Department of Defense

MANUAL

NUMBER 6055.18-M
May 11, 2010
Incorporating Change 2 July 16, 2019

USD(P&R)

SUBJECT: Safety Standards for Microbiological and Biomedical Laboratories

References: See Enclosure 1

1. PURPOSE. In accordance with the authority in DoD Directive (DoDD) 5134.01 (Reference (a)) and the guidance in DoDD 4715.1E (Reference (b)) and DoD Instruction (DoDI) 6055.1 (Reference (c)), this Manual prescribes the technical safety requirements for the Department of Defense to use, handle, transport, transfer, store, or dispose of infectious agents and toxins (IAT):

a. Rated at biosafety level 2 (BSL-2) and above.

b. Used in microbiological activities in biomedical and biological research settings, microbiology teaching laboratories, and veterinary reference laboratories.

2. APPLICABILITY. This Manual applies to:

a. OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").

b. All DoD biomedical and biological research settings, microbiology teaching laboratories, veterinary reference laboratories, and nonclinical facilities that use, handle, transport, transfer, store, or dispose of IAT.

c. Deployable, semi-permanent, or permanent laboratories deployed in support of a geographic Combatant Command for the analysis and surveillance of IAT that use, handle, transport, transfer, store, or dispose of IAT.

3. DEFINITIONS. See Glossary.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosures 3 through 12.

6. RELEASABILITY. Cleared for public release. This Manual is available on the Directives Division Website at https://www.esd.whs.mil/dd/.

7. SUMMARY OF CHANGE 2. This change reassigns the office of primary responsibility for this Manual to the Under Secretary of Defense for Personnel and Readiness in accordance with the April 10, 2019 Deputy Secretary of Defense Memorandum (Reference (am)) and administratively updates the releasability information.

7. EFFECTIVE DATE. This Manual is effective immediately.

Ashton B. Carter
Under Secretary of Defense
for Acquisition, Technology and Logistics

Enclosures

1. References
2. Responsibilities
3. Principles of Biosafety
4. Biological Safety Program
5. Occupational Health Program
6. Facility Safety Controls
7. Safety Equipment
8. Biosafety Practices
9. PPE
10. Transportation and Transfer of IAT and BSAT
11. Decontamination and Disposal
12. Emergency Planning and Response

Glossary

TABLE OF CONTENTS

TABLES

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5134.01, "Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L))," December 9, 2005
(b) DoD Directive 4715.1E, "Environment, Safety, and Occupational Health (ESOH)," March 19, 2005
(c) DoD Instruction 6055.1, "DoD Safety and Occupational Health (SOH) Program," August 19, 1998
(d) Centers for Disease Control and Prevention, "Biosafety in Microbiological and Biomedical Laboratories (BMBL)," current edition
(e) DoD Directive 5105.02, "Deputy Secretary of Defense," February 18, 2009
(f) DoD Instruction 6055.05, "Occupational and Environmental Health (OEH)," November 11, 2008
(g) DoD Instruction 5200.08, "Security of DoD Installations and Resources," December 10, 2005
(h) DoD 5200.08-R, "Physical Security Program," April 9, 2007
(i) Appendix B to subpart I of part 1910 and sections 1910.134, 1910.151, 1910.1030, 1910.1200, and 1910.1450 of title 29, Code of Federal Regulations
(j) Section 73 of title 42, Code of Federal Regulations
(k) Part 331 of title 7, Code of Federal Regulations
(l) Parts 1, 2, 3, and 121 of title 9, Code of Federal Regulations
(m) DoD Instruction 6055.07, "Accident Investigation, Reporting, and Record Keeping," October 3, 2000
(n) National Institutes of Health, "NIH Guidelines for Research Involving Recombinant DNA Molecules," current edition
(o) Federal Acquisition Regulation, subparts 1.3, "Agency Acquisition Regulations," and 1.4, "Deviations from the FAR," current edition
(p) Defense Federal Acquisition Regulation Supplement, subparts 201.3, "Agency Acquisition Regulations," and 201.4, "Deviations from the FAR," current edition
(q) National Institutes of Health, "Biosafety Level 3-Laboratory Certification Requirements," current edition
(r) Centers for Disease Control and Prevention, "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," December 1, 2006
(s) National Archives and Records Administration, "General Records Schedules," as amended[1]
(t) DoD 6055.05-M, "Occupational Medical Examinations and Surveillance Manual," May 2, 2007
(u) National Sanitation Foundation/American National Standards Institute Standard 49, "Class II (Laminar Flow) Biosafety Cabinetry," current edition[2]
(v) U.S. Department of Health and Human Services, "Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets," current edition

[1] Available at http://www.archives.gov/records-mgmt/grs
[2] Available for purchase at http://webstore.ansi.org

(w) American National Standards Institute/American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 110-1995, "Method of Testing Performance of Laboratory Fume Hoods," current edition[2]
(x) American Conference of Governmental Industrial Hygienists, "2009 TLVs and BEIs"[3]
(y) National Research Council, "Guide for the Care and Use of Laboratory Animals," current edition
(z) DoD Instruction 6050.05, "DoD Hazard Communication (HAZCOM) Program," August 15, 2006
(aa) American National Standards Institute Standard Z358.1, "Emergency Eyewash and Shower Equipment," current edition[4]
(ab) Part 20 of title 10, Code of Federal Regulations
(ac) Part 261 of title 40, Code of Federal Regulations, as amended (also known as "The Resource Conservation and Recovery Act (RCRA) of 1976, as amended")
(ad) National Research Council, "Occupational Health and Safety in the Care of Research Animals," 1997
(ae) American Committee on Arthropod-Borne Viruses, "Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates," published in the "American Journal of Tropical Medicine and Hygiene," Volume 29(6), pages 1359-1381[5]
(af) American Society of Heating, Refrigeration, and Air-Conditioning Engineers Standard 62, "Ventilation for Acceptable Indoor Air Quality," current edition[6]
(ag) American Society of Safety Engineers/American National Standards Institute Standard Z87.1, "Occupational and Educational Personal Eye and Face Protection Devices," current edition[7]
(ah) Title 49, Code of Federal Regulations
(ai) International Civil Aviation Organization, "Technical Instructions for the Safe Transport of Dangerous Goods by Air," current edition[8]
(aj) International Air Transport Association, "Dangerous Goods Regulations," 51st edition[9]
(ak) Chapter 204 of the Defense Transportation Regulations 4500.9-R-Part II, "Cargo Movement," as amended
(al) DoD Instruction 6055.17, "DoD Installation Emergency Management (IEM) Program," January 13, 2009
(am) Deputy Secretary of Defense Memorandum, "Safety and Occupational Health Policy and Oversight Functions," April 10, 2019

[3] Available for purchase at http://www.acgih.org/store/ProductDetail.cfm?id=2039
[4] Available for purchase at http://www.constructionbook.com/ansi-z3581-2004-american-national-standard-for-emergency-eyewash-shower-equipment/ansi/
[5] Available for purchase at http://www.ajtmh.org/cgi/reprint/29/6/1359
[6] Available for purchase at http://www.ashrae.org/publications/page/1285
[7] Available for purchase at http://engineers.ihs.com/document/abstract/VOCGDBAAAAAAAAAA
[8] Available at http://www.icao.int/icaonet/dcs/9284.html
[9] Available for purchase at http://www.iata.org/ps/publications/dgr/Pages/index.aspx

ENCLOSURE 2

RESPONSIBILITIES

1. UNDER SECRETARY OF DEFENSE FOR ACQUISITION, TECHNOLOGY, AND LOGISTICS (USD(AT&L)). The USD(AT&L) shall:

a. Oversee implementation of this Manual.

b. Develop and update biological safety program policy to continuously improve biological safety and health matters.

2. DEPUTY UNDER SECRETARY OF DEFENSE FOR INSTALLATIONS AND ENVIRONMENT (DUSD(I&E)). The DUSD(I&E), under the authority, direction, and control of the USD(AT&L), shall:

a. Monitor the effectiveness of this Manual though annual program reviews and data calls.

b. Represent the Secretary of Defense on biological safety and health matters.

3. HEADS OF THE DoD COMPONENTS. The Heads of the DoD Components conducting microbiological activities at BSL-2 and above in biomedical and biological research settings, microbiology teaching laboratories, veterinary reference laboratories, and deployable labs that use, handle, transport, transfer, store, or dispose of IAT shall:

a. Implement the procedures in this Manual by establishing and maintaining a biological safety program as part of the safety and occupational health (SOH) program.

b. Comply with host-nation requirements for review, approval, certification, incident reporting, and compliance requirements. Such compliance guidance may be either national or international.

ENCLOSURE 3

PRINCIPLES OF BIOSAFETY

1. GENERAL. Structured biological safety programs, mishap risk management, biological risk assessments to determine BSLs, and safety controls protect employees and members of the public from the hazards associated with IAT from microbiological activities.

2. BIOLOGICAL SAFETY PROGRAM

a. Each DoD Component conducting microbiological activities at BSL-2 and above in biomedical and biological research settings, microbiology teaching laboratories, veterinary reference laboratories, and deployable labs that use, handle, transport, transfer, store, or dispose of IAT shall include a biological safety section in their written SOH program that:

(1) Prescribes responsibilities and procedures for program implementation.

(2) Includes a biological occupational health program with the capabilities and activities necessary to identify, assess, and control disease and injury risks to personnel from exposures to IAT encountered due to their occupation.

(3) Includes location-specific emergency response procedures.

b. When the DoD Component conducting microbiological activities is a tenant on an installation, that Component shall coordinate its biological SOH program with the installation commander.

3. MISHAP RISK MANAGEMENT. The mishap risk management process shall:

a. Identify and assess hazards.

b. Determine the risk.

c. Develop, evaluate, and select controls.

d. Make risk decisions.

e. Implement and manage those decisions to improve operational effectiveness and conserve resources.

f. Provide recommendations on whether to accept or resolve potential consequences of hazards associated with a given activity.

4. BIOLOGICAL RISK ASSESSMENT AND DETERMINATION OF BSL. Biological risk assessment (as opposed to risk assessment in general) shall be conducted to determine the BSL for handling a particular IAT. Procedures for defining the BSL are contained in the Centers for Disease Control and Prevention (CDC) publication (Reference (d)). 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:

a. Infectivity.

b. Severity of disease.

c. Availability of preventive measures and effective treatments for the disease.

d. Transmissibility.

e. Nature of the work being conducted.

f. Origin of the agent (whether indigenous or exotic).

5. SAFETY CONTROLS. Safety controls shall be as recommended or required by Reference (d) and shall:

a. Be identified in the risk management process and prescribed in statutory and regulatory requirements.

b. Be documented in the DoD Component safety program, the laboratory specific biosafety manual, standing operating procedures (SOPs), etc.

c. Include:

(1) Facility safety controls (e.g., directional airflow, emergency back-up power, continuity of seal between the floor and wall).

(2) Safety equipment (e.g., biological safety cabinets (BSCs), glove boxes, laboratory chemical hoods).

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

(4) Personal protective equipment (PPE).

(5) Access control and rosters.

(6) Signage, labeling of containers, and safety communications.

(7) Medical surveillance and immunizations.

(8) Disinfection and sterilization.

(9) Hazardous biological waste handling, decontamination, packaging, and disposal.

(10) Emergency procedures.

ENCLOSURE 4

BIOLOGICAL SAFETY PROGRAM

1. GENERAL. The DoD Components conducting microbiological activities at BSL-2 and above in biomedical and biological research settings, microbiology teaching laboratories, veterinary reference laboratories, and deployable labs that use, handle, transport, transfer, store, or dispose of IAT will develop and implement a biological safety program to address:

a. Program policy and goals.

b. Program responsibilities.

c. Composition and conduct of biological safety committees.

d. Requirements and procedures for risk assessments and selection of appropriate BSL.

e. Requirements and procedures for SOPs.

f. Occupational health requirements and procedures.

g. Facility design and commissioning.

h. Access control.

i. Engineering controls and safety equipment (selection, use, training, testing, and maintenance).

j. Biosafety practices.

k. PPE (selection, use, training, testing, and maintenance).

l. Labeling and posting of hazards.

m. Chemical hygiene plan.

n. Personnel qualifications and training.

o. Safety information.

p. Inspections.

q. Facility, utilities, and equipment continuing maintenance plan.

r. Pest management.

s. Transportation and transfer of IAT.

t. Decontamination and disposal of IAT.

u. Emergency planning and response.

v. Mishap investigation and reporting.

w. Select agent registration, if applicable.

x. Recombinant deoxyribonucleic acid (DNA), if applicable.

y. Radiation safety, if applicable.

z. Animal safety, if applicable.

aa. Contract activities, if applicable.

2. BIOLOGICAL SAFETY COMMITTEE

a. Organizations that use, handle, transport, transfer, store, or dispose of IAT will establish and charter a biological safety committee or similar committee consisting of representatives of occupational health, industrial hygiene, facility maintenance, safety, and the employees. Members of said committees shall be DoD contractors or full-time or permanent part-time Federal employees.

b. At a minimum, the committee will review results of compliance inspections.

c. The biological safety committee will meet at least quarterly. Minutes shall be prepared and staffed through the commanding officer or institute director, available for review, and maintained according to DoDD 5105.02 (Reference (e)).

3. BIOSAFETY OFFICER

a. Organizations that use, handle, transport, transfer, store, or dispose of IAT will designate a biosafety officer. Biosafety officers will be trained and qualified as specified in paragraph 8.a. of this enclosure.

b. Biosafety officers will serve as biosafety subject matter experts and provide and support risk assessments, risk management, biosafety controls, biological safety program management, SOPs, biosafety training, inspections, mishap notification, investigation and reporting, and emergency planning and response.

4. RISK ASSESSMENT AND MANAGEMENT

a. A risk assessment shall be conducted for every microbiological and biomedical laboratory activity and activity involving IAT. In assessing and managing risk, the activity will be broken down into subtasks. 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 shall be identified. Facilities conducting IAT activities shall use Service-specific risk management worksheets and document risk assessments pursuant to Service-specific requirements.

b. Facilities conducting IAT activities shall perform and document a risk assessment for any deviation from a required or recommended procedure or safeguard.

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

d. The general approach to risk assessment and management is provided in DoDI 6055.05 (Reference (f)).

5. SOPs

a. An SOP will be established for each laboratory activity or activity involving IAT. A copy of the SOP will be maintained or made available electronically in each work area where the activity is conducted. SOPs will address:

(1) Any unique procedures and requirements needed that are not described as universally required in the biological safety program (e.g., 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 biological safety program.

(3) Emergency procedures.

b. SOPs will be periodically reviewed and revised as needed. The review cycle will be based on the complexity and hazards of the process but will not exceed 12 months for any SOP.

c. SOPs will:

(1) Limit personnel to the minimum number of appropriately qualified and trained personnel to engage in the activity. The number of appropriately qualified and trained personnel will be determined by the supervisor and the SOP approval official. Limit the period of time to

the shortest, and the amount of material to the minimum, that is consistent with program objectives and safe operations.

(2) Maximize use of engineering and administrative controls to preclude or minimize the need for PPE.

d. Personnel with specialized knowledge (e.g., safety, occupational health, industrial hygiene, environmental protection regulatory compliance, logistics, quality assurance, fire and emergency services, engineering, and host-nation agreements and requirements) will review SOPs for accuracy, compliance with standards and regulations, and conformity with accepted practices, and will provide concurrence with the SOP prior to it being signed by the approving authority.

e. SOPs will include:

(1) A cover sheet with:

(a) Activity name.

(b) Name of process.

(c) Unique SOP number.

(d) Date of SOP.

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

(f) Signatures and office titles of individuals responsible for reviewing and concurring with SOP (e.g., safety, emergency services, engineering).

(g) Name and title of approving authority and date of approval.

(2) A signature page or pages with signatures of:

(a) Supervisors or persons-in-charge indicating they have read the SOP and associated risk assessment, understand operations involved in the task, have verified that operators (and will ensure that new operators) are trained and understand the SOP, and that the task can be executed in a safe and efficient manner.

(b) Operator(s) to attest to the fact that they have read or have had read to them and understand the SOP and the associated risk assessment.

(c) All personnel affected by the activity indicating they have read the SOP, understand operations involved in the task, have verified that operators are trained and understand the SOP, and that the task can be executed in a safe and efficient manner when:

1. First assigned to supervise the task.

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

3. A change is made to the SOP.

4. Following periodic reviews and updates as described in paragraph 5.b. of this enclosure.

f. An index of all approved SOPs will be made available. The index will contain:

(1) SOP number and title.

(2) Name of office submitting the SOP.

(3) Date of approval.

(4) Next review date.

6. FACILITY DESIGN AND COMMISSIONING. Prior to initial use, BSL-3 and BSL-4 laboratories shall be validated for safe operation through a commissioning survey. Host-nation agencies shall be notified prior to a laboratory commissioning and, where appropriate and feasible, shall be involved in the commissioning survey. Facility design and commissioning survey criteria are contained in Appendix 1 of this enclosure. Organizations conducting commissioning surveys shall:

a. Have the architectural, mechanical, electrical, and civil engineering and safety and occupational health subject matter expertise (in-house or contracted) necessary to assess the criteria in Appendix 1.

b. Be experienced in conducting commissioning surveys at the same, or higher, BSL of the laboratory to be commissioned.

c. Have access to the materials and equipment necessary to conduct the review, testing, and validation.

7. ACCESS CONTROL

a. Access to areas defined as BSL-2 and higher where work with IAT is present will be limited in accordance with DoD Component policies. Only persons who have been advised of the potential hazard and meet specific entry requirements (e.g., approval of principle investigator or supervisor, required PPE, training, medical screening, security clearance) may enter the individual laboratory or animal rooms. The laboratory supervisor will enforce institutional

policies that control access to the laboratory per the approved access roster. (See DoDI 5200.08 and DoD 5200.08-R (References (g) and (h)).)

b. Access to areas defined as BSL-3 will be limited in accordance with paragraph 7.a. of this enclosure, and will be restricted to those persons whose presence in the facility or individual laboratory rooms is required for program or support purposes. All personnel must don prescribed PPE prior to entry, and must strictly adhere to all prescribed procedures to contain microbiological hazards prior to exiting for the BSL-3 facility. Doors leading to BSL-3 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 will be limited as stated in paragraphs 7.a. and 7.b. of this enclosure. This will be done with secure, locked doors with access controlled by the commanding officer 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. Prescribed PPE shall be donned prior to entry and all shower, vacuum, and microbiological sterilization procedures will be strictly adhered to prior to exit from the BSL-4 facility. A record will be maintained of all personnel indicating the date and time of each entry and exit.

8. PERSONNEL QUALIFICATIONS AND TRAINING

a. Biosafety officers shall have these qualifications:

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

(2) One year of laboratory experience at equivalent BSL or animal biosafety level (ABSL).

(3) Four-day DoD Component-approved biosafety course (commercially available).

(4) Four- to eight-hour DoD biosafety requirements course.

(5) Training in DoD Component safety policy and standards and risk management.

b. Supervisors overseeing the labs shall:

(1) Understand IAT operations and safety policy and standards for microbiological and biomedical activities.

(2) Ensure that employees have been trained to safely execute the IAT operations.

(3) Ensure safety equipment and controls are available, safe, functioning, inspected, tested, and maintained.

(4) Ensure that personnel entering a microbiological laboratory or biomedical research laboratory meet applicable access control, medical, and SOH training requirements.

c. Personnel working with IAT shall, prior to performing assigned duties, be aware of the associated hazards, receive training and annual update training that adequately prepares them for their assigned duties, and be proficient in microbiological practices and procedures. This training will be developed in coordination with the safety office and documented to include the date of the training session, the contents or a summary of the training, and the 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, and the potential acute and chronic health effects and signs and symptoms associated with the IAT to which workers are potentially exposed.

(4) Facility safety controls.

(5) Selection and use of safety equipment (e.g., BSCs, glove boxes, laboratory chemical hoods).

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

(7) Bloodborne pathogens (pursuant to section 1910.1030 of title 29, Code of Federal Regulations (CFR) (Reference (i))); hazard communication (pursuant to section 1910.1200 of Reference (i)); and occupational exposure to hazardous chemicals in laboratories (pursuant to section 1910.1450 of Reference (i)).

(8) Selection and use of PPE (pursuant to appendix B to subpart I of part 1910 of Reference (i)).

(9) Access control.

(10) Facility signage, labeling of containers, and safety communications.

(11) The purpose and description of the occupational health program, including specific medical surveillance and immunization requirements associated with the IAT to which workers are potentially exposed.

(12) Hazardous biological waste handling, decontamination, packaging, disposal, and approaches to minimizing the volume of waste.

(13) Disinfection and sterilization.

(14) Emergency procedures.

(15) Reporting mishaps.

(16) Inspection requirements in accordance with paragraph 10 of this enclosure.

(17) Transportation (packaging and shipment) and transfer of IAT, when applicable.

(18) Applicable host-nation requirements.

d. Training for all new employees working with IAT will include a period of supervised orientation in the facilities, as prescribed in the DoD Component biological safety program, by a scientist or technician with specific training in the procedures and properties of the IAT in use. During the training period, new laboratory personnel will be under the supervision of appropriately trained personnel.

e. Biosafety personnel working with biological select agents and toxins (BSAT) will comply with the refresher training requirement of section 73.15 of title 42, CFR (Reference (j)).

9. SAFETY INFORMATION. A system of communication shall be established to:

a. Provide information addressing useful biological safety advice and accounts of laboratory mishaps, along with the lessons to be learned from them.

b. Ensure reference books and regulations concerning laboratory hazards, occupational health, containment, and proper laboratory practices (see paragraph 5.a. of this enclosure) are readily available. It is not, however, necessary to maintain these in the laboratory work area.

c. Ensure that material safety data sheets (MSDS) for hazardous chemicals and IAT (when an MSDS is available for the IAT) used in the work area are readily available to employees in the work area. Each employee is trained in, and demonstrates the knowledge of, accessing these MSDS.

d. Ensure there is no hindrance to employee accessibility to MSDS or other appropriate health and safety references during their work shift. If MSDS are accessed electronically (e.g., computer on the Internet or CD-ROM), each employee is trained on a back-up access procedure in the event the electronic system is not available.

10. INSPECTIONS

a. Before performing an operation with IAT, operators will survey the work area. Operators will have a means to correct the deficiencies found or to report any unsafe conditions and have them corrected prior to beginning operations.

b. A laboratory safety point of contact trained and qualified in accordance with subparagraph 8.b.(4) and paragraph 8.c. of this enclosure will be designated for each laboratory room or suite and will:

(1) Be responsible for monitoring the availability, safety, functioning, inspection, testing, and maintenance of required laboratory safety controls and equipment. Logs will be posted on specific items (such as BSCs, chemical hoods, autoclaves, centrifuges, freezers, and refrigerators) and every day the laboratory is in use laboratory personnel will document checks to ensure proper operation and identify any malfunction or safety concern.

(2) Ensure that malfunctions of room or building systems are reported to the supervisor.

(3) Ensure that any malfunctioning laboratory safety controls or equipment or shortages in required equipment and supplies are reported to the appropriate individuals.

(4) Ensure that the laboratory room and/or safety controls and equipment are labeled to warn of any malfunctions and indicate that they should not be used until repaired and, as applicable, tested.

c. The laboratory supervisor (trained in accordance with paragraph 8.b. of this enclosure) or a designated individual (trained and qualified in accordance with subparagraph 8.b.(4) and paragraph 8.c. of this enclosure, typically the laboratory safety officer) shall conduct and document a monthly inspection of the laboratories.

d. The safety officer, biosafety officer, or qualified SOH personnel (see Glossary) designated by the commanding officer or institute director shall inspect all active BSL-2 and toxin laboratories at least semiannually, and BSL-3 and BSL-4 laboratories and those in which dry forms of toxins are handled at least quarterly. Host-nation representatives will be invited to participate in the inspections, as appropriate, and a representative of the facility's occupational health staff will participate in inspections at least annually. 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 semiannual or quarterly inspections can be an SOH inspection.

e. A qualified industrial hygienist (0690 job series) or military equivalent will conduct an industrial hygiene survey of research microbiology laboratories on an annual basis. The survey shall identify and document chemical, physical, biological, and ergonomic hazards. Industrial hygienists shall evaluate and assess the exposure risk for each identified hazard and recommend appropriate hazard controls.

f. Deficiencies or procedures that create a potentially life-threatening situation shall be immediately referred to supervisory personnel, the safety office, the commanding officer or institute director and, if the facility is a tenant on an installation, the installation commander. The operation will be stopped, and corrective actions immediately implemented, or the residual risk will be accepted at the appropriate level in accordance with DoD risk acceptance policy in Reference (c).

g. Reports of deficiencies for other than life-threatening situations shall 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 shall be notified.

11. MISHAP NOTIFICATION, INVESTIGATION, AND REPORTING

a. Commanders and directors will establish procedures to:

(1) Ensure initial notification, investigation, and reporting of a biological mishap are accomplished in accordance with the requirements of this Manual; Reference (j); part 331 of title 7, CFR (Reference (k)); part 121 of title 9, CFR (Reference (l)); and applicable State and local requirements.

(2) Investigate all biological mishaps for the purpose of accident prevention.

b. BSAT (including clinical, diagnostic, or proficiency test specimen) mishaps shall be reported as follows:

(1) In accordance with References (j) and (k) and part 121 of Reference (l), immediately notify the CDC or the Animal and Plant Health Inspection Service (APHIS) upon discovery of a release of a BSAT causing occupational exposure or occurring outside of the primary containment barriers of the biocontainment area (e.g., in BSCs, trunnion centrifuge cups, and aerosol-containing blenders). In accordance with host-nation laws and bilateral agreements, immediately notify the appropriate host-nation agencies. This requirement applies to clinical or diagnostic laboratories and other entities that possess, use, or transfer BSAT contained in a specimen presented for diagnosis, verification, or proficiency testing. Provide the CDC, APHIS, or host-nation agencies:

(a) Name of the BSAT and any identifying information (e.g., strain or other characterizing information).

(b) Estimate of the quantity released.

(c) Date, time, and duration of release.

(d) Environment into which the release occurred (e.g., in building or outside of building, waste system).

(e) Location (installation, activity, building, room) from which the release occurred or where the exposure occurred.

(f) Number of individuals potentially exposed at the entity.

(g) Brief description of what happened (e.g., spill, needle stick).

(h) Actions taken to respond to the release.

(i) Hazards posed by the release.

(2) Notify the appropriate State and local health agencies.

(3) Report all mishaps that were reported to the CDC or APHIS to the first flag officer (or equivalent) in the mishap reporting chain. If the facility is a tenant on an installation, also report the mishap to the installation commander. The first flag officer (or equivalent) receiving the report will forward it up the chain of command to the appropriate DoD Component safety office.

(4) In addition, submit serious incident reports on BSAT mishaps in accordance with applicable internal DoD Component guidance for:

(a) Discharge of BSAT external to the containment laboratory and into the ambient air or environment.

(b) Mishaps where 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) Submit a completed APHIS/CDC Form 3, "Report of Theft, Loss, or Release of Select Agents and Toxins," to the CDC or APHIS within 7 calendar days, with a copy forwarded through the first flag officer in the chain of command to the appropriate DoD Component safety office. An electronic version of this form is available at http://www.selectagents.gov/tlrForm.html.

(6) Submit a close-out report to the appropriate DoD Component safety office with a copy furnished through normal command channels after the mishap investigation is complete.

c. Non-BSAT (IAT not characterized as BSAT) shall be reported as follows:

(1) Upon discovery of a non-BSAT occupational exposure or release of a non-BSAT outside of the laboratory, immediately notify the first flag officer (or equivalent) in the mishap reporting chain. Include information in the reports required in subparagraph 11.b.(1) of this enclosure. If the facility is a tenant on an installation, also report the mishap to the installation commander. The first flag officer (or equivalent) receiving the report will forward it up the chain of command to the appropriate DoD Component safety office. The facility should notify

the appropriate State and local health agencies and, in accordance with host-nation laws and bilateral agreements, the appropriate host-nation agencies.

(2) After the mishap investigation is complete, submit a close-out report to the appropriate DoD Component safety office with a copy furnished through normal command channels.

d. Class A-D accidents occurring during biological activities shall be reported in accordance with DoDI 6055.07 (Reference (m)).

12. RECOMBINANT DNA

a. When work with recombinant DNA is undertaken, an institutional biosafety committee (IBC) is established to review recombinant DNA activities and protocols. The IBC functions as stated in National Institutes of Health (NIH) publication (Reference (n)).

b. Activities funded by NIH involving recombinant DNA will comply with all requirements of Reference (n) 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.

13. CONTRACT ACTIVITIES. Contracting officers will ensure that biological safety clauses are made contractually binding on all contractors required to possess or use DoD-provided infectious agents and toxins.

a. The contracting officer will designate a contracting officer's representative to monitor the contract.

b. At the conclusion of the contract, the contractor will manage the final disposition of the IAT in accordance with the plan specified in the contract.

c. Each DoD Component is responsible for development of the biological safety contract clauses. Such clauses will be promulgated in accordance with subparts 1.3 and 1.4 of the Federal Acquisition Regulation (FAR) (Reference (o)) and subparts 201.3 and 201.4 of the Defense FAR Supplement (Reference (p)).

d. The contracting officer will ensure that contract facilities handling DoD-supplied infectious agents and toxins are pre-inspected for compliance with biological safety clauses and this manual. BSL-3 and BSL-4 laboratories will be re-inspected on an annual basis.

Appendixes

1. BSL-3 and BSL-4 Facility Commissioning Criteria
2. Laboratory Safety Inspection Checklists

APPENDIX 1 TO ENCLOSURE 4

BSL-3 AND BSL-4 FACILITY COMMISSIONING CRITERIA

Use the NIH publication (Reference (q)) and the requirements in Table 1 as criteria for commissioning BSL-3 and BSL-4 laboratories.

Table 1. Commissioning Criteria for BSL-3 and BSL-4 Laboratories

BSL-3	BSL-4	REQUIREMENT
LABORATORY SITING		
Optional	Mandatory	Containment labs are located away from outside building envelope walls.
Optional	Mandatory	Containment labs are located adjacent to or nearby mechanical rooms to minimize lengths of containment ducts.
Mandatory	Mandatory	Office areas are outside laboratory containment zone.
LABORATORY CONTAINMENT PERIMETER		
Optional	Mandatory	Walls are reinforced structural masonry, reinforced non-load-bearing masonry, steel frame reinforced non-load-bearing masonry, or reinforced concrete.
Optional	Mandatory	Entrance doors are interlocked with manual overrides.
AIR HANDLING		
Optional	Mandatory	Room air supply is independent from adjoining laboratory zones.
Optional	Mandatory	Room air supply is high efficiency particulate air (HEPA)-filtered or provided with bubble-tight dampers.
DECONTAMINATION, STERILIZATION, AND WASTE DISPOSAL SYSTEMS		
Optional	Mandatory	Refrigerated space for lockable, closed storage for biomedical waste is provided and disposed of off site.
SAFETY AND HEALTH EQUIPMENT		
Optional	Mandatory	Eye- and face-washing facilities are equipped with in-use audio/visual alarm (not applicable for positive pressure suit mode).
Optional	Mandatory	Clothing change area is adjacent to containment area (0.5 square meters per person).
Optional	Mandatory	Storage space is provided for laboratory clothing in lab or adjacent change area (minimum 300 linear millimeters for each peg).
UTILITIES		
NA	Mandatory	Equipped with bottled back-up breathing air sufficient to provide 30 minutes per person.
Optional	Mandatory	Equipped with positive-pressure hood respirators with compressed breathing air cylinders located in support area.

Table 1. Commissioning Criteria for BSL-3 and BSL-4 Laboratories, Continued

BSL-3	BSL-4	REQUIREMENT
PERFORMANCE, VERIFICATION, AND TESTING		
Mandatory	NA	Seams, floors, walls, and ceiling surfaces are sealed (integrity of seals demonstrated by visual inspection) and spaces around door and ventilation opening are capable of being sealed to facilitate space decontamination. Construction of laboratory perimeter is able to withstand loading characteristics imposed by negative air pressure required in laboratory operation.
NA	Mandatory	Walls, floors, and ceilings of the laboratory are constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion. Floors are monolithic, sealed, and coved. All penetrations in the internal shell of the laboratory and inner change room (and suit room storage for suit laboratories) are sealed. For cabinet laboratories, openings around doors into the cabinet room and inner change room are minimized and capable of being sealed to facilitate decontamination. Construction of laboratory perimeter is 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 gauge (wg) loss/min) at 2" wg.
Optional	Mandatory	All air supply and exhaust ductwork tested in situ is leak-tight by pressure decay: BSL-3 not > 0.2% duct vol/min at 2" wg (500 Pascal (Pa)); BSL-4 not > 0.1% duct vol/min at 2" wg (500 Pa).
Mandatory	Mandatory	All air supply and exhaust ductwork is verified to have backdraft protection.
Mandatory	Mandatory	All HEPA filters are tested to meet required specification after installation.
Optional	Mandatory	All HEPA-filter housings are tested to be leak tight: not > 0.2% of vol/min at 10" wg (2500 Pa) and located outside of containment.
Mandatory	Mandatory	Testing of BSCs meets required specifications after installation. All BSCs are equipped with a monitoring gauge.
Mandatory	Mandatory	HEPA filters are tested as installed and are accessible to facilitate decontamination.
Mandatory	Mandatory	Autoclaves are tested to meet specified standards after installation by the use of biological indicators.
Mandatory	Mandatory	Fume hoods are tested according to Table 5 in Enclosure 7.
NA	Mandatory	Drainage and liquid-waste-disposal systems, including sampling ports, are tested to ensure efficacy by use of biological indicators.
NA	Mandatory	Integrity of sewage lines is verified; all waste is directed to a sewer.
Mandatory	Mandatory	Alarm systems for air systems failure (exhaust, supply, room pressure, breathing air) are verified.
Mandatory	Mandatory	Alarm systems are verified for electrical failure and back-up generators: back-up generators are required for essential equipment, including BSCs.
Mandatory	Mandatory	Fire alarm systems are verified.
Optional	Mandatory	Communication systems are verified between containment area and outside support areas.
Mandatory	Mandatory	Directional airflow is tested, demonstrated by field tests with visual smoke. Elimination of dead zones within laboratory is verified.
NA	Mandatory	Integrity of positive pressure suits is verified.

Table 1. Commissioning Criteria for BSL-3 and BSL-4 Laboratories, Continued

BSL-3	BSL-4	REQUIREMENT
NA	Mandatory	Breathing air is tested pursuant to section 1910.134 of Reference (i).
NA	Mandatory	Regular and emergency air systems are tested.
Optional	Mandatory	Ventilation, electrical, compressed gas cylinders, plumbing, etc., are accessible from outside of the containment lab.
Mandatory	Mandatory	Operation of backflow preventers on air, gas, and water supply lines is verified.

APPENDIX 2 TO ENCLOSURE 4

LABORATORY SAFETY INSPECTION CHECKLISTS

Tables 2 through 4, adopted from Reference (d), list items to consider when inspecting facilities where IAT are used. They provide basic guidelines on the specific requirements for biological laboratories at BSL-2, BSL-3, and BSL-4. The checklist for the BSL to be inspected, as well as those for lower BSLs, as applicable, will be used. When conducting a BSL-3 or BSL-4 laboratory inspection and using multiple checklists, in the event of multiple, similar requirements (e.g., Table 2 item 17 and Table 3 item 4), the more stringent will apply.

Table 2. BSL-2 Checklist

#	IAT LABORATORIES, BSL-2	YES	NO	NA	COMMENTS
1	Laboratory supervisor enforces institutional policies that control access to the laboratory.				
2	Personnel with access have been screened for or enrolled in an appropriate medical surveillance program.				
3	Personnel wash hands after working with potentially hazardous materials and before leaving the laboratory.				
4	Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not allowed in laboratory areas.				
5	Mouth pipetting is prohibited; mechanical pipetting devices are used.				
6	Sharps such as needles, scalpels, pipettes, and broken glassware are handled safely. Precautions taken include: needles are never bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; puncture-resistant containers are accessible for sharps disposal; broken glassware is not handled directly; and plastic-ware is substituted for glassware whenever possible.				
7	Work surfaces are decontaminated after completion of work and after any spill or splash of potentially hazardous material.				
8	Potentially infectious materials are decontaminated before disposal.				
9	Biohazard symbol is at the entrance to the laboratory with the laboratory's BSL, supervisor's name (or other responsible personnel), telephone numbers (office, cell, and home), and required procedures for entering and exiting the lab.				
10	All people who enter the laboratory are advised of potential hazards.				
11	A laboratory-specific biosafety manual is available and accessible both inside and outside of the lab.				
12	Potentially infectious materials are placed in a durable, leak-proof container during collection, handling, processing, storage, or transport within a facility.				

Table 2. BSL-2 Checklist, Continued

#	IAT LABORATORIES, BSL-2	YES	NO	N/A	COMMENTS
13	Laboratory equipment is routinely decontaminated, as well as after spills, splashes, or other potential contamination and before repair, maintenance, or removal from the laboratory.				
14	Animals and plants not associated with the work being performed are not permitted in the laboratory.				
15	Any procedure involving the manipulation of infectious materials that may generate an aerosol is conducted within a BSC or other physical containment device.				
16	PPE is worn when working with hazardous materials unless the risk assessment indicates it is not required. PPE is removed before leaving for non-laboratory areas.				
17	Eye, face, and respiratory protection is used in rooms containing infected animals unless the risk assessment indicates it is not required.				
18	Laboratory doors are self-closing and have locks in accordance with institutional policies.				
19	The laboratory has a sink for hand washing located near the exit door.				
20	The laboratory is designed so that it can be easily cleaned and decontaminated. There are no carpets or rugs.				
21	Laboratory furniture is capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.				
22	Bench tops are impervious to water and resistant to heat, solvents, acids, and other chemicals.				
23	Chairs used in laboratory work are covered with a nonporous material that can be easily decontaminated.				
24	Laboratory windows that open to the exterior are fitted with screens.				
25	BSCs are located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.				
26	Vacuum lines are protected with HEPA filters or their equivalent.				
27	Filters are replaced as needed.				
28	Liquid disinfectant traps are used when required.				
29	An eyewash station is readily available.				
30	BSCs are certified annually.				
31	A method for decontaminating all laboratory wastes is available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).				

Table 3. BSL-3 Checklist

#	IAT LABORATORIES, BSL-3	YES	NO	NA	COMMENTS
1	All procedures involving the manipulation of infectious materials are conducted within a BSC (preferably Class II or Class III) or other physical containment device.				
2	PPE with a solid front such as tie-back or wraparound gowns, scrub suits, or coveralls are worn by workers in the laboratory.				
	PPE is not worn outside of the laboratory.				
3	Reusable clothing is decontaminated with appropriate disinfectant before being laundered.				
4	Eye, face, and respiratory protection are used in rooms containing infected animals.				
5	Laboratory doors are self-closing and have locks in accordance with institutional policies.				
	The laboratory is separated from areas that are open to unrestricted traffic flow within the building.				
	Access to the laboratory is restricted to entry by a series of two self-closing doors.				
6	Laboratory has a sink (hands-free or automatically operated) for hand washing. If the lab is divided into different laboratories, a sink is available for hand washing in each zone.				
7	Seams, floors, walls, and ceiling surfaces are sealed. Spaces around doors and ventilation openings are capable of being sealed to facilitate space decontamination.				
8	Floors are slip resistant, impervious to liquids, and resistant to chemicals.				
9	Walls are constructed to produce a sealed, smooth finish that can be easily cleaned and decontaminated.				
10	Ceilings are constructed, sealed, and finished in the same general manner as walls.				
11	All windows in the laboratory are sealed.				
12	A ducted air ventilation system provides sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas.				
13	Laboratory personnel are able to verify directional air flow. A visual monitoring device that confirms directional air flow and room negative pressure is provided at the laboratory entrance.				
14	Laboratory exhaust air is not re-circulated to any other area of the building.				
15	A method for decontaminating all laboratory wastes is available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).				
16	Equipment that may produce infectious aerosols is contained in devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory.				
	HEPA filters should be tested and/or replaced at least annually.				
	Disinfectants and decontaminants should be readily available for use prior to leaving the BSL-3 lab.				

Table 4. BSL-4 Checklist

#	IAT LABORATORIES, BSL-4	YES	NO	NA	COMMENTS
PRECAUTIONS FOR ALL AREAS					
1	All penetrations through the walls and ceilings are sealed.				
2	The appropriate decontaminants are available and used properly.				
3	All entrances to the facility are posted with the appropriate special provisions for entry.				
4	All entrances to the facility are posted with the universal biohazard symbol.				
5	All entrances to the facility are posted with the name and telephone number (office, cell, and home) of the laboratory director or other responsible person.				
6	Access to the laboratory is strictly controlled and documented.				
7	Monitors indicate that the room is under negative pressure relative to all entrances.				
8	All vacuum lines are protected with HEPA filters and liquid disinfectant traps.				
9	The autoclave is properly maintained and certified.				
10	Foot, elbow, and automatic hand wash sinks operate properly.				
11	Self-closing doors to the facility operate properly.				
12	Personnel completely exchange street clothing for laboratory clothing before entry and shower upon exiting.				
13	The dunk tank disinfectant is fresh and appropriate for the agents in use.				
SUIT AREAS					
14	All operations with IAT are conducted in Class I or II BSCs.				
15	Procedures are in place to ensure that, as much as possible, contamination remains inside the BSCs (e.g., everything removed from the cabinets, such as gloves, instruments, glassware, or similar items, is first decontaminated and properly packaged).				
16	Class I and II cabinets are certified at least annually and after repair, movement, maintenance, or filter change.				
17	The suit decontamination shower has adequate appropriate decontaminant available.				
18	The suit decontamination shower has been used or tested in the last month.				
19	The ventilated suit air supply and emergency air supply are adequate and working properly.				
20	The emergency alarm system is working properly.				
21	All of the one-piece positive pressure suits available for use are in serviceable condition.				
22	Infected animals are housed in appropriate primary containment systems.				
23	The static pressure in the suit area is negative to all surrounding areas.				
NON-SUIT AREAS					
24	All operations with IAT are conducted inside Class III BSCs.				
25	Class III BSCs are certified before personnel initiate the current operation.				
26	All infected animals are housed in Class III cabinet containment caging systems.				

ENCLOSURE 5

OCCUPATIONAL HEALTH PROGRAM

1. GENERAL. The occupational health program shall:

a. Consist 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.

b. Be part of the installation, medical treatment facility (MTF), or laboratory biological SOH program.

c. Address the relevant requirements from the occupational health and immunoprophylaxis section of Reference (d), and the other specific elements as they apply to the biological safety program. An occupational health program should ensure that:

(1) Supervisors identify to the competent medical authority (CMA) the employees' proposed tasks for working with IAT.

(2) Supervisors and biosafety professionals conduct detailed risk assessments to determine exposure hazards and communicate those to the CMA and employees.

(3) The CMA bases the content of pre-placement, periodic, and termination medical surveillance examinations on the exposure hazards identified in the risk assessments and the functional requirements of the job.

(4) The CMA informs the workers as to availability of medical support services, examinations, immunizations, and post-exposure 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 CDC publication (Reference (r)).)

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

(7) The CMA, with biological safety professionals, conducts periodic visits 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 prevention strategies is indicated.

2. CMAs

a. 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:

(1) The Medical Management of Chemical and Biological Casualties course (6H-F26), conducted jointly by the U.S. Army Medical Research Institute for Infectious Diseases and the U.S. Army Medical Research Institute of Chemical Defense.

(2) The Fundamentals of Occupational Medicine course (6H-F20), conducted by the U.S. Army Medical Department Center and School.

(3) The CDC's International Symposium on Laboratory Biological Safety, "Protecting Workers in Clinical Laboratories, Research, Animal Care, and Public Health Communities."

(4) The Army's Biological Surety Medical Support course.

b. Medical professionals should have this training to be considered CMAs.

3. MEDICAL SURVEILLANCE EXAMINATIONS

a. Pre-Placement Examinations. Workers who may be exposed to IAT should receive a pre-placement medical evaluation. The supervisor incorporates relevant portions of the risk assessment or job hazard analysis associated with the position, and completes an occupational health survey form detailing the:

(1) Requirements for the position.

(2) Potential chemical, physical, and biological hazards.

(3) PPE requirements.

b. CMA Role in Pre-Placement Examinations. The CMA will be provided with the occupational health survey form prior to the examination. The CMA shall:

(1) Review the worker's medical history; current medications; allergies to medicines, animals, and other environmental proteins; and prior immunizations.

(2) Determine the content of the medical surveillance examination and what medical services (e.g., serologies and immunizations) are indicated to permit the individual to safely assume the duties of the position.

(3) Review pre-existing medical records, if applicable, to address specific concerns regarding an individual's medical fitness to perform the duties of a specific position.

(4) Determine an individual's vulnerability to infection with specific agents. Some occupational exposures present a substantially greater hazard to identifiable subpopulations of workers. Immunodeficient workers or non-immune pregnant female workers may experience devastating consequences from exposures that pose a possible risk to pregnant women with prior immunity and other immunocompetent workers (e.g., cytomegalovirus or toxoplasmosis).

(a) Where appropriate, the CMA should use serologic testing to document baseline vulnerability to specific infections to which the worker might be exposed, and non-immune 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.

(b) The CMA should inform the worker of potential health hazards in the work area, review steps that should be taken in the event of an accidental exposure, and conform to any relevant bloodborne pathogen program requirements.

c. Periodic Medical Surveillance. The CMA should:

(1) Conduct periodic medical surveillance that includes:

(a) Updating the employee's medical and occupational history from the previous year.

(b) Reviewing any changes in job activities or exposure hazards.

(c) Updating respirator clearances, as required.

(2) In special circumstances, offer booster immunizations or periodic laboratory testing to workers with substantial risk of exposure to infectious agents to detect pre-clinical or subclinical evidence for an occupationally acquired infection. Before asymptomatic workers without specific exposures are tested for seroreactivity, the CMA should:

(a) Justify the benefit of such testing.

(b) Delineate plans for further investigation of indeterminate test results.

(c) Develop clearly defined criteria for interpreting the results.

(3) Identify workers and support personnel who have been designated or granted approval for facility access during etiological agent operations, and review their risk assessment in conjunction with all occupational health examinations or screenings.

d. Termination Examinations

(1) Employees enrolled in medical surveillance who work in a BSL-3 or BSL-4 laboratory area will suspend work in those laboratories 30 days prior to termination to ensure proper medical surveillance.

(2) The CMA will perform a termination of employment examination or a termination of exposure examination on employees within 30 days after their removal from the exposure that required the medical surveillance. The examination will document 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 will ensure that a termination examination has been administered or offered to workers who have been enrolled in the medical surveillance program.

e. Post-Exposure Examinations for Occupational Illnesses and Injuries

(1) In the event of injury, consultation among the CMA, the employee, and the employee's supervisor is required for proper medical management and recordkeeping (mishap report, Office of Workers' Compensation Program report, and Occupational Safety and Health Administration (OSHA) log). 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:

(a) Develop exposure-specific protocols that define appropriate first aid, potential post-exposure 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 they should be distributed to potential healthcare providers (e.g., 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.

(b) Review and define appropriate first-aid treatment, and issue 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 workplace and that the injured worker can provide to the treating facility. The CMA's description of the injury should include:

1. The potential infectious agent.

2. The mechanism and route of exposure (percutaneous, splash to mucous membranes or skin, aerosol, etc.).

3. Time and place of the incident.

4. PPE used at the time of the injury.

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

6. 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 post-exposure prophylaxis. The CMA should:

(a) Develop protocols in advance that clearly identify the situations in which post-exposure prophylaxis are to be considered, including the appropriate treatment and the source of products and expert consultation. Post-exposure regimens may involve off-label use of licensed products (e.g., 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 understanding of the value of some post-exposure interventions. In these cases, consultations with subject matter experts are especially useful. Appropriate post-exposure prophylactic response is always pathogen- and exposure-dependent, may be host-factor dependent, and may also be influenced by immediate post-exposure management.

(b) Before prophylactic treatment is undertaken, confirm the likelihood that an exposure occurred and that prophylaxis is indicated and not contraindicated by past medical history. Conveying this information to the injured worker requires clear, honest communication. The CMA shall:

1. Carefully explain and document in the medical record the clinical risk assessment, treatment decision process, and medical follow-up plan.

2. Promptly reconsider the initial risk assessment of each incident and reevaluate current strategies to reduce the possibility of future exposures.

f. Documentation of Medical Opinion. The CMA shall record a written opinion in the medical record for each medical surveillance examination that 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 an etiologic agent.

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

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

(5) Notification of the employee's supervisor of relevant job-related medical recommendations.

4. HEALTH HAZARD EDUCATION

a. At the time of the medical examination, supervisors will ensure that healthcare providers are made aware of all hazardous substances with which each employee works. The CMA's findings will include an assessment of whether an employee has any health condition that would preclude work with an etiologic agent. If any of the findings obtained during the examination are outside the normal range, the CMA shall:

(1) Notify the employee and provide information on the courses of action available.

(2) Notify the employee's supervisor of any duty limitations.

(3) Conduct a safety and health audit to identify any potential occupational causes for the abnormalities; take corrective measures if applicable.

b. Employee health education includes:

(1) Employee Health Training. The CMA should:

(a) 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.

(b) Conduct and document (e.g., memorandum for record) this review on an annual basis.

(2) Access to Health Education Materials. The biosafety officer shall ensure that health education materials used in the employee training programs are readily available to all individuals with an exposure potential to etiologic agents. Co-location of these documents with MSDS used in the laboratory is recommended.

5. IMMUNOPROPHYLAXIS

a. CMAs offering immunoprophylaxis as a means of personal protection will develop SOPs and a written immunoprophylaxis program.

(1) SOPs will address procedures for vaccine administration, follow-up, and recordkeeping.

(2) Written immunoprophylaxis programs will address:

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

(b) Requirements for higher-headquarters oversight and program approval.

(c) Responsibilities and criteria for determining personnel to receive vaccines.

(d) Requirements and recommendations for specific vaccines.

(e) Requirements and procedures for informing employees of vaccine requirements and recommendations, benefits and risks of vaccines, and possible systemic reactions.

(f) Requirements and procedures for employees to notify immunization program administrators, supervisors, or the CMA of changes in the status of their health and of possible systemic reactions.

(g) Recordkeeping requirements.

b. The MTF or commanding officer or institute director shall review and approve immunoprophylaxis programs.

c. Recommendations for the use of vaccines can be found in References (d) and (p).

d. Records shall be kept on all:

(1) Immunizations. The lot number, date of manufacture, and related laboratory data for all immunizations must be documented in the employee's occupational health record and the recommended DoD-approved electronic immunization tracking record.

(2) Vaccine Reactions. All vaccine reactions and untoward effects must be reported and documented in accordance with MTF policy.

e. SIP was established so that vaccines would be available and controlled in order to provide an additional level of protection to at-risk individuals involved in biological defense activities. The SIP uses Food and Drug Administration (FDA)-licensed vaccines as well as unlicensed vaccines given under IND protocols.

(1) Immunization with a licensed vaccine, or a statement of declination from the individual, may be required as a prerequisite for working with certain biological agents. Licensed vaccines are currently available for anthrax, hepatitis B, Japanese encephalitis, rabies, smallpox, and yellow fever. Required immunizations will be administered by local medical facilities, by a means made available to provide them without cost to the employee, or as defined in contracts.

(2) Due to the investigational, unlicensed status and the limited availability of vaccines given under IND protocols, immunization with an IND vaccine is strictly voluntary and is limited to those individuals to whom the risk of their use has been fully analyzed and justified. Vaccines given under IND protocols are only to be used to provide an additional level of protection, and are not to be used in lieu of safe laboratory practices, agent containment, or PPE. Vaccines given under IND protocols are currently available, in limited supply, for Botulinum toxin, Eastern equine encephalitis virus, Rift Valley fever virus, Venezuelan equine encephalitis virus (TC 83), Venezuelan equine encephalitis virus (C 84), and Tularemia.

(3) 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 both of these criteria are met:

(a) The hazard analysis and 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 12 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 the CMA 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 participate in the SIP.

(4) If an IND will be used, the individual will be informed by the CMA 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.

(5) When requesting enrollment or re-enrollment in SIP, documentation showing satisfaction of the requirements in subparagraphs 5.e.(1) through (4) of this enclosure, along with a copy of the applicable research protocols, will be provided to the SIP program coordinator. Medical records for individuals enrolled in SIP shall accurately document the receipt of SIP vaccines and satisfaction of the requirements. In accordance with requirements of the National Archives and Records Administration General Records Schedule (Reference (s)), medical records will be maintained for the duration of employment plus 30 years. Records are to be transferred to the National Personnel Records Center in St. Louis, Missouri, 30 days after the employee separates.

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 staff prior to resumption of duties.

b. Personnel who are enrolled in the medical surveillance program may be required to report all illnesses, healthcare received, and medication used 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 SOH 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 nonspecific 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.

7. FITNESS FOR DUTY

a. Supervisors will ensure that employees are referred for required job-related medical surveillance as described in section 3 of this enclosure.

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. DoD 6055.05-M (Reference (t)) is mandated for use by all the DoD Components in developing, performing, interpreting the results of, and conducting population-based surveillance with the results of occupational medical examinations. Where published medical standards may not address all conditions that influence safe worker health, the CMA may document physical standards or deficiencies. The worker should self-identify conditions to the CMA and supervisor that may not be published in standards or requirements but could lead to an increased risk of mishap. The CMA may further evaluate these deficiencies, and may determine they require communicating to the local management level for decision of waiver. Waivers are an administrative and human resources process that may require detailed medical input. An example could be an employee with a recent seizure history or high-risk cardiovascular disease, to whom working in a BSL-3 or BSL-4 laboratory could pose increased risk from incapacitation or delays in receiving medical care. Supervisors and human resource staff should be advised of the increased risk and determine if it can be accommodated or waived.

ENCLOSURE 6

FACILITY SAFETY CONTROLS

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 Reference (d).

a. Prior to selecting facility equipment, the function of the equipment shall be analyzed and the methods for testing and decontamination documented.

b. BSL-3 and BSL-4 facilities shall be commissioned using criteria set forth in Appendix 1 to Enclosure 4.

c. If laboratory mission requirements dictate operations or substances not suited to the existing facilities or equipment, the laboratory supervisor, assisted by the safety or biosafety officer, will advise and assist the laboratory worker in developing or obtaining adequate facilities or equipment and designing appropriate work procedures prior to work commencing.

2. LARGE-SCALE FACILITIES. Large-scale facilities and laboratories shall be designed in accordance with the requirements in appendix K of Reference (n). These guidelines are written for cultures of viable organisms containing recombinant DNA molecules; however, research and production will follow these requirements regardless of whether the IAT has recombinant DNA.

ENCLOSURE 7

SAFETY EQUIPMENT

1. GENERAL. Safety equipment includes primary barriers such as BSCs, chemical fume hoods, and other enclosed containers (e.g., the safety centrifuge cup). They are the primary means of protecting personnel and the environment from exposure to IAT. Safety equipment requirements for each BSL are outlined in Reference (d).

2. ENGINEERING CONTROLS. Facilities conducting IAT activities will certify engineering controls and will:

a. Meet local, State, Federal, and host-nation emissions standards during use and certification.

b. Certify BSCs annually and after repair, movement, maintenance, or filter change.

c. Ensure Class II BSCs conform to and are certified to meet National Sanitation Foundation/American National Standards Institute (ANSI) Standard 49 (Reference (u)) for the applicable type of cabinet.

(1) Ensure that cabinets are tested according to Reference (u) and the manufacturer's recommendations after installation and before use, annually thereafter, and whenever:

(a) HEPA filters are changed.

(b) Maintenance repairs are made to internal parts.

(c) Cabinets are moved.

(d) Changes are made to the heating, ventilating, and air conditioning system; equipment; or room geometry that could affect the cabinet's performance.

(2) Ensure certification and testing are performed by experienced, qualified personnel. It is strongly recommended that, whenever possible, accredited field certifiers be used to test and certify BSCs.

d. Train all individuals in the use of engineering controls, and ensure they demonstrate both the understanding and skill to use these devices properly and safely.

e. Meet the BSC requirements in Reference (d) and:

(1) Protect BSC internal electrical outlets by ground fault circuit interrupters supplied by an independent circuit.

(2) When propane or natural gas is provided, install a clearly marked emergency gas shut-off valve outside the cabinet for fire safety. All non-electrical utility services should have exposed, accessible shut-off valves.

(3) Avoid the use of compressed gases within a BSC. If a compressed gas must be used, it should be carefully controlled to prevent aerosol production and the potential of pressure-based release.

(4) Refer to additional guidance on the design, selection, function, and use of BSCs in the U.S. Department of Health and Human Services publication (Reference (v)).

3. LABORATORY CHEMICAL HOODS. Laboratory chemical hoods are designed to contain chemical vapors, gases, and fumes within the hood, thereby reducing airborne chemical exposure to workers. Though work with toxins is allowed, conventional laboratory chemical hoods shall not be used for biological hazards and infectious agents. These hoods are not HEPA-filtered to protect the environment from IAT aerosols and they do not provide product protection from contaminated air within the room. Laboratory supervisors will:

a. Ensure laboratory chemical hoods meet all three performance criteria specified in Table 5.

b. Provide laboratory chemical hoods used with toxins with an audible alarm to give a warning should the ventilation system fail or the hood face velocity fall below an average of 80 linear feet per minute (lfpm).

c. Conduct hood certification tests at least annually in accordance with ANSI/American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 110-1995 (Reference (w)) and whenever the system has undergone repairs, maintenance, a filter change, or a significant change has been made to the operational characteristics of the system.

4. CLASS III BSC. Class III BSCs will:

a. Be used when extreme containment is needed for IAT and highly toxic chemicals, especially for substances that can be swept out of containers by the airflow in hoods.

b. Not be used with volatile flammable materials or volatile toxic materials unless dilution ventilation is provided.

c. Be maintained at a pressure of at least 0.25 inches wg less than their surroundings when all openings are closed, and at least 100 feet per minute (fpm) inward air velocity when the largest operating opening is open. A manometer or magnehelic gauge will indicate the pressure differential. Indicator devices will display a loss of pressure below 0.25 inches wg.

d. Change gloves at appropriate intervals (dependent on the box contents) to ensure they provide the protection needed.

e. Protect inlets that provide dilution air by appropriate filtration.

Table 5. Laboratory Chemical Hood Performance Criteria

PERFORMANCE CRITERIA	REQUIREMENT
1 - Hood face velocity[1,2,3]	Each hood shall have an average face velocity of 80-120 fpm through the "working opening," with no point velocity measurement used to compute the average face velocity deviating more than 20% from the average face velocity.
2 - Cross drafts at the face of the hood	With the hood exhaust off (or with the hood sash closed), the average velocity of air currents at the face of the hood shall not exceed one-third the average face velocity.
3 - Hood containment aerosol tests[1,2,4]	Sash in static positions: no visible aerosol using a smoke test shall escape from the face of the hood with someone standing in front of the hood and smoke source, all along the working opening, with the sash in the minimum and maximum working opening position.
	Sash movement effect: no visible aerosol using a smoke test shall escape from the face of the hood with someone standing in the front and center of the hood working opening and smoke source, while the sash is raised from the minimum working opening position to the fully open working opening position, and lowered from the fully open working opening position to the minimum working opening position. The sash will be raised and lowered in a smooth motion at a rate of between 1.0 and 1.5 feet per second.

[1] Limit the working opening by sash stops (e.g., spring-loaded) if there are other positions where the criteria (i.e., face velocity, cross drafts, hood containment aerosol tests) cannot be met.

[2] When volatile chemicals having low parts per billion occupational exposure limits (i.e., threshold limit values published by the American Conference of Governmental Industrial Hygienists (Reference (x)) are used inside laboratory chemical hoods, even when hoods meet all three performance criteria, initially conduct air sampling and medical surveillance for several days during an operation when such chemicals are not sufficiently diluted.

[3] The maximum permissible average face velocity of 120 fpm need not be observed if any of the following are met:

a. A hood performance test has been conducted in accordance with Reference (w) and a control level of 4 AM 0.01, 4 AI 0.05, or 4 AU 0.1 has been demonstrated at the working opening. (AM, AI, and AU are abbreviations for "as manufactured," "as installed," and "as used.") If using 4 AM 0.01 as evidence that the hood performance is acceptable, then the average velocity of the cross drafts at the hood face must not exceed one-third the average face velocity in the laboratory where the hood is installed.

b. Only chemicals having occupational exposure limits or OSHA-permissible exposure limits are used within the hood until it has been demonstrated by an industrial hygienist that potential exposures will not exceed occupational exposure limits.

c. The hood meets all of the performance criteria (i.e., face velocity, cross drafts, and hood containment aerosol tests) with the sash in the minimum and maximum working opening position, except that the average face velocity exceeds 120 fpm at the minimum working opening position, and either of the following is met:

(1) Personal air sampling conducted or supervised by an industrial hygienist has clearly shown that exposures are less at the minimum working opening position than at the maximum working opening position.

(2) Lowering the sash height causes the average face velocity to exceed 120 fpm, yet an industrial hygienist or safety professional has determined that a safety hazard (e.g., potential of a splash hazard, runaway reaction, fire) exists with a particular operation that has significant injury consequences. If an industrial hygienist has determined that the potential for increased airborne vapor concentrations outside the hood is not of any health significance, then the industrial hygienist may provide for an exception to the maximum average face velocity requirement of 120 fpm while that particular operation is in progress.

[4] During hood containment aerosol tests, the smoke source must be placed inside the hood at the required minimum source-to-sash working distance, which should be demarcated (e.g., with paint or tape).

5. VENTILATED BALANCE ENCLOSURES. Laboratory workers will:

a. Use a ventilated balance enclosure when containment of a balance is required to weigh hazardous materials that have a low vapor pressure (such as toxins).

b. Use these enclosures when it is best to use the balance in other than a laboratory chemical hood (due to the turbulence and vibration) and when BSCs or glove boxes are inappropriate or unavailable.

c. Weigh dry forms of toxins in these enclosures.

d. Not handle volatile or highly toxic volatile materials in ventilated balance enclosures unless they are placed in closed containers in a properly functioning laboratory chemical hood before being transferred to the balance enclosure.

e. Ensure the flow through the openings in the enclosure is at least 60 lfpm and averages between 60 and 80 lfpm.

f. Certify containment prior to first use and annually thereafter by smoke tubes.

g. Certify the airflow initially and annually by averaging readings taken from the face of the opening.

6. VENTILATED CAGE ENCLOSURES. Ventilated cage enclosures are used to house animals at levels corresponding to the various classes of BSCs. The proper functioning of these enclosures will be tested initially, upon each connection to exhaust sources, and at least annually. Inward flow rates on the partial containment systems and pressure checks on the total containment cages will be performed. Although not a complete list, the four different types of ventilated animal cages are the filter-top cage, forced ventilation cage, cubicle-type isolation cage, and total containment cage. (See Glossary for definitions.)

a. Filter-Top Cage. Adequate ventilation around these cages is essential since they may contain elevated ammonia and carbon dioxide levels and high temperature and humidity. Ventilation recommendations in the National Research Council publication (Reference (y)) should be followed.

b. Forced Ventilation Cage. A minimum airflow of 0.03 cubic meters per minute (m^3/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. 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. Total Containment Cage. 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.

7. VENTILATED CAGE AREAS. The containment for these areas is equivalent to the Class I BSC. Smoke tests shall be performed annually to verify containment.

ENCLOSURE 8

BIOSAFETY PRACTICES

1. GENERAL PRACTICES APPLICABLE TO IAT. Facilities will develop or adopt a laboratory biosafety manual based on the recommendations in Reference (d). These specific requirements must be included in biosafety manuals:

a. Hallways and Stairways. Do not use hallways and stairways for storage.

b. Labeling

(1) Chemicals. Label all solutions and reagents in accordance with DoDI 6050.05 (Reference (z)).

(2) IAT. Label all primary or secondary containers with contents (e.g., the rack containing 100 microfuge tubes with the same culture can be labeled instead of the individual tubes).

c. Storage

(1) Label equipment used to store IAT (e.g., freezers and refrigerators) with the universal biohazard sign and indicate the IAT identity and BSL contained in them.

(2) Periodically inspect refrigerators, deep freezers, and dry ice chests for integrity of any ampoules, tubes, or other vessels stored. Defrost and clean out refrigerators and deep freezers in accordance with the manufacturer's recommendations and when broken ampoules or tubes are found or spills are visible.

(3) Store flammable solutions, required to be kept cold, in approved laboratory-safe refrigerators or freezers.

d. Eyewash and Shower Equipment. Install, use, inspect, test, and maintain emergency eyewash and shower equipment in accordance with ANSI Standard Z358.1 (Reference (aa)).

2. ADDITIONAL TECHNIQUES APPLICABLE TO WORK WITH IAT. 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, and response to vaccines and toxoids). These minimum handling requirements prevent accidental infection created by incidental aerosols:

a. Establish a preventive maintenance program for centrifuges and shakers as recommended by the manufacturer.

(1) Before centrifuging, check tubes, rotors, seals, and gaskets for cleanliness and integrity. Do not use tubes that show cracks or stress marks. Inspect seals on safety buckets and rotors prior to use.

(2) Use centrifuge safety cups or sealed rotor heads for all centrifugation in the open laboratory. Load and unload them in a BSC or equivalent.

(3) Avoid decanting from centrifuge tubes. If decanting is necessary, wipe the outer rim with a disinfectant after decanting so that material on the lip cannot spin off as an aerosol.

(4) Do not fill centrifuge tubes beyond the level the manufacturer recommends. Ensure that the load is balanced prior to centrifugation.

(5) Train employees on proper use and care of centrifuges, ensuring the owner's manual is available to provide safety and other relevant information.

b. Shake broth cultures in a manner that avoids wetting the plug or cap. Remove plugs or caps in a BSC if they become contaminated.

c. Since disinfectants vary, incorporate instructions on water bath disinfection into the lab-specific biosafety manual to identify appropriate anti-microbial disinfectants against the agent and change frequency.

d. Exercise care when using membrane filters to obtain sterile filtrates of viable IAT. Due to the fragility of the membranes and other factors, do not consider such filtrates noninfectious until laboratory cultures or other tests have proven their sterility.

e. Work with open containers of dry powders of IAT in gas-tight BSCs. 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.

3. OPERATIONS WITH RADIOACTIVE MATERIAL

a. Operations that combine IAT and radioactive material must implement a radiation program meeting the requirements of part 20 of title 10, CFR (Reference (ab)). Organizational policy documents should describe the requirements for acquiring radioactive material and the procedures for handling, labeling, storing, monitoring, and disposing of radioactive material.

b. The radiation safety officer (RSO) will approve all SOPs involving the use of radioactive material. Laboratory operators must be fully trained, with annual training updates as required by the existing license.

c. Operations combining IAT with radioactive material present unique problems.

(1) Radioactive waste must be segregated, labeled, and disposed of after the etiological agent has been decontaminated. It cannot be autoclaved. It should not be mixed with non-radioactive waste as the disposal of radioactive waste is much more complex and expensive. When hazardous waste listed in part 261 of title 40, CFR (also known and hereafter referred to as "The Resource Conservation and Recovery Act (RCRA) of 1976, as amended" (Reference (ac))) is mixed with radioactive waste, it becomes "mixed waste," which must be disposed of in accordance with all applicable Federal and State regulations.

(2) Use of radioisotopes must be confined to the smallest number of areas or rooms consistent with requirements.

(3) Decontamination methods specific to IAT will not always remove residual radioactivity. The RSO should be consulted for appropriate decontamination methods, such as specialized detergents and solvents designed for this use.

4. CERTIFICATION OF INACTIVATED MICROORGANISMS. Prior to working with inactivated organisms, the laboratory supervisor shall obtain a written statement that the microorganisms have been killed. (Certification of inactivated organisms is not required for FDA-cleared assays and kits.) The statement will include:

a. Name of supplier.

b. Date the microorganisms were killed (sterilized).

c. Method of sterilization.

d. Test procedure performed by the supplier on the sample and the control to ensure there were no infectious microorganisms in the sample.

e. Date of the test.

5. WORKING WITH VERTEBRATE ANIMALS

a. If experimental animals are used, the facility biological safety program and appropriate SOPs will address hazards and controls associated with animals. Special considerations may include aerosol generation, animal bites and scratches, and working with animals that are intoxicated or infected with zoonotic disease. (See the National Research Council publication (Reference (ad)) for additional information.)

b. Laboratory animal facilities, operational practices, and animal care shall meet the requirements of Reference (y) and parts 1, 2, and 3 of Reference (l).

6. WORKING WITH INVERTEBRATE VECTORS AND HOSTS. Facility standards and practices for invertebrate vectors and hosts can be found in the American Committee on Arthropod-Borne Viruses publication (Reference (ae)).

7. SPECIFIC REQUIREMENTS FOR BSL-4. In addition to requirements listed in Reference (d), BSL-4 facilities shall:

a. Have laboratory staff members supervised by competent scientists who are trained and experienced in working with Risk Group 4 agents.

b. Conduct all activities involving Risk Group 4 agents in Class III BSCs or in Class I or II BSCs in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system in accordance with Reference (d).

c. Remove no materials, except for biological materials that must remain in a viable or intact state, from the maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or material that might be damaged by high temperature or steam shall be decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

d. Have an approved SOP detailing methods and procedures for the movement of various types of materials (e.g., paper, heavy equipment, cages, PPE) in and out of maximum containment areas.

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

f. Have a ventilation system that is dedicated to the BSL-4 laboratory and provides fresh air meeting ASHRAE Standard 62 (Reference (af)).

g. Test and certify BSCs at the time of installation, at least annually thereafter, or whenever HEPA filters are damaged, maintenance repairs are made to internal parts, or the cabinet is moved. If the filtered cabinet exhaust is discharged through the building exhaust system, connect it to this system in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system. 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. Class II Type B1 and B2 BSCs should be installed with flow monitors and alarms; the Class II Type B2 BSC should be installed with an interlock system to prevent cabinet pressurization in case of a failure of the building exhaust system.

h. Use the facility requirements for a BSL-4 laboratory in conjunction with the ABSL-4 facility requirements listed in Reference (d) when BSL-4 animal areas are included as an integral part of BSL-4 cabinet laboratories or suit laboratories.

8. TOXINS. Laboratory safety precautions appropriate for handling toxins closely parallel those for handling nonvolatile hazardous chemicals. The following requirements, in addition to those listed in Reference (d), 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 will conduct the high-risk activity, the other will act as a safety observer and emergency responder in the event of an incident. A third person outside of the BSL facility should be on alert to call emergency response personnel and act as a guide.

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 Reference (aa).

c. After working with toxins in a Class III BSC, laboratory workers will:

(1) Decontaminate all items inside the Class III BSC upon removal. Place materials such as experimental samples that cannot be decontaminated directly in a closed secondary container, the exterior of which is decontaminated. Label secondary containers appropriately immediately upon removal from the Class III BSC.

(2) Decontaminate the interior of the glove box or cabinet periodically, for example, at the end of a series of related experiments. Until decontaminated, mark the box or cabinet to indicate that toxins are in use and that access to the equipment and apparatus is restricted to necessary, authorized personnel.

9. INTEGRATED PEST MANAGEMENT (IPM). Microbiological laboratories and biomedical research facilities will institute an effective IPM program to identify and control the infestation by and harborage of animal or insect vectors or pests.

ENCLOSURE 9

PPE

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 depends upon the proposed operations and the potential hazards associated with that activity. While PPE is an important item of personal protection, it serves as only a secondary line of protection against hazards in the workplace laboratory. Engineering controls, combined with common sense, education, experience, good microbiological practices, and adherence to SOPs, are the primary barriers to exposure. Because it is impractical or impossible to rely exclusively on engineering controls and good microbiological practices, PPE must be used as a secondary protective barrier.

b. PPE, including equipment for the eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers shall be:

(1) Provided by the employer at no cost to the employee.

(2) Used and maintained in a sanitary and reliable condition per manufacturers' specifications.

(3) Used wherever it is necessary by reason of hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation, or physical contact.

(4) Of safe design and construction for the work to be performed and will properly fit employees. Defective or damaged PPE will not be used.

c. PPE selection shall be based on a risk assessment and, at a minimum, shall include close-toed shoes in addition to the requirements listed in Reference (d) to provide the appropriate level of protection to affected employees from the identified hazards. Supervisors will verify that the required risk assessment has been performed and documented. The risk assessment showing the PPE selection decisions will be posted in a visible area prior to entering the laboratory.

d. Each affected employee will demonstrate an understanding of their training in PPE and the ability to use PPE properly before being allowed to perform work requiring the use of PPE. When a supervisor or SOH professional believes any trained employee does not have the requisite understanding of the training and ability to use PPE properly, the employee shall be retrained.

2. SPECIFIC REQUIREMENTS FOR INDIVIDUAL PPE. Laboratory supervisors will ensure that:

a. Eye and face protection meet or exceed the requirements of American Society of Safety Engineers/ANSI Standard Z87.1 (Reference (ag)). Special eyewear may be required when working near ultraviolet (UV) light sources and lasers.

b. Gloves are examined prior to each use and replaced or changed as necessary during operations, and that an option to use latex gloves is available in the event of latex allergies.

c. Class III BSC gloves are inspected prior to each operation and after each sterilization. When using glove boxes (Class III BSC), operators should don a pair of gloves prior to inserting their hands into the BSC gloves.

d. Laboratory clothing is checked before it is worn to ensure that it is free from defects that would compromise its usefulness. Laboratory clothing will not be released for laundering from the laboratory until decontaminated or until a risk assessment has been performed to show there is an acceptable low risk of contamination.

e. One-piece positive pressure suits are inspected before each use to check for indications of significant wear or leakage, and that:

(1) A life-support system is provided with alarms and emergency backup breathing tanks.

(2) Air is provided that meets OSHA breathing air requirements in section 1910.134 of Reference (i).

(3) A HEPA filter is in-line between the disconnect on the suit and the breathing space in the suit. When the suits 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.

(4) Suits are worn with impervious boots over the foot area of the suit and with outer gloves attached over the hand portion.

(5) Suits that are maintained for emergency use are inspected at least quarterly and respiratory equipment is inspected monthly.

f. When respirators are used, the facility's safety or occupational health office establishes a respiratory equipment protection program that conforms to section 1910.134 of Reference (i).

ENCLOSURE 10

TRANSPORTATION AND TRANSFER OF IAT AND BSAT

1. GENERAL

a. Commanding officers or institute directors will establish controls to ensure that IAT are transported (including importing and exporting) or transferred with proper authorization, controls, and procedures.

b. U.S. and/or host-nation permits for import and export of IAT will be obtained as appropriate. If international import or export of IAT is anticipated, the laboratory will coordinate with CDC, APHIS, and appropriate host-nation agencies for overseas labs.

2. TRANSPORTATION AND TRANSFER OF IAT. The transportation or shipping officer shall:

a. Not ship unlabeled or improperly packaged IAT.

(1) Package all IAT for shipment in accordance with title 49, CFR (Reference (ah)), and the packing instructions in the International Civil Aviation Organization publication (Reference (ai)) and International Air Transport Association publication (Reference (aj)).

(2) Ship and transport IAT according to the requirements (as applicable) in chapter 204 of the Defense Transportation Regulations 4500.9-R-Part II (Reference (ak)).

b. Train all personnel who certify a shipment of infectious substances in accordance with chapter 204 of Reference (ak).

3. TRANSPORTATION AND TRANSFER OF BSAT. The transportation or transfer of BSAT shall be in accordance with Reference (ah).

ENCLOSURE 11

DECONTAMINATION AND DISPOSAL

1. GENERAL. Lab supervisors are responsible for ensuring that all contaminated or potentially contaminated materials and equipment or apparatus are decontaminated before being washed, stored, or discarded. Lab supervisors shall:

a. Consult with installation legal counsel regarding local, Federal, State, or host-nation safety, health, and environmental requirements for necessary approvals. (E.g., the use of formaldehyde may require a permit from the Environmental Protection Agency (EPA) or a State agency.)

b. Follow the decontamination requirements listed in the Reference (d).

2. METHODS OF DECONTAMINATION

a. Autoclave

(1) General. The use of 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. Lab supervisors shall:

(a) Verify sterilization with biological indicators (e.g., Bacillus stearothermophilus (Geobacillus stearothermophilus) spores) at locations throughout the autoclave, including:

1. When the autoclave is first put into service.

2. After any maintenance or repairs.

3. On a monthly basis.

(b) Verify autoclave sterilization with placement of biological indicators (e.g., autoclave tape, labels, or strips) at locations throughout the autoclave, including placement in the center of a test load.

(c) Equip each autoclave with a permanent means to record the time and temperature of each operational event as a means of ensuring sterilization.

(d) Review the type of materials, volume, contamination level, and other factors of materials being autoclaved and establish standard conditions for sterilization. As a guide, consult the manufacturer's manual for the autoclaves as a starting point in establishing these

conditions. In each case, establish the conditions based on tests that verify that the conditions selected are effective.

b. Dry Heat

(1) General. Dry heat requires longer times and/or higher temperatures than wet heat requires.

(2) Validation. If used, lab supervisors shall determine the specific sterilization times and temperatures for each type of material being sterilized. Sterilization by dry heat occurs at 169-170 degrees Celsius 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) General. If used as a disinfectant, liquids must be proven effective against the organism or toxin in use. Liquid disinfectants shall be mixed and used in accordance with the manufacturer's instructions and Reference (d).

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

d. Vapors and Gases

(1) General. Vapors and gases such as formaldehyde-paraformaldehyde, hydrogen peroxide, and chlorine dioxide can be used for room or space decontamination.

(2) Validation. If used for decontamination, a validation method must be in place.

e. UV Radiation

(1) General. UV light exposure at a wavelength of 253.7 nanometers is a practical method for inactivating airborne viruses, Mycoplasma, bacteria, and fungi on clean surfaces such as a laboratory bench. However, UV radiation usefulness on exposed surfaces is limited by its low penetrating power, and it should therefore only be used to decontaminate surfaces when conventional methods, such as autoclaving or the use of liquid disinfectants, would make the product unusable. Data sheets that must be brought out of a BSL-3 or BSL-4 laboratory are an example. The UV intensity must be at least 40 microwatts per cubic centimeter (cm^3) 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. Protective eye wear and clothing may be necessary when working around UV radiation.

(2) Validation. Lab supervisors shall use a calibrated photoelectric UV intensity meter capable of measuring UV radiation at a wavelength of 253.7 nanometers whenever a new UV source is installed, and quarterly thereafter, to ensure the UV source is providing at least 40

microwatts per cm^3 at the work surface. They shall clean bulbs routinely to remove any accumulated dust, prolong bulb performance, and assure proper energy output.

f. Gamma Irradiation

(1) General. Gamma irradiation is used to sterilize medical devices, organisms, or unknown agents.

(2) Validation. Lab supervisors shall check the sterility of organisms or objects decontaminated with gamma irradiation.

3. DISPOSAL. Lab supervisors shall:

a. Consult with installation legal counsel and follow all applicable local, State, Federal, and host-nation procedures for disposal of IAT.

b. Dispose of IAT only after materials have been properly treated by autoclaving, decontamination, or other appropriate means.

ENCLOSURE 12

EMERGENCY PLANNING AND RESPONSE

1. GENERAL. The laboratory facility commander or director shall:

a. Establish specific emergency plans for all IAT biological laboratories and their facilities and coordinate with installation emergency management programs in accordance with DoDI 6055.17 (Reference (al)). Emergency plans may be stand-alone or incorporated into an installation emergency response plan, and shall include:

(1) Procedures for liaison through proper channels with local emergency groups and community officials.

(2) Plans for both the building and the individual laboratories.

(3) SOPs for personal decontamination and responsibilities for spill control and emergency shutdown.

(4) A description of evacuation routes, assembly areas, procedures to account for all individuals, facilities for medical treatment, and procedures for reporting mishaps and emergencies.

b. Inform emergency groups and community officials of emergency plans in advance of any call for assistance. Before they are adopted, the laboratory facility commander or director shall test emergency plans to ensure they are capable of effectively responding to the emergency in a timely manner and, after they are adopted, shall:

(1) Reinforce the plans by drills at least semiannually. Conduct basic drills of plans and communications by simulating an emergency and requiring on- and off-post emergency responders identified in the plan to simulate their communication and response procedures. Internal agencies shall participate in all drills; external agencies shall participate in drills at least annually.

(2) Conduct after-action reviews of drills and exercises to identify lessons learned; incorporate these into emergency plan updates and future drills.

2. EMERGENCY PROCEDURES

a. General Emergency Procedures. Supervisors and employees shall follow these emergency procedures for laboratory mishaps:

(1) Using appropriate personal protection, assist personnel involved, remove contaminated clothing if necessary, decontaminate affected areas, and remove personnel from

exposure. (Do not, however, move an injured person who is 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, immediately activate the emergency alarm system and call the appropriate emergency services, fire department, or community fire brigade. Follow local rules for dealing with incipient fire. If personnel are expected to use portable fire extinguishers, train them in their use. Inform supporting emergency agencies, such as law enforcement, fire departments, health departments, and governments, of IAT activities and the appropriate support necessary, including any equipment and training for effective emergency response. Formalize agreements with external agencies.

(4) Prepare laboratories 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. Stop all potentially hazardous laboratory work 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 an MTF or healthcare providers within 10 minutes must have personnel trained in first aid available during working hours in accordance with section 1910.151 of Reference (i).

(6) For mishaps with 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, then follow through with those for the lesser hazards to ensure that all appropriate steps have been taken.

(7) Considerations for emergency procedures for BSAT shall be in accordance with Reference (ah).

b. Emergency Alarm System. Lab supervisors shall:

(1) Have a system in place to alert personnel to an emergency that requires evacuation of the laboratory or building. Ensure laboratory personnel are familiar with the location and operation of alarm equipment.

(2) Equip isolated areas (e.g., cold, warm, or sterile rooms) with an alarm or communication system to alert others outside to the presence of a worker inside, or to warn workers inside of an emergency that requires evacuation. Make sure the system is equipped to warn individuals with hearing and vision impairments or other physical challenges.

(3) Include a strobe light in containment, maximum containment, cage wash, and other areas with loud background or nuisance noise or in areas where hearing-impaired personnel may work or transit.

c. Shut-Down and Start-Up Procedures. Lab supervisors shall:

(1) Develop SOPs for shutting down operations during an emergency evacuation and make them available in writing. Include procedures for handling emergencies related to any power failures and start-up operations for the laboratory emergency.

(2) Provide written procedures to ensure that personnel do not return to the building or laboratory, or enter any emergency area until the emergency is declared ended and the authorization has been made by the incident commander. Those procedures must also contain start-up operations for the laboratory.

3. SPILLS. Lab supervisors shall:

a. Train designated personnel in all areas where work with IAT is performed to respond to spills of hazardous materials. Make available appropriate PPE, safety equipment, and materials necessary to contain and clean the spill. PPE used in general laboratory operations may not be sufficient for spill cleanups and may have to be supplemented based on the hazardous materials in use. Provide sufficient and appropriate supplies on hand to control the hazard and quantities of the spilled substance.

b. Notify the immediate supervisor and safety office of spills (other than minor spills). The first line supervisor will ensure the use of proper cleanup techniques.

c. Have a spill control plan available in the laboratory that has been reviewed by the safety and environmental offices and includes:

(1) The containment method to limit the spread of a spill.

(2) The disinfecting agent, the approach to its application, and contact time.

(3) Other parameters such as volume, degree of hazard of materials, and associated laboratory reagents.

d. Ensure that agents requiring BSL-3 and BSL-4 containment posing a high risk to workers and possibly to the environment are managed by well-informed professional staff trained and equipped to work with Risk Group 3 or 4 IAT in accordance with Reference (d).

e. Follow these procedures for cleaning up a spill within a BSC:

(1) General Procedures

(a) Contain the spill using absorbent material to limit spread.

(b) Confine the spill to a small area while minimizing the substance's conversion to an aerosol.

(c) Mark or annotate the area of the spill. (Absorbent material placed over the spill can fulfill this purpose.)

(d) If the spill is outside of engineering controls, evacuate the room, close all doors, and remove or decontaminate clothing.

(e) Chemically decontaminate or neutralize the spill (beginning at the perimeter of the spill and working towards the center, allowing a sufficient contact time), then clean and carefully dispose of the residue.

(f) If the spilled material is volatile, it may be allowed to evaporate, but must be exhausted by a chemical hood or ventilation system.

(2) Special Procedures. A spill of IAT material within a BSC requires a special response and cleanup procedure.

(a) Initiate cleanup while the cabinet continues to operate using an effective chemical decontaminating agent.

(b) Prevent aerosol generation during decontamination and the escape of contaminants from the cabinet.

(c) Exercise caution in choosing the decontaminant, keeping in mind that fumes from flammable organic solvents, such as alcohol, can reach dangerous concentrations within a BSC.

f. When reentry is necessary to clean a spill outside of a hood or BSC, perform a risk assessment to determine PPE requirements, entry and exit procedures (leaving outer garments of PPE in the laboratory or going through a personal decontamination station), and/or other specialized procedures. The risk assessment will be conducted with those knowledgeable of the spill, the safety and environmental offices, and those performing the cleanup.

g. Follow these procedures to clean combined radioactive and biological spills:

(1) Immediately notify the RSO and safety personnel whenever there is a spill of radioactive biological material, regardless of amount. Laboratory personnel may be expected to clean the spill. The RSO will direct the cleanup in accordance with the Nuclear Regulatory Commission license for the facility and/or applicable host-nation regulatory agency requirements.

(2) Clean the spill in a way that minimizes the generation of aerosols and the spread of contamination. Dispose of all items used in cleaning up the spill as radioactive waste.

(3) Following cleanup, survey the area, affected protective clothing, and all affected equipment and supplies for residual radioactive contamination. Wipe-test all potentially affected areas and items that are not disposable to verify that unfixed radioactive contamination has been

removed. If fixed contamination is found, the RSO will determine the requirements for additional cleanup.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ABSL	animal biosafety level
AI	as installed
AM	as manufactured
ANSI	American National Standards Institute
APHIS	Animal and Plant Health Inspection Service
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
AU	as used
BSAT	biological select agents and toxins
BSC	biological safety cabinet
BSE	bovine spongiform encephalopathy
BSL	biosafety level
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
cm^3	cubic centimeter
CMA	competent medical authority
DNA	deoxyribonucleic acid
DoDD	DoD Directive
DoDI	DoD Instruction
DUSD(I&E)	Deputy Under Secretary of Defense for Installations and Environment
EPA	Environmental Protection Agency
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
fpm	feet per minute
HEPA	high efficiency particulate air
IAT	infectious agents and toxins
IBC	institutional biosafety committee
IND	investigational new drug
IPM	integrated pest management
lfpm	linear feet per minute
m^3	cubic meters
m^3/min	cubic meters per minute
MSDS	material safety data sheet

MTF	medical treatment facility
NIH	National Institutes of Health
OPM	Office of Personnel Management
OSHA	Occupational Safety and Health Administration
Pa	pascal
PPE	personal protective equipment
RCRA	Resource Conservation and Recovery Act
RSO	radiation safety officer
SIP	Special Immunization Program
SOH	safety and occupational health
SOP	standing operating procedure
USD(AT&L)	Under Secretary of Defense for Acquisition, Technology, and Logistics
UV	ultraviolet
wg	water gauge

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Manual.

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

airborne droplet nuclei. Small particle residue of evaporated droplets less than 5 micrometers in size containing microorganisms that remain suspended in air for long periods of time.

airborne transmission. A means of spreading infection when airborne droplet nuclei are inhaled by the susceptible host.

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

biomedical research. The application of biological science for medical research, development, test, and evaluation.

BSAT. The biological select agents and toxins listed in sections 73.3 and 73.4 of Reference (j), section 331.3 of Reference (k), and sections 121.3 and 121.4 of Reference (l).

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

Class I, II, and III BSC. Defined in Reference (d).

Class II Type B1 and B2 BSCs. Defined in Reference (d).

BSLs-2, -3, and -4. Defined in Reference (d).

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 BSLs.

Class A-D accidents. Defined in Reference (m).

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 (e.g., ultrasonic cleaners) with appropriate chemical agents.

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 healthcare facility responsible for the provider's place of duty or, if not privileged for independent practice (e.g., a physician assistant or nurse practitioner), then is supervised by an appropriately trained CMA physician who is privileged to practice independently. A CMA is someone who has been specifically trained as a CMA and appointed in writing as a CMA by the MTF commander (or contracting officer representative) responsible for reviewing healthcare services or conducting clinical evaluations for purposes of the personnel reliability program. For activities that do not require a personnel reliability program, a CMA may be required to have training and qualifications supporting risk management of the specific processes. Occupational Medicine privileges would be sufficient and the requirement of appointment in writing as a CMA would not be required.

commanding officer or institute director. The commanding officer or institute director of an activity conducting research, development, test, evaluation, or sampling and analysis with IAT, or the equivalent at a research organization under contract to the biological defense program.

competent. By way of training, experience, education, licensing, and/or certification (as appropriate), is knowledgeable of applicable principles, practices, and standards of a particular

activity; is capable of identifying risks and hazards relating to the activity; and has authority to ensure the safety of an activity.

decontamination. The physical or chemical processes by which an object or area, contaminated with a harmful or potentially harmful IAT, is made safe for handling or use. Such processes include physical removal of most contaminants, thermal destruction of biological activity (sterilization), chemical inactivation (biocidal process), or a combination of these methods.

disinfection. A generally less lethal process of microbial inactivation (compared to sterilization) that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

germicide. A chemical that destroys microorganisms. Germicides may be used to inactivate microorganisms in or on living tissue (antiseptics) or on environmental surfaces (disinfectants).

glove box. An enclosure that provides a positive barrier from liquids, solids, aerosols, and chemical vapors. The box maintains personnel protection through solid barriers and maintenance of a negative pressure relative to its surroundings.

HEPA filter. A filter that removes particulate matter down to submicron-sized particles from the air passed through it with a minimum efficiency of 99.97 percent. 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 etiological agents from air exhausted from engineering controls and facilities.

high-level disinfection. A disinfection process that inactivates vegetative bacteria, mycobacteria, fungi, and viruses, but not necessarily high numbers of bacterial spores.

IAT. Fungi, virus, bacteria, prions, rickettsia, parasites, or a viable microorganism or its toxin or a prion that lacks nucleic acids and that causes or may cause disease, and any material of biological origin that poses a degree of hazard similar to those organisms.

inactivated. A microbiological sample that is free from living organisms, including spores. The organisms are nonviable and cannot under any circumstance be viable (infectious).

institution. An organization (institute, agency, center, etc.), a contract organization such as a school of medicine, or a research institute that conducts research, development, test, evaluation, 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 facilities. Research or production facilities involving viable IAT in quantities greater than 10 liters of culture.

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 (i.e., 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 (i.e., 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 agent in transmissible spongiform encephalopathies that causes diseases such as Creutzfeldt-Jakob disease, kuru, scrapie, bovine spongiform encephalopathy (BSE), and the human version of BSE, which is variant Creutzfeldt-Jakob disease.

qualified SOH personnel. Civilian personnel who meet Office of Personnel Management (OPM) standards for SOH 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, and/or Environmental Health Technician GS-699, and military personnel equally qualified when compared to OPM standards. In addition, in order to be considered SOH qualified for microbiological and biomedical safety, the individual must demonstrate that he or she has attended and successfully completed microbiological and laboratory courses of instruction as approved by the appropriate DoD safety office.

RCRA-listed hazardous waste. The waste materials listed by the EPA under authority of the RCRA for which the agency regulates disposal. A description and listing of these wastes is located in the RCRA.

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 to an absolute minimum worker and environment risk of exposure to an agent.

Risk Groups 3 and 4. Defined in Reference (d).

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 being in 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.

ventilated balance enclosure. 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.

ventilated cage areas. Areas within a room that have solid walls for containing multiple cages housing infected or intoxicated animals.

ventilated cage enclosures. The four types of ventilated animal cages are:

filter-top cage. A small laboratory animal polystyrene or polycarbonate cage bottom fitted with a dome-shaped glass fiber or polyester filter cage cover. The dome-shaped filter helps reduce the dissemination of aerosols.

forced ventilation cage. A small HEPA-filtered animal cage connected to a centralized exhaust system.

cubicle-type isolation cage. A partial containment unit that holds several animal cages. This unit is a negative pressure HEPA-filtered stainless steel cage.

total containment cage. 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 BSC.

working opening. The size of the opening created from the sash position at the front of a chemical fume hood. Although each sash position creates a different face velocity, the working opening represents that sash position used while working in the hood. It may represent a single sash position or a range (i.e., 12- to 18-inch opening) and must be such that the face velocity is within 80-120 fpm as specified in Table 5.