**OFFICE OF RESEARCH OVERSIGHT**

**GUIDANCE CHECKLIST FOR RESEARCH SAFETY AND SECURITY**

**May 21, 2025**[[1]](#footnote-1)

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GENERAL INSTRUCTIONS**:**

The following checklist has been prepared as a self-assessment tool for internal, programmatic use for the evaluation of VHA Research Safety and Security Programs. NOTE: Appendix A defines acronyms used in this document. The items in this checklist originate from various regulations and policies[[2]](#footnote-2) such as:

* 29 CFR 1910, Occupational Safety and Health Standards;
* 29 CFR 1960, Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters;
* VHA Directive 7701, Comprehensive Occupational Safety and Health Program;
* VHA Directive 1200.08(1), Safety of Personnel and Security of Laboratories Involved in VA Research;
* Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition;
* NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines);
* 42 CFR 73 Select Agents and Toxins; Final Rule (DHHS);
* 7 CFR 331 Agricultural Bioterrorism Protection Act of 2002 – Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule (USDA: Agriculture);[[3]](#footnote-3)
* 9 CFR 121 Agricultural Bioterrorism Protection Act of 2002 – Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule (USDA: Animals and Animal Products);
* Guide for the Care and Use of Laboratory Animals, 8th edition (the Guide); and
* Other applicable Federal regulations, VHA Directives, VHA Handbooks, NFPA codes[[4]](#footnote-4), etc.

The checklist is intended to provide guidance for developing and monitoring research safety and security program compliance.

* Always refer to the precise text of cited source documents for more specific requirements or when the meaning of any checklist element is unclear.
* The EPA regulations for hazardous waste must be considered in the context of individual state and local requirements, which may vary considerably.

# FACILITY DOCUMENTS/SOURCE INFORMATION:

The following facility documents may assist with the self-review:

1. Copies of last 2 years AWE reports, conducted by the OSH VISN Team (VHA Directive 7701 §2.h(7) – only information relating to research areas is needed);
2. Summary of annual review of research-specific plans and results of annual drills to evaluate the effectiveness for the following plans: safety/biosafety, chemical hygiene, security, and emergency management (VHA Directive 1200.08(1) §5.n(9-10)(a)&(b));
3. Summary of occupational accidents, injury and/or illness reports in a research laboratory or dedicated research area from the SRS and Facility Safety and Occupational Health Management Office (VHA Directive 1200.08(1) §5.n(10)(c));
4. Summary of results from safety inspections of VA research laboratories, including leased locations and reports from non-VA entities for approved off-site locations where VA research is conducted (VHA Directive 1200.08(1) §5.n(10)(d));
5. Research Program Organizational Chart;
6. RSSP Plan (VHA Directive 1200.08(1) §3.f. and §5.n(10)(a)) and/or Research Service Safety Manual;
7. Medical Center Memoranda/SOPs establishing various Subcommittees, if applicable;
8. R&D Committee, SRS, and IBC Rosters and Member Letters of Appointment (including terms);
9. Minutes of the R&D, SRS, IBC and other relevant Committees/Subcommittees for the last 12 months;
10. A list of all active protocols reviewed by the SRS and IBC for the last 12 months;
11. Safety training records for Investigators and all laboratory staff and any additional agent-specific training records, if applicable (VHA Directive 1200.08(1) §10.d);
12. SRS and RSSP Policies, Procedures, and Plans, including:
    1. Policy or other document describing process for activating and decommissioning laboratories that includes assignment of laboratories from one PI to another;
    2. Biosafety manual(s), if applicable;
    3. BSL-3 SOPs/Manuals, if applicable;
    4. Bloodborne Pathogen Exposure Control Plan;
    5. Radiation Safety Manual, if applicable;
13. Copy of CDC/APHIS Certificate of Registration for Select Agents and Toxins, if applicable;
14. Copy of IBC registrations/renewals with NIH-OSP, if applicable;
15. Radiation Safety Program permits, if applicable;
16. Copy of the inspection records conducted by external government agencies such as OIG, OSHA, CDC/APHIS and EPA, if applicable;
17. All applicable MOUs and CRADO/ORD waivers and/or approval.

| **ORO CHECKLIST FOR RESEARCH SAFETY AND SECURITY** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Determine whether the following items are appropriately and sufficiently implemented by the facility and mark either “Yes,” “No,” “Partial,” or “Not Applicable.” Use the final column to annotate documentation or evidence that can be cited to support the determination of that compliance level.** | | | | | | | |
|  | | **Yes** | **No** | **Partial** | **N/A** | **Source of Reference** | **Facility Comments** |
| A. RESEARCH SAFETY AND SECURITY PROGRAMS | | | | | | | |
| 1. The R&D Service has created and ensured updates of the RSSP that addresses the general required components of research safety and security for all research laboratories:    1. safety; | |  |  |  |  | VHA Directive 1200.08(1) §3.f(1-7);  VHA Directive 1200.08(1) §5.f(1);  VHA Directive 1200.08(1) §5.g(2) |  |
| * 1. security; | |  |  |  |  |  |
| * 1. inventory control; | |  |  |  |  |  |
| * 1. inspections; | |  |  |  |  |  |
| * 1. emergency management; | |  |  |  |  |  |
| * 1. training; | |  |  |  |  |  |
| * 1. record keeping/management. | |  |  |  |  |  |
| 1. The ACOS/R&D has a process in place to review research safety and security for VA research conducted in laboratories located in approved off-site facilities (e.g., VA research covered by an ORD off-site waiver). | |  |  |  |  | VHA Directive 1200.08(1) §5.g(2) |  |
| 1. The R&D Service has adequate staffing and resources available to cover key functions of the RSSP. | |  |  |  |  | VHA Directive 1200.08(1) §5.f(2) |  |
| 1. VA laboratories and other specialized research areas, including animal care facilities, have physical security, regardless of their BSL. | |  |  |  |  | VHA Directive 1200.08(1) §5.f(5) |  |
| 1. Mechanisms are in place that ensure access to VA research areas are monitored and evaluated regularly to prevent unauthorized persons from gaining access. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(4) |  |
| 1. The R&D Service provides the facility police service with information and support necessary to meet police responsibilities for research security including: 2. Ensuring all research areas are included in the routine vulnerability assessment of the facility to security breaches conducted by the police service; | | **☐** | **☐** | **☐** | **☐** | VHA Directive 1200.08(1) §5.g(5) |  |
| 1. Supporting the performance of routine (annual) security and incident response drills or exercises required by the Emergency Management Program or Safety Office; | | **☐** | **☐** | **☐** | **☐** |  |
| 1. Informing the facility police service of any changes in research that affect the facility’s security needs. | | **☐** | **☐** | **☐** | **☐** |  |
| 1. Efforts and communication have been coordinated among all relevant officials, committees and individuals to ensure successful implementation of the RSSP. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(3) |  |
| 1. Process is in place to notify ORD and ORO when any new BSL-3 research laboratory construction, renovation of existing BSL-3 research laboratory, or reactivation of any inactive BSL-3 laboratory is planned. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(6) |  |
| 1. Process is in place to notify ORD and ORO when a BSL-3 laboratory will be inactivated or closed. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(7) |  |
| 1. Access to BSL-3 laboratory is authorized only for individuals that meet requirements for maintaining appropriate security. | |  |  |  |  | VHA Directive 1200.08(1) §5.f(10) |  |
| 1. Process is in place to notify the SRS whenever a space is decommissioned or when the identification and disposal or decontamination of hazardous materials and/or equipment is required between uses. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(8) |  |
| 1. Mechanism is in place to ensure that all personnel conducting VA research (including VA contractors, students, visiting fellows, and those with VA appointments) comply with all VA standards for safety and security. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(9) |  |
| 1. A BSO is appointed if VA research involves the use of recombinant or synthetic nucleic acid molecules at BSL-3, or large scale (greater than 10-L cultures) research on or production involving recombinant or synthetic nucleic acid molecules, as required by *NIH Guidelines*. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(14);  *NIH Guidelines* Section IV.B.3 |  |
| 1. ACOS/R&D reviews and approves requests for a CDC or APHIS laboratory registration number before VA research laboratories receive, transfer control/ownership to another individual, or use select agents or toxins. | |  |  |  |  | VHA Directive 1200.08(1) §5.g(15) |  |
| 1. Drills to test the effectiveness of the safety/biosafety, security, and emergency management plans are conducted annually. | |  |  |  |  | VHA Directive 1200.08(1) §5.n(9) |  |
| B. SUBCOMMITTEE ON RESEARCH SAFETY | | | | | | | |
| 1. Committee composition complies with VHA requirements. 2. At least 5 voting members appointed by the medical facility Director in addition to the ex-officio members. | |  |  |  |  | VHA Directive 1200.08(1) §5.f(6);  VHA Directive 1200.08(1) §6.b(1-2) |  |
| 1. Members with appropriate expertise in etiological agents, chemical hazards, and/or physical/radiation hazards, conducting scientific research, as applicable; | |  |  |  |  |  |
| 1. Minimum of 2 non-affiliated members when non-exempt rDNA research is planned (i.e., if the SRS also serves as an IBC); | |  |  |  |  |  |
| 1. BSO, as applicable. | |  |  |  |  |  |
| 1. Among the voting members expertise in OSH, environmental protection, DOT IATA, and knowledge of the space and facilities assigned to each PI is available. | |  |  |  |  |  |
| 1. Includes members from the facility safety committee (i.e., Safety Officer or member of the Facility Infection Control Committee); and the Radiation Safety Officer or an appropriate individual with Radiation Safety expertise. | |  |  |  |  |  |
| 1. At least one individual who regularly attends IACUC meetings to serve as liaison between the SRS and IACUC. May be voting or non-voting. | |  |  |  |  |  |
| 1. Ex-officio members include: | |  |  |  |  |  |
| 1. R&D Committee liaison (non-voting member of the SRS); | |  |  |  |  |  |
| 1. Employee union representative, as determined by the local union contract. | |  |  |  |  |  |
| 1. The SRS Chair and members (not including ex-officio members) have been appointed in writing by the VA Medical Facility Director, for the term of up to 3 years, which may be renewed. | |  |  |  |  | VHA Directive 1200.08(1) §5.f(6)&(7) |  |
| 1. The SRS reviews information from the PI that includes, but not limited to, the protocol and the RPSS or an alternative form that contains at a minimum, the same information as the VA Form 10-0398. | |  |  |  |  | VHA Directive 1200.08(1) §6.d(2) |  |
| 1. All research protocols subject to SRS review are initially reviewed at a convened meeting. The initial review assessed: | |  |  |  |  | VHA Directive 1200.08(1) §6.d(3);  VHA Directive 1200.08(1) §6.e(1) |  |
| 1. the risks associated with the research including, but not limited to, risks to personnel, research subjects, the facility, and the environment; | |  |  |  |  |  |
| 1. the level of containment, laboratory procedures and practices, personal protective equipment, and training required for the research to be conducted safely; | |  |  |  |  |  |
| 1. the expertise, experience, and training of personnel involved with the protocol; | |  |  |  |  |  |
| 1. the adequacy of the available laboratory space and resources; | |  |  |  |  |  |
| 1. the status of the research, with respect to NIH Guidelines, when the research involved recombinant or synthetic nucleic acid molecules, and whether IBC approval had been obtained, if required. | |  |  |  |  |  |
| 1. The SRS reviews, at least annually, each PI’s VA laboratory program at a convened meeting. The review must include: | |  |  |  |  | VHA Directive 1200.08(1) §6.f(1) |  |
| 1. a list of projects that utilize SRS approved protocols; | |  |  |  |  |  |
| 1. an evaluation of all SRS approved protocols (individual or umbrella) to ensure that the hazards, BSL, risk assessments, training of personnel and status of the project are up to date; | |  |  |  |  |  |
| 1. laboratory inspection report including findings and plans to address any deficiencies; | |  |  |  |  |  |
| 1. summary of all changes or amendments to the safety components of the protocol approved since the last review; | |  |  |  |  |  |
| 1. changes in space allocation; | |  |  |  |  |  |
| 1. reports of any issues related to employee safety and security. | |  |  |  |  |  |
| 1. All SRS official business (including review and approval of protocols) is conducted with a quorum of voting members present. | |  |  |  |  | VHA Directive 1200.08(1) §6.d(3)(b) |  |
| 1. Members with a conflict of interest (e.g., Investigator on the study or other conflict) are recused during deliberations and voting on the study. The recusal of the individual and verification that quorum is maintained is documented in the SRS minutes. | |  |  |  |  | VHA Directive 1200.08(1) §6.d(3)(c) |  |
| 1. For protocols subject to IBC review and approval, the findings of the IBC, including but not limited to the assigned BSL and the required safety measures, are reviewed by the SRS prior to its final approval. | |  |  |  |  | VHA Directive 1200.08(1) §6.e(2) |  |
| 1. The R&DC and the Investigator are notified in writing of the outcome of the SRS review. The SRS specifies the duration (up to one year) that the approval is valid. | |  |  |  |  | VHA Directive 1200.08(1) §6.e(3-4) |  |
| 1. When the SRS withholds approval, the Investigator is provided with the reasons for such action. | |  |  |  |  | VHA Directive 1200.08(1) §6.e(7) |  |
| 1. Use of an external SRS is formally established with an MOU that addresses at least the following: | |  |  |  |  | VHA Directive 1200.08(1) §6.a(1-2);  VHA Directive 1200.08(1) §5.f(8) |  |
| 1. the roles and responsibilities of the affiliate or other VA committee; | |  |  |  |  |  |
| 1. adherence to VA requirements; | |  |  |  |  |  |
| 1. appointment of at least one VA employee and an alternate to represent VA interests and requirements; they must have at least a 5/8-VA-compensated appointment; | |  |  |  |  |  |
| 1. management of ongoing exchange of information between the VA facility and the institution hosting the external SRS regarding the actions of the external SRS. These included, but are not limited to: | |  |  |  |  |  |
| 1. minutes of the meetings; | |  |  |  |  |  |
| 1. documentation of review and approval of projects; | |  |  |  |  |  |
| 1. reports of laboratory safety inspections; | |  |  |  |  |  |
| 1. documentation of mandatory drills conducted; | |  |  |  |  |  |
| 1. documentation of semiannual review of chemical inventories; | |  |  |  |  |  |
| 1. reports of findings of accident investigations; | |  |  |  |  |  |
| 1. reports of noncompliance. | |  |  |  |  |  |
| 1. Research conducted in VA research laboratories that do not involve any hazards must be documented by completion of the RPSS, VA Form 10-0398, or alternate form where all questions are answered “No.” | |  |  |  |  | VHA Directive 1200.08(1) §6.c(3) |  |
| 1. The process for conducting an administrative review to determine whether a protocol is exempt from SRS review is described in the SRS SOP/guidelines. If administrative reviews are conducted by someone other than the SRS Chair, this assignment is documented in writing. The outcome of this review is documented as part of the SRS records, reported to the SRS at its next meeting, and documented in the meeting minutes. | |  |  |  |  | VHA Directive 1200.08(1) §6.c(4) |  |
| 1. A process to activate and decommission laboratories, including transfers of assignment of laboratories from one PI to another, has been developed. | |  |  |  |  | VHA Directive 1200.08(1) §5.n(1) |  |
| 1. Research-specific plans for safety/biosafety, security, chemical hygiene and emergency management have been developed and implemented. | |  |  |  |  | VHA Directive 1200.08(1) §5.n(9) |  |
| 1. A process is in place to identify individuals who require health surveillance and/or exposure monitoring, on the basis of their involvement in specific VA research projects, or their other risks of exposure to hazards involved in VA research. | |  |  |  |  | VHA Directive 1200.08(1) §5.n(11)(b)&(c) |  |
| 1. The SRS works with Occupational Health and Facility Safety to ensure that appropriate surveillance and monitoring is provided. | |  |  |  |  | VHA Directive 1200.08(1) §5.n(11)(c) |  |
| 1. The SRS reviews and approves any change in a research project that affects the safety of the personnel or the environment submitted by the PI for review and approval prior to the implementation of the change. | | ☐ | ☐ | ☐ | ☐ | VHA Directive 1200.08(1) §5.n(4) |  |
| 1. The following are evaluated, addressed and reported according to regulatory requirements, including VHA Directive 1058: 2. human death associated with VA laboratory research; | |  |  |  |  | VHA Directive 1200.08(1) §5.n(8);  VHA Directive 1058 §3.e |  |
| 1. VA laboratory research events involving serious accident, injury, illness, or exposure of a human; | |  |  |  |  |  |
| 1. serious or continuing noncompliance involving VA laboratory research; | |  |  |  |  |  |
| 1. VA laboratory research safety and security events reportable to other federal entities; | |  |  |  |  |  |
| 1. other events involving VA research safety and security reportable to ORO. | |  |  |  |  |  |
| 1. The SRS ensures that current inventories of all hazardous agents in each VA local research laboratory are maintained and reviewed by the CHO at least semiannually so that appropriate security measures can be implemented. | | ☐ | ☐ | ☐ | ☐ | VHA Directive 1200.08(1) §5.n(5) |  |
| 1. The SRS reviews inspection reports of each VA research laboratory at least annually, to ensure that appropriate safety equipment and procedures and security measures are in place for all of the projects/protocols being conducted in that laboratory.   *NOTE:* For VA research conducted in approved off-site facilities that are not owned, leased by VA, or occupied by VA under a legal agreement the SRS may rely on inspections conducted by non-VA entities with primary responsibility for the space (e.g., academic affiliate) provided that the inspections are conducted at least annually and the SRS reviews the results of those inspections. | | ☐ | ☐ | ☐ | ☐ | VHA Directive 1200.08(1) §5.n(6) |  |
| 1. The SRS reviews the results of all research laboratory and safety-related inspections (e.g., Environment of Care, AWE, Security Vulnerability Assessments, inspections by regulatory bodies, etc.) and ensures the implementation and completion of corrective actions, as appropriate. | | ☐ | ☐ | ☐ | ☐ | VHA Directive 1200.08(1) §5.n(7) |  |
| 1. The SRS ensures access to BSL-3 research laboratories is appropriately controlled: | |  |  |  |  | VHA Directive 1200.08(1) §5.n(12) |  |
| 1. By reviewing and acting on requests for access to BSL-3 research laboratories, for employees (compensated, WOC, or IPA appointments) or contractors. | |  |  |  |  |  |
| 1. By reviewing at least annually the appropriateness of the security status of personnel with access to VA BSL-3 research laboratories. This review is to include consideration of each individual’s need for access (based on the individual’s duties in the research being conducted), the individual’s appointment status, and the status of the individual’s Security Risk Assessment by the Criminal Justice Information Services of the FBI. | |  |  |  |  |  |
| 1. By reviewing requests to construct a new BSL-3 facility, to make major renovations to an existing BSL-3 facility, or to re-activate an inactive BSL-3 facility before they are submitted to the medical facility Director, the VISN Director, ORD, and ORO. | |  |  |  |  |  |
| 1. The SRS annually reviews the effectiveness of the RSSP and identifies and implements any updates, revisions, or corrections needed. A summary of this evaluation is documented in the SRS minutes and sent to the Medical Facility Director through the R&D Committee. The evaluation includes:    1. a review of the RSSP; | |  |  |  |  | VHA Directive 1200.08(1) §5.n(10) |  |
| 1. the results of all relevant annual drills or exercise; | |  |  |  |  |  |
| 1. summary of any research-related accidents or injuries; | |  |  |  |  |  |
| 1. a summary of results of safety inspections of VA research laboratories, including leased locations and reports from non-VA off-site locations where VA research is conducted; | |  |  |  |  |  |
| 1. concerns raised during any Police vulnerability assessments. | |  |  |  |  |  |
| C. INSTITUTIONAL BIOSAFETY COMMITTEE | | | | | | | |
| * + - 1. Committee composition complies with *NIH Guidelines* and VHA requirements.  1. No fewer than five members that collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. | |  |  |  |  | *NIH Guidelines* Section IV-B-1-b;  *NIH Guidelines* Section IV-B-2-a-(1);  *NIH Guidelines* Section IV-B-1-c;  *NIH Guidelines* Section IV-B-1-e;  *NIH Guidelines* Section IV-B-1-f;  VHA Directive 1200.08(1) §7.a |  |
| 1. At least two members shall not be affiliated with the institution and who represent the interest of the surrounding community with respect to health and protection of the environment. | |  |  |  |  |  |
| 1. At least one scientist with expertise in animal containment principles when experiments utilizing Appendix M, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals, require Institutional Biosafety Committee prior approval. | |  |  |  |  |  |
| 1. BSO, when the facility conducts recombinant or synthetic nucleic acid molecule research at BSL-3. | |  |  |  |  |  |
| 1. When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution ensures that the IBC has adequate expertise and training (using ad hoc consultants if necessary). IBC approval is obtained from the clinical trial site. | |  |  |  |  |  |
| 1. The VA IBC-of record is registered with NIH-OSP.   *NOTE:* The IBC must be registered with NIH-OSP by each facility that it serves. | |  |  |  |  | VHA Directive 1200.08(1) §5.o;  *NIH Guidelines* – FAQs on Institutional Biosafety Committee (IBC) Administration – April 2024[[5]](#footnote-5) |  |
| 1. Local guidelines describe procedures for VA IBC review and approval of VA research. | |  |  |  |  | VHA Directive 1200.08(1) §7.c |  |
| 1. The facility ensures appropriate training for the IBC Chair and members, BSO and other applicable containment experts, PIs, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. | |  |  |  |  | *NIH Guidelines* Section IV-B-1-h |  |
| 1. IBC Chair ensures that all IBC members are appropriately trained. | |  |  |  |  | *NIH Guidelines* Section IV-B-1-h |  |
| 1. The facility or IBC ensures that the PI has sufficient training on the *NIH Guidelines*. | |  |  |  |  | *NIH Guidelines* Section IV-B-1-h |  |
| 1. The PI:    * + - 1. ensures laboratory staff are appropriately trained when working with recombinant or synthetic nucleic acid molecules; | |  |  |  |  | *NIH Guidelines* Section IV-B-1-h;  *NIH Guidelines* Section IV-B-7-d-(2-3) |  |
| * + - * 1. instructs and trains laboratory staff in   the practices and techniques required to ensure safety; | |  |  |  |  |  |
| the procedures for dealing with accidents; | |  |  |  |  |  |
| * + - * 1. informs the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection). | |  |
| 1. The IBC notifies the PI in writing or electronically regarding the outcome of the review. The notification includes the date of approval, the specific BSL that applies to the protocol, and a description of any additional measures required by the IBC. | |  |  |  |  | VHA Directive 1200.08(1) §5.o(4);  *NIH Guidelines* Section IV-B-2-b-(2) |  |
| 1. The IBC conducts and documents an annual review of those portions of the RSSP that apply to the safety of VA research involving recombinant or synthetic nucleic acid molecules, identifying concerns and ensuring that corrective actions are completed, as appropriate. This report, or summary thereof, is provided to both the SRS and the R&D Committee. | |  |  |  |  | VHA Directive 1200.08(1) §5.o(5) |  |
| 1. Use of an external IBC is formally established with an MOU that addresses at least the following: 2. the roles and responsibilities of the affiliate or other VA committee; | |  |  |  |  | VHA Directive 1200.08(1) §7.f;  *NIH Guidelines* – FAQs on Externally Administered IBCs – April 2024[[6]](#footnote-6) |  |
| 1. adherence to VA requirements; | |  |  |  |  |  |
| 1. appointment of at least one VA-compensated employee and an alternate to represent VA interests and requirements; | |  |  |  |  |  |
| 1. the VA established and maintains registration with NIH-OSP indicating that the external IBC serves as the IBC-of-record for the VA facility; | |  |  |  |  |  |
| 1. management of ongoing exchange of information between the VA facility and the institution hosting the external IBC regarding the actions of the external IBC. These included, but are not limited to:   minutes of the meetings; | |  |  |  |  |  |
| documentation of review and approval of projects; | |  |  |  |  |  |
| reports of laboratory safety inspections; | |  |  |  |  |  |
| documentation of mandatory drills conducted; | |  |  |  |  |  |
| documentation of semiannual review of chemical inventories; | |  |  |  |  |  |
| reports of finding of accident investigations; | |  |  |  |  |  |
| reports of noncompliance. | |  |  |  |  |  |
| 1. Use of an external IBC hosted by a second VA facility follows all conditions: 2. The IBC was internal to the second VA; | |  |  |  |  | VHA Directive 1200.08(1) §7.e |  |
| 1. The second VA facility meets the *NIH Guidelines* requirement for community representation of the requesting VA. | |  |  |  |  |  |
| 1. The IBC of the second VA is knowledgeable of the containment facilities of the requesting VA facility. | |  |  |  |  |  |
| 1. A VA-compensated employee from the requesting VA was appointed as a voting member to the IBC of the second VA. | |  |  |  |  |  |
| 1. The requesting VA established and maintains registration with NIH-OSP indicating that the IBC at the second VA facility serves as the IBC-of-record for the requesting VA facility. | |  |  |  |  |  |
| 1. The facility files an annual report with NIH-OSP including an IBC roster, indicating Chair, contact person BSO, applicable experts, and biographical sketches of all IBC members (including community members). | |  |  |  |  | *NIH Guidelines* Section IV-B-2-a-(3) |  |
| 1. The facility establishes and implements policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecule research and that ensure compliance with the *NIH Guidelines*. | |  |  |  |  | *NIH Guidelines* Section IV-B-1-a |  |
| 1. The IBC ensures the adoption of emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research. | |  |  |  |  | *NIH Guidelines* Section IV-B-2-b-(6) |  |
| 1. IBC review includes:    * + - 1. independent assessment of required containment levels for proposed research; | |  |  |  |  | *NIH Guidelines* Section IV-B-2-b-(1) |  |
| * + - * 1. assessment of facilities, procedures, practices, and training and expertise of personnel involved in research | |  |  |  |  |  |
| * + - * 1. for research involving human research participants, assessment focused on biosafety issues (e.g., administration, shedding). | |  |  |  |  |  |
| 1. No member of the IBC is involved, except to provide information requested by the IBC, in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest. | |  |  |  |  | *NIH Guidelines* Section IV-B-2-a-(4) |  |
| 1. The facility makes available to the public, upon request, all IBC meeting minutes, and any documents submitted to or received from funding agencies. | |  |  |  |  | *NIH Guidelines* Section IV-B-2-a-(7) |  |
| 1. If public comments have been made on IBC actions, the facility forwards the public comments and the IBC response to NIH-OSP, preferably by email [NIHGuidelines@od.nih.gov](mailto:NIHGuidelines@od.nih.gov). | |  |  |  |  | *NIH Guidelines* Section IV-B-2-a-(7) |  |
| 1. The facility determines the necessity for health surveillance of personnel involved in connection with individual recombinant or synthetic nucleic acid molecule projects; and if appropriate, conducts a health surveillance program for such projects, including establishing and maintaining a health surveillance program for personnel engaged in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules which require BSL-3 containment at the laboratory scale and personnel engaged in animal research involving viable recombinant or synthetic nucleic acid molecule-containing microorganisms that require BSL-3 or greater containment in the laboratory. | |  |  |  |  | *NIH Guidelines* Section IV-B-1-i |  |
| 1. The facility reports any significant violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH-OSP within thirty days, unless the institution determines that the report has already been filed by the PI or IBC. | |  |  |  |  | *NIH Guidelines* Section IV-B-1-j |  |
| 1. The IBC reports any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH-OSP within 30 days, unless the IBC determines that a report has already been filed by the PI. | |  |  |  |  | *NIH Guidelines* Section IV-B-2-b-(7) |  |
| 1. PIs reports any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the BSO (where applicable), Greenhouse/Animal Facility Director (where applicable), IBC, NIH-OSP, and other appropriate authorities (if applicable) within 30 days. | |  |  |  |  | *NIH Guidelines* Section IV-B-7-a-(3) |  |
| 1. A BSO is appointed, if conducting recombinant or synthetic nucleic acid research at BSL-3 or higher, or greater than 10 L, and has been assigned the BSO duties specified in the *NIH Guidelines*. | |  |  |  |  | *NIH Guidelines* Section IV-B-3-a;  *NIH Guidelines* Section IV-B-3-b;  *NIH Guidelines* Section IV-B-3-d-(1-5) |  |
| 1. PIs do not initiate or modify any recombinant or synthetic nucleic acid molecule research which requires IBC approval prior to initiation until that research or proposed modification has been approved by the IBC and has met all other requirements of the *NIH Guidelines*. | |  |  |  |  | *NIH Guidelines* Section IV-B7-a-(1) |  |
| 1. PIs comply with shipping requirements for recombinant or synthetic nucleic acid molecules (see Appendix H of the *NIH Guidelines*). | |  |  |  |  | *NIH Guidelines* Section IV-B-7-a-(7) |  |
| 1. PIs supervise the safety performance of laboratory staff to ensure that the required safety practices and techniques are employed. | |  |  |  |  | *NIH Guidelines* Section IV-B-7-e-(1) |  |
| 1. PIs correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials. | |  |  |  |  | *NIH Guidelines* Section IV-B-7-e-(3) |  |
| 1. PIs ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics). | |  |  |  |  | *NIH Guidelines* Section IV-B-7-e-(4) |  |
| D. LABORATORY SAFETY – GENERAL | | | | | | | |
| 1. The work area is free of unnecessary clutter. Fume hoods and BSC are not used for general storage, storage of chemicals, and have vents/ductwork unobstructed. | |  |  |  |  | NPFA 45 (2024) §8.3.4.7;  BMBL Section IV |  |
| 1. Carpets and/or rugs are not used in labs or work areas where biological or chemical materials are handled. | |  |  |  |  | BMBL Section IV BSL-1 D.4 |  |
| 1. For rooms equipped with sprinklers, all items on shelves have a minimum vertical clearance of 18-inches from sprinkler heads, heating pipes, and lighting fixtures. | |  |  |  |  | 29 CFR §1910.159(c)(10) |  |
| 1. Functional fire extinguishers, appropriate for the hazard(s) present, are readily available and unobstructed. | |  |  |  |  | 29 CFR §1910.157(c-d) |  |
| 1. Personnel have access to emergency first aid services or kits. | |  |  |  |  | 29 CFR §1910.151(a-b) |  |
| 1. Safety showers and eyewashes are located wherever corrosive chemicals are used. | |  |  |  |  | 29 CFR §1910.151(c);  VHA Directive 7704(1) Appendix A |  |
| 1. Eyewash and safety showers are tested annually and activated at specified intervals. Results are documented in accordance with facility policy. | |  |  |  |  | VHA Directive 7704(1) Appendices D & E |  |
| 1. An occupational noise monitoring program is implemented when potentially hazardous noise exists. | |  |  |  |  | 29 CFR §1910.95 |  |
| 1. Personnel who are required to use respirators have undergone medical evaluations and have been properly trained and fitted for their use. Personnel who are permitted to voluntarily use respirators are provided a copy of 29 CFR §1910.134 Appendix D. | |  |  |  |  | 29 CFR §1910.134(c), (e-h) & (j-k);  29 CFR §1910.1450(i) |  |
| 1. Use of flexible cords (e.g., extension cords) is in accordance with OSHA: 2. not used as permanent wiring; 3. not run through doors, windows, ceilings, etc. | |  |  |  |  | 29 CFR §1910.305(g)(1)(iv);  2018 NFPA 1 §11.1.5.1-6 |  |
| 1. GFI electrical outlets are used in wet or high-risk areas. | |  |  |  |  | 29 CFR §1910.305(e)(1);  NEC (Article 210-8);  2020 NFPA/NEC 70 §210.8(B)(5-6) |  |
| 1. Compressed gas cylinders are: 2. transported on cylinder carts (secured and capped); 3. secured with chains or straps; 4. capped when not in use. | |  |  |  |  | 29 CFR §1910.101 |  |
| 1. Hazardous chemical storage is: 2. in properly identified and compatible containers and in a non-flammable storage room or non-flammable cabinets; | |  |  |  |  | 29 CFR §1910.106(d)(1-4);  NFPA 45 (2024) §8.3.4.2;  NFPA 45 (2024) §8.3.4.3;  NFPA 45 (2024) §8.3.4.4;  NFPA 45 (2024) §8.3.4.6;  NFPA 45 (2024) §9.1.1 |  |
| 1. below eye level, but not on the floor; | |  |  |  |  |  |
| 1. segregated according to compatibility (flammables separate from oxidizers, acids separate from bases, etc.); | |  |  |  |  |  |
| 1. appropriate for flammable liquids (safety cans for volumes greater than 4 L and cabinets for volumes greater than 10 L); | |  |  |  |  |  |
| 1. organic and inorganic (mineral) acids not comingled; | |  |  |  |  |  |
| 1. within appropriate cabinetry if flammable or corrosive; | |  |  |  |  |  |
| 1. in explosion-proof refrigerators when flammable cold storage is required; | |  |  |  |  |  |
| 1. monitored for disposal prior to expiration – particularly for peroxide-forming reagents; | |  |  |  |  |  |
| 1. examined periodically (at least annually) for replacement, deterioration, and container integrity. | |  |  |  |  |  |
| 1. All chemical and biological/medical lab wastes are collected and stored in compatible containers. Waste accumulation is minimized and limited to the lab area. Waste disposal is in accordance with federal and state regulations. | |  |  |  |  | 40 CFR §262.43(c), subpart C (EPA);  29 CFR §1910.1030(d)(4)(iii)(B) (regulated biological/medical wastes) |  |
| 1. Spill control programs are in place and may include spill kits. Training is provided when spill kits are available. | |  |  |  |  | BMBL Appendix B |  |
| 1. Controlled substances are properly secured and inventoried. | |  |  |  |  | 21 CFR §1301.71-76;  21 CFR §1304.11;  *Pharmacist’s Manual: An Informational Outline of the Controlled Substances Act* (2020);  VHA Directive 1108.01 (01) §4.f(3);  VHA Directive 1108.01 (01) §7.a(4) |  |
| 1. Select carcinogens, reproductive toxins, and substances with a high degree of acute toxicity are handled in designated areas. | |  |  |  |  | 29 CFR §1910.1450(e)(3)(viii)(A) |  |
| 1. Eating, drinking, smoking, handling contact lenses, and/or applying cosmetics are prohibited in all labs and/or areas where chemicals and/or blood or OPIM are used. | |  |  |  |  | 29 CFR §1910.141(g)(2);  29 CFR §1910.1030(d)(2)(ix) |  |
| 1. A PPE hazard assessment is conducted for each lab. A copy of the certified hazard assessment is maintained in each laboratory. All employees working in the lab are trained on the PPE required for use in the lab. | |  |  |  |  | 29 CFR §1910.132(d) |  |
| 1. PPE are be provided, used, and maintained in accordance with OSHA requirements and facility policies, (i.e., removal prior to leaving work area, cleaning and laundering, training, maintenance & care). | |  |  |  |  | 29 CFR §1910.132(a) |  |
| 1. SDSs are appropriately managed. | |  |  |  |  | 29 CFR §1910.1450(h)(1)(ii);  VHA Directive 1200.08 §5.p(7)(b) |  |
| 1. Chemical inventories are reviewed twice a year by the CHO/facility Safety Officer and appeared to accurately reflect the actual chemicals on hand. | |  |  |  |  | VHA Directive 1200.08(1) §5.h(1);  VHA Directive 1200.08(1) §5.k;  VHA Directive 1200.08(1) §5.n(5) |  |
| 1. Liquid nitrogen and/or dry ice are stored appropriately,[[7]](#footnote-7) and PPE is available during dispensing. | |  |  |  |  | 29 CFR §1910.132(d)(1)(i);  29 CFR §1960.8(a) |  |
| 1. Sharps containers are present, when required, and appropriately used. | |  |  |  |  | 29 CFR §1910.1030(d)(4)(iii)(A)(2)(i-iii) |  |
| E. LABORATORY SECURITY REQUIREMENTS | | | | | | | |
| 1. Access to VA research laboratories is controlled at all times. Physical security of all VA research areas meets appropriate standards determined by the facility police service (see VA Directive 0730, and VA Handbook 0730/4), applicable regulatory agencies (e.g., CDC, APHIS, NRC), and cognizant VA oversight offices (e.g., radiation or nuclear medicine offices). The facility’s VA police service are consulted prior to purchasing or installing security devices and/or before initiating construction designed to improve security. | |  |  |  |  | VHA Directive 1200.08(1) §8 |  |
| F. TRAINING REQUIREMENTS | | | | | | | |
| 1. All individuals (VA employees appointed as full-time, part-time, intermittent, fee-basis, or WOC, as well as contractors) and individuals appointed through IPA actions, either working in or directly administering VA research laboratories, are appropriately trained to ensure safety and security within research laboratories. | |  |  |  |  | VHA Directive 1200.08(1) §10.a |  |
| 1. Training requirements include specific training, as necessary, related to the laboratory areas where they are assigned to work and to the hazards or agents that may be encountered while conducting research. This requirement includes site-specific initial and annual refresher training on the research safety (exposure control plan), chemical hygiene, hazardous waste, security, and individual laboratory-specific safety plans [and] requirements set forth by VA, OSHA, EPA, CDC, DOT, NRC and other applicable agencies (e.g., BBP training, hazardous chemical and waste disposal training, personal protective equipment training, emergency response, fire extinguisher, and training on the shipping of hazardous materials). | |  |  |  |  | VHA Directive 1200.08(1) §10.a(1-2) |  |
| 1. All new research staff, staff with collateral OSH duties, and administrators responsible for VA research laboratories complete the required training prior to their duties. | |  |  |  |  | VHA Directive 1200.08(1) §10.b |  |
| 1. All individuals with potential exposure to human blood or OPIM receive initial and annual (every 12-months) BBP training. The training contains all required elements and includes an opportunity for questions and answers while being completed. | |  |  |  |  | 29 CFR §1910.1030(g)(2)(i-vii);  VHA Directive 1200.08(1) §10.a(1-2) |  |
| 1. All individuals engaged in laboratory use of chemicals are provided information and training to apprise them of the chemical hazards. | |  |  |  |  | 29 CFR §1910.1450(f)(1-4);  VHA Directive 1200.08(1) §10.a(1-2) |  |
| 1. All individuals receive additional training prior to assignments that may involve new risks or potential exposures, and when security systems or procedures are changed. | |  |  |  |  | 29 CFR §1910.1450(f)(2);  VHA Directive 1200.08(1) §10.c |  |
| 1. Training records are maintained by the facility Research Office for both initial and refresher training. At a minimum, these records include the identity of the individual, the date of completion of the training, and a description of the training. | |  |  |  |  | VHA Directive 1200.08(1) §10.d |  |
| G. BSL-1 AND ABSL-1 LABORATORIES | | | | | | | |
| Standard Microbiological Practices | | | | | | | |
| The Lab or Animal Facility Director (PI if nonexempt rDNA) enforces the institutional policies that control safety in and access to the animal facility and/or laboratory. Access to the animal room is limited. Only those persons required for experimental, husbandry, or support services are authorized to enter the facility. | |  |  |  |  | BMBL Section IV BSL-1 A.1;  BMBL Section V ABSL-1 A.2;  *NIH Guidelines* Appendix G-II-A-1-a |  |
| The animal facility director establishes and enforces policies, procedures for biosafety, biosecurity, and emergencies within the animal facility. | |  |  |  |  | BMBL Section V ABSL-1 A.1 |  |
| Each institution ensures that worker safety and health concerns are addressed as part of the animal protocol review process. Consideration is given to specific biohazards unique to the animal species and protocol in use. Prior to beginning a study, animal protocols are reviewed and approved by the IACUC as well as IBC, as appropriate. | |  |  |  |  | BMBL Section V ABSL-1 A.3 |  |
| The laboratory supervisor ensures that:Laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious materials necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained; | |  |  |  |  | BMBL Section IV BSL-1 A2 |  |
| Personnel receive annual updates and additional training when equipment, procedures, or policies change; | |  |  |  |  |  |
| All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. | |  |  |  |  |  |
| The supervisor ensures that:Animal care, facility, and support personnel receive appropriate training regarding their duties, animal husbandry procedures, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization); | |  |  |  |  | BMBL Section V ABSL-1 A.4 |  |
| Personnel receive annual updates and additional training when equipment, procedures, or policies change. Records are maintained for all hazard evaluations, training sessions, and staff attendance; | |  |  |  |  |  |
| All persons, including facility equipment personnel, service workers, and visitors, are advised of the potential hazards (e.g., naturally acquired or research pathogens, allergens); are instructed on the appropriate safeguards; and read and follow instructions on practices and procedures; | |  |  |  |  |  |
| An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered. | |  |  |  |  |  |
| All personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution’s healthcare provider for appropriate counseling and guidance. Facility supervisors ensure that medical staff are informed of potential occupational hazards within the animal facility, to include those associated with research, animal husbandry duties, animal care, and manipulations. | |  |  |  |  | BMBL Section IV BSL-1 A.3;  BMBL Section V ABSL-1 A.5 |  |
| Appropriate occupational medical services are in place, as determined by risk assessment. | |  |  |  |  | BMBL Section V ABSL-1 A.6 |  |
| 1. An animal allergy prevention program is part of the medical surveillance; | |  |  |  |  |  |
| 1. Personnel using respirators for animal allergy prevention are enrolled appropriately constituted respiratory protection program. | |  |  |  |  |  |
| A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated, as necessary. | |  |  |  |  | BMBL Section IV BSL-1 A.4;  BMBL Section V ABSL-1 A.7 |  |
| 1. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed. | |  |  |  |  |  |
| 1. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies. | |  |  |  |  |  |
| A sign is posted at the entrance to the laboratory and/or entrance to the animal room when infectious materials/agents are present. Posted information includes: the laboratory’s/rooms Biosafety Level, the supervisor’s or other responsible personnel’s name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy. | |  |  |  |  | BMBL Section IV BSL-1 A.5;  BMBL Section V ABSL-1 A.8 |  |
| Long hair is restrained so that it cannot contact hands, animals, specimens, containers, or equipment. | |  |  |  |  | BMBL Section IV BSL-1 A.6;  BMBL Section V ABSL-1 A.9 |  |
| Gloves are worn to protect hands from exposure to hazardous materials and when handling animals. | |  |  |  |  | 29 CFR §1910.1030(d)(3)(ix)(A);  29 CFR §1910.1030(d)(3)(ix)(B);  BMBL Section IV BSL-1 A.7;  BMBL Section V ABSL-1 A.10 |  |
| 1. Glove selection is based on an appropriate risk assessment. | |  |  |  |  |  |
| 1. Consider the need for bite and/or scratch-resistant gloves. | |  |  |  |  |  |
| 1. Gloves are not worn outside the laboratory. | |  |  |  |  |  |
| 1. Gloves worn inside the animal facility are not worn outside the animal facility. | |  |  |  |  |  |
| 1. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary. | |  |  |  |  |  |
| 1. Do not wash or reuse disposable gloves and dispose of used gloves with other contaminated laboratory waste. | |  |  |  |  |  |
| Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated. | |  |  |  |  | BMBL Section IV BSL-1 A.8;  BMBL Section V ABSL-1 A.11 |  |
| Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory. | |  |  |  |  | BMBL Section IV BSL-1 A.9;  BMBL Section V ABSL-1 A.12;  *NIH Guidelines* Appendix G-II-A-1-f;  *NIH Guidelines* Appendix G-II-B-1-f;  *NIH Guidelines* Appendix G-II-C-1-e |  |
| Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area. | |  |  |  |  | 29 CFR §1910.1030(d)(2)(ix);  BMBL Section IV BSL-1 A.10;  BMBL Section V ABSL-1 A.13;  *NIH Guidelines* Appendix G-II-A-1-e;  *NIH Guidelines* Appendix G-II-B-1-e;  *NIH Guidelines* Appendix G-II-C-1-d |  |
| Mouth pipetting is prohibited. Mechanical pipetting devices are used. | |  |  |  |  | 29 CFR §1910.1030(d)(2)(xii);  BMBL Section IV BSL-1 A.11;  BMBL Section V ABSL-1 A.14;  *NIH Guidelines* Appendix G-II-A-1-d;  *NIH Guidelines* Appendix G-II-B-1-d;  *NIH Guidelines* Appendix G-II-C-1-c |  |
| Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include: | |  |  |  |  | 29 CFR §1910.1030(d)(2)(vii-viii);  29 CFR §1910.1030(d)(4)(ii)(D);  29 CFR §1910.1030(d)(4)(iii)(A)(1-4);  BMBL Section IV BSL-1 A.12;  BMBL Section V ABSL-1 A.15 |  |
| 1. Plasticware is substituted for glassware whenever possible. | |  |  |  |  |  |
| 1. Use of needles and syringes or other sharp instruments is limited in the laboratory and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible. | |  |  |  |  |  |
| 1. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick. | |  |  |  |  |  |
| 1. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. | |  |  |  |  |  |
| 1. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle). | |  |  |  |  |  |
| 1. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use. | |  |  |  |  |  |
| 1. Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving. | |  |  |  |  |  |
| 1. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps. | |  |  |  |  |  |
| Perform all procedures to minimize the creation of splashes and/or aerosols. | |  |  |  |  | 29 CFR §1910.1030(d)(2)((xi);  BMBL Section IV BSL-1 A.13;  BMBL Section V ABSL-1 A.16;  *NIH Guidelines* Appendix G-II-A-1-g;  *NIH Guidelines* Appendix G-II-B-1-g;  *NIH Guidelines* Appendix G-II-C-1-f |  |
| Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory and/or animal facility. | |  |  |  |  | BMBL Section IV BSL-1 A.14;  BMBL Section V ABSL-1 A.17;  *NIH Guidelines* Appendix G-II-A-1-b;  *NIH Guidelines* Appendix G-II-B-1-b;  *NIH Guidelines* Appendix G-II-C-1-a |  |
| Decontaminate all cultures, stocks, and OPIM before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport: | |  |  |  |  | BMBL Section IV BSL-1 A.15;  BMBL Section V ABSL-1 A.18;  *NIH Guidelines* Appendix G-II-A-2-a;  *NIH Guidelines* Appendix G-II-B-2-a;  *NIH Guidelines* Appendix G-II-C-2-b;  DOT HM 181 (Hazardous Materials Regulations) |  |
| 1. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label. | |  |  |  |  |  |
| 1. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations. | |  |  |  |  |  |
| An effective integrated pest management program is implemented. | |  |  |  |  | 29 CFR §1910.141(a)(5);  BMBL Section IV BSL-1 A.16;  BMBL Section V ABSL-1 A.19;  BMBL Appendix G;  *NIH Guidelines* Appendix G-II-A-2-b;  *NIH Guidelines* Appendix G-II-B-2-e;  *NIH Guidelines* Appendix G-II-C-2-h |  |
| Animal and plants not associated with the work being performed are not permitted in the laboratory and/or where animals are housed or manipulated. | |  |  |  |  | BMBL Section IV BSL-1 A.17;;  BMBL Section V ABSL-1 A.20 |  |
| Special Practices | | | | | | | |
| None required. | |  |  |  |  |  |  |
| Safety Equipment (Primary Barriers and Personal Protective Equipment) | | | | | | | |
| Protective laboratory coats, gowns, or uniforms are worn to prevent contamination of personal clothing. Protective outer clothing is not worn outside areas where infectious materials and/or animals are housed or manipulated. Gowns and uniforms are not worn outside the animal facility. | |  |  |  |  | BMBL Section IV BSL-1 C.2;  BMBL Section V ABSL-1 C.2 |  |
| Protective eyewear is worn by personnel when conducting procedures that have the potential to create splashes and sprays of microorganisms or other hazardous material. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use. | |  |  |  |  | 29 CFR §1910.1030 (d)(3);  29 CFR §1910.1030(d)(3)(x);  BMBL Section IV BSL-1 C.3;  BMBL Section V ABSL-1 C.3 |  |
| In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens. | |  |  |  |  | BMBL Section IV BSL-1 C.4 |  |
| Persons having contact with Non-Human Primates assess the risk of mucous membrane exposure and wear protective equipment (e.g., face shield, surgical mask, goggles), as appropriate. | |  |  |  |  | BMBL Section V ABSL-1 C.4 |  |
| Additional PPE is considered for persons working with large animals. | |  |  |  |  | BMBL Section V ABSL-1 C.5 |  |
| Facilities (Secondary Barriers) | | | | | | | |
| Laboratories have doors for access control. | |  |  |  |  | BMBL Section IV BSL-1 D.1 |  |
| ABSL-1 facilities should be separated from the general traffic patterns of the building and restricted as appropriate. | |  |  |  |  | BMBL Section V ABSL-1 D-1 |  |
| 1. External facility doors are self-closing and self-locking. | |  |  |  |  |  |
| 1. Access to the animal facility is restricted. | |  |  |  |  |  |
| 1. Door to areas where infectious materials and/or animals are housed open inward, are self-closing, are kept closed when experimental animals are present, and never propped open. | |  |  |  |  |  |
| Laboratories have a sink for handwashing. | |  |  |  |  | 29 CFR §1910.1030(d)(2)(iii) for BBP;  BMBL Section IV BSL-1 D.2;  *NIH Guidelines* Appendix G-II-A-4-d |  |
| The animal facility has a sink for handwashing. | |  |  |  |  | BMBL Section V ABSL-1 D.2 |  |
| 1. Emergency eyewash and shower are readily available, easily accessible, and appropriately maintained. | |  |  |  |  |  |
| 1. Sink traps are filled with water and/or appropriate disinfectant to prevent the migration of vermin and gases. | |  |  |  |  |  |
| 1. If open floor drains are provided, the traps are filled with water and/or appropriate disinfectant or sealed to prevent the migration of vermin and gases. | |  |  |  |  |  |
| An eyewash station is readily available in the laboratory. | |  |  |  |  | BMBL Section IV BSL-1 D.3 |  |
| The laboratory is designed so that it can be easily cleaned. | |  |  |  |  | BMBL Section IV BSL-1 D.4;  *NIH Guidelines* Appendix G-II-A-4-a;  *NIH Guidelines* Appendix G-II-A-4-c |  |
| 1. Carpets and rugs in laboratories are not appropriate. | |  |  |  |  |  |
| 1. Spaces between chairs, cabinets, and equipment are accessible for cleaning. | |  |  |  |  |  |
| The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (e.g., walls, floors, ceilings) are water-resistant. | |  |  |  |  | BMBL Section V ABSL-1 D.3 |  |
| 1. Floors are slip-resistant, impervious to liquids, and resistant to chemicals. Floors with drains are sloped toward drains to facilitate cleaning. | |  |  |  |  |  |
| 1. It is recommended that penetrations in floors, walls, and ceilings be sealed, including openings around ducts, doors, doorframes, outlets, and switch plates to facilitate pest control and proper cleaning. | |  |  |  |  |  |
| 1. Internal facility fixtures, such as light features, air ducts, and utility pipes, are designed and installed to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites. | |  |  |  |  |  |
| 1. External windows are not recommended; if present, they are resistant to breakage. Where possible, windows are sealed. If the animal facility has windows that open, they are fitted with fly screens. | |  |  |  |  |  |
| 1. Illumination is adequate for all activities and avoids reflections and glare that could impede vision. | |  |  |  |  |  |
| Laboratory furniture can support anticipated loads and uses. | |  |  |  |  | BMBL Section IV BSL-1 D.5;  BMBL Section V ABSL-1 D.4;  *NIH Guidelines* Appendix G-II-A-4-b;  *NIH Guidelines* Appendix G-II-A-4-c;  *NIH Guidelines* Appendix G-II-B-4-b;  *NIH Guidelines* Appendix G-II-B-4-c;  *NIH Guidelines* Appendix G-II-C-4-c;  *NIH Guidelines* Appendix G-II-C-4-d |  |
| 1. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. | |  |  |  |  |  |
| 1. Chairs used in laboratory work and/or animal areas are covered with a non-pervious material that can be easily cleaned and decontaminated with appropriate disinfectant and sealed to prevent harboring of insects/vermin. | |  |  |  |  |  |
| 1. Equipment and furnishings are carefully evaluated to minimize exposure of personnel to pinch points and sharp edges and corners. | |  |  |  |  |  |
| Laboratory windows that open to the exterior are fitted with screens. | |  |  |  |  | BMBL Section IV BSL-1 D.6;  *NIH Guidelines* Appendix G-II-A-4-e;  *NIH Guidelines* Appendix G-II-B-4-e |  |
| Illumination is adequate for all activities and avoids reflections and glare that could impede vision. | |  |  |  |  | BMBL Section IV BSL-1 D.7 |  |
| Ventilation is provided in accordance with the Guide. Ventilation system design considers the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process. | |  |  |  |  | BMBL Section V ABSL-1 D.5 |  |
| Cages are washed manually or preferably in a mechanical cage washer. The mechanical cage washers have a final rinse temperature of at least 180°F. If manual cage washing is utilized, ensure that appropriate disinfectants are selected. | |  |  |  |  | BMBL Section V ABSL-1 D.6 |  |
| H. BSL-2 AND ABSL-2 LABORATORIES (ONLY COMPLETE IF APPLICABLE) | | | | | | | |
| **BSL/ABSL 2 labs must implement all of the requirements listed above for BSL/ABSL 1 labs, plus the additional requirements listed below.** | | | | | | | |
| Standard Microbiological Practices | | | | | | | |
| 1. All BSL-1/ABSL-1 standard microbiological practices are followed. |  | |  |  |  | BMBL Section IV BSL-1 A.1-17;  BMBL Section V ABSL-1 A.1-20 |  |
| Special Practices | | | | | | | |
| 1. Access to the laboratory is controlled when work in being conducted. |  | |  |  |  | BMBL Section IV BSL-2 B.1;  *NIH Guidelines* Appendix G-II-B-1-a & B-2-b |  |
| 1. The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-2 containment. |  | |  |  |  | BMBL Section IV BSL-2 B.2 |  |
| 1. Animal care staff are provided information on signs and symptoms of disease, receive occupational medical services including medical evaluation, surveillance, and treatment, as appropriate, and are offered available immunizations for agents handled or potentially present in the facility. |  | |  |  |  | BMBL Section V ABSL-2 B.1 |  |
| 1. Laboratory personnel are provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory. *NOTE:* Medical surveillance program is based on risk assessment. |  | |  |  |  | BMBL Section IV BSL-2 B.3 |  |
| 1. Properly maintained BSCs or other physical containment devices are used, when possible, whenever: |  | |  |  |  | BMBL Section IV BSL-2 B.4;  BMBL Section V ABSL-2 B.2;  *NIH Guidelines* Appendix G-II-B-3-a(1) |  |
| 1. Procedures with a potential for creating infectious aerosols or splashes are conducted. These include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs. |  | |  |  |  |  |
| 1. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotors or centrifuge safety cups with loading and unloading of the rotors and centrifuge safety cups in the BSC or another containment device. |  | |  |  |  |  |
| 1. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of appropriate personal protective equipment and administrative controls are used, based on a risk assessment. |  | |  |  |  |  |
| 1. Equipment, cages, and racks are handled in a manner that minimizes contamination of other areas. Cages are decontaminated prior to washing. |  | |  |  |  |  |
| 1. Laboratory equipment is decontaminated routinely; after spills, splashes, or other potential contamination; and before repair, maintenance, or removal from the laboratory. |  | |  |  |  | 29 CFR §1910.1030(d)(2)(xiv);  29 CFR §1910.1030(d)(4)(ii);  BMBL Section IV BSL-2 B.5 |  |
| 1. A method for decontaminating all laboratory waste is available (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method). |  | |  |  |  | BMBL Section IV BSL-2 B.6 |  |
| 1. The animal facility develops and implements an appropriate decontamination program in compliance with applicable institutional, local, and state requirements. |  | |  |  |  | BMBL Section V ABSL-2 B.3 |  |
| 1. Equipment is decontaminated before repair, maintenance, or removal from the animal facility. A method for decontaminating routine husbandry equipment and sensitive electronic or medical equipment is identified and implemented. |  | |  |  |  |  |
| 1. Decontamination of an entire animal room is considered when there has been gross contamination of the space, significant changes in usage, and for major renovations or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the animal room is based on the risk assessment. |  | |  |  |  |  |
| 1. Decontamination processes are verified on a routine basis. |  | |  |  |  |  |
| 1. Incidents that may result in exposure to infectious materials are immediately evaluated per institutional policies. All such incidents are reported to the laboratory or animal facility supervisor and any other personnel designated by the institution. Appropriate records are maintained. |  | |  |  |  | BMBL Section IV BSL-2 B.7;  BMBL Section V ABSL-2 B.4;  *NIH Guidelines* Appendix G-II-B-2-k |  |
| Safety Equipment (Primary Barriers and Personal Protective Equipment) | | | | | | | |
| 1. Protective laboratory coats, gowns, or uniforms designated for laboratory use are worn while working with hazardous materials and removed before leaving for non-laboratory areas (e.g., cafeteria, library, and administrative offices). Protective clothing is disposed of appropriately or deposited for laundering by the institution. Laboratory clothing is not taken home. |  | |  |  |  | BMBL Section IV BSL-2 C.1 |  |
| 1. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield or other splatter guard) are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials when the animal or microorganisms is handled outside the BSC or another containment device. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use. |  | |  |  |  | BMBL Section IV BSL-2 C.2;  BMBL Section V ABSL-2 C.3 |  |
| 1. The risk assessment considers whether respiratory protection is needed for the work with hazardous materials. If needed, relevant staff are enrolled in a properly constituted respiratory protection program. |  | |  |  |  | 29 CFR §1910.132;  29 CFR §1910.1030 (d)(3);  BMBL Section IV BSL-2 C.3;  BMBL Section V ABSL-2 C.6 |  |
| 1. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens. |  | |  |  |  | BMBL Section IV BSL-2 C.4 |  |
| 1. Properly maintained BSCs and other physical containment devices or equipment are used whenever conducting procedures with a potential for creating aerosols, splashes, or other potential exposures to hazardous materials. These include the necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, and intranasal inoculation of animals. A risk assessment dictates the type of other physical containment devices used when BSCs may not be suitable. |  | |  |  |  | BMBL Section V ABSL-2 C.1 |  |
| 1. When indicated by risk assessment, animals are housed in primary biosafety containment equipment appropriate for the animal species, such as solid wall and bottom cages covered with micro-isolator lids or other equivalent primary containment systems for larger animals. |  | |  |  |  |  |
| 1. If used, actively ventilated caging systems are designed to contain microorganisms. Exhaust plenums for these systems are sealed. Safety mechanisms are in place to prevent the cage and exhaust plenums from becoming positively pressurized if the exhaust fan fails. The system is also alarmed to indicate operational malfunctions. Exhaust HEPA filters and filter housings are certified annually. |  | |  |  |  |  |
| 1. Protective clothing, such as gowns, uniforms, scrubs, or laboratory coats, and other PPE are worn while in the areas where infectious materials and/or animals are housed or manipulated. |  | |  |  |  | BMBL Section V ABSL-2 C.2 |  |
| 1. Scrubs and uniforms are removed before leaving the animal facility. |  | |  |  |  |  |
| 1. Reusable clothing is appropriately contained and decontaminated before being laundered. Animal facility and protective clothing is never taken home. |  | |  |  |  |  |
| 1. Disposable PPE and other contaminated waste are appropriately contained and decontaminated prior to disposal. |  | |  |  |  |  |
| Facilities (Secondary Barriers) | | | | | | | |
| 1. Laboratory doors are self-closing and have locks in accordance with the institutional policies. |  | |  |  |  | 29 CFR §1910.1030(e)(2)(ii)(D) & (g)(1)(ii);  BMBL Section IV BSL-2 D.1 |  |
| 1. Laboratories have a sink for hand washing. It should be located near the exit door. |  | |  |  |  | BMBL Section IV BSL-2 D.2;  *NIH Guidelines* Appendix G-II-B-4-d |  |
| 1. ABSL-2 facilities should be separated from the general traffic patterns of the building and restricted, as appropriate. Consider placing animal areas away from exterior walls of buildings to minimize the impact from the outside environment temperatures |  | |  |  |  | BMBL Section V ABSL-2 D.1;  NFPA 101 §7.2.1.8.1 |  |
| 1. External facility doors are self-closing and self-locking. |  | |  |  |  |  |
| 1. Access to the animal facility is restricted. |  | |  |  |  |  |
| 1. Doors to areas where infectious materials and/or animals are housed open inward and are self-closing, kept closed when experimental animals are present, and never to be propped open. |  | |  |  |  |  |
| 1. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically. |  | |  |  |  |  |
| 1. A handwashing sink is located at the exit of the areas where infectious materials and/or animals are housed or manipulated. Additional sinks for handwashing are located in other appropriate locations within the facility. If the animal facility has segregated areas where infectious materials and/or animals are housed or manipulated, a sink is also available for handwashing at the exit from each segregated area. |  | |  |  |  | BMBL Section IV ABSL-2 D.2 |  |
| 1. Emergency eyewash and shower are readily available, easily accessible, and appropriately maintained. |  | |  |  |  |  |
| 1. Sink traps are filled with water and/or appropriate disinfectant to prevent the migration of vermin and gases. |  | |  |  |  |  |
| 1. If open floor drains are provided, the traps are filled with water and/or appropriate disinfectant or sealed to prevent the migration of vermin and gases. |  | |  |  |  |  |
| 1. The laboratory is designed so that it can be easily cleaned. |  | |  |  |  | BMBL Section IV BSL-2 D.4 |  |
| 1. Carpets and rugs in laboratories are not appropriate. |  | |  |  |  |  |
| 1. Spaces between benches, cabinets, and equipment are accessible for cleaning. |  | |  |  |  |  |
| 1. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (e.g., walls, floors, and ceilings) are water-resistant. |  | |  |  |  | BMBL Section V ABSL-2 D.3 |  |
| * 1. Floors are slip-resistant, impervious to liquids, and resistant to chemicals. Floors with drains are sloped toward drains to facilitate cleaning. |  | |  |  |  |  |
| * 1. Penetrations in floors, walls, and ceiling surfaces are sealed, including openings around ducts, doors, doorframes, outlets, and switch plates to facilitate pest control and proper cleaning. |  | |  |  |  |  |
| * 1. Internal facility fixtures, such as light features, air ducts, and utility pipes, are designed and installed to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites. |  | |  |  |  |  |
| * 1. External windows are not recommended; if present, they are sealed and resistant to breakage. |  | |  |  |  |  |
| * 1. llumination is adequate for all activities and avoids reflections and glare that could impede vision. |  | |  |  |  |  |
| 1. Vacuum lines in use are protected with liquid disinfectant traps and in-line HEPA filters or their equivalent. Filters are replaced, as needed, or are on a replacement schedule determined by a risk assessment.   *NOTE:* See Appendix A, Figure 11(BMBL). |  | |  |  |  | BMBL Section IV BSL-2 D.8;  BMBL Section IV BSL-3 D.8;  BMBL Section V ABSL-2 D.8;  BMBL Section V ABSL-3 D.9 |  |
| 1. There are no specific requirements for ventilation systems. However, the planning of new facilities considers mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. |  | |  |  |  | BMBL Section V BSL2 D.9 |  |
| 1. BSCs and other primary containment barrier systems are installed and operated in a manner to ensure their effectiveness. See Appendix A (BMBL). |  | |  |  |  | BMBL Section IV BSL-2 D.10;  BMBL Section V ABSL-2 D.7 |  |
| 1. BSCs are installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs are located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions. |  | |  |  |  |  |
| 1. BSCs can be connected to the laboratory exhaust system by either a canopy connection (Class IIA only) or directly exhausted to the outside through a hard connection (Class IIB, IIC, or III). Class IIA or IIC BSC exhaust can be safely recirculated back into the laboratory environment if no volatile toxic chemicals are used in the cabinet. |  | |  |  |  |  |
| 1. BSCs are certified at least annually to ensure correct performance, or as specified in Appendix A, Part 7 (BMBL). |  | |  |  |  |  |
| 1. Ventilation is provided in accordance with the *Guide*. |  | |  |  |  | BMBL Section V ABSL-2 D.5 |  |
| 1. Ventilation system design considers the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process. |  | |  |  |  |  |
| 1. The direction of airflow into the animal facility is inward; animal rooms maintain inward directional airflow compared to adjoining hallways. |  | |  |  |  |  |
| 1. A ducted exhaust air ventilation system is provided. |  | |  |  |  |  |
| 1. Exhaust air is discharged to the outside without being recirculated to other rooms. |  | |  |  |  |  |
| 1. Mechanical cage washers have a final rinse temperature of at least 180°F. The cage wash area is designed to accommodate the use of high-pressure spray systems, humidity, strong chemical disinfectants, and 180°F water temperatures during the cage/equipment cleaning process. |  | |  |  |  | BMBL Section V ABSL-2 D.6 |  |
| 1. An autoclave is present in the animal facility to facilitate decontamination of infectious materials and waste. A validated alternative process (e.g., alkaline digestion, incineration) may be used for decontamination and disposal of carcasses. |  | |  |  |  | BMBL Section V ABSL-2 D.9 |  |
| I. BSL-3 AND ABSL-3 LABORATORIES (ONLY COMPLETE IF APPLICABLE) | | | | | | | |
| BSL/ABSL 3 labs must meet all requirements for BSL/ABSL 1 and 2 labs listed above, plus the following additional requirements. | | | | | | | |
| Standard Microbiological Practices | | | | | | | |
| 1. All BSL/ABSL-1 and BSL/ABSL-2 standard microbiological practices are followed. | |  |  |  |  | BMBL Section IV BSL-1 A.1-17;  BMBL Section V ABSL-1 A.1-20 |  |
| Special Practices | | | | | | | |
| 1. All persons entering the laboratory are advised of the potential hazards and meet specific entry/exit requirements in accordance with institutional policies. Only persons whose presence in the facility or laboratory areas is required for scientific or support purposes are authorized to enter. | |  |  |  |  | BMBL Section IV BSL-3 B.1 |  |
| 1. All persons who enter operational laboratory areas are provided information on signs and symptoms of disease and receive occupational medical services including medical evaluation, surveillance, and treatment, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory. | |  |  |  |  | BMBL Section IV BSL-3 B.2;  BMBL Section V ABSL-3 B.1 |  |
| 1. The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-3 containment. | |  |  |  |  | BMBL Section IV BSL-3 B.3;  *NIH Guidelines* Appendix G-II-C-2-d |  |
| 1. A system is established for reporting and documenting near misses, laboratory accidents, exposures, unanticipated absences due to potential Laboratory-associated infection, and for the medical surveillance of potential laboratory-associated illnesses. | |  |  |  |  | BMBL Section IV BSL-3 B.4;  BMBL Section V ABSL-3 B.2 |  |
| 1. Incidents that result in exposure to infectious materials are immediately evaluated per institutional policy. All such incidents are reported to the laboratory supervisor, institutional management, and appropriate safety, compliance, and security personnel according to institutional policy. Appropriate records are maintained. | |  |  |  |  | BMBL Section IV BSL-3 B.5;  BMBL Section V ABSL-3 B.3 |  |
| 1. Only necessary equipment and supplies are recommended to be taken inside the animal facility. | |  |  |  |  | BMBL Section V ABSL-3 B.4 |  |
| 1. Biological materials that require BSL-3 containment are placed in a durable leak-proof sealed primary container and then enclosed in a non-breakable, sealed secondary container prior to removal from the laboratory/animal facility. Once removed, the primary container is opened within a BSC in BSL-3 containment unless a validated inactivation method is used. See Appendix K (BMBL). The inactivation method is documented in-house with viability testing data to support the method. | |  |  |  |  | BMBL Section IV BSL-3 B.6;  BMBL Section V ABSL-3 B.6 |  |
| 1. All procedures involving the manipulation of infectious materials are conducted within a BSC or other physical containment device, when possible. No work with open vessels is conducted on the bench. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of personal protective equipment and other administrative and/or engineering controls, such as centrifuge safety cups or sealed rotors, are used, based on a risk assessment. Loading and unloading of the rotors and centrifuge safety cups take place in the BSC or another containment device. | |  |  |  |  | BMBL Section IV BSL-3 B.7;  BMBL Section V ABSL-3 B.5 |  |
| 1. Laboratory equipment is routinely decontaminated after spills, splashes, or other potential contamination, and before repair, maintenance, or removal from the laboratory. | |  |  |  |  | BMBL Section IV BSL-3 B.8 |  |
| 1. A method for decontaminating all laboratory waste is available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, or other validated decontamination method). | |  |  |  |  | BMBL Section IV BSL-3 B.9 |  |
| 1. Develop and implement an appropriate decontamination program in compliance with applicable institutional, local, state, and federal requirements. | |  |  |  |  | BMBL Section V ABSL-3 B.7.a |  |
| Equipment is decontaminated before repair, maintenance, or removal from the areas where infectious materials and/or animals are housed or manipulated. A method for decontaminating routine husbandry equipment and sensitive electronic or medical equipment is identified and implemented. | |  |  |  |  |  |
| 1. Decontamination of the entire laboratory/animal room is considered when there has been gross contamination of the space, significant changes in laboratory usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the laboratory is based on a risk assessment. | |  |  |  |  | BMBL Section IV BSL-3 B.10;  BMBL Section V ABSL-3 B.7.b |  |
| 1. Decontamination processes are verified on a routine basis. | |  |  |  |  | BMBL Section V BSL-3 B.11;  BMBL Section V ABSL-3 B.7.c |  |
| Safety Equipment (Primary Barriers and PPE) | | | | | | | |
| 1. Laboratory workers wear protective clothing with a solid-front, such as tie-back or wrap-around gowns, scrub suits, or coveralls. Protective clothing is not worn outside of the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when contaminated. | |  |  |  |  | BMBL Section IV BSL-3 C.1 |  |
| 1. Based on work being performed, additional PPE may be required. | |  |  |  |  | BMBL Section IV BSL-3 C.2 |  |
| 1. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield or other splash guard) are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use. | |  |  |  |  |  |
| 1. Two pairs of gloves are worn when appropriate. | |  |  |  |  |  |
| 1. Respiratory protection is considered. Staff wearing respiratory protection are enrolled in a properly constituted respiratory protection program. | |  |  |  |  |  |
| 1. Shoe covers are considered. | |  |  |  |  |  |
| 1. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens. | |  |  |  |  | BMBL Section IV BSL-3 C.3 |  |
| 1. Properly maintained BSCs and other physical containment devices or equipment are used for manipulations of infectious materials and animals as determined by risk assessment. | |  |  |  |  | BMBL Section V ABSL-3 C.1 |  |
| 1. The risk of infectious aerosols from infected animals or their bedding can be reduced if animals are housed in containment caging systems, such as solid wall and bottom cages covered with micro-isolator lids, open cages placed in inward flow ventilated enclosures, HEPA filter isolators and caging systems, or other equivalent primary containment systems. | |  |  |  |  |  |
| Actively ventilated caging systems are designed to prevent the escape of microorganisms from the cage. Exhaust plenums are sealed to prevent the escape of microorganisms if the ventilation system becomes static, and the exhaust is HEPA-filtered. Safety mechanisms are in place to prevent the cage and exhaust plenums from becoming positive to the surrounding area should the exhaust fan fail. The system is alarmed to indicate operational malfunctions. | |  |  |  |  |
| 1. When animals cannot be housed in ventilated containment cages/units, certain features of the animal room act as the primary barriers. The procedures in place include how workers are protected from agents shed by the animals (e.g., PPE enhancements) as well as how the environment is protected from such agents through the use of biocontainment enhancements such as some combination of boot or PPE change or surface decontamination at the door, a personal shower at the room level, and/or other procedures. | |  |  |  |  |  |
| 1. Special consideration is given to the potential for cross-contamination when open caging is used. See Appendix D (BMBL) for additional information. | |  |  |  |  | BMBL Section V ABSL-3 C.2 |  |
| 1. Personnel within the animal facility wear protective clothing, such as uniforms or scrubs | |  |  |  |  | BMBL Section V ABSL-3 C.3 |  |
| 1. Disposable PPE such as non-woven, olefin cover-all suits, or wrap-around or solid-front gowns are worn over this clothing before entering areas where infectious materials and/or animals are housed or manipulated. Front-button, laboratory coats are unsuitable. | |  |  |  |  |  |
| 1. Reusable clothing is appropriately contained and decontaminated before being laundered. Animal facility and protective clothing is never taken home. | |  |  |  |  |  |
| 1. Disposable PPE is removed when leaving the areas where infectious materials and/or animals are housed or manipulated. Scrubs and uniforms are removed before leaving the animal facility. | |  |  |  |  |  |
| 1. Disposable PPE and other contaminated waste are appropriately contained and decontaminated prior to disposal. | |  |  |  |  |  |
| 1. All personnel entering areas where infectious materials and/or animals are housed or manipulated wear appropriate head covering, eye, face, and respiratory protection. To prevent cross-contamination, boots, shoe covers, or other protective footwear are used where indicated and disposed of or decontaminated after use. | |  |  |  |  | BMBL Section V ABSL-3 C.4 |  |
| 1. Head covering, eye protection, and face protection are disposed of with other contaminated animal facility waste or decontaminated after use. | |  |  |  |  | BMBL Section V ABSL-3 C.5 |  |
| 1. Procedures may require wearing two pairs of gloves (i.e., double glove). Change outer gloves when contaminated, glove integrity is compromised, or when otherwise necessary. | |  |  |  |  | BMBL Section V ABSL-3 C.6 |  |
| 1. Additional PPE is considered for persons working with large animals. | |  |  |  |  | BMBL Section V ABSL-3 C.7 |  |
| Facilities (Secondary Barriers) | | | | | | | |
| 1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building. | |  |  |  |  | BMBL Section IV BSL-3 D.1;  *NIH Guidelines* Appendix G-II-C-4-a;  *NIH Guidelines* Appendix G-II-C-4-g |  |
| Laboratory access is restricted. Laboratory doors are lockable in accordance with institutional policies. Access to the laboratory is through two consecutive self-closing doors. A clothing change room and/or an anteroom may be included in the passageway between the two self-closing doors. | |  |  |  |  |  |
| 1. ABSL-3 facilities should be separated from the general traffic patterns of the building and restricted as appropriate. Consider placing animal areas away from exterior walls of buildings to minimize the impact from the outside environment temperatures. | |  |  |  |  | BMBL Section V ABSL-3 D.1 |  |
| 1. External facility doors are self-closing and self-locking. | |  |  |  |  |  |
| 1. Access to the animal facility is restricted. | |  |  |  |  |  |
| 1. Doors to areas where infectious materials and/or animals are housed open inward, are self-closing, are kept closed when experimental animals are present, and are never propped open. | |  |  |  |  |  |
| 1. Entry into the containment area is via a double-door entry, which constitutes an anteroom/airlock and a change room. Exit showers may be considered based on risk assessment. An additional double-door anteroom or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility. | |  |  |  |  |  |
| 1. Laboratories have a sink for handwashing. The sink is hands-free or automatically operated and should be located near the exit door. If a laboratory suite is segregated into different zones, a sink is also available for handwashing in each zone. | |  |  |  |  | BMBL Section IV BSL-3 D.2;  *NIH Guidelines* Appendix G-II-C-4-e |  |
| 1. A handwashing sink is located at the exit of the areas where infectious materials and/or animals are housed or manipulated. Additional sinks for handwashing are located in other appropriate locations within the facility. If the animal facility has segregated areas where infectious materials and/or animals are housed or manipulated, a handwashing sink is also available near the exit from each segregated area. | |  |  |  |  | BMBL Section V ABSL-3 D.2;  *NIH Guidelines* Appendix G-II-C-4-e |  |
| 1. The sink is hands-free or automatically operated. | |  |  |  |  |  |
| 1. Emergency eyewash and shower are readily available, easily accessible, and appropriately maintained. | |  |  |  |  |  |
| 1. Sink traps are filled with water and/or appropriate disinfectant or sealed to prevent the migration of vermin and gases. | |  |  |  |  |  |
| 1. Floor drains are maintained and filled with water and/or appropriate disinfectant or sealed to prevent the migration of vermin and gases. | |  |  |  |  |  |
| 1. The laboratory is designed, constructed, and maintained to facilitate cleaning, decontamination, and housekeeping. | |  |  |  |  | BMBL Section IV BSL-3 D.4 |  |
| 1. Carpets and rugs are not permitted. | |  |  |  |  |  |
| 1. Spaces between benches, cabinets, and equipment are accessible for cleaning. | |  |  |  |  |  |
| 1. Seams, floors, walls, and ceiling surfaces are sealed. Spaces around doors and ventilation openings are capable of being sealed to facilitate space decontamination. | |  |  |  |  |  |
| 1. Floors are slip-resistant, impervious to liquids, and resistant to chemicals. Flooring is seamless, sealed, or poured with integral cove bases. | |  |  |  |  |  |
| 1. Walls and ceilings are constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated. | |  |  |  |  |  |
| 1. The animal facility is designed, constructed, and maintained to facilitate cleaning, decontamination, and housekeeping. The interior surfaces (e.g., walls, floors, and ceilings) are water-resistant. | |  |  |  |  | BMBL Section V ABSL-3 D.3 |  |
| 1. Floors are slip-resistant, impervious to liquids, and resistant to chemicals. Flooring is seamless, sealed, or poured with integral cove bases. Floors slope to drain, if present. | |  |  |  |  |  |
| 1. Penetrations in floors, walls, and ceiling surfaces are sealed, including openings around ducts, outlets, switch plates, and doorframes, to facilitate pest control, proper cleaning, and decontamination. Walls, floors, and ceilings form a sanitizable and sealed surface. | |  |  |  |  |  |
| 1. Internal facility fixtures, such as light features, air ducts, and utility pipes, are designed and installed to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites. | |  |  |  |  |  |
| 1. External windows are not recommended; if present, they are sealed and resistant to breakage. | |  |  |  |  |  |
| 1. Illumination is adequate for all activities and avoids reflections and glare that could impede vision. | |  |  |  |  |  |
| 1. Furniture is minimized and can support anticipated loads and uses. | |  |  |  |  | BMBL Section V ABSL-3 D.4 |  |
| 1. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. | |  |  |  |  |  |
| 1. Chairs used in animal areas are covered with a non-porous material that can be easily cleaned and decontaminated with an appropriate disinfectant and sealed to prevent harboring of insects/vermin. | |  |  |  |  |  |
| 1. Equipment and furnishings are carefully evaluated to minimize exposure of personnel to pinch points and sharp edges and corners. | |  |  |  |  |  |
| 1. All windows in the laboratory are sealed. | |  |  |  |  | BMBL Section IV BSL-3 D.6;  *NIH Guidelines* Appendix G-II-C-4-f |  |
| 1. A ducted mechanical air ventilation system is required. This system provides sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas. The laboratory is designed such that under failure conditions the airflow will not be reversed at the containment barrier. | |  |  |  |  | BMBL Section IV BSL-3 D.9;  *NIH Guidelines* Appendix G-II-C-4-I;  *NIH Guidelines* Appendix G-II-C-2-o |  |
| 1. A visual monitoring device that confirms directional airflow is provided at the laboratory entry. Audible alarms to notify personnel of airflow disruption are considered. | |  |  |  |  |  |
| 1. The laboratory exhaust air is not re-circulated to any other area in the building. | |  |  |  |  |  |
| 1. The laboratory exhaust air is dispersed away from occupied areas and from building air intake locations or the exhaust air is HEPA filtered. | |  |  |  |  |  |
| 1. Ventilation is provided in accordance with the *Guide.* | |  |  |  |  | BMBL Section V ABSL-3 D.5 |  |
| 1. Ventilation system design considers the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process. | |  |  |  |  |  |
| 1. The direction of airflow into the animal facility is inward; animal rooms maintain inward directional airflow compared to adjoining hallways. A visual monitoring device, which confirms directional airflow, is provided at the animal room entrance. | |  |  |  |  |  |
| 1. A ducted exhaust air ventilation system is provided. Exhaust air is discharged to the outside without being recirculated to other rooms. This system creates directional airflow, which draws air into the animal room from “clean” areas and toward “contaminated” areas. | |  |  |  |  |  |
| 1. The exhaust air is dispersed away from occupied areas and from building air intake locations or the exhaust air is HEPA-filtered. | |  |  |  |  |  |
| 1. The ABSL-3 animal facility is designed such that under failure conditions the airflow will not be reversed at the containment barrier. Alarms are considered to notify personnel of ventilation and HVAC system failure. | |  |  |  |  |  |
| 1. Cages are decontaminated prior to removal from the containment barrier and prior to washing in a mechanical cage washer. The cage wash area is designed to accommodate the use of high-pressure spray systems, humidity, strong chemical disinfectants, and 180°F water temperatures during the cage/equipment cleaning process. | |  |  |  |  | BMBL Section V ABSL-3 D.6 |  |
| 1. BSCs and other primary containment barrier systems are installed and operated in a manner to ensure their effectiveness. See Appendix A (BMBL). | |  |  |  |  | BMBL Section IV BSL-3 D.10;  BMBL Section V ABSL-3 D.7 |  |
| 1. BSCs are installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs are located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions. | |  |  |  |  |  |
| 1. BSCs can be connected to the laboratory exhaust system by either a canopy connection (Class IIA only) or directly exhausted to the outside through a hard connection (Class IIB, IIC, or III). Class IIA or IIC BSC exhaust can be safely recirculated back into the laboratory environment if no volatile toxic chemicals are used in the cabinet. | |  |  |  |  |  |
| 1. BSCs are certified at least annually to ensure correct performance, or as specified in Appendix A, Part 7 (BMBL). | |  |  |  |  |  |
| 1. Class III BSCs are provided supply air in such a manner that prevents positive pressurization of the cabinet or the room. | |  |  |  |  |  |
| 1. An autoclave is available within the containment barrier. The autoclave is utilized to decontaminate infectious materials and waste before moving these materials to the other areas of the facility. If not within the containment barrier, special practices are developed for the transport of infectious materials to designated alternate locations for decontamination. A validated alternative process (e.g., alkaline digestion, incineration) may be used for decontamination and disposal of carcasses. | |  |  |  |  | BMBL Section IV ABSL-3 D.10 |  |
| 1. Equipment that may produce infectious aerosols is used within primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters are tested annually and replaced as needed. | |  |  |  |  | BMBL Section IV BSL-3 D.11;  BMBL Section V ABSL-3 D.8 |  |
| 1. All vacuum lines are protected with HEPA filters, or their equivalent, or are capped. Vacuum lines in use are protected with liquid disinfectant traps and in-line HEPA filters or their equivalent. Filters are replaced, as needed, or are on a replacement schedule determined by a risk assessment. The placement of an additional HEPA filter immediately prior to a central vacuum pump is considered. | |  |  |  |  | BMBL Section V ABSL-3 D.9 |  |
| 1. Facility is constructed to allow decontamination of the entire laboratory when there has been gross contamination of the space, significant changes in usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the laboratory is based on the risk assessment.   Facility design consideration is given to means of decontaminating large pieces of equipment before removal from the laboratory. | |  |  |  |  | BMBL Section IV BSL-3 D.12 |  |
| 1. Enhanced environmental and personal protection may be necessary based on risk assessment and applicable local, state, or federal regulations. These laboratory enhancements may include one or more of the following: an anteroom for clean storage of equipment and supplies with dress-in, shower-out capabilities; gas-tight dampers to facilitate laboratory/animal room isolation; final HEPA filtration of the laboratory/animal room exhaust air; laboratory/animal room effluent decontamination; containment of other piped services; or advanced access control devices, such as biometrics. | |  |  |  |  | BMBL Section IV BSL-3 D.13;  BMBL Section V ABSL-3 D.12 |  |
| 1. When present, HEPA filter housings have gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out (with appropriate decontamination procedures) capability. All HEPA filters are located as near as practicable to the laboratory to minimize the length of potentially contaminated ductwork. The HEPA filter housings allow for leak testing of each filter and assembly. The filters and housings are certified at least annually. | |  |  |  |  | BMBL Section IV BSL-3 D.14 |  |
| 1. The BSL-3/ABSL-3 facility design, operational parameters, and procedures are verified and documented prior to operation. Facilities are tested annually or after significant modification to ensure operational parameters are met. Verification criteria are modified as necessary by operational experience. | |  |  |  |  | BMBL Section IV BSL-3 D.15;  BMBL Section V ABSL-3 D.11 |  |
| 1. Appropriate communication systems are provided between the laboratory and the outside (e.g., voice, fax, and computer). Provisions for emergency communication and emergency access or egress are developed and implemented. | |  |  |  |  | BMBL Section IV BSL-3 D.16 |  |

# APPENDIX A: ACRONYMS

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| --- | --- |
| ABSL | Animal Biosafety Level |
| ACOS/R&D | Associate Chief of Staff – Research and Development |
| APHIS | Animal and Plant Health Inspection Service (USDA) |
| AWE | Annual Workplace Evaluation |
| BBP | Bloodborne Pathogens |
| BSC | Biological Safety Cabinet |
| BSL | Biosafety Level |
| BSO | Biological Safety Officer |
| CDC | Centers for Disease Control and Prevention (DHHS) |
| CFR | Code of Federal Regulations |
| CHO | Chemical Hygiene Officer |
| CRADO | Chief of Research and Development Officer |
| DHHS | U.S. Department of Health and Human Services |
| DOT | U.S. Department of Transportation |
| EPA | U.S. Environmental Protection Agency |
| FBI | Federal Bureau of Investigation |
| GFI | Ground fault interrupter |
| HEPA | High Efficiency Particulate Air |
| HVAC | Heating, Ventilation, and Air-Conditioning |
| IACUC | Institutional Animal Care and Use Committee |
| IATA | International Air Transport Association |
| IBC | Institutional Biosafety Committee |
| IO | Institutional Official |
| IPA | Intergovernmental Personnel Act |
| L | Liter |
| MOU | Memorandum of Understanding |
| NEC | National Electrical Code |
| NFPA | National Fire Prevention Association |
| NHPP | Nuclear Health Physics Program |
| NIH | National Institutes of Health (DHHS) |
| NIH-OSP | National Institutes of Health Office of Science Policy |
| NRC | U.S. Nuclear Regulatory Commission |
| OIG | Office of Inspector General |
| OPIM | Other Potentially Infectious Materials |
| ORD | Office of Research and Development |
| ORO | Office of Research Oversight |
| OSH | Occupational Safety and Health |
| OSHA | Occupational Safety and Health Administration |
| PI | Principal Investigator |
| PPE | Personal Protective Equipment |
| R&D | Research and Development |
| rDNA | Recombinant DNA (deoxyribonucleic acid) |
| RPSS | Research Protocol Safety Survey |
| RSSP | Research Safety and Security Program |
| SAFE | Safety Automated Facility Evaluation |
| SDS | Safety Data Sheets |
| SOPs | Standard Operating Procedures |
| SRS | Subcommittee on Research Safety |
| USDA | U.S. Department of Agriculture |
| VA | U.S. Department of Veterans Affairs |
| VHA | Veterans Health Administration |
| VISN | Veterans Integrated Service Network |
| WOC | Without Compensation |

1. *NOTE:* Checklist will expire 3 years after the initial publication date. [↑](#footnote-ref-1)
2. ***VHA Directive 1200.08(1) §4.*** “It is VHA policy that each VA medical facility conducting research must safeguard the safety of personnel, the public and the environment, and the security of research laboratories and other applicable research space in compliance with all applicable VA policies, Federal statutes and regulations from OSHA, EPA, NRC, NIH and CDC guidelines, and State and local requirements.” [↑](#footnote-ref-2)
3. Applies to plants and plant products. [↑](#footnote-ref-3)
4. Access to NFPA Codes are available through free VA/CEOSH subscriptions: <https://vaww.hefp.va.gov/resources/standards-codes-library> (last accessed February 26, 2025) [↑](#footnote-ref-4)
5. Accessible at: <https://osp.od.nih.gov/biotechnology/faqs-on-ibc-administration/> (last accessed May 20, 2025) [↑](#footnote-ref-5)
6. Accessible at: <https://osp.od.nih.gov/biotechnology/faqs-on-externally-administered-ibcs/> (last accessed May20, 2025) [↑](#footnote-ref-6)
7. Accessible at: <https://www.osha.gov/sites/default/files/publications/OSHAquickfacts-lab-safety-cryogens-dryice.pdf> (last accessed February 20, 2025) [↑](#footnote-ref-7)