



DoD MANUAL 6055.18

SAFETY STANDARDS FOR MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES

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Purpose: In accordance with the authority in DoD Directive 5124.11 and the April 10, 2019 Deputy Secretary of Defense Memorandum, and the guidance in DoD Instructions (DoDIs) 6055.01 and 6055.05, this issuance assigns responsibilities and prescribes technical safety requirements for the DoD to use, handle, transport, transfer, store, and dispose of infectious agents and toxins (IAT):

- In DoD laboratories rated at biosafety level (BSL)-2, animal biosafety level (ABSL)-2, and higher (not including clinical laboratories).
- Used in microbiological laboratories in biomedical and biological research settings, microbiology teaching laboratories, public health laboratories, and veterinary reference laboratories that use, handle, transport, transfer, store, or dispose of IAT.

TABLE OF CONTENTS

SECTION 1: GENERAL ISSUANCE INFORMATION	5
1.1. Applicability.	5
SECTION 2: RESPONSIBILITIES	6
2.1. Assistant Secretary of Defense for Readiness.	6
2.2. DoD Component Heads.	6
2.3. Secretary of the Army.	6
SECTION 3: PRINCIPLES OF BIOSAFETY	7
3.1. General.	7
3.2. Biological Safety Program.	7
3.3. Risk Management.	8
3.4. Biological Risk Assessment and Determination of BSL.	8
3.5. Safety Controls.	9
SECTION 4: BIOLOGICAL SAFETY PROGRAM	11
4.1. General.	11
4.2. Biological Safety Committee.	12
4.3. Biosafety Officer.	12
4.4. Risk Assessment and Management.	13
4.5. SOPs.	14
4.6. Facility Design, Commissioning and Decommissioning.	15
4.7. Access Control.	16
4.8. Personnel Qualifications and Training.	17
4.9. Safety Information.	20
4.10. Inspections.	20
4.11. Mishap Notification, Investigation, and Reporting.	22
4.12. Recombinant or Synthetic Nucleic Acid Molecules.	24
4.13. Contract Activities.	25
4.14. Maintenance Controls.	25
APPENDIX 4A: LABORATORY SAFETY INSPECTION CHECKLISTS	26
SECTION 5: OH PROGRAM.	31
5.1. General.	31
5.2. CMA Responsibilities.	31
5.3. CMA Training.	32
5.4. Medical Qualification and Medical Surveillance Examinations.	32
a. Pre-Placement Examinations.	32
b. CMA Role in Pre-Placement Examinations.	33
c. Baseline Medical Surveillance Examinations.	34
d. Periodic Medical Surveillance.	34
e. Termination Examinations.	35
f. Post-Exposure Examinations for Occupational Illnesses and Injuries.	35
g. Documentation of Medical Opinion.	36
5.5. Health Hazard Education.	37
5.6. Immunoprophylaxis.	38
5.7. Illness and Absence Monitoring.	40

5.8. Serum Banking.....	40
5.9. Medical Qualification Determination.	41
SECTION 6: FACILITY SAFETY CONTROLS	43
6.1. Facility Design, Commissioning and Decommissioning (Secondary Barriers).	43
6.2. Emergency Back-Up Power.....	43
6.3. Large-Scale Production and Research Activities.....	43
SECTION 7: SAFETY EQUIPMENT	44
7.1. General.....	44
7.2. Engineering Controls.	44
7.3. Class III BSC.	46
7.4. Ventilated Balance Enclosures.	47
7.5. Ventilated Cage Enclosures.	47
7.6. General Practices Applicable to IAT.	48
a. Hallways and Stairways.	48
b. Labeling.	48
c. Storage.....	48
d. Eyewash and Shower Equipment.....	49
7.7. Ventilated Cage Areas.	49
SECTION 8: BIOSAFETY PRACTICES	50
8.1. Additional Techniques Applicable to Work with IAT.	50
8.2. Operations with Radioactive Material.	51
8.3. Certification of Inactivated Microorganisms and Removal.....	51
8.4. Working with Vertebrate Animals.....	52
8.5. Working with Invertebrate Vectors and Hosts.....	52
8.6. Specific Requirements for BSL-4 and ABSL-4.....	52
8.7. Toxins.	53
8.8. Integrated Pest Management.....	54
SECTION 9: PPE	55
9.1. General.....	55
9.2. Specific Requirements for Individual PPE.	56
SECTION 10: TRANSPORTATION AND TRANSFER OF IAT AND BSAT	57
10.1. General.....	57
10.2. Transportation and Transfer of IAT.....	57
10.3. Transportation and Transfer of BSAT.	58
SECTION 11: INACTIVATION, DECONTAMINATION, AND DISPOSAL	59
11.1. General.....	59
11.2. Inactivation.	59
11.3. Methods of Decontamination.....	59
a. Autoclave.	59
b. Dry Heat.....	60
c. Liquids.....	60
d. Vapors and Gases.....	61
e. UV Radiation.	61
f. Gamma Irradiation.....	62
11.4. Disposal.....	62

SECTION 12: EMERGENCY PLANNING AND RESPONSE..... 63

- 12.1. General..... 63
- 12.2. Emergency Procedures..... 63
 - a. General Emergency Procedures. 63
 - b. Emergency Alarm System. 64
 - c. Shut-Down and Start-Up Procedures. 65
- 12.3. Spills. 65

GLOSSARY 68

- G.1. Acronyms. 68
- G.2. Definitions..... 69

REFERENCES 77

TABLES

- Table 1. United States and HN Consensus Standards for BSCs and Fume Hoods 7
- Table 2. BSL-2 and ABSL-2 Checklist 26
- Table 3. BSL-3 and ABSL-3 Checklist 28
- Table 4. BSL-4 and ABSL-4 Checklist 29
- Table 5. Chemical Fume Hood Performance Criteria 45
- Table 6. Ventilated Animal Cages 48

SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

This issuance:

a. Applies to:

(1) 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 DoD (referred to collectively in this issuance as the “DoD Components”).

(2) All DoD biomedical and biological research settings, microbiology teaching laboratories, environmental and public health laboratories, veterinary laboratories, and nonclinical microbiological laboratories that use, handle, transport, transfer, store, or dispose of IAT.

b. Does **not** apply to clinical laboratories and chemical, biological, radiological, and nuclear medical contingency response laboratories that:

(1) Routinely grow and manipulate Risk Group 2 or higher bacteria, viruses, and fungi that comply with the requirements of Section 493.1101(d) of Title 42, Code of Federal Regulations (CFR); Section 1910.1030 of Title 29, CFR; and DoD Manual 6440.02.

(2) Import IAT into the United States in accordance with Section 71.54 of Title 42, CFR and Part 122 of Title 9, CFR.

SECTION 2: RESPONSIBILITIES

2.1. ASSISTANT SECRETARY OF DEFENSE FOR READINESS.

Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the Assistant Secretary of Defense for Readiness:

- a. Monitors the effectiveness of this issuance through annual program reviews and data calls.
- b. Develops and updates biological safety program policy to continuously improve safety and occupational health (SOH).
- c. Represents the Secretary of Defense on biological SOH.

2.2. DOD COMPONENT HEADS.

When conducting microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2), the DoD Component heads:

- a. Implement the procedures in this issuance by establishing and maintaining a biological safety program as part of the SOH program.
- b. Comply with host nation (HN) requirements for review, approval, certification, incident reporting, and national or international compliance requirements.

2.3. SECRETARY OF THE ARMY.

In addition to the responsibilities in Paragraph 2.2., the Secretary of the Army:

- a. Serves as the DoD Executive Agent for the DoD Biological Select Agents and Toxins (BSAT) Biosafety Program, in accordance with DoD Directive 5101.20E.
- b. Is responsible for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handle BSAT and has the tasking authority of all DoD Components for this purpose.
- c. Develops and coordinates BSAT security classification guidance, as appropriate, and provides that guidance to the DoD Components for consistency in classification and dissemination of information related to BSAT.

SECTION 3: PRINCIPLES OF BIOSAFETY

3.1. GENERAL.

a. Structured biological safety programs, mishap risk management, and biological risk assessments to determine BSLs and safety controls are required to protect employees and the public from hazards associated with IAT from microbiological activities.

b. All settings, laboratories, and facilities specified in Paragraph 1.1.a.(2) will follow consensus standards as applicable. Outside the continental United States, laboratories will use U.S. consensus standards at a minimum; HN consensus standards if they meet or exceed U.S. standards; and follow prescribed status-of-forces agreements, if applicable, for laboratory construction and operation. See Table 1 for an example of consensus standards for biological safety cabinets (BSCs) and fume hoods.

Table 1. United States and HN Consensus Standards for BSCs and Fume Hoods

	BSC CONSENSUS STANDARDS	FUME HOOD CONSENSUS STANDARDS
United States	National Sanitation Foundation/ American National Standards Institute (NSF/ANSI) Standard 49	ANSI/American Society of Safety Engineers Standard Z9.5 ANSI/American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 110
Europe	European Standard (EN) 12469	British Standard (BS) EN 14175-1 BS EN 14175-2 BS EN 14175-3 BS EN 14175-4 European Committee for Standardization/ Technical Specification 14175-5 BS EN 14175-7
Britain	BS 5726	BS 7989
Japan	Japanese Standards Association JIS K 3800	

3.2. BIOLOGICAL SAFETY PROGRAM.

a. Each DoD Component conducting microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2), will 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 (OH) 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 occupational duties and activities.

(3) Includes location-specific emergency response procedures.

b. When the DoD Component conducting microbiological activities is a tenant on an installation, that Component will coordinate its biological SOH program with the installation commander, or senior mission commander or designated representative if serving in the same capacity as the installation commander, and designated SOH representatives.

3.3. RISK MANAGEMENT.

The risk management process will:

- a. Anticipate and identify hazards.
- b. Assess hazards to determine risk from exposure.
- c. Develop controls and make risk decisions.
- d. Implement controls.
- e. Supervise and evaluate control effectiveness.

3.4. BIOLOGICAL RISK ASSESSMENT AND DETERMINATION OF BSL.

Biological risk assessment determines the appropriate BSL for handling a particular IAT. Procedures for defining the BSL and ABSL are in the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories (BMBL). The four ascending levels of containment, BSL-1 and ABSL-1 through BSL-4 and ABSL-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. IAT infectivity and toxicity.
- b. Severity of disease and toxic effects caused by IAT.
- c. Availability of preventive measures, countermeasures, and effective treatments for disease and toxic effects caused by IAT.
- d. Transmissibility, dose, and potential exposure routes of infectious agents.
- e. Nature of the work being conducted.
- f. Origin of the agent (whether indigenous, exotic, or genetically modified).

3.5. SAFETY CONTROLS.

Safety controls will follow the BMBL and:

- a. Be identified in the risk management process and conform with statutory and regulatory requirements.
- b. Be documented in the DoD Component safety program, the laboratory specific biosafety manual, and standard operating procedures (SOPs).
- c. Include:
 - (1) Specific requirements for facility design, commissioning and decommissioning, and construction (secondary barriers), such as directional airflow, emergency back-up power, and continuity of seals between the floors and walls.
 - (2) Safety equipment (e.g., BSCs, glove boxes, laboratory fume hoods).
 - (3) Laboratory practices and safety requirements, including special practices and requirements.
 - (4) Personal protective equipment (PPE) (e.g., respiratory protection, eyewear, face shields, gloves, protective overgarments).
 - (5) Access controls and rosters.
 - (6) Signage, labeling of containers, and safety communications.
 - (7) Hazard-specific medical surveillance and immunizations.
 - (8) Disinfection and sterilization.
 - (9) Hazardous biological waste handling, decontamination, packaging, and disposal.
 - (10) Spill response and emergency procedures.
- d. For design and implementation of safety controls, follow the hierarchy of controls and priority listed below:
 - (1) Hazard elimination.
 - (2) Substitution of less hazardous materials, processes, operations, or equipment.
 - (3) Engineering controls.
 - (4) Administrative controls, such as warning labels and markings.

(5) PPE, which will be used after the completion of a hazard assessment meeting the requirements of Sections 1910.132 and 1910.1030(d)(3) of Title 29, CFR, as appropriate, when:

- (a) Other higher priority controls are not feasible or do not sufficiently control the hazard;
- (b) Development or installation of engineering controls are pending; or
- (c) Use will be for short-term, non-routine, or emergency operations for which engineering controls are not practical (e.g., spills response and cleanup, malfunctions, emergency egress, damage-control activities).

SECTION 4: BIOLOGICAL SAFETY PROGRAM

4.1. GENERAL.

The DoD Components conducting microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2) must develop and implement a biological safety program. Biological safety programs and requirements must be tailored to the laboratory's mission (e.g., biological research, development, test, and engineering; food and environmental surveillance; public health) and address:

- a. Program policy, goals, and responsibilities.
- b. Composition and conduct of biological safety committees, if applicable. This requirement may not be appropriate for a deployable laboratory.
- c. Requirements and procedures for risk assessments, selection of appropriate BSL, and OH.
- d. Facility design, commissioning and decommissioning, if applicable. This requirement may not be appropriate for a deployable laboratory.
- e. Access control.
- f. Engineering controls, safety equipment (selection, use, training, testing, and maintenance), and safety information.
- g. Biosafety practices, biosafety manuals, and SOPs.
- h. PPE (selection, use, training, testing, and maintenance).
- i. Labeling and posting of hazards.
- j. Chemical hygiene plan.
- k. Personnel qualifications and training.
- l. Surveillance, monitoring activities, and inspections.
- m. Facility, utilities, and equipment continuing maintenance plan.
- n. Pest management.
- o. Transportation, transfer, decontamination, and disposal of IAT.
- p. Emergency planning and response.
- q. Mishap investigation and reporting.
- r. Select agent registration, if applicable.

- s. Recombinant or synthetic nucleic acid molecules, if applicable.
- t. Radiation safety, if applicable.
- u. Animal safety requirements described in DoDI 3216.01, if applicable.
- v. Contract activities, if applicable.
- w. Institutional review board requirements when human subjects research is being conducted.

4.2. BIOLOGICAL SAFETY COMMITTEE.

a. Organizations conducting microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2) must establish and charter a biological safety or similar committee. Smaller laboratories may consider joining to form a regional biological safety committee. This biological safety committee should consist of qualified occupational and environmental health (OEH) personnel, equipment and facility maintenance and safety personnel, and members of the organization's workforce.

b. Members of these committees should be DoD contractors, full-time or permanent part-time federal employees, or assigned military personnel. An alternative option is to add biosafety responsibilities to an existing committee, when the makeup is consistent with that of a stand-alone biological safety committee, with appropriate changes made to the charter of that committee to reflect the addition of biosafety responsibilities.

c. At a minimum, the committee must:

- (1) Review proposed work activities and facility modifications.
- (2) Assist in performing biological risk assessments.
- (3) Discuss mishaps and near misses.
- (4) Review results of compliance inspections.

d. The biological safety committee will meet regularly (at least annually), at a minimum. Minutes will be prepared and staffed through executive leadership and made available for review, and maintained for at least 3 years.

4.3. BIOSAFETY OFFICER.

a. Organizations conducting microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2) must designate a biosafety officer. Biosafety officers will be trained and qualified as specified in Paragraph 4.8.a.

b. Biosafety officers serve as biosafety subject matter experts (SMEs) 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.

c. It may be appropriate to designate a regional biosafety officer who would serve as the biosafety SME, providing support to organizations conducting microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2) within a specified region or area of responsibility. The DoD Components would determine the appropriate designation and specific role of a regional biosafety officer, based on available resources and organizational requirements. The biosafety officer:

(1) When employed on a regional basis will, at a minimum, contact the commander's or director's designated safety point of contact every 6 months and determine if support is needed with the laboratory's risk assessments, risk management, biosafety controls, biological safety program management, SOPs, biosafety training, inspections, mishap notification, investigation and reporting, and emergency planning and response.

(2) When notified of a biological mishap, will contact the commander's or director's designated safety point of contact and offer assistance with mishap notification, investigation, and reporting. All contact with the laboratory and support provided will be documented and retained for 3 years.

4.4. RISK ASSESSMENT AND MANAGEMENT.

a. Organizations conduct a risk assessment for microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2). 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, primary barriers, facility design, commissioning and decommissioning), residual risk level, and means for implementing the recommended controls will be identified. Organizations will use DoD Component-specific risk management processes and document risk assessments in accordance with Component-specific requirements.

b. Organizations must perform and document a risk assessment for any deviation from a required or recommended procedure or safeguard.

c. The principal investigator or immediate supervisor is responsible for conducting the risk assessment in close coordination with laboratory, safety, OEH, and biosafety personnel and the biological safety committee, if required, to comply with established guidelines and regulations.

d. The general approach to risk assessment and management is provided in DoDI 6055.05.

4.5. SOPS.

a. Each DoD organization conducting microbiological activities at BSL-2, ABSL-2, and higher in the settings, laboratories, and facilities specified in Paragraph 1.1.a.(2) must establish an SOP for each hazardous laboratory activity and activity involving IAT. A copy of the SOP (either an electronic copy or a paper copy) must be maintained and made available in each work area where the activity is conducted. Designated individuals (e.g., supervisors, laboratory managers, and safety managers) must also maintain a library of all SOPs in a centralized, accessible location. SOPs must address:

(1) Any unique procedures and requirements 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, personnel monitoring).

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

(3) Emergency procedures.

b. If the laboratory uses external-agency standardized SOPs (e.g., SOPs developed by the CDC for Laboratory Response Network laboratories), any of the items in Paragraphs 4.5.a.(1) through 4.5.a.(3) that are not addressed in the SOP must be addressed in the laboratory-specific safety manual or in an addendum to the SOP.

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

d. SOPs must:

(1) Limit personnel engaged in an activity to the minimum number of appropriately qualified and trained personnel required to safely complete the activity. The supervisor and the SOP approving official determine the number of appropriately qualified and trained personnel.

(2) Limit the period of activity to the shortest time necessary, and the amount of material handled to the minimum that is appropriate and consistent with program objectives and safe operations.

(3) Maximize use of engineering controls, work practices, and administrative controls to minimize the need for PPE.

e. Personnel with specialized knowledge (e.g., safety, OEH, biosafety, environmental protection, regulatory compliance, logistics, quality assurance, fire and emergency services, engineering, HN agreements and requirements, as required) must:

(1) Review SOPs for accuracy, compliance with standards and regulations, and conformity with accepted practices.

(2) Provide concurrence with the SOP before it is signed by the approving authority.

f. SOPs should include:

(1) Activity name.

(2) Name of process.

(3) Unique SOP number.

(4) Date and version or document control number of the SOP.

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

(6) Signatures of:

(a) Supervisors or persons in charge, indicating that they have read the SOP and associated risk assessment, 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:

1. Within the first year of assignment.

2. Beginning an operation that is intermittent and has not been performed within 6 months.

3. A change is made to the SOP.

4. Following periodic reviews and updates as described in Paragraph 4.5.c.

(b) Operator(s) attesting to the fact that they have read and understand the SOP and associated risk assessment.

(7) The use of an alternative form of electronic tracking and acknowledgement of SOPs and the requirements as specified in Paragraph 4.5.f.(6).

g. Supervisors, safety personnel, OEH personnel, and biosafety professionals must evaluate SOP validity and compliance during routine inspections (i.e., observe employees performing work and validate that risks are appropriately and comprehensively identified, controls implemented, and procedures followed).

4.6. FACILITY DESIGN, COMMISSIONING AND DECOMMISSIONING.

a. The design of new construction or major modification of biological facilities should follow the requirements specified in the BMBL and be reviewed by engineering, safety, security, biosafety, and OEH personnel. These reviews should be conducted through all phases of design in order to preempt and eliminate design problems, such as those often encountered during the

ventilation verification process. These efforts often prevent costly retrofits necessary to meet current standards and guidelines.

b. Before initial use, BSL-3, ABSL-3, BSL-4, and ABSL-4 laboratories must be validated for safe operation through a commissioning survey. As part of the commissioning process for laboratories working with BSAT, the laboratories must be in contact and coordinate with the DoD BSAT Biorisk Program Office to ensure the facility meets all federal requirements. HN agencies must be notified before a laboratory commissioning and should be involved in the commissioning survey. Facility design and commissioning survey criteria are contained in the BMBL and NIH Biosafety Level 3 Laboratory Certification Requirements. Organizations conducting commissioning surveys must:

(1) Have the architectural, mechanical, electrical, civil engineering, safety, biosafety, and OEH subject matter expertise (in-house or contracted) necessary to assess the criteria in the BMBL and NIH Biosafety Level 3 Laboratory Certification Requirements. If contracted, personnel must include DoD SMEs (e.g., qualified safety, OEH, biosafety, environmental protection, regulatory compliance, logistics, quality assurance, fire and emergency services, engineering) and HN agreements and requirements in the development, planning, and review of contracts for compliance with standards and regulations and conformity with accepted practices.

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

(3) Have access to the materials and equipment necessary to conduct the review, testing, and validation of the surveys.

c. A preoperational survey must be completed before starting operations at BSL-3, BSL-4, ABSL-3, and ABSL-4 facilities that are new or have undergone major modifications that affect one or more of the facility biosafety or biosecurity principles or commissioning criteria described in the BMBL and NIH Biosafety Level 3 Laboratory Certification Requirements. The preoperational survey must evaluate the implementation and effectiveness of the facility's biosafety control measures and compliance with this issuance, including simulation of selected operational and emergency response operations.

d. Pre-operational survey teams should be composed of safety, biosafety, OEH, and laboratory operations SMEs. Laboratories that work with BSAT will contact the DoD BSAT Biorisk Program Office to confirm the final facility meets federal requirements.

e. Decommissioning is complex and must follow the guidance found in ANSI/American Society of Safety Engineers Z9.11-2016.

4.7. ACCESS CONTROL.

a. Access to BSL-2 and ABSL-2 facilities and higher where work with IAT is present must be limited in accordance with this issuance and DoD Component policies. Only persons who have been advised of the potential hazard and meet specific entry requirements (e.g., approval of principal 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. See DoDIs 5210.88 and 5200.08 and DoD 5200.08-R for more information on physical security requirements.

b. Access to BSL-3 and ABSL-3 facilities must be limited in accordance with Paragraph 4.7.a. and will be restricted to those persons whose presence in the facility or individual laboratory rooms is required for program or support purposes. Doors leading to these areas must have access restriction signs posted and be secured with locks (or equivalent means) to prevent unauthorized entry. All personnel must wear prescribed PPE before entry.

c. Access to BSL-4 and ABSL-4 facilities will be limited in accordance with Paragraphs 4.7.a. and 4.7.b. 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 must be advised of appropriate safeguards. Authorized persons must comply with these instructions and all other applicable entry and exit procedures.

d. All personnel must wear prescribed PPE before entry into the BSL-4 and ABSL-4 facilities and adhere to all prescribed procedures to contain hazards while inside the facility as described within the BMBL. Before exiting, all personnel must remove PPE and shower according to prescribed procedures of the BMBL. A record will be maintained of all personnel indicating the date and time of each entry and exit.

4.8. PERSONNEL QUALIFICATIONS AND TRAINING.

a. Biosafety officers must be federal employees (military or civilian) and have the following education, experience, training, and credentialing requirements:

(1) Graduation from an accredited college or university with a bachelor's degree in a physical or biological science field (e.g., microbiology, biology, laboratory sciences, environmental sciences, environmental health, epidemiology, environmental engineering). This should include coursework in general biology, microbiology, epidemiology, or pathogenic microbiology. Biosafety experience equivalent to 8 years or more may substitute for a bachelor's degree. Examples of qualifying biosafety experience include:

(a) Serving as an assistant biosafety officer responsible for a biosafety management program in a BSL-2, ABSL-2, or higher work setting where IAT was used, handled, transported, transferred, stored, or disposed.

(b) Performing and enforcing evidence-based safe laboratory practices, procedures, and proper use of containment equipment and facilities in a BSL-2, ABSL-2, or higher work setting where IAT was used, handled, transported, transferred, stored, or disposed to:

1. Prevent injury, infection, and death of employees and the public.
2. Prevent environmental contamination.

3. Ensure compliance with federal, State, and local regulations and guidelines.

(c) Hands-on application of methods for biological safety program implementation to safely control IAT in research, clinical, production, testing, or educational organizations in a BSL-2, ABSL-2, or higher work setting where IAT was used, handled, transported, transferred, stored, or disposed.

(2) A total of 5 years or more of professional biological safety experience as described in Paragraph 4.8.a.(1). Experience as an installation, biomedical facility, or hospital safety officer does not count towards fulfilling this experience requirement. If 8 or more years of biosafety experience is used to satisfy the bachelor's degree requirement described in Paragraph 4.8.a.(1), this requirement has been met.

(a) A master's degree in a relevant discipline counts for 2 years toward this 5-year requirement.

(b) A doctoral degree in a relevant discipline counts for 3 years toward this 5-year requirement.

(3) Completed Service-approved biosafety course that includes training in Service-specific safety policies and standards and risk management, when available. Commercially available courses may be substituted when Service-specific courses are unavailable.

(4) Recognized professional credentials, such as the Certified Biological Safety Professional or a Registered Biosafety Professional are desired. Individuals having any of these recognized professional credentials do not have to meet the education and experience requirements described in Paragraphs 4.8.a.(1) and 4.8.a.(2).

b. Supervisors overseeing the laboratories will:

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

(2) Provide appropriate training to employees, including required refresher training, to safely execute the IAT operations.

(3) Provide appropriate safety equipment and controls that are safe, functioning, inspected, tested, and maintained.

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

c. Before performing assigned duties, personnel working with IAT will receive initial training to develop awareness of the associated hazards and demonstrate proficiency in microbiological practices and procedures. Personnel will subsequently receive annual refresher training, developed in coordination with the safety office and documented including 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. Since some laboratory personnel work with an extensive listing of IAT within the laboratory, it is sufficient to complete this training for classes or groupings of IAT.
- (4) Facility safety controls.
- (5) Selection, use, and care of safety equipment (e.g., BSCs, glove boxes, laboratory fume hoods).
- (6) Laboratory practices and safety requirements, including all applicable SOPs and special practices and requirements.
- (7) Bloodborne pathogens (BBPs) pursuant to Section 1910.1030 of Title 29, CFR; hazard communication pursuant to Section 1910.1200 of Title 29, CFR; and occupational exposure to hazardous chemicals in laboratories pursuant to Section 1910.1450 of Title 29, CFR.
- (8) Selection and use of PPE pursuant to Appendix B to Subpart I of Part 1910 of Title 29, CFR and Section 1910.1030(d)(3) of Title 29, CFR, as appropriate.
- (9) Access control.
- (10) Facility signage, labeling of containers, and safety communications.
- (11) The purpose and description of the OH 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 4.10.
- (17) Transportation (packaging and shipment) and transfer of IAT, when applicable.

(18) Applicable HN 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 orientation period, new laboratory personnel will be under the supervision of appropriately trained personnel.

e. Personnel working with BSAT will comply with all training and certification requirements, including refresher training, described in DoDI 5210.88 and Section 331.15 of Title 7, CFR; Section 121.15 of Title 9, CFR; and Section 73.15 of Title 42, CFR, as applicable.

4.9. SAFETY INFORMATION.

Commanders and directors must establish a system of communications to provide:

- a. Biological safety advice and accounts of laboratory mishaps, including lessons learned.
- b. Training for laboratory personnel on information within SOPs, safety data sheets (SDSs), regulations, and other safety and health references used in work activities.
- c. Access to SDSs or other appropriate health and safety references during the work shift. If SDSs are accessed electronically (e.g., Internet, CD-ROM), each employee will be trained on an alternative procedure to access SDSs in the event the laboratory's electronic access is not available.
- d. Training for laboratory personnel about the process for accessing SDSs for hazardous chemicals and IAT used in the work area and for accessing laboratory SOPs.

4.10. INSPECTIONS.

- a. Before performing an operation with IAT, operators will survey the work area. Operators will have a means to correct any deficiencies found or report any unsafe conditions and have them corrected before beginning operations.
- b. The laboratory supervisor will designate a laboratory safety point of contact for each shift or operational period, trained and qualified in accordance with Paragraphs 4.8.b.(4) and 4.8.c., for each laboratory. The laboratory point of contact 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 or near specific items (such as BSCs, fume hoods, autoclaves, centrifuges, freezers, and refrigerators) and, every day the laboratory is in use, laboratory personnel will document checks performed for proper operation and identify any malfunction or safety concern.
 - (2) Report malfunctions of room or building systems to the supervisor.

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

(4) Label the laboratory room, safety controls, and equipment 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 4.8.b.) or a designated individual (trained and qualified in accordance with Paragraphs 4.8.b.(4) and 4.8.c., typically the laboratory safety officer) will conduct and document semiannual inspections of the laboratories. The checklists provided in Appendix 4A describe the minimum requirements to follow for these inspections and can be modified at each facility to address additional laboratory-specific requirements.

d. The safety officer, biosafety officer, or qualified SOH personnel designated by the commanding officer or institute director, must inspect all active BSL-2, ABSL-2, and toxin laboratories at least semiannually, along with BSL-3, ABSL-3, BSL-4, and ABSL-4 laboratories and those in which dry forms of toxins are handled. Outside, independent SMEs and HN representatives can be invited to participate in the inspections, as appropriate.

e. A representative of the facility's OH staff should participate in inspections at least annually to identify potential workplace OH hazards and determine if revision of exposure prevention strategies is indicated. These documented inspections may be unannounced and will include coverage of general safety practices and requirements applicable to the laboratory's BSL or ABSL. One of the semiannual inspections can be an SOH inspection.

f. Qualified SOH personnel, as defined in DoDI 6055.05, must periodically conduct an industrial hygiene (IH) survey of organizations with a setting, laboratory, or facility specified in Paragraph 1.1.a.(2) based on DoD Component-specific IH program timelines and priorities, but, as a minimum, at least on an annual basis. The survey should:

(1) Identify and document chemical, physical, biological, and ergonomic hazards in accordance with DoDI 6055.05. Qualified SOH personnel will assess hazards to determine risk and recommend appropriate hazard controls as detailed in DoDI 6055.05.

(2) Be documented in the Defense Occupational and Environmental Health Readiness System-Industrial Hygiene (DOEHRs-IH) for those DoD Components that use DOEHRs-IH to document IH surveys.

g. Laboratory operators and personnel who identify deficiencies or procedures that create a potentially life-threatening situation must immediately notify supervisory personnel. Supervisors will notify the safety office and commanding officer or institute director and, if the facility is a tenant on an installation, the installation commander and installation emergency manager, as appropriate. The operation will be stopped and corrective actions immediately implemented, or the residual risk accepted at the appropriate level in accordance with DoD risk acceptance policy in DoDI 6055.01.

h. Reports of deficiencies for other than life-threatening situations will be made, as soon as possible, to the appropriate supervisor, with copies furnished to the safety office. All affected personnel must be notified.

4.11. MISHAP NOTIFICATION, INVESTIGATION, AND REPORTING.

Responsible officials must investigate all biological mishaps for the purpose of accident prevention.

a. The responsible official will notify, investigate, and report BSAT mishaps in accordance with the requirements of this issuance; DoDI 5210.88; Part 73 of Title 42, CFR; Part 331 of Title 7, CFR; Part 121 of Title 9, CFR; the DoD BSAT Biorisk Program Office; and applicable State and local requirements.

b. BSAT mishaps must also be reported in accordance with DoDI 5210.88 and will:

(1) Be in accordance with Part 73 of Title 42, CFR; Part 331 of Title 7, CFR; and Part 121 of Title 9, CFR, as applicable, and immediately notify the CDC or the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) on discovery of a release of a BSAT causing a potential occupational exposure or occurring outside of the primary containment barriers of the biocontainment area (e.g., BSCs, trunnion centrifuge cups, aerosol-containing blenders). In accordance with HN laws and bilateral agreements, immediately notify the appropriate HN agencies. Provide the CDC Division of Select Agents and Toxins (DSAT), USDA APHIS, or HN agencies with:

(a) Name of the BSAT and any identifying information (e.g., strain and agent 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 (e.g., installation, activity, building, room) from which the release occurred or where the exposure occurred.

(f) Number of individuals potentially exposed.

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

(h) Actions taken to respond to the release.

(i) Hazards posed by the release.

(2) Notify the appropriate installation emergency manager and State and local health agencies of an exposure that could present a threat to public health or a release of BSAT outside of the containment barrier.

(3) Report all serious BSAT mishaps as described in Paragraph 4.11.b.(4) that were reported to the CDC DSAT or USDA APHIS to the DoD BSAT Biorisk Program Office and to first general officer/flag officer (GO/FO) (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 GO/FO (or equivalent) receiving the report will forward it up the chain of command to the appropriate DoD Component safety office.

(4) Submit incident reports on BSAT mishaps in accordance with applicable internal DoD Component guidance for:

(a) Release 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 4-fold or higher rise in a specific antibody titer to the BSAT in question, or a confirmed clinical diagnosis of intoxication or disease. See routine medical surveillance details in Paragraph 5.4.

(c) The theft, loss, recovery, suspected theft, inventory shortage or overage, wrongful disposition, and unauthorized use or destruction of BSAT.

(d) Attempts to steal or divert BSAT outside of physical security controls.

(e) Actual or attempted unauthorized access at a facility or laboratory where BSAT is stored and handled.

(f) Significant or disabling damage to a facility where BSAT is stored and handled.

(g) Other incidents not identified in Paragraphs 4.11.c.(4)(a) through (f) that the commander determines to be of immediate concern based on the nature, gravity, and potential for adverse publicity, or potential consequences of the incident.

(5) Submit a completed USDA APHIS/CDC Form 3, "Incident Notification and Reporting (Theft, Loss, or Release)," to the CDC DSAT or USDA APHIS within 7 calendar days, with a copy forwarded through the first GO/FO (or equivalent) in the chain of command, to the appropriate DoD Component safety office and the DoD BSAT Biorisk Program Office. An electronic version of this form is available at <https://www.selectagents.gov/form3.html>.

(6) Submit a close-out report to the DoD BSAT Biorisk Program Office and 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) will be reported as follows:

(1) On discovery of a non-BSAT potential exposure or release of a non-BSAT outside of the laboratory that is a result of theft or criminal action, or poses a potential public health concern;

(a) Immediately notify the first GO/FO (or equivalent) in the mishap reporting chain. Include information in the reports required in accordance with Paragraph 4.11.b.(1).

(b) If the facility is a tenant on an installation, also report the mishap to the installation commander.

(c) The first GO/FO (or equivalent) receiving the report will forward it up the chain of command to the appropriate DoD Component safety office.

(d) The facility must notify law enforcement, as appropriate, and coordinate with the installation emergency management office to ensure notification of State and local health agencies and, in accordance with HN laws and bilateral agreements, the appropriate HN 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. BSAT mishaps occurring during biological activities will be reported in accordance with DoDI 6055.07.

e. All occupational exposures in DOEHRS-IH will be documented in accordance with DoDI 6055.05.

4.12. RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES.

a. When work with recombinant or synthetic nucleic acids (e.g., molecules, cells, organisms, and viruses containing such molecules) is undertaken that presents a significant risk to health or the environment as determined by the BSO, and excluding those primers used in diagnostic and detection assays including deoxyribonucleic acid plasmids used for diagnostic polymerase chain reaction controls, an institutional biosafety committee (IBC) must be established to review recombinant or synthetic nucleic acid activities and protocols. The IBC functions are stated in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

b. Activities funded by NIH involving recombinant or synthetic nucleic acid molecules, and cells, organisms, and viruses containing such molecules, must comply with all requirements of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and are subject to IBC approval. Facilities conducting work with these materials that are not funded by the NIH should adopt these guidelines as best practices.

4.13. CONTRACT ACTIVITIES.

Contracting officers will oversee and review contract biological safety clauses so that all clauses are contractually binding for those contractors who possess or use DoD-provided IAT. Each DoD Component is responsible for development of the biological safety contract clauses. Such clauses will be issued in accordance with Subparts 1.3 and 1.4 of the Federal Acquisition Regulation and Subparts 201.3 and 201.4 of the Defense Federal Acquisition Regulation Supplement.

4.14. MAINTENANCE CONTROLS.

A continuing maintenance process must be implemented for equipment and facilities. The maintenance process, at a minimum, will:

- a. Identify equipment and utility system components that require routine maintenance and inspection and must sustain specific operating performance criteria.
- b. Inspect, test, certify, maintain, and document equipment and utility system operating components for equipment and components identified in Paragraph 4.14.a.
- c. Investigate, report, and correct equipment and utility system problems, failures, and user errors.
- d. Require maintenance personnel to have the necessary knowledge, skills, and qualifications to inspect, test, certify, and maintain critical equipment and utility systems. This requirement exists for all maintenance personnel and should be specified in maintenance contracts.
- e. Respond to equipment and utility system failures or disruptions.

APPENDIX 4A: LABORATORY SAFETY INSPECTION CHECKLISTS

Tables 2 through 4, adapted from the BMBL, list items to consider when inspecting facilities where IAT is used. They provide basic guidelines on many of the requirements for BSL-2, ABSL-2, BSL-3, ABSL-3, BSL-4, and ABSL-4 laboratories. These checklists do not represent all of the laboratory safety requirements, but they represent basic, minimum requirements and should be modified, as necessary, to address additional areas like training, competency management, medical surveillance, and laboratory-specific requirements. 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 and ABSL-3 or BSL-4 and ABSL-4 laboratory inspection and using multiple checklists—in the event of multiple, similar requirements (e.g., item 18 in Table 2 and item 2 in Table 3)—the more stringent will apply.

Table 2. BSL-2 and ABSL-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 if appropriate for IAT in use.				
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, including 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 before and after completion of work and after any spill or splash of potentially hazardous material.				
8	Potentially infectious materials are decontaminated before disposal. If disposal is performed as a contracted service, the contract must specify this requirement.				
9	Biohazard symbol is at the entrance to the laboratory with the laboratory's BSL/ABSL, supervisor's name (or other responsible personnel), telephone numbers (office, cell, and home), agents in use (as per facility policy) and required procedures for entering and exiting the laboratory.				

Table 2. BSL-2 and ABSL-2 Checklist, Continued

#	IAT LABORATORIES, BSL-2	YES	NO	NA	COMMENTS
10	An integrated pest management program is in place.				
11	All people who enter the laboratory are advised of potential hazards.				
12	A laboratory-specific biosafety manual is available and accessible both inside and outside of the laboratory.				
13	Potentially infectious materials are placed in a durable, leak-proof container during collection, handling, processing, storage, or transport within a facility.				
14	Laboratory equipment is routinely decontaminated, as well as after spills, splashes, or other potential contamination and before repair, maintenance, or removal from the laboratory.				
15	Animals and plants not associated with the work being performed are not permitted in the laboratory.				
16	Any procedure involving the manipulation of infectious materials that may generate an aerosol is conducted within a BSC or other physical containment device.				
17	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.				
18	Eye, face, and respiratory protection are used in rooms containing infected animals unless the risk assessment indicates it is not required.				
19	Laboratory doors are self-closing and have locks in accordance with institutional policies.				
20	The laboratory has a sink for hand washing located inside the laboratory.				
21	The laboratory is designed so that it can be easily cleaned and decontaminated. There are no carpets or rugs.				
22	Laboratory furniture is capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.				
23	Bench tops are impervious to water and resistant to heat, solvents, acids, and other chemicals.				
24	Chairs used in laboratory work are covered with a nonporous material that can be easily decontaminated.				
25	Laboratory windows that open to the exterior are fitted with screens.				
26	BSCs are located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.				
27	Vacuum lines are protected with liquid disinfectant traps.				
28	An eyewash station is readily available.				
29	BSCs are certified annually.				
30	A method for decontaminating all laboratory wastes is available, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method) unless removed by an approved contractor.				

Table 3. BSL-3 and ABSL-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 Tyvek® or wraparound gowns, scrub suits, or coveralls are worn by workers in the laboratory.				
3	PPE is not worn outside of the laboratory.				
4	Reusable clothing is decontaminated with appropriate disinfectant before being laundered.				
5	Eye, face, and respiratory protection are used in rooms containing infected animals.				
6	Laboratory doors are self-closing and have locks in accordance with institutional policies.				
7	The laboratory is separated from areas that are open to unrestricted traffic flow within the building.				
8	Access to the laboratory is restricted to entry by a series of two self-closing doors.				
9	Laboratory has a sink (hands-free or automatically operated) for hand washing. If the laboratory is divided into different laboratories, a sink is available for hand washing in each zone.				
10	Seams, floors, walls, and ceiling surfaces are sealed. Spaces around doors and ventilation openings are capable of being sealed to facilitate space decontamination.				
11	Floors are slip resistant, impervious to liquids, and resistant to chemicals.				
12	Walls are constructed to produce a sealed, smooth finish that can be easily cleaned and decontaminated.				
13	Ceilings are constructed, sealed, and finished in the same general manner as walls.				
14	All windows in the laboratory are sealed.				
15	Vacuum lines are protected with high-efficiency particulate air (HEPA) filters, or their equivalent. Filters replaced as needed. Liquid disinfectant traps are present where required.				
16	A ducted air ventilation system provide sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas.				
17	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.				
18	Laboratory exhaust air is not re-circulated to any other area of the building.				
19	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).				
20	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.				
21	HEPA filter housings have gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing allows for leak testing of each filter and assembly and is certified at least annually.				
22	HEPA filters on exhaust air systems will be tested and certified or replaced annually.				
23	Disinfectants and decontaminants should be readily available for use before leaving the BSL-3/ABSL-3 laboratories.				

Table 4. BSL-4 and ABSL-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	Entry is limited by means of secure, locked doors. A logbook, or other means of documenting the date and time of all persons entering and leaving the laboratory is maintained.				
7	Personnel enter and exit the laboratory through the clothing change and shower rooms except during emergencies. All personal clothing is removed in the outer clothing change room.				
8	Monitors indicate that the room is under negative pressure relative to all entrances.				
9	All vacuum lines are protected with HEPA filters and liquid disinfectant traps.				
10	The autoclave is properly maintained and certified.				
11	Foot, elbow, and automatic hand wash sinks operate properly.				
12	Self-closing doors to the facility operate properly.				
13	Personnel completely exchange street clothing for laboratory clothing before entry and shower on exiting.				
14	Removal of biological materials to remain in viable or intact state are transferred to a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container. These materials are transferred through a disinfectant dunk tank, fumigation chamber, or decontamination shower. Once removed, material is not be opened outside BSL-4 containment unless inactivated by a validated method.				
15	The dunk tank disinfectant is fresh and appropriate for the agents in use.				
16	Supplies and materials not brought into the BSL-4 laboratory through the change room are brought in through a decontaminated double-door autoclave, fumigation chamber, or airlock.				
SUIT AREAS					
17	All operations with IAT are conducted in Class I or II BSCs.				
18	Procedures are in place so 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).				
19	Class I and II cabinets are certified at least annually and after repair, movement, maintenance, or filter change.				
20	The suit decontamination shower has adequate appropriate decontaminant available.				
21	The suit decontamination shower has been used or tested in the last month.				
22	The ventilated suit air supply and emergency air supply are adequate and working properly.				
23	The emergency alarm system is working properly.				

Table 4. BSL-4 and ABSL-4 Checklist, Continued

#	IAT LABORATORIES, BSL-4	YES	NO	NA	COMMENTS
SUIT AREAS					
24	All of the one-piece positive pressure suits available for use are in serviceable condition.				
25	Infected animals are housed in appropriate primary containment systems.				
26	The static pressure in the suit area is negative to all surrounding areas.				
NON-SUIT AREAS					
27	All operations with IAT are conducted inside Class III BSCs.				
28	Class III BSCs are certified before personnel initiate the current operation.				
29	All infected animals are housed in Class III cabinet containment caging systems.				

SECTION 5: OH PROGRAM

5.1. GENERAL.

The OH program will:

- 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 occupational duties and activities.
- b. Be part of the installation, medical treatment facility (MTF), or laboratory biological SOH program.
- c. Address the relevant requirements from the OH and immunoprophylaxis section of the BMBL and the other specific elements as they apply to the biological safety program. The OH program requires:
 - (1) Supervisors to identify to the competent medical authority (CMA) the employees' proposed tasks for working with IAT.
 - (2) Supervisors and biosafety professionals to conduct detailed risk assessments to determine exposure hazards and communicate those to the CMA and employees.

5.2. CMA RESPONSIBILITIES.

The CMA:

- a. Bases the content of pre-placement, periodic, and termination medical surveillance examinations on the exposure hazards identified in the risk assessments, IH survey and similar exposure group reports, and functional requirements of the job.
- b. Informs the workers of availability of medical support services, examinations, immunizations, and post-exposure prophylaxes.
- c. Provides licensed vaccines, when available and recommended based on risk assessment and medical opinion, for personnel whose duties may potentially expose them to IAT. Current immunization recommendations are provided in the CDC "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices."
- d. 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.
- e. Annually reviews occupational illness and injury reports, with the assistance of biological safety professionals, to determine if revision of exposure prevention strategies is indicated.

5.3. CMA TRAINING.

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 of Infectious Diseases (USAMRIID) 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 Biological Surety Medical Support Course, conducted by the U.S. Army Medical Department Center and School.

b. Medical professionals should complete specialized training before being clinically privileged and appointed to serve as CMAs.

5.4. MEDICAL QUALIFICATION AND MEDICAL SURVEILLANCE EXAMINATIONS.

The purpose of the medical qualification examination is to determine medical fitness to perform the duties of the specific position. Medical surveillance examinations are performed on employees when there are potential occupational exposures that can cause injury or illness to the employee. The purpose of the medical surveillance examination is to ensure the employee is protected from these occupational exposures and identify necessary actions needed to reduce or reverse the progression of adverse medical outcomes.

a. Pre-Placement Examinations.

Workers who may be exposed to IAT must receive a pre-placement medical evaluation. The purpose of the pre-placement examination is to establish medical qualification for the specific position, and secondarily may establish baseline health status for medical surveillance. Pre-placement examination standards are published by the Office of Personnel Management and may be supplemented by DoD Component-specific qualification standards. Once the examiner has performed the initial history, physical exam, and required testing (repeated if necessary to confirm abnormal results), he or she will determine the examinee's medical qualification.

(1) If the pre-placement exam results indicate a medical condition that likely precludes safe job performance, the examinee will be medically disqualified. If findings are insufficient to determine that the examinee is qualified, either because findings are not within defined limits or because findings are not conclusive, the examiner must find the examinee either not qualified or qualified with limitations.

(2) Once a determination has been made that an examinee is not medically qualified for the position, the employee will be notified of the disqualifying medical condition, and the government will not pay for any additional medical tests or consults.

(3) Examinees who have been found not medically qualified and wish to dispute those findings may, at their own expense, obtain and submit medical documentation that supports their claim that they are medically qualified for the position.

(4) The CMA must review any medical documentation provided by the examinee. If the CMA determines that a change in medical qualification status is indicated based on the documentation provided by the examinee (e.g., test results that confirm a definitive diagnosis different from a presumptive diagnosis made on the basis of the initial exam), the appropriate change in medical qualification status must be made and documented, and the employee's supervisor informed of the recommended change in status.

(5) The supervisor incorporates relevant portions of the risk assessment or job hazard analysis associated with the position, and completes an OH survey form detailing:

- (a) Requirements for the position.
- (b) Potential chemical, physical, and biological hazards.
- (c) PPE requirements.

b. CMA Role in Pre-Placement Examinations.

The CMA will be provided with the OH survey form (i.e., Optional Form 178, "Certificate of Medical Evaluation") before the examination and:

(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, 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 concerns regarding an individual's medical fitness to perform the duties of a specific position, and provide medical clearance for the wearing of respirators or other required PPE, as appropriate.

(4) Assess the adequacy of the worker's immune function. Impaired immune function may lead to a greater risk of laboratory-acquired infections. Immunosuppression can be the result of congenital or acquired immunodeficiency disorders, or as the result of disease states, such as human immunodeficiency virus infection, leukemia, lymphoma, splenectomy, diabetes mellitus, collagen vascular diseases, autoimmune diseases, use of high-dose corticosteroids, alkylating agents, antimetabolites, or radiation. The CMA must evaluate and document any evidence of impaired humoral or cell-mediated immunity, and obtain consultations from medical specialists, when appropriate. The CMA should:

(a) Use serologic testing to document baseline vulnerability to specific infections to which the worker might be exposed and inform non-immune workers about risks. In specific settings, serologic documentation that individual workers have pre-existing immunity to specific infections may be required for the protection of research animals.

(b) Inform the worker of potential health hazards in the work area, review steps that should be taken in the event of a potential exposure, and conform to any relevant BBP program requirements.

c. Baseline Medical Surveillance Examinations.

While these examinations may have been completed during the pre-placement exam, baseline medical surveillance examinations may be performed as separate examinations. For these examinations, the CMA must:

(1) Conduct baseline medical surveillance including updating medical and occupational history in the employee OH record. Laboratory tests conducted recently (e.g., within the past 3 months or during pre-placement examinations) may be used for the purpose of baseline surveillance examinations.

(2) If not already conducted, verify required immunizations and titers and offer vaccinations that are needed.

(3) Inform the worker of potential health hazards in the work area, review steps that should be taken in the event of a potential exposure, and conform to any relevant BBP program requirements.

d. Periodic Medical Surveillance.

The CMA must:

(1) Conduct periodic medical surveillance and:

(a) Update the employee's medical and occupational history from the previous year, including an assessment of the employee's immune status.

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

(c) Update respirator clearances, as required.

(2) In special circumstances, offer booster immunizations or check serological titers in workers with substantial risk of exposure to IAT to detect subclinical evidence of a laboratory-acquired infection. Before asymptomatic workers without prior history of IAT exposure potential 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 IAT operations, and review their risk assessment in conjunction with all OH examinations or screenings.

e. Termination Examinations.

(1) When possible, employees enrolled in medical surveillance who work in a BSL-3 or BSL-4 laboratory area will stop work in those laboratories 30 days before termination to allow for proper medical surveillance.

(2) The CMA should perform a termination-of-employment examination or a termination-of-exposure examination on employees within 30 days from 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 IAT exposure.

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

f. Post-Exposure Examinations for Occupational Illnesses and Injuries.

(1) In the event of injury or illness, consultation among the CMA, employee, and employee's supervisor is required for proper medical management and recordkeeping (i.e., a mishap report, Office of Workers' Compensation Program report, and Occupational Safety and Health Administration (OSHA) log). The supervisor and biological safety officer must report to the CMA all occupational injuries and potential exposures to IAT meeting pre-established potential exposure criteria. Strategies for responding to biohazard exposures should be formulated in advance. The CMA must:

(a) Identify or develop IAT-specific medical protocols, as practicable, that outline the proper clinical approach for assessing the circumstances of exposure, pathogenicity of the organism or potency of the toxin, route of exposure, risk of exposure and disease, medical history, targeted physical examination, diagnostic testing, and post-exposure prophylaxis or treatment. These medical protocols should:

1. Address how after-hours medical care will be provided or accessed.

2. Be provided to local hospitals with which the CMA has developed external support agreements, along with contact information for the CMA or other SMEs.

(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 (e.g., percutaneous, splash to mucous membranes or skin, aerosol).
3. Time and place of the incident.
4. PPE used at the time of the injury.
5. First aid previously 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 source of products and expert consultation.

1. 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 evidence 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 SMEs are especially useful.

2. 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. The CMA will:

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 re-evaluate current strategies to reduce the possibility of future exposures.

g. Documentation of Medical Opinion.

The CMA must record a written opinion in the medical record for each medical surveillance examination, including:

- (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 IAT.
- (3) Any recommended limitations on the potential exposure to an IAT 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.

5.5. HEALTH HAZARD EDUCATION.

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

- (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 and take corrective measures, if applicable.

b. Employee health education includes:

(1) Employee Health Training.

The CMA must:

(a) Review and provide input on employee training materials, local plans, policies, or procedures on the health effects or treatment aspects of IAT exposure; patient or skin decontamination procedures; use of respiratory, ocular, or dermal protective equipment to protect against IAT 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 or supervisor must provide health education materials for use in the employee training programs for all individuals with an exposure potential to IAT. Co-location of these documents with SDS used in the laboratory is recommended.

5.6. IMMUNOPROPHYLAXIS.

a. The CMA provides licensed vaccines, when available and recommended based on risk assessment and medical opinion, for laboratory workers whose duties may potentially expose them to IAT. Immunization recommendations from the CDC Advisory Committee on Immunization Practices are updated routinely at <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>, and from the Department of Health and Human Services at www.vaccines.gov. CMAs who offer licensed vaccines, as a means of lowering the risk of contracting laboratory-acquired infections, must develop a written immunoprophylaxis program document, with implementing SOPs.

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

(2) Written immunoprophylaxis programs must 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 commanding officer or institute director must review and approve immunoprophylaxis programs.

c. Recommendations for the use of vaccines can be found in the BMBL.

d. Records must be kept on all:

(1) *Immunizations.*

The date, immunization given, dose, anatomical location of administration, lot number, manufacturer, vaccine information sheet date, the identification of the person administering the vaccine, and related laboratory data for all immunizations must be documented in the employee's OH record and the recommended DoD-approved electronic immunization tracking record.

(2) Vaccine Reactions.

All vaccine reactions must be reported and documented in accordance with MTF policy.

e. In addition to licensed vaccines, the USAMRIID obtains and uses certain investigational vaccines administered under IND protocols via the SIP. The CMA may refer employees to the SIP at USAMRIID when risk assessments indicate that the individual may be a candidate to receive an IND vaccine in association with workplace exposure potentials to specific IAT. Immunization with IND vaccines is voluntary and should never be a pre-condition for either enrollment in IAT medical surveillance programs, or work with other IAT found within biocontainment laboratories. Decisions concerning enrollment in the SIP for IAT are under the purview of USAMRIID and outside the scope of the CMA's IAT medical surveillance program.

(1) 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.

(2) To avoid placing individuals at undue risk and provide for the continued availability of the 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:

1. Lists, as a hazard of the activity, one or more of the IAT for which a SIP vaccine is available.

2. Justifies use of the SIP vaccine.

(b) The individual has been informed by the principal investigator of the purpose, benefits, 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.

(3) When requesting enrollment or re-enrollment in the SIP, documentation showing satisfaction of the requirements in Paragraphs 5.6.e.(1) through 5.6.e.(3), along with a copy of the applicable research protocols, must be provided to the SIP program coordinator. Medical records for individuals enrolled in the SIP must accurately document the receipt of the SIP vaccines and satisfaction of the requirements.

(4) In accordance with requirements of the National Archives and Records Administration General Records Schedule, medical records must be maintained in accordance with SIP recordkeeping requirements as governed by the U.S. Food and Drug Administration and for the duration of employment plus 30 years. Records are transferred to the National Personnel Records Center in St. Louis, Missouri, 30 days after the employee departs active federal service.

5.7. ILLNESS AND ABSENCE MONITORING.

a. Personnel who are participating in the medical surveillance program who have an unplanned absence from the workplace will be contacted by the supervisor to rule out an occupational-related concern. Personnel who are working in a BSL-3 or BSL-4 laboratory and who are absent for 3 or more workdays due to a medical condition that relates to a possible exposure to IAT must be evaluated and cleared by OH staff before returning to duty.

b. Personnel who are participating in the medical surveillance program must report to the CMA all illnesses associated with exposure to IAT, healthcare received, and medication used, regardless of whether or not it led to an absence from the workplace. The CMA will make recommendations to the supervisor on the disposition of the employee.

c. Supervisors, in coordination with SOH SMEs, 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 Risk Group 3 and Risk Group 4 agents involves special challenges for OH. Infections of laboratory staff by such agents could result in serious or lethal disease for which limited treatment options exist. These agents are frequently geographically exotic to the areas in which high-containment laboratories are located, but may produce immediate public health concern if infections occur in laboratory staff. Potential transmission from infected staff into the human or animal populations in the areas surrounding the laboratories may raise such concerns to higher levels.

e. SOPs for BSL-3, ABSL-3, BSL-4, and ABSL-4 settings require special attention to management of unexplained worker absence, including protocols for monitoring, medical evaluation, and follow-up of workers with unexplained nonspecific illness. Advance planning for the provision of medical care to workers potentially infected with these agents is a fundamental component of an OH program for BSL-3, ABSL-3, BSL-4, and ABSL-4 facilities.

5.8. SERUM BANKING.

a. The CMA, in coordination with the laboratory manager and principal investigators, should carefully consider the need for collecting and storing baseline serum samples, commonly known as serum banking, before the initiation of work with the IAT. Serum banking has value when its purpose is to obtain data for conducting occupational risk assessments. It can be used to establish baseline seroreactivity if additional blood samples are collected for serological testing following a recognized or suspected exposure.

b. Institutions with BSL-4 and ABSL-4 laboratories that have determined the need for serum banking will establish written guidelines, in the form of policies and procedures, for the collection and storage of serum samples from at-risk personnel working in these laboratories. These written guidelines are also recommended, but not required, for BSL-2, ABSL-2, BSL-3, and ABSL-3 laboratories. The written policies and procedures must:

- (1) Be written by the laboratory directors, and reviewed and approved by the CMA.
- (2) Clearly delineate the basis for establishing the serum banking program.
- (3) Be reviewed whenever a new IAT is added to the research laboratory.
- (4) Explicitly consider items, such as:
 - (a) Risk-based assessments on the IAT that are used within specific laboratories.
 - (b) The respective exposure and disease potentials of IAT.
 - (c) Medical countermeasures or treatments available for respective IAT.
 - (d) The availability of useful diagnostic tests for specific IAT.
 - (e) The logistical feasibility for a serum banking program.

c. The elements of a serum banking program that should be addressed in the guidelines include:

- (1) Voluntary participation, with informed consent (or declination statements) to both obtain and store samples and later to run specific diagnostic tests.
- (2) Procedures for obtaining and processing serum samples for storage in accordance with recommendations found in the “Occupational Health Support Service Elements,” “Preplacement Medical Evaluations,” and “Medical Support for Occupational Illnesses and Injuries” paragraphs of Section VII of the BMBL.
- (3) Storage requirements (e.g., temperature, security, accountability, and location).
- (4) Chain of custody procedures.
- (5) Procedures for running diagnostic tests on samples.

5.9. MEDICAL QUALIFICATION DETERMINATION.

a. The CMA should evaluate employees in positions requiring specific standards of physical fitness.

b. DoD 6055.05-M is mandated for use by all the DoD Components in developing, performing, and interpreting the results of occupational medical examinations.

(1) The worker must self-identify conditions to the CMA and supervisor that could lead to an increased risk of mishap.

(2) The CMA must evaluate 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 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, ABSL-3, BSL-4, and ABSL-4 laboratory could pose increased risk from incapacitation or delays in receiving medical care. Supervisors and human resources staff should be advised of the increased risk and determine if it can be accommodated or waived.

SECTION 6: FACILITY SAFETY CONTROLS

6.1. FACILITY DESIGN, COMMISSIONING AND DECOMMISSIONING (SECONDARY BARRIERS).

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

a. BSL-3, ABSL-3, BSL-4, and ABSL-4 facilities will be commissioned using criteria set forth in the BMBL and NIH “Biosafety Level 3 Laboratory Certification Requirements.”

b. 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, must advise and assist the laboratory worker in developing or obtaining adequate facilities or equipment and designing appropriate work procedures before work is allowed to begin.

6.2. EMERGENCY BACK-UP POWER.

a. For BSL-4 and ABSL-4 laboratories, an automatically activated emergency power source must be provided, at a minimum, for the laboratory exhaust system, life-support systems, alarms, dedicated emergency lighting, entry and exit controls, and door gaskets.

b. For BSL-4 and ABSL-4 laboratories, monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit controls, and security systems must be on an uninterruptable power supply (i.e., emergency back-up power source).

6.3. LARGE-SCALE PRODUCTION AND RESEARCH ACTIVITIES.

Facilities and laboratories performing large-scale production or research must be designed in accordance with requirements described in Appendix K of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Physical containment for large-scale uses of organisms containing recombinant or synthetic nucleic acid molecules must follow the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. While these guidelines are written for cultures of viable organisms containing recombinant or synthetic nucleic acid molecules, research and production activities must follow these guidelines regardless of whether or not the organism contains recombinant or synthetic nucleic acid molecules.

SECTION 7: SAFETY EQUIPMENT

7.1. 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 the BMBL.

7.2. ENGINEERING CONTROLS.

Facilities conducting IAT activities must certify that the engineering controls satisfy the minimum requirements of Table 5 and:

a. Meet local, State, federal, and HN emissions standards and any certification requirements, as appropriate.

b. Certify that BSCs conform to the requirements of NSF/ANSI Standard 49 for the applicable type of cabinet.

(1) Test cabinets according to NSF/ANSI Standard 49 and the manufacturer's instructions for use (IFU) after installation and before use, annually thereafter, and when:

(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 cabinets' performance.

(2) Provide competent and NSF-accredited personnel to complete all certification and testing. In deployed areas and some areas outside the continental United States, NSF accreditation of personnel that assess BSCs may not be feasible due to the impracticality of attaining and maintaining the accreditation or the logistical burden to transport accredited BSC assessors and their equipment to locations outside the continental United States. In these cases:

(a) Personnel who have successfully completed the NSF/ANSI Standard 49 basic and advanced training may evaluate BSCs following NSF/ANSI Standard 49 criteria.

(b) Documentation validating that the BSC was assessed for compliance with NSF standards and requirements will be completed and provided to the BSC owner, but the BSC is not considered NSF certified since it was not assessed by an NSF-certified official.

c. Train all individuals in the use of engineering controls, and establish procedures to demonstrate both their understanding and skill to use these devices properly and safely.

Table 5. Chemical Fume Hood Performance Criteria

PERFORMANCE CRITERIA¹	REQUIREMENT
Hood face velocity ^{2,3,4}	Each hood will have an average face velocity of 80-120 feet per minute (fpm) through the “working opening,” with no point velocity measurement used to compute the average face velocity deviating more than 20 percent from the average face velocity.
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 will not exceed one-third the average face velocity.
Hood containment aerosol tests ^{2,3,5}	Sash in static positions: no visible aerosol using a smoke test will 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 will 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.
<p>¹ ANSI/ASHRAE Standard 110. Hoods should only be used after performance has been validated by an industrial hygienist or qualified professional as described in paragraph 7.2.b.</p> <p>² 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.</p> <p>³ When volatile chemicals do not have low occupational exposure limits and are used inside laboratory fume 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.</p> <p>⁴ The maximum permissible average face velocity of 120 fpm need not be observed if any of the following are met:</p> <ul style="list-style-type: none"> a. A hood performance test has been conducted in accordance with ANSI/ASHRAE Standard 110 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 not having occupational exposure limits or OSHA-permissible exposure limits are used within the hood and it has been demonstrated by an industrial hygienist that potential exposures are acceptable. c. The hood meets all of the performance criteria (e.g., face velocity, cross drafts, and hood containment aerosol tests) with the sash in the minimum and maximum working opening position, but the average face velocity exceeds 120 fpm at the minimum working opening position, maintenance is planned and documented on the hood to provide for operation within normal design parameters and either of the following is met: <ul style="list-style-type: none"> (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) does not exist. <p>⁵ 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).</p>	

d. Connect filtered cabinet exhaust, when discharged through the building exhaust system, to the exhaust system in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system.

e. For Class II and higher Type B1 and B2 BSCs, will be:

(1) Hard-ducted (directly connected) to the exhaust system to function properly and not use a thimble unit.

(2) Installed with flow monitors and alarms.

(3) Installed with an interlock system to prevent cabinet pressurization in case of a failure of the building exhaust system.

f. Meet the BSC requirements in the BMBL 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.

g. Make available and readily accessible all owner's manuals for equipment to provide operation, test, inspection, maintenance, safety, and other relevant information.

7.3. 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 inch water gauge less than their surroundings when all openings are closed, and at least 100 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 inch water gauge.

d. Have gloves changed at appropriate intervals (dependent on the box contents) for the appropriate level of protection needed. This change schedule will be documented in either the facility safety plan or an approved SOP.

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

7.4. VENTILATED BALANCE ENCLOSURES.

As specified in Section 627.55 of Title 32, CFR, 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 instead of a laboratory fume 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 fume hood before being transferred to the balance enclosure.
- e. Check the flow through the openings in the enclosure to verify that it is at least 60 linear fpm and averages between 60 and 80 linear fpm.
- f. Certify containment before first use, and annually thereafter by testing with smoke tubes.
- g. Certify the airflow initially and annually by averaging readings taken from the face of the opening.

7.5. VENTILATED CAGE ENCLOSURES.

As specified in Section 627.56 of Title 32, CFR, ventilated cage enclosures are used to house animals at levels corresponding to the various classes of BSCs. The proper functioning of these enclosures must be tested initially, on 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 must be performed. Table 6 provides detailed information on several kinds of ventilated animal cages.

Table 6. Ventilated Animal Cages

ANIMAL CAGE	DESCRIPTION	MINIMUM AIRFLOW	VENTILATION RATE
Filter-Top	Small, laboratory animal, polystyrene or polycarbonate cages fitted with a dome-shaped glass fiber or polyester filter cage cover.	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 (NRC) "Guide for the Care and Use of Laboratory Animals" should be followed.
Forced Ventilation	Small HEPA-filtered cage connected to a centralized exhaust system.	A minimum airflow of 0.3 cubic meters per minute per cage is required.	Ventilation rates may vary with the size of the cage and the number and type of animals being housed.
Cubicle-Type Isolation	Partial containment unit that holds several animal cages. The unit is a negative pressure, HEPA-filtered stainless steel cage.		
Total Containment	HEPA-filtered stainless steel cage with the filters incorporated into the design.		

7.6. GENERAL PRACTICES APPLICABLE TO IAT.

Facilities will develop or adopt a laboratory biosafety manual based on the recommendations in the latest BMBL edition and their laboratory accreditation standards, as appropriate. These specific requirements must be included in biosafety manuals, and all personnel must be trained in accordance with the manual and appropriate work procedures:

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.

(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) 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 IFU 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/International Safety Equipment Association Standard Z358.1.

7.7. VENTILATED CAGE AREAS.

As specified in Section 627.56 of Title 32, CFR and Department of the Army Pamphlet 385-69, these are areas within a room that have a solid wall for containing multiple cages housing infected or intoxicated animals. Containment for these areas is equivalent to the Class I BSC. Smoke tests will be performed annually to verify containment.

SECTION 8: BIOSAFETY PRACTICES

8.1. ADDITIONAL TECHNIQUES APPLICABLE TO WORK WITH IAT.

The major objective of these techniques is to protect against laboratory-acquired infections. Air sampling studies have shown that aerosols are generated from most of the manipulations of bacterial and viral samples common to laboratories. The generation of aerosols during routine laboratory manipulations must be considered when evaluating the individual degree of risk, keeping in mind the four main factors governing infection: dosage, virulence of the organism, route of infection (e.g., skin, eyes, mouth, lungs), and host susceptibility (e.g., state of health, natural resistance, previous infection, response to vaccines and toxoids). 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's IFU.

(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 before 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 indicated in the manufacturer's IFU. Balance the load before centrifugation.

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

(6) Make no modifications or additions to centrifuges. Employees will follow the owner's manual when operating the centrifuge.

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 laboratory-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 non-infectious 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 fume hood with proper respiratory protection, or in other ways as determined by a risk assessment.

8.2. OPERATIONS WITH RADIOACTIVE MATERIAL.

a. Operations that combine IAT and radioactive material must implement a radiation protection program meeting the requirements of Part 20 of Title 10, CFR. 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. Laboratory workers working with radioactive materials must be enrolled in the radiation protection program and receive periodic medical surveillance examinations, as appropriate, in accordance with the recommendation of the RSO and OH personnel.

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

(1) Radioactive waste must be segregated, labeled, and disposed of after the IAT 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, is mixed with radioactive waste, it becomes “mixed waste,” which must be disposed of in accordance with all applicable federal and State regulations and DoD guidance found in DoD 4715.6-R.

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

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

8.3. CERTIFICATION OF INACTIVATED MICROORGANISMS AND REMOVAL.

A validated method to render a microbial organism non-viable must be in place. This means that the method must be scientifically sound and that it will produce consistent results each time the method is used such that the expected result can be demonstrated. Before working with inactivated organisms, the principal investigator must obtain documentation of non-viability. The documentation must include:

- a. Name of supplier.
- b. Date the microorganisms were rendered non-viable.
- c. Methods used to render microorganisms non-viable.

- d. Viability test conducted to validate non-viable status of the microorganisms.
- e. Date the viability test was conducted.
- f. Date of removal from the laboratory.

8.4. 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 infected with zoonotic disease. See the NRC “Occupational Health and Safety in the Care of Research Animals” for additional information.

b. Laboratory animal facilities, operational practices, and animal care will meet the requirements of the NRC Guide for the Care and Use of Laboratory Animals; Parts 1, 2, and 3 of Title 9, CFR; and DoDI 3216.01.

c. Laboratory personnel working with animals must complete pre-employment medical screening and enroll in a medical surveillance program specific for laboratory animal workers.

8.5. 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’ Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates and in the American Committee of Medical Entomology’s Arthropod Containment Guidelines, Version 3.2.

8.6. SPECIFIC REQUIREMENTS FOR BSL-4 AND ABSL-4.

In addition to the requirements listed in the BMBL, BSL-4 and ABSL-4, facilities must:

a. Have laboratory staff members supervised by competent scientists who are trained, experienced, and qualified 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 positive pressure encapsulating suits ventilated by a life-support system in accordance with the BMBL.

c. Remove only materials from the maximum containment laboratory that have been properly inactivated by a validated method or prepared for shipment to another institution. Equipment or material that might be damaged by high temperature or steam will 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. Have only water fountains provided for a cabinet laboratory that are exclusively foot operated and located in the facility corridors outside the laboratory.

f. Have a ventilation system that is dedicated to the BSL-4 or ABSL-4 laboratory and provides fresh air in accordance with ANSI/ASHRAE Standard 62.

g. Use the facility requirements for an ABSL-4 laboratory when working with animals in a BSL-4 laboratory space as prescribed in the BMBL.

8.7. TOXINS.

Laboratory safety precautions appropriate for handling toxins closely parallel those for handling nonvolatile hazardous chemicals. In addition to those requirements listed in the BMBL, follow the guidance in Paragraphs 8.8.a. through 8.8.c. for the handling of toxins of biological origin.

a. Two knowledgeable individuals must be present in the laboratory during high-risk operations involving dry forms of toxins, intentional aerosol formation, or the use of hollow-bore needles 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 or ABSL facility must be on alert to call emergency response personnel and facilitate response actions.

b. All facilities in which toxins are used must:

(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 ANSI/International Safety Equipment Association Standard Z358.1.

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

(1) Decontaminate all items inside the Class III BSC on 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 as described in Paragraph 8.1.b. immediately on removal from the Class III BSC.

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

8.8. INTEGRATED PEST MANAGEMENT.

Microbiological laboratories and biomedical research facilities must institute an effective integrated pest management program to identify and control the infestation by, and harborage of, animal or insect vectors or pests. Specific requirements for integrated pest management within DoD facilities are described in DoDI 4150.07.

SECTION 9: PPE

9.1. 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 on 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 must be:

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

(2) Used and maintained in a sanitary and reliable condition in accordance with manufacturer's IFU.

(3) Used where necessary because of physical, chemical, biological, or radiological hazards 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 must properly fit employees. Defective or damaged PPE must not be used.

c. PPE selection must be based on a risk assessment and, at a minimum, will include closed-toe shoes in addition to the requirements listed in the BMBL to provide the appropriate level of protection to affected employees from the identified hazards. Supervisors must verify that the required risk assessment has been performed and documented and make it available to personnel entering the laboratory. The PPE selection decisions must be posted in a visible area before entering the laboratory.

d. Each affected employee must 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. PPE training must be documented along with all other requisite workplace training. 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 must be retrained.

e. All personnel required to wear respiratory protection equipment must be medically evaluated and receive a medical determination of their ability to use a respirator in accordance with Subpart I, Section 1910.134 of Title 29, CFR.

9.2. SPECIFIC REQUIREMENTS FOR INDIVIDUAL PPE.

Laboratory supervisors must:

a. Provide eye and face protection that meets or exceeds the requirements of ANSI/International Safety Equipment Association Standard Z87.1. Special eyewear may be required when working near ultraviolet (UV) light sources and lasers. Where applicable, employers will provide eye protection incorporating the employee's prescription into the design of the eye protection, or provide eye protection that can be worn over prescription lenses without disturbing the proper position of the prescription lenses or the protective eyewear.

b. Provide gloves that are examined before each use and replaced or changed, as necessary, and make non-latex gloves available in the event of latex allergies.

c. Establish procedures for the inspection of Class III BSC gloves before each operation and after each sterilization. When using glove boxes (Class III BSC), operators should don a pair of gloves before inserting their hands into the BSC gloves.

d. Establish procedures for the inspection of laboratory clothing before it is worn to confirm that it is free from defects that would compromise its effectiveness. Laboratory clothing (e.g., protective overgarments, laboratory coats, gloves, aprons) will not be released from the laboratory for laundering until decontaminated or until a risk assessment has been performed to show there is an acceptable low risk of contamination.

e. For BSL-4 laboratories, have one-piece, positive-pressure, encapsulating suits inspected before each use to check for indications of significant wear or leakage, and verify 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 Title 29, CFR.

(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 in accordance with Section 1910.134 of Title 29, CFR.

f. Collaborate with the facility's safety or OH office when respirators are used to establish a respiratory protection program that conforms to Section 1910.134 of Title 29, CFR.

SECTION 10: TRANSPORTATION AND TRANSFER OF IAT AND BSAT

10.1. GENERAL.

- a. Commanding officers or institute directors must establish controls so that IAT is transported (including importing and exporting) or transferred with proper authorization, controls, and procedures.
- b. U.S. and HN permits for import and export of IAT must be obtained, as appropriate. If international import or export of IAT is anticipated, the laboratory will coordinate with the CDC, Department of Commerce, APHIS, and appropriate HN agencies for overseas laboratories. International transfers must be conducted in accordance with the DoD policy for international transfers in DoDI 2040.02. In those instances when items for export are subject to the requirements of Parts 120 through 130 of Title 22, CFR (also known and referred to in this issuance as the “International Traffic in Arms Regulations”) the DoD must coordinate with the Department of State Directorate of Defense Trade Controls.
- c. Transportation of IAT by DoD-owned and DoD-controlled sealift or airlift must be performed in accordance with Chapter 204 of Part II of Defense Transportation Regulation (DTR) 4500.9-R and Parts 171 through 180 of Title 49, CFR.
- d. Transfer of BSAT is regulated by the CDC and APHIS in accordance with Part 73 of Title 42, CFR; Part 331 of Title 7, CFR; and Part 121 of Title 9, CFR, as applicable, and all applicable guidance documents of the Federal Select Agent Program (FSAP). Entities importing or exporting BSAT must be registered with the FSAP. All international exports subject to Parts 730 through 774 of Title 15, CFR must be preauthorized by the Department of Commerce.
- e. In accordance with Part 73 of Title 42, CFR; Part 331 of Title 7, CFR; and Part 121 of Title 9, CFR, as applicable, APHIS/CDC Form 2, “Request to Transfer Select Agents and Toxins,” must be submitted for approval before transportation of select agents or toxins. An electronic version of this form is available at <https://www.selectagents.gov/form2.html>. In those instances when BSAT is subject to the International Traffic in Arms Regulations, the DoD must ensure such exports are authorized by the Department of State.

10.2. TRANSPORTATION AND TRANSFER OF IAT.

The transportation or shipping officer must:

- a. Not ship IAT if it is unlabeled or improperly packaged.

(1) Package all IAT for shipment in accordance with Subchapter C of Title 49, CFR and the packing instructions in the International Civil Aviation Organization Technical Instructions on the Safe Transport of Dangerous Goods by Air and the International Air Transport Association Dangerous Goods Regulations.

(2) Ship and transport IAT according to the requirements, as applicable, in Chapter 204 of Part II of DTR 4500.9-R.

b. Train all personnel who certify a shipment of infectious substances in accordance with Chapter 204 of Part II of DTR 4500.9-R.

10.3. TRANSPORTATION AND TRANSFER OF BSAT.

The transportation or transfer of BSAT will be in accordance with Chapter 204 of Part II of DTR 4500.9-R; DoDI 5210.88; Parts 171 through 180 of Title 49, CFR; Part 73 of Title 42, CFR; Part 331 of Title 7, CFR; Part 121 of Title 9, CFR; all applicable FSAP guidance documents, and Army Directive 2016-24.

SECTION 11: INACTIVATION, DECONTAMINATION, AND DISPOSAL

11.1. GENERAL.

Laboratory supervisors are responsible for verifying that all contaminated or potentially contaminated materials and equipment or apparatus are decontaminated before being washed, stored, or discarded. Laboratory supervisors must:

- a. Consult with installation legal counsel regarding local, federal, State, or HN safety, health, and environmental requirements for necessary approvals. For example, the use of formaldehyde may require a permit from the Environmental Protection Agency or a State agency.
- b. Follow the decontamination requirements listed in the BMBL.

11.2. INACTIVATION.

Inactivation of *Bacillus anthracis* must be in accordance with the revised FSAP policy statement, “Inactivated *Bacillus anthracis* and *Bacillus cereus* Biovar *anthracis*,” available at http://www.selectagents.gov/policystatement_bacillus.html, and all applicable FSAP policy updates to include exemptions. Guidance on the inactivation of other BSAT and exemptions in accordance with the FSAP can be found at <https://www.selectagents.gov/irg-intro.html>. Inactivation of BSAT must be performed in accordance with Part 73 of Title 42, CFR; Part 331 of Title 7, CFR; Part 121 of Title 9, CFR; and all applicable guidance documents specified by the FSAP.

11.3. METHODS OF DECONTAMINATION.

In each case of decontamination, it is essential to establish and validate that the decontamination method has been effective.

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.

Laboratory supervisors must:

- (a) Verify autoclave sterilization with biological indicators (e.g., *Bacillus stearothermophilus* (*Geobacillus stearothermophilus*) spores) by placement of indicators at locations throughout the autoclave, including placement in the center of a test load:

1. When the autoclave is first put into service.
2. After any maintenance or repairs.
3. On a monthly basis.

(b) Equip each autoclave with a permanent means to record the time and temperature of each operational event as a means of verifying sterilization. New equipment will be purchased with manufacturer-installed or manufacturer-included recorder options. If the existing equipment does not have a data recorder, the laboratory supervisor, in coordination with the equipment manager, will provide a permanent means of recording the time and temperature of each operational event as a means of verifying sterilization. Records and logs will not be placed or stored over, or on top of, vents, fans, lights, indicators, or other affixed equipment labels.

(c) 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 IFU for the autoclaves as a starting point in establishing these conditions.

b. Dry Heat.

(1) General.

Dry heat decontamination is based on time and temperature. Dry heat requires either longer times or higher temperatures when compared to wet heat.

(2) Validation.

Laboratory supervisors must determine the specific sterilization times and temperatures for each type of material being sterilized. Higher temperatures reduce the time requirements. The heat transfer properties and spatial relation or arrangement of materials in the load are critical for 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 will be mixed and used in accordance with the manufacturer's IFU and the BMBL.

(2) Validation.

If used for sterilization, a validation method must be in place to confirm and verify 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.

(3) Decontamination System Operation.

Vapor and gas decontamination systems must be set up, calibrated, and used according to the manufacturer's IFU.

(4) Fumigation Management Plan.

A fumigation management plan must be developed for each site. The fumigation management plan must address:

(a) Planning and preparation, including characterization of the site (e.g., room size, physical layout, equipment, construction materials).

(b) Monitoring and documentation, including measurements of vapor and gas levels, temperature, and relative humidity, to be conducted during the operation.

(c) Notification of personnel within the area as well as appropriate fire and emergency responders.

(d) Sealing rooms and space enclosures to prevent leaks.

(e) Application procedures and fumigation periods.

(f) Post-application operations, including restrictions on area use pending monitoring results.

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 effectiveness on exposed surfaces is limited by its low penetrating power, and it should 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, ABSL-3, BSL-4, or ABSL-4 laboratory are an example.

(a) The UV intensity must be at least 40 microwatts per cubic centimeter 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 per side.

(b) Protective eyewear and clothing may be necessary when working around UV radiation. The laboratory supervisor should consult with the biosafety officer before using UV decontamination to determine whether a more suitable method is available.

(2) **Validation.**

To confirm that a UV source is providing at least 40 microwatts per cubic centimeter at the work surface, laboratory supervisors will 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 when used as the primary source of disinfection. When UV is used as a secondary source of disinfection at:

(a) BSL-3, ABSL-3, BSL-4, and ABSL-4 facilities, the UV source must be checked semiannually.

(b) BSL-2 and ABSL-2 facilities, the UV source must be checked annually.

f. Gamma Irradiation.

(1) **General.**

Gamma irradiation is used to sterilize medical devices, organisms, or unknown agents.

(2) **Validation.**

Laboratory supervisors must establish specific procedures to develop, validate, and control sterilization procedures and establish routine checks to verify the inactivation of organisms or the sterility of objects decontaminated with gamma irradiation.

11.4. DISPOSAL.

Laboratory supervisors must:

a. Dispose of IAT and associated equipment only after materials have been properly treated by autoclaving, decontamination, or other appropriate means. Such disposals must also be conducted in accordance with applicable requirements in the DoD demilitarization program and DoDI 4160.28, and associated procedures in Volume 3 of DoD Manual 4160.28. Disposals, including sales and donation of certain DoD IAT and associated equipment to non-DoD parties, must be conducted in accordance with DoDI 2030.08.

b. Consult with the local supporting environmental management office and legal counsel, as needed, for applicable and appropriate local, State, federal and HN IAT disposal procedures.

SECTION 12: EMERGENCY PLANNING AND RESPONSE

12.1. GENERAL.

The laboratory facility commander or director must:

a. Establish specific emergency plans for all BSL-3 and BSL-4 biological laboratories and their facilities and coordinate with installation emergency management programs in accordance with DoDI 6055.17. Emergency plans will be integrated into an installation emergency management plan and must include:

(1) Procedures for liaison through installation or local emergency operations center and 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 shut down.

(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 coordinate with the Installation Emergency Management Working Group of emergency plans in advance of any call for assistance. If required by States, provide emergency plans to local and State emergency management officials.

(1) Before the plans are adopted, the laboratory facility commander or director will test emergency plans to confirm that they are capable of effectively responding to the emergency in a timely manner.

(2) After the plans are adopted, the laboratory facility commander or director must:

(a) Reinforce the plans by conducting exercises at least annually. Basic exercises will be conducted by simulating an emergency and requiring on- and off-post emergency responders identified in the plan to simulate their communication and response procedures.

(b) Conduct after-action reviews of exercises and real-world events in accordance with DoDI 6055.17 to identify lessons learned and incorporate into corrective actions, emergency plan updates, and future exercises.

12.2. EMERGENCY PROCEDURES.

a. General Emergency Procedures.

Supervisors and employees must follow these emergency procedures for laboratory mishaps:

(1) Use 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 provider within 10 minutes must have personnel trained in basic life support (BLS) and first aid available during working hours in accordance with Section 1910.151 of Title 29, CFR.

(a) Individuals trained in BLS and first aid must maintain their certification to be considered valid BLS and first-aid providers.

(b) Administrative plans must be in place for personnel trained and certified in BLS and first aid to be available in the workplace and able to respond to an emergency.

(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 confirm that all appropriate steps have been taken.

(7) Conduct emergency procedures for BSAT in accordance with Part 73 of Title 42, CFR; Part 331 of Title 7, CFR; Part 121 of Title 9, CFR; and applicable guidance documents provided by the FSAP. During shipment and transportation, follow the requirements of Subchapter C of Title 49, CFR.

b. Emergency Alarm System.

Laboratory supervisors must:

(1) Have a system in place to alert personnel to an emergency that requires an emergency response (e.g., active shooter, natural disaster) or evacuation of the laboratory or building.

Establish procedures to confirm that laboratory personnel are familiar with the location and operation of alarm equipment, communication systems, and response actions.

(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 pass through.

c. Shut-Down and Start-Up Procedures.

Laboratory supervisors must:

(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.

(2) Provide written procedures so 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.

12.3. SPILLS.

Laboratory supervisors must:

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 that would result in negligible hazards. The first-line supervisor should manage the spill and direct the use of proper cleanup techniques.

c. Have a spill control plan available in the laboratory that has been reviewed by the safety, OH, 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. Provide professional staff who are trained and equipped to work with Risk Group 3 or 4 IAT to manage agents requiring BSL-3, ABSL-3, BSL-4, and ABSL-4 containment as outlined in the BMBL.

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 meet this need.

(d) If the spill is outside of engineering controls, evacuate the room if there is a risk from aerosolization and inhalation exposure, close all doors, and remove or decontaminate clothing.

(e) Chemically decontaminate or neutralize the spill. Begin at the perimeter of the spill and work towards the center, allowing a sufficient contact time with an appropriate disinfectant in the recommended concentration. Then clean and carefully dispose of the residue.

(f) If the spilled material is volatile, allow it to evaporate and exhaust by a fume 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. Review the spill response procedures in the SDS, if available.

(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.

(d) Consult the product's SDS for information on use of the proper decontamination solution and spill cleanup procedures.

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 other specialized

procedures. The risk assessment will be conducted with those knowledgeable of the spill; the safety, OH, 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. Many licensed materials have notification procedures once a loss of containment is known. The RSO for the Nuclear Regulatory Commission license must be notified who will then notify the license holder.

(2) Coordinate with the RSO who will direct the cleanup in accordance with the Nuclear Regulatory Commission license for the facility and applicable HN regulatory agency requirements, as appropriate.

(3) 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.

(4) Following cleanup, survey the affected area, protective clothing, and all 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

G.1. ACRONYMS.

ACRONYM	MEANING
ABSL	animal biosafety level
ANSI	American National Standards Institute
APHIS	Animal and Plant Health Inspection Service
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
BBP	bloodborne pathogen
BLS	basic life support
BMBL	biosafety in microbiological and biomedical laboratories
BS	British standard
BSAT	biological select agents and toxins
BSC	biological safety cabinet
BSL	biosafety level
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CMA	competent medical authority
DoDI	DoD instruction
DOEHRS-IH	Defense Occupational and Environmental Health Readiness System-Industrial Hygiene
DSAT	Division of Select Agents and Toxins
DTR	Defense Transportation regulation
EN	European standard
fpm	feet per minute
FSAP	Federal Select Agent Program
GO/FO	general officer/flag officer
HEPA	high-efficiency particulate air
HN	host nation
IAT	infectious agents and toxins
IBC	institutional biosafety committee
IFU	instructions for use
IH	industrial hygiene
IND	investigational new drug

ACRONYM	MEANING
MTF	medical treatment facility
NIH	National Institutes of Health
NRC	National Research Council
NSF	National Sanitation Foundation
OEH	occupational and environmental health
OH	occupational health
OSHA	Occupational Safety and Health Administration
PPE	personal protective equipment
RSO	radiation safety officer
SDS	safety data sheet
SIP	special immunization program
SME	subject matter expert
SOH	safety and occupational health
SOP	standard operating procedure
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USDA	U.S. Department of Agriculture
UV	ultraviolet

G.2. DEFINITIONS.

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

TERM	DEFINITION
aerosol	Fine solid particle suspensions or liquid droplets in air or another gas that can be generated by human or environmental sources and can remain airborne for extended periods in exterior or indoor environments.
airborne	A means of spreading infection when airborne droplet nuclei are inhaled by the susceptible host.
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.

TERM	DEFINITION
bacterial spore	Dormant bacterial stage that remains inactive until exposed to a favorable condition that helps to activate and transform the spore to become an active cell form.
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 IAT (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 for the purpose of disease prevention and product development.
BSAT	Listed in Sections 73.3 and 73.4 of Title 42, CFR; Section 331.3 of Title 7, CFR; and Sections 121.3 and 121.4 of Title 9, CFR.
BSC	<p>An engineering control designed to enable laboratory workers to handle IAT and 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.</p> <p>Class I, II, and III BSC. Defined in the BMBL.</p> <p>Class II Type B1 and B2 BSCs. Defined in the BMBL.</p>
BSL-2, BSL-3, and BSL-4	Defined in the BMBL.
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 DoDI 6055.07.
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.

TERM	DEFINITION
CMA	<p>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 who has been:</p> <p>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), is supervised by an appropriately trained CMA physician who is privileged to practice independently.</p> <p>Specifically trained as a CMA and is 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.</p> <p>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.</p> <p>Occupational medicine privileges would be sufficient and the requirement of appointment in writing as a CMA would not be required.</p>
commanding officer or institute director	<p>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.</p>
competent	<p>By way of training, experience, education, licensing, and 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 approve the safety of an activity.</p>
containment laboratory	<p>A laboratory or suite that meets the requirements for a BSL-3 facility. The area may be an entire building or a single room within the building.</p>

TERM	DEFINITION
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 (e.g., sterilization), chemical inactivation (e.g., biocidal process), or a combination of these methods.
disinfection	Destroying or inactivating pathogenic microorganisms. Disinfection may not be effective against all bacterial forms or agents (bacterial spores, prions). Disinfectants used for disinfection must have demonstrated efficacy against the target agents or toxins.
exposure examination	A medical evaluation conducted by a competent medical authority which documents workplace exposure activities, the circumstances of exposure, pathogen or toxin of interest, the type of engineering controls or levels of PPE used to preclude exposure, a medical history and review of systems, relevant physical examination results, and serological titers (where appropriate) on a potentially exposed worker.
exposure potential	Workplace conditions in which IAT or BSAT may be present in liquid, aerosol, or solid forms, in suspension of other mixtures, in sample matrices, or powdered forms in varying quantities, and may pose an exposure hazard to workers by inhalation, absorption, ingestion, or dermal or mucous membrane contact, given the nature of the operation or activity.
fume hood	Defined in ANSI/American Society of Safety Engineers Standard Z9.5, “American National Standard for Laboratory Ventilation.”
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 IAT from air exhausted from engineering controls and facilities.

TERM	DEFINITION
IAT	Fungi, virus, bacteria, prions, rickettsia, parasites, a viable microorganism or its toxin, toxicants, 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 including biological agents and toxins as defined in Section 73.1 of Title 42, CFR.
inactivated	A microbiological sample treated physically or chemically that is free from living organisms, including spores. The organisms are non-viable and cannot under any circumstance be viable (infectious). The organisms are non-viable and are no longer capable of growing, replicating, infecting, or causing disease.
infectious aerosol	An aerosol that contains pathogens or toxins that are of a respirable size (1- to 5-micrometer aerodynamic diameter) and maintain infectiousness or toxicity that can pose a health risk.
institution	An organization (e.g., institute, agency, center), or 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.
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 production and research activities	Research or production facilities involving viable IAT in quantities greater than 10 liters of culture.
maximum containment laboratory	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).

TERM	DEFINITION
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).
potential exposure	An event in a biocontainment or biomedical laboratory that may result in a workplace exposure by inhalation; ingestion; dermal, eye, or mucous membrane contact; other percutaneous injury; or subcutaneous injection to a propagating or non-propagating IAT or BSAT.
potential exposure criteria	These include any breach in established safety practices involving work with IAT or BSAT (this would include compromise of PPE posture or failures of engineering controls, in the setting of active IAT or BSAT operations); all injuries which occur in biocontainment laboratories while handling IAT or BSAT; and any unexplained, acute illnesses or febrile diseases in a IAT or BSAT worker. Of particular interest are febrile illnesses with temperatures greater than 100.4 degrees Fahrenheit [38 degrees Celsius] in individuals who worked in a biocontainment suite within the past 1 to 3 weeks, depending on the incubation period of the IAT or BSAT with which the individual worked.
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, and the human version of bovine spongiform encephalopathy, which is a variant Creutzfeldt-Jakob disease.

TERM	DEFINITION
qualified SOH personnel	Civilian personnel who meet Office of Personnel Management 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, Environmental Health Technician GS-699, and military personnel equally qualified when compared to Office of Personnel Management standards. In addition, in order to be considered SOH qualified for microbiological and biomedical safety, individuals must demonstrate they have attended and successfully completed microbiological and laboratory courses of instruction as approved by the appropriate DoD safety office.
release	An event that results in the presence of IAT outside of containment or an occupational exposure to personnel.
risk assessment	An assessment of the probability that harm, injury, or disease will occur, focusing primarily on the prevention of laboratory-associated infections. A 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.
SDS	Defined in Section 1910.1200(c) Title 29, CFR.
sterilization	The use of a physical or chemical procedure to destroy all microbial life, including large numbers of highly resistant bacterial endospores.
toxin	Defined in Section 73.1 of Title 42, CFR.
validation	Confirming that equipment or a process is functioning as desired and designed and satisfies its intended purpose. The confirmation process typically involves the completion of specific tests or procedures with performance indicators or outcomes that can confirm adequacy with the equipment or process.
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.

TERM	DEFINITION
ventilated cage enclosures	<p>The four types of ventilated animal cages are:</p> <p><u>filter-top cage</u>. 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.</p> <p><u>forced ventilation cage</u>. A small HEPA-filtered animal cage connected to a centralized exhaust system.</p> <p><u>cubicle-type isolation cage</u>. A partial containment unit that holds several animal cages. This unit is a negative pressure HEPA-filtered stainless steel cage.</p> <p><u>total containment cage</u>. A negative or positive pressure HEPA-filtered, stainless steel cage that has the filters incorporated into the design. It is halogen-gas-leak tight and is considered a Class III BSC.</p>
working opening	<p>The size of the opening created from the sash position at the front of a 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 (e.g., 12-inch to 18-inch opening) and must be such that the face velocity is within 80-120 fpm as specified in Table 6.</p>

REFERENCES

- American Committee of Medical Entomology, “Arthropod Containment Guidelines,” Version 3.2¹
- American Committee on Arthropod-Borne Viruses, “Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates,” “American Journal of Tropical Medicine and Hygiene,” Volume 29(6), pages 1359-1381, November 1980²
- American National Standards Institute/American Society of Heating, Refrigeration, and Air-Conditioning Engineers Standard 62, “Ventilation for Acceptable Indoor Air Quality,” current edition³
- American National Standards Institute/American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 110, “Method of Testing Performance of Laboratory Fume Hoods,” current edition⁴
- American National Standards Institute/American Society of Safety Engineers Standard Z9.5, “American National Standard for Laboratory Ventilation,” 2012⁵
- American National Standards Institute/American Society of Safety Engineers Standard Z9.11-2016, “Laboratory Decommissioning,” 2016
- American National Standards Institute/International Safety Equipment Association Standard Z358.1, “Emergency Eyewash and Shower Equipment,” current edition⁶
- American National Standards Institute/International Safety Equipment Association Standard Z87.1, “American National Standard for Occupational and Educational Personal Eye and Face Protection Devices,” current edition⁷
- Army Directive 2016-24, “Department of Defense Biological Select Agent and Toxins Biosafety Program,” July 25, 2016
- British Standard 5726, “Microbiological safety cabinets. Information to be supplied by the purchaser to the vendor and to the installer, and siting and use of cabinets. Recommendations and Guidance,” 2005⁸
- British Standard 7989, “Specification for Recirculatory Filtration Fume Cupboards,” July 15, 2001⁹

¹ Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6396570/>

² Available for purchase at <http://www.ajtmh.org/cgi/reprint/29/6/1359>

³ Available for purchase at <https://www.ashrae.org/resources--publications/bookstore/standards-62-1--62-2>

⁴ Available for purchase at http://www.techstreet.com/standards/ashrae-110-2016?product_id=1914730

⁵ Available for purchase at <http://www.asse.org/ansi/aiha/asse-z9-5-2012-american-national-standard-for-laboratory-ventilation/>

⁶ Available for purchase at <http://www.asse.org/ansi/isea-z358-1-2014-american-national-standard-for-emergency-eyewash-and-shower-equipment-/>

⁷ Available for purchase at <http://www.asse.org/ansi/isea-z87-1-2015-american-national-standard-for-occupational-and-educational-personal-eye-and-face-protection-devices-electronic-copy/>

⁸ Available for purchase at <http://shop.bsigroup.com/ProductDetail/?pid=00000000030078821>

⁹ Available for purchase at <http://standards.globalspec.com/std/767750/bsi-bs-7989>

- Centers for Disease Control and Prevention and National Institutes of Health, “Biosafety in Microbiological and Biomedical Laboratories,” current edition¹⁰
- Centers for Disease Control and Prevention, “General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP),” current edition
- Code of Federal Regulations, Title 7
- Code of Federal Regulations, Title 9
- Code of Federal Regulations, Title 10, Part 20
- Code of Federal Regulations, Title 15, Parts 730 through 774
- Code of Federal Regulations, Title 22, Parts 120 through 130 (also known as the “International Traffic in Arms Regulations”)
- Code of Federal Regulations, Title 29
- Code of Federal Regulations, Title 32
- Code of Federal Regulations, Title 40, Part 261, as amended
- Code of Federal Regulations, Title 42
- Code of Federal Regulations, Title 49
- Defense Federal Acquisition Regulation Supplement, Subpart 201.3, “Agency Acquisition Regulations,” current edition
- Defense Federal Acquisition Regulation Supplement, Subpart 201.4, “Deviations from the FAR,” current edition
- Defense Transportation Regulation 4500.9-R, Part II, Chapter 204, “Cargo Movement,” May 2014, as amended
- Department of the Army Pamphlet 385-69, “Safety Standards for Microbiological and Biomedical Laboratories,” May 6, 2009, as amended
- Deputy Secretary of Defense Memorandum, “Implementation of the Recommendations in the Comprehensive Review Report: Inadvertent Shipment of Live *Bacillus anthracis* (Anthrax) Spores by Department of Defense,” July 23, 2015
- Deputy Secretary of Defense Memorandum, “Safety and Occupational Health Policy and Oversight Functions,” April 10, 2019
- DoD 4715.6-R, “Low Level Radioactive Waste Disposal Program,” January 17, 2001, as amended
- DoD 5200.08-R, “Physical Security Program,” April 9, 2007, as amended
- DoD 6055.05-M, “Occupational Medical Examinations and Surveillance Manual,” May 2, 2007, as amended
- DoD Directive 5124.11, “Assistant Secretary of Defense for Readiness (ASD(R)),” September 6, 2019

¹⁰ Available at <https://www.cdc.gov/biosafety/publications/bmb15/bmb1.pdf>

- DoD Instruction 2030.08, “Implementation of Trade Security Controls (TSC) for Transfers of DoD Personal Property to Parties Outside DoD Control,” February 19, 2015, as amended
- DoD Instruction 2040.02, “International Transfers of Technology, Articles, and Services,” March 27, 2014, as amended
- DoD Instruction 3216.01, “Use of Animals in DoD Programs,” March 20, 2019
- DoD Instruction 4150.07, “DoD Pest Management Program,” December 26, 2019
- DoD Instruction 4160.28, “DoD Demilitarization (DEMIL) Program,” April 7, 2011, as amended
- DoD Instruction 5200.08, “Security of DoD Installations and Resources and the DoD Physical Security Review Board (PSRB),” December 10, 2005, as amended
- DoD Instruction 5210.88, “Security Standards for Safeguarding Biological Select Agents and Toxins,” May 26, 2020
- DoD Instruction 6050.05, “DoD Hazard Communication (HAZCOM) Program,” February 26, 2019, as amended
- DoD Instruction 6055.01, “DoD Safety and Occupational Health (SOH) Program,” October 14, 2014, as amended
- DoD Instruction 6055.05, “Occupational and Environmental Health (OEH),” November 11, 2008, as amended
- DoD Instruction 6055.07, “Mishap Notification, Investigation, Reporting, and Record Keeping,” June 6, 2011, as amended
- DoD Instruction 6055.17, “DoD Emergency Management (IEM) Program,” February 13, 2017, as amended
- DoD Manual 4160.28, Volume 3, “Defense Demilitarization: Procedural Guidance,” June 7, 2011, as amended
- DoD Manual 6440.02, “Clinical Laboratory Improvement Program (CLIP) Procedures,” May 29, 2014, as amended
- European Committee for Standardization/Technical Specification CEN/TS 14175-5, “Fume Cupboards: Recommendations for Installation and Maintenance,” 2006¹¹
- European Standard BS EN 14175-1, “Fume Cupboards. Vocabulary,” 2003¹²
- European Standard BS EN 14175-2, “Fume Cupboards. Safety and Performance Requirements,” 2003¹³
- European Standard BS EN 14175-3, “Fume Cupboards. Type Test Methods,” 2003¹⁴
- European Standard BS EN 14175-4, “Fume Cupboards: On-site Test Methods,” 2004¹⁵

¹¹ Available for purchase at <http://shop.bsigroup.com/ProductDetail/?pid=000000000030290002>

¹² Available for purchase at <http://webstore.ansi.org/RecordDetail.aspx?sku=BS+EN+14175-1%3A2003>

¹³ Available for purchase at <http://webstore.ansi.org/RecordDetail.aspx?sku=BS+EN+14175-2%3A2003>

¹⁴ Available for purchase at <http://webstore.ansi.org/RecordDetail.aspx?sku=BS+EN+14175-3%3A2003>

¹⁵ Available for purchase at <http://webstore.ansi.org/RecordDetail.aspx?sku=BS+EN+14175-4%3A2004>

- European Standard EN 12469, “Biotechnology - Performance Criteria for Microbiological Safety Cabinets,” May 2000¹⁶
- European Standards BS EN 14175-7, “Fume Cupboards: Fume Cupboards for High Heat and Acidic Load,” 2012¹⁷
- Federal Acquisition Regulation, Subpart 1.3, “Agency Acquisition Regulations,” current edition
- Federal Acquisition Regulation, Subpart 1.4, “Deviations from the FAR,” current edition
- International Air Transport Association, “Dangerous Goods Regulations,” current edition¹⁸
- International Civil Aviation Organization, “Technical Instructions for the Safe Transport of Dangerous Goods by Air,” current edition¹⁹
- Japanese Standards Association JIS K 3800, “Class II Biological Safety Cabinets,” 2009²⁰
- National Archives and Records Administration, “General Records Schedule,” current edition²¹
- National Institutes of Health, “Biosafety Level 3 Laboratory Certification Requirements,” current edition
- National Institutes of Health, “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,” current edition
- National Research Council, “Guide for the Care and Use of Laboratory Animals,” current edition
- National Research Council, “Occupational Health and Safety in the Care of Research Animals,” 1997²²
- National Sanitation Foundation/American National Standards Institute Standard 49, “Biosafety Cabinetry: Design, Construction, Performance and Field Certification,” 2016²³

¹⁶ Available at https://standards.nsf.org/apps/group_public/download.php/1840/EN%2012469%202000.pdf

¹⁷ Available for purchase at <http://shop.bsigroup.com/ProductDetail/?pid=000000000030290006>

¹⁸ Available for purchase at https://store.iata.org/IEC_ProductDetails?id=9065-58

¹⁹ Available at <http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx>

²⁰ Available for purchase at

https://webstore.ansi.org/RecordDetail.aspx?sku=JIS%20K%203800:2009&source=google&adgroup=jis&gclid=CjwKEAjlwoLfHBRD_jLW93remyAQSJABlYgGpYLddmHKiUy5C1Asba8TQWnoLapqFL2sRkCDNt886qRoCPSnw_wcB

²¹ Available at <https://www.archives.gov/records-mgmt/grs.html>

²² Available for purchase at <https://www.nap.edu/catalog/4988/occupational-health-and-safety-in-the-care-and-use-of-research-animals>

²³ Available at https://www.nsf.org/newsroom_pdf/NSF_49-2016_Annex_E.pdf