NIH Policy Manual

3037 - NIH Biological Surety Program

Issuing Office: OD/OM/ORS/SR/DOHS **Phone:** (301) 496-2960

Release Date: 7/31/2015 ? **Technical Revision Date:** 12/12/2018 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** This chapter establishes the National Institutes of Health (NIH) policy governing the applicability of the NIH Biological Surety Program.
2. **Filing Instructions:**

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A. Purpose

This chapter establishes the National Institutes of Health (NIH) policy governing the applicability of the NIH Biological Surety Program.

B. Background

The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. NIH conducts basic and translational research to develop therapeutics, diagnostic tests, vaccines, and civilian biodefense countermeasures in an effort to mitigate the risks of current and emerging pathogens facing the public.

The safe management and operation of laboratories, animal facilities, and related program support spaces is crucial to the NIH mission. Since the 2001 anthrax attacks, the NIH has greatly accelerated its biodefense and emerging diseases research program, launching a variety of new initiatives to investigate pathogens that pose high risk to the health of individuals and the community. The accidental or intentional release of biological materials

held in high-containment or maximum-containment spaces could result in serious adverse consequences to the individual, public, and/or environment.

The NIH Biological Surety Program (BSP) is established to ensure that work pertaining to high risk infectious disease research is performed in the safest and most responsible manner possible by a trained, responsible, and reliable workforce.

The BSP is managed by the Biorisk Management Group, Division of Occupational Health and Safety (DOHS), Office of Scientific Resources (SR), Office of Research Services (ORS), across the NIH entities dealing with, or conducting high risk infectious disease research (e.g., the NIH Bethesda Campus, Bethesda, Maryland; Rocky Mountain Laboratories (RML), Hamilton, Montana; and the Integrated Research Facility (IRF), Frederick, Maryland). All questions related to requirements of the program can be directed to the DOHS at 301-496-2960.

C. Policy

1. The goals of the Biological Surety Program are to:

    a. Ensure a trained, responsible and reliable workforce.
    b. Foster rigorous procedures to protect employee health and promote a safe work environment.
    c. Enhance the safety culture by promoting worker cohesiveness, resilience, trust, respect and reliability.
    d. Preserve the integrity of the research being conducted.
    e. Protect valuable research materials and products.
    f. Prevent loss, theft, diversion or misuse of biological materials handled in Tier 1 Select Agent Laboratories; and Biosafety Level 3 (BSL-3), Animal Biosafety Level 3 (ABSL-3), Biosafety Level 4 (BSL-4), Animal Biosafety Level 4 (ABSL-4) laboratories.

2. The Biological Surety Program applies to all intramural NIH personnel, Federal and non-federal, and visitors assigned to work in BSP spaces. BSP spaces are defined as unique areas designed to accommodate the safe and secure manipulation of Tier I Select Agents and Toxins or other designated materials required for vaccine development and basic research on emerging diseases that may pose a potential threat to human, animal and plant life. In addition, all NIH ABSL-4, BSL-4, ABSL-3 and BSL-3 facilities, including areas of critical infrastructure, and information systems, that support these laboratories are designated BSP spaces under the NIH BSP.
3. No person shall be granted unescorted access into a BSP space without prior certification from the NIH Certifying Official.

    Note: Program requirements for certification are described in Section G. Procedures.
4. No person shall be granted access to a select agent or toxin without the specific and prior approval from the Secretary of Health and Human Services (HHS), the NIH Responsible Official, and the NIH Certifying Official.

5. At minimum, annual medical qualification assessments are required for BSP participants.
6. BSP participants are required to undergo, at minimum, annual behavioral health screenings, including qualification assessment meetings with the Behavioral Health Screening Official or designee.
7. All BSP participants are subject to: 1) a deemed export review per 15 CFR 734.8(c) , which will ensure technology is not released to foreign nationals without appropriate evaluation, 2) an annual Collective Foreign Threats Screening, and 3) an appropriate background investigation based on job duties.
8. Participants and visitors must receive documented, site-specific training on laboratory risks, applicable personal protective equipment, and entry and exit requirements before entering BSP spaces. Training requirements are specific to job duties. All questions related to requirements of the program should be directed to the DOHS at 301-496-2960.
9. Participants must receive annual documented training in biosafety, biosecurity, biocontainment, and incident response.
10. Continued participation in the program is contingent upon compliance with program requirements and annual recertification (See Section G. Procedures).

D. References

1. 42 CFR Part 73 – Select Agents and Toxins
2. 9 CFR Part 121 – Possession, Use, and Transfer of Select Agents and Toxins
3. 7 CFR Part 331 – Possession, Use, and Transfer of Select Agents and Toxins
4. 15 CFR Part 734 – Scope of the Export Administration Regulations
5. NIH Exposure Control Plan for Non-Hospital Personnel
6. NIH Manual Chapter 1340 – NIH Occupational Safety and Health Management
7. NIH Manual Chapter 1743 – Keeping and Destroying Records
8. NIH Manual Chapter 2300-339-2 - Medical Qualifications Determinations
9. NIH Manual Chapter 3035 –Working Safely with Potentially Hazardous Biological Materials
10. Biosafety in Microbiological and Biomedical Laboratories (current edition)
11. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act)
12. NIH Delegations of Authority, Program: General, No. 46 – Designated Agency Safety and Health Official (DASHO)

E. Definitions

1. **ANACI:** Access National Agency Check and Inquiry. This is a security background investigation that is completed by the Office of Personnel Management.
2. **Animal Biosafety Level 3:** Animal Biosafety Level 3 (ABSL-3) involves practices suitable for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission, and agents causing serious or potentially lethal disease. ABSL-3 laboratories have special engineering and design

features. See the *Biosafety in Microbiological and Biomedical Laboratories (current edition)* for additional ABSL-3 standard practices, procedures, containment equipment and guidelines.

3. **Animal Biosafety Level 4:** Animal Biosafety Level 4 (ABSL-4) is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments or a related agent with unknown risk of transmission. See the *Biosafety in Microbiological and Biomedical Laboratories (current edition)* for additional ABSL-4 standard practices, procedures, containment equipment and guidelines.
4. **Behavioral Health Screen:** A series of behavioral health and management instruments administered by the Behavioral Health Screening Official or designee to assess an individual's personal resilience with regard to working with high consequence pathogens in BSL-3 and 4 laboratories and likelihood of compliance with safety and security procedures, rules and regulations.
5. **Biosafety Level 3:** Biosafety Level 3 (BSL-3) is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. See the *Biosafety in Microbiological and Biomedical Laboratories (current edition)* for additional BSL-3 standard practices, procedures, containment equipment and guidelines.
6. **Biosafety Level 4:** Biosafety Level 4 (BSL-4) is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments or a related agent with unknown risk of transmission. See the *Biosafety in Microbiological and Biomedical Laboratories (current edition)* for additional BSL-4 standard practices, procedures, containment equipment and guidelines.
7. **Biological Surety Program (BSP)** (DOHS/SR/ORS/OM/OD)**:** Management framework that incorporates elements of personnel reliability, biosafety, biosecurity, and quality assurance to reduce the risk of loss, theft, diversion, and misuse of biological materials.
8. **Biosafety:** Discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.
9. **Biosecurity:** Discipline identifying and mitigating threats posed to human and animal health, the environment, and the economy through deliberate misuse or release of infectious microorganisms or other hazardous biological materials
10. **Collective Foreign Threats Assessment:** Screening process conducted using national and international sources to identify restricted individuals or entities.
11. **Critical Infrastructure:** Equipment, systems, or technology that directly affect the functionality or security of high-containment and maximum-containment spaces (e.g., HVAC systems, electrical systems, effluent decontamination systems, access control systems, etc.).
12. **Deemed Export Review:** The deemed export review is the tool used by the NIH to determine "fundamental research", per 15 CFR 734.8(c), on behalf of NIH BSP

participants. The deemed export review considers whether BSP participants are subject to the deemed export rule, whether they engage in fundamental research, and whether they ultimately require a Department of Commerce (DOC) deemed export license for the release of technology.

13. **High-Containment:** BSL-3 or ABSL-3 laboratories.
14. **Maximum-Containment:** BSL-4 or ABSL-4 laboratories.
15. **Personnel:**NIH federal government employees, contractors, and visitors.
16. **Personnel Reliability:** Program policies and procedures established to ensure a reliable, trained, resilient, and trustworthy workforce.
17. **Quality Assurance:** The systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.
18. **Select Agent or Toxin:** Any biological material listed in 42 CFR 73, 9 CFR 121, or 7 CFR 331.
19. **Tier 1:** A subset of select agents and toxins that present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety.
20. **Tier 1 Select Agent Laboratory:** A laboratory registered for handling, storage, transfer or use of Tier 1 Select Agents and Toxins through the Federal Select Agent Program and in compliance with 42 CFR 73, 9 CFR 121, or 7 CFR 331.
21. **USA PATRIOT Act:** An Act of Congress that was signed into law on October 26, 2001. Its title is a ten-letter acronym that stands for "Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism" Act.
22. **Visitor:** Any person entering a BSP space who has not been granted unescorted access to that space by the NIH Certifying Official.

F. Responsibilities

1. **Director, NIH:**
   Through DOHS and the Deputy Director for Intramural Research (DDIR), provides executive leadership in the development and implementation of biological safety policies, standards and procedures applicable to the NIH. The DOHS provides staff necessary to effectively administer a comprehensive occupational safety and health program.
2. **Deputy Director for Intramural Research (DDIR):**
   The DDIR is the principal liaison with the NIH intramural research community regarding safety and health matters. The DDIR receives safety policies approved by ORS and communicates them to the IC Scientific Directors. Further, the DDIR raises safety concerns to ORS as they are brought to the DDIR's attention from the intramural research community.
3. **Designated Agency Safety and Health Official (DASHO):**
   The Institutional Official responsible for management and administration of the NIH occupational safety and health program. This authority is delegated by the Director, NIH.

4. **Institute and Center (IC) Scientific Directors:**
   Scientific Directors are responsible for ensuring full compliance with this policy within the IC and promoting safety in all work areas.
5. **NIH Biological Safety Officer (BSO):**
   The NIH BSO performs the duties of the Biological Safety Officer as specified in the *NIH Guidelines* and specified in the Institutional Biosafety Committee (IBC) Charter and Committee delegations. The BSO serves as the executive secretary for the NIH IBC.
6. **Office of Research Services (ORS):**
   The Office of Research Services (ORS), through the Division of Occupational Health and Safety (DOHS) has overall responsibility for biological safety and biosecurity at NIH. The promotion of safe working practices is the responsibility of each member of the NIH community. ORS is the primary operational component for developing and implementing NIH-wide biorisk management programs through the DOHS. This is accomplished through provision of guidance, consultation, training, and relevant Occupational Medical Service programs.
7. **Director, Office of Research Services:**
   The ORS Director is the NIH DASHO and appoints the NIH Certifying Official.
8. **NIH Certifying Official:**
   Appointed by the Director, ORS and is responsible for granting final approval for personnel participation in the BSP.
9. **NIH Select Agent Program (NIH SAP) DOHS/SR/ORS/OM/OD:**
   Responsible for managing the possession, use, and transfer of select agents or toxins as required by 42 CFR 73, 9 CFR 121, or 7 CFR 331.
10. **NIH Responsible Official (RO) and Alternate Responsible Officials (AROs):**
    The individuals responsible for managing the daily operation of the NIH Select Agent Program in compliance with 42 CFR 73, 9 CFR 121, or 7 CFR 331.
11. **Principal Investigators (PI):**
    Must ensure their employees are properly trained and guided in the use of safe practices within the laboratory.
12. **Supervisors:**
    Responsible for and must promote the safe conduct of work in laboratories under their jurisdiction. Further, Supervisors:

    a. Must notify the NIH BSP of the need for personnel enrollment in the Program.
    b. Ensure that personnel correctly use necessary and prescribed personnel protective equipment while conducting work in laboratories or while in the proximity of laboratory operations utilizing hazardous materials.
    c. Register all work with human pathogens and work with recombinant or synthetic nucleic acid molecules that are subject to the NIH Guidelines with the NIH IBC as described in NIH Manual 3035 – Working Safely with Potentially Hazardous Biological Materials.
    d. Review work practices, comply with and enforce all applicable occupational safety and health standards, rules, regulations and orders by competent authority pertaining to the activities under their jurisdiction.

e. Ensure and verify that employees are trained in safe practices and methods of job performance and for assuring that subordinates demonstrate competency in performing assigned work pertaining to work assignments.
f. Assure that all visitors and support services personnel are appropriately informed about potential hazards present and any special precautions required to prevent exposure to these potential hazards.
g. Acquire the knowledge and information needed to recognize and control hazardous conditions in the workplace.

13. **Employees:**
Must comply with all occupational safety and health standards, rules, regulations, orders, and safe operating procedures applicable to the NIH and promptly advise the supervisor regarding all work related accidents resulting in personal injury, illness, and/or property damage. Promptly report to supervisor, appropriate occupational safety and health personnel, and/or IC Safety and Health Committee Members any unsafe or unhealthful conditions in the work environment. All participants are responsible for ensuring a safe and secure work environment by complying with safety, health and security standards, rules, regulations, orders, practices, and procedures of NIH and the NIH BSP. Employees are responsible for using prescribed personal protective equipment (PPE) during performance of work. Employees are expected to perform their work in a safe manner and ensure they do not place themselves or others at risk of injury or illness due to unsafe practices. In the performance of all job duties, all employees should ensure their work exhibits the best safety practices.
14. **Division of Personnel Security and Access Control (DPSAC):**
The office responsible for verifying personal identity, validating suitability, initiating background investigations through the Office of Personnel Management (OPM), and issuing identification (ID) badges for NIH personnel participating in the BSP.
15. **Director, Division of Personnel Security and Access Control (DPSAC/SER/ORS/OM/OD**):
Responsible for verifying personal identity, initiating background checks, and issuing ID badges for NIH personnel, including those enrolled in the BSP.
16. **Associate Director, Security and Emergency Response Services (ADSER) (SER/ORS/OM/OD):**
Responsible for planning, directing, coordinating and evaluating all functions related to NIH Emergency Preparedness and Coordination, Police, Fire/Rescue/HAZMAT, Fire Marshal, and Physical Security Management to ensure a comprehensive protection and security program.
17. **Biorisk Program Manager (DOHS/SR/ORS/OM/OD):**
Responsible for daily operations of the BSP and for coordinating biorisk management activities at the NIH campuses and for providing quality assurance review of the program.
18. **Director, Occupational Medical Service (OMS/DOHS/SR/ORS/OM/OD):**
Serves as the Certifying Medical Authority (CMA) and is responsible for providing and overseeing occupational medical services to participants in the BSP. The CMA certifies that the participant is medically qualified for participation in the NIH BSP.

19. **Behavioral Health Screening Official (DOHS/SR/ORS/OM/OD)**: Administers, or supervises the administration of the behavioral health screen, certifies the results of the behavioral health screen, conducts BSP qualification meetings, and provides recommendations concerning personnel reliability and BSP participation to the NIH Certifying Official.

G. Procedures

To participate in the BSP, the employee's supervisor must contact the NIH Certifying Official or the BSP Manager and request the employee's participation in the program. The BSP will contact the employee and provide necessary information and documentation to begin the enrollment process. The BSP will initiate required medical appointments.

The NIH BSP will conduct the Collective Foreign Threats Assessment and deemed export review. The employee must register for the appropriate biosafety training courses at www.safetytraining.nih.gov. DPSAC will initiate and complete the appropriate background investigation for each employee.

In addition to meeting the BSP requirements, those employees who require access to Tier 1 select agents or toxins have the following additional requirements: 1) Access National Agency Check and Inquiry (ANACI) Background Investigation or equivalent; 2) Security Risk Assessment; and 3) HHS Secretary's approval to access the specific select agent or toxin; and 4) NIH Select Agent Program training.

The NIH Certifying Official and ADSER may approve interim access to a specific select agent or toxin prior to completion of the appropriate background investigation if all other program requirements have been met.

The Certifying Medical Authority or designee will provide, at minimum, initial and annual medical evaluations to determine whether existing medical conditions or treatments may potentially impact the employee's ability to perform duties in designated areas safely and reliably.

The Behavioral Health Screening Official or designee will provide initial and annual behavioral health screening to all participants.

The NIH Certifying Official or designee reviews participants' completion of all program requirements initially and on an annual basis thereafter to ensure that BSP compliance is maintained. Correspondence will be provided to employees annually regarding BSP status.

All records regarding an employee's BSP status are kept in their BSP file and or medical record. The NIH Certifying Official or designee will review the file with each employee annually. Employees may view and/or request copies of the information in their file(s) at any time.

Concerns regarding a BSP participant's reliability may be confidentially reported to the NIH Certifying Official, Behavioral Health Screening Official, Certifying Medical Authority,

Biological Surety Program Manager, or in cases involving a select agent or toxin, the NIH Select Agent Responsible Official. These individuals may be reached by calling 301 496-2960. The NIH Certifying Official will determine the appropriate follow-up.

H. Records Retention and Disposal

All records pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedules" (as amended). These records must be maintained in accordance with current NIH Records Management and Federal guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information.

I. Internal Controls

The purpose of this manual chapter is to establish the NIH policy for the NIH Biological Surety Program.

1. **Issuing Office Responsible for Reviewing Internal Controls Relative to this Chapter:** Through this manual issuance, the DOHS, SR, ORS is accountable for the method used to ensure that management or internal controls have been implemented and are working.
2. **Frequency of Review (in years):** Annual review.
3. **Method of Review:** The Director, DOHS will conduct an annual review of the program including effectiveness of standard operating procedures, participant compliance and annual completion rates.
4. **Review Reports:** An annual summary detailing effectiveness of standard operating procedures, participant compliance and annual completion rates will be sent to the Director, DOHS by the NIH Biorisk Manager. Issues of concern will be brought to the attention of the Director, ORS.