operations
Research or production involving viable IAT in quantities greater than 10 liters of culture.

Low-level disinfection
A disinfection process that will inactivate most vegetative bacteria, some fungi, and some viruses, but cannot be relied upon to inactivate resistant microorganisms (for example, mycobacteria or bacterial spores).

Maximum containment laboratory or suite
A laboratory or suite that meets the requirements for a BSL–4 facility. The area may be an entire building or a single room within the building.

Microbiology
The science and study of microorganisms, including protozoans, algae, fungi, bacteria, viruses, and prions.

Negative pressure
Air pressure differential between two adjacent airspaces such that air flow is directed into the room relative to the corridor ventilation (for example, room air is prevented from flowing out of the room and into adjacent areas).

Positive pressure
Air pressure differential between two adjacent air spaces such that air flow is directed from the room relative to the corridor ventilation (for example, air from corridors and adjacent areas is prevented from entering the room).

Prion
Proteinaceous infectious particle. Considered to consist of protein only, and the abnormal isoform of this protein is thought to be the causative agent in transmissible spongiform encephalopathies that causes diseases such as Creutzfeldt-Jakob disease (CJD), kuru, scrapie, bovine spongiform encephalopathy (BSE), and the human version of BSE which is variant CJD (vCJD).

Qualified Safety and Health Personnel
Civilian personnel who meet Office of Personnel Management standards for Safety and Occupational Health Manager/Specialist GS–018, Safety Engineering Technician GS–802, Safety Engineer GS–803, Safety Technician GS–019, Aviation Safety Officer GS–1825, Air Safety Investigating Officer GS–1815, Fire Protection Engineer GS–804, Fire Protection Specialist/Marshall GS–081, Medical Officer GS–602, Health Physicist GS–1306, Industrial Hygienist GS–690, Occupational Health Nurse GS–610, Environmental Health Technician GS–699, and military personnel equally qualified when compared to the above OPM standards. In addition, in order to be considered safety and occupational health qualified for microbiological and biomedical safety, the individual must demonstrate they have attended and successfully completed microbiological and laboratory courses of instruction as approved by the ODASAF.

Resource Conservation Recovery Act of 1976 Listed Hazardous Waste
The waste materials listed by the Environmental Protection Agency under authority of the Resource Conservation Recovery Act for which the agency regulates disposal. A description and listing of these wastes is located in 40 CFR Part 261.

Risk assessment
An assessment of the probability that harm, injury, or disease will occur. In the context of the microbiological and biomedical laboratories, risk assessment focuses primarily on the prevention of laboratory-associated infections. Risk assessment is used to assign the BSLs (facilities, equipment, and practices) that reduce the workers' and the environment's risk of exposure to an agent to an absolute minimum.

Sterilization
The use of a physical or chemical procedure to destroy all microbial life, including large numbers of highly resistant bacterial endospores.

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

Vegetative bacteria
Bacteria that are actively growing and metabolizing, as opposed to a bacterial state of quiescence that is achieved when certain bacteria (gram-positive bacilli) convert to spores when the environment can no longer support active growth.

Section III
Special Abbreviations and Terms
There are no special abbreviations or terms.