



Environmental
Health and Safety

**Biosafety Manual
2023**



Revised 10/16/2023

Policy Statement

It is the policy of Northern Arizona University (NAU) to provide a safe working environment. The primary responsibility for ensuring safe conduct and conditions in the laboratory resides with the Principal Investigator.

The NAU EHS Office of Biological Safety is committed to providing up-to-date information, training, and monitoring to the research and biomedical community concerning the safe conduct of biological, recombinant, and acute toxin research and the handling of biological materials in accordance with all pertinent local, state, and federal regulations, guidelines, and laws. To that end, this manual is a resource, to be used in conjunction with the CDC and NIH guidelines, the NAU Select Agent Program, Biosafety in Microbiological and Biomedical Laboratories (BMBL), and other resource materials.

Introduction

This Biological Safety Manual is intended for use as a guidance document for researchers and clinicians who work with biological materials. It should be used in conjunction with the Laboratory-Specific Safety Manual, which provides more general safety information. These manuals describe policies and procedures that are required for the safe conduct of research at NAU. The NAU Personnel Policy on Safety 5.03 also provides guidance for safety in the workplace.

Responsibilities

In the academic research/teaching setting, the **Principal Investigator (PI)** is responsible for ensuring that all members of the laboratory are familiar with safe research practices. In the clinical laboratory setting, the faculty member who supervises the laboratory is responsible for safety practices.

Lab managers, supervisors, technicians, and others who provide supervisory roles in laboratories and clinical settings are responsible for overseeing the safety practices in laboratories and reporting any problems, accidents, and spills to the appropriate faculty member.

Employees who work with biological materials are responsible for reading this manual and carrying out the safety practices outlined here.

The NAU EHS Office of Biological Safety will provide guidance, information, review, monitoring, and training regarding biological safety programs, when appropriate. This includes implementing registration activities for certain research projects, acting as a consultant for departments regarding implementation and enforcement of biological safety programs, evaluating work practices and personal protective equipment, providing educational materials, tracking employee training, and medical monitoring.

The mission of the EHS Office of Biological Safety is to minimize injury to faculty, staff, students, and visitors and to minimize damage to university property. Inherent in this mission is the charge to provide a safe and healthy environment in which the University's activities can be pursued.

All applicable federal and state safety laws, rules and regulations are adopted by the University. In order to carry out its duties and responsibilities, the EHS Office of Biological Safety will adhere to standards or codes related to biosafety which have been adopted and promulgated by nationally recognized standards-setting organizations. The interpretation of biosafety regulations and guidelines is the responsibility of the EHS Office of Biological Safety.

In order to assure an effective Biosafety Program for NAU, it is imperative that all individuals associated with the University comply fully with the policies and procedures set forth in the manual.

Emergency Phone Numbers

General

University Police Department	911
Flagstaff Fire Department	911
Gas leak	911

Spills/Accidents

Biological or Recombinant Materials	480-248-0741
Chemicals (laboratory)	928-523-1146
Radioactive Materials	928-220-1728
Select Agents	480-248-0741
Incidents involving Air Monitoring	928-220-1728

Medical Emergency

Campus Health Services	928-523-2131
Flagstaff Medical Center Emergency	928-779-3366

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1.0 BIOLOGICAL SAFETY

1.1 Principles of Biological Safety

The term “containment” is used in describing safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents.

Both good microbiological technique and the use of appropriate safety equipment provide primary containment, the protection of personnel, and the immediate laboratory environment from exposure to infectious agents. The use of vaccines may provide an increased level of personal protection. Secondary containment, the protection of the environment external to the laboratory from exposure to infectious materials, is provided by a combination of facility design and operational practices. Therefore, the three elements of containment include *laboratory practice* and *technique*, *safety equipment*, and *facility design*. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements.

1.1.1 Laboratory Practice and Technique

The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infectious materials must be aware of potential hazards and must be trained and proficient in the practices and techniques required for handling such material safely. The director or person in charge of the laboratory is responsible for providing or arranging for appropriate training of personnel.

Each laboratory shall develop or adopt a biosafety or operations manual that identifies the hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks. Personnel shall be advised of special hazards and shall be required to read and to follow the required practices and procedures. A scientist trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents must direct laboratory activities.

When standard laboratory practices are not sufficient to control the hazard associated with a particular agent or laboratory procedure, additional measures may be needed. The laboratory director is responsible for selecting additional safety practices, which must be in keeping with the hazard associated with the agent or procedure.

Laboratory personnel, safety practices, and techniques must be supplemented by appropriate facility design and engineering features, safety equipment, and management practices.

1.1.2 Safety Equipment (Primary Barrier)

Safety equipment includes biological safety cabinets (BSCs), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The biological safety cabinet (BSC) is the principal device used to provide

containment of infectious splashes or aerosols generated by many microbiological procedures. Three types of BSCs (Class I, II, III) used in microbiological laboratories are described in Section 2 of this manual, as illustrated in Appendix A of the [BMBL 6th Edition](#).

Biosafety Cabinets: Open-fronted Class I and Class II BSCs are primary barriers which offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques. The Class II BSC also provides protection from external contamination of the materials (e.g., cell cultures, microbiological stocks) being manipulated inside the cabinet. The gas-tight Class III BSC provides the highest attainable level of protection to personnel and the environment.

Centrifuges: Other examples of primary barriers include centrifuge sealed rotors and safety cups to prevent aerosols from being released during centrifugation. To minimize this hazard, containment controls such as BSCs or centrifuge cups must be used for handling infectious agents that can be transmitted through the aerosol route of exposure.

Personnel Protective Equipment (PPE): Safety equipment also may include items for personal protection equipment (PPE) such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, eye protection, or ear plugs. Personal protective equipment is often used in combination with biological safety cabinets and other devices that contain the agents, animals, or materials being worked with. In some situations, which it is impractical to work in biological safety cabinets, personal protective equipment may form the primary barrier between personnel and the infectious materials. Examples include certain animal studies, animal necropsy, agent production activities, and activities relating to maintenance, service, or support of the laboratory facility.

1.1.3 Facility Design and Construction (Secondary Barriers)

The design of the facility is important in providing a barrier to protect persons working inside and outside of the laboratory within the facility, and to protect persons or animals in the community from infectious agents that may be accidentally released from the laboratory. Facilities must be commensurate with the laboratory's function and the recommended biosafety level for the agents being manipulated. Design features based on the risk level may include the following:

- Ventilation requirements found in the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE);
- Effluent treatment and decontamination;
- Anterooms installed prior to lab spaces; and
- Airlocks that control room air pressures.

The recommended secondary barrier(s) will depend on the risk of transmission of specific agents. For example, the exposure risks for most laboratory work in Biosafety Level 1 and 2 facilities will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments. Secondary barriers in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave), and hand washing facilities.

As the risk for aerosol transmission increases, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features could include specialized ventilation systems to assure directional air flow, air treatment systems to decontaminate or remove agents from exhaust air, controlled access zones, airlocks as laboratory entrances, or separate buildings or modules for isolation of the laboratory.

Design engineers for laboratories may refer to specific ventilation recommendations as found in the Applications Handbook for Heating, Ventilation, and Air-conditioning (HVAC) published by the American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE). Design recommendations depends on the laboratory facility, and may require additional design recommendations by the following agencies:

- [The National Institutes of Health \(NIH\) Design Requirements Manual](#);
- [World Health Organization \(WHO\) Laboratory Biosafety Manual](#);
- [World Organization for Animal Health \(OIE\) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals](#); and/or
- Other similar national or international design reference documents.

1.1.4 Facility Practices and Procedures

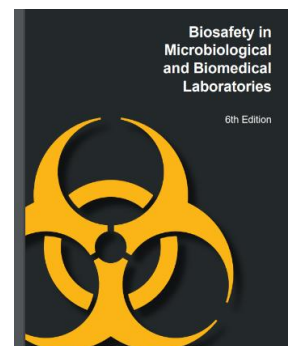
The implementation of best practices and procedures are essential to a biosafety program. A necessary feature is that laboratory personnel understand the hazardous biological agents that are handled in the lab and are trained in the necessary practices and procedures of these agents. Laboratory management are responsible for providing necessary training of staff, and for strict adherence of documented laboratory best practices and procedures, since failure of adherence to a laboratory's standard operating procedures may lead to accidental exposure and/or unintended release of biological agents or toxins.

All laboratory facilities need to develop and implement biosafety standard operating procedures that includes the following:

1. Identification of the hazards used or stored in the facility;
2. Conduct a risk assessment to identify possible modes of exposure and accidental release; and
3. Development of a biosafety plan that outlines standard operating procedures that addresses prevention and mitigation of a possible exposure or accidental release.

1.1.5 Biosafety Levels

Four biosafety levels (BSLs) are described in the [Biosafety in Microbiological and Biomedical Laboratories 6th Edition](#), which are differentiated through the unique combinations of laboratory practices and techniques, safety equipment, and laboratory facilities that are required for each level. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity.



The recommended BSLs for various organisms represent those conditions under which the agent can ordinarily be safely handled. The Principal Investigator (PI) is specifically and primarily responsible for assessing risks and for appropriately applying the recommended biosafety level precautions. Generally, work with known agents shall be conducted at the biosafety level recommended. When specific information is available to suggest that virulence, pathogenicity, antibiotic resistance patterns, vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified.

Identification of the appropriate biosafety controls must be based on the risk assessment, even when working with well-defined organisms. This is especially the case if there is information indicating that virulence, pathogenicity, antibiotic resistance patterns, vaccine and treatment availability, or other factors may be significantly altered, which will require additions to biosafety controls.

Please note that the Biosafety Laboratory levels described in this section do not directly apply to the Agent Risk Groups, which are described in the [*National Institutes of Health Guidelines for research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)*](#). For example, if a biological agent is listed as Risk Group 3 does not mean that this agent must occur in a BSL-3 laboratory. Biological agents and toxins are assigned to a relevant Risk Group based on the ability to cause disease (pathogenicity) in healthy human adults and transmissibility within a community.

NIH GUIDELINES FOR RESEARCH
INVOLVING
RECOMBINANT OR SYNTHETIC
NUCLEIC ACID MOLECULES
(NIH GUIDELINES)

APRIL 2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Visit the NIH OSP Web site at:
<https://osp.od.nih.gov>

Biosafety Level 1 practices, safety equipment, and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Organisms exempt under the *NIH Guidelines* are representative of microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple in vivo passages shall not be considered avirulent simply because they are vaccine strains.

Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a door, a sink for hand washing, non-porous work surfaces that are cleanable and easy to decontaminate, a universal biohazard symbol posted at laboratory entrances, and an integrated pest management program.

Biosafety Level 2 practices, equipment, and facilities are applicable to clinical, diagnostic, teaching, and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities

conducted on the open bench, provided the potential for producing splashes or aerosols is low. Biosafety Level 2 is appropriate when work is done with any human, animal, or plant-derived specimens (e.g., blood, body fluids, tissues, or primary cell lines) where the presence of a biological agent or toxin may be unknown. Laboratory personnel working with human-derived materials shall refer to the Bloodborne Pathogen Standard for specific, required precautions and contact NAU's Office of Biological Safety to receive Bloodborne Pathogen training.



Primary hazards to personnel working with these agents include accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials. Extreme precaution with contaminated needles or sharp instruments must be emphasized. Even though organisms routinely manipulated at BSL-2 are not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted within a physical containment device such as a BSC or safety centrifuge cups. Primary containment equipment is also recommended when high-risk infectious agents are suspected to be present in any human, animal, or plant-derived specimens. Selection of personal protective equipment must be based on the risks identified by each facility. Special practices for BSL-2 and ABSL-2 may be found in Sections IV & V of the *Biosafety in Microbiological and Biomedical Laboratories*.

Secondary barriers such as hand washing, waste decontamination facilities must be available to reduce potential environmental contamination, and separation of laboratory spaces from office and public spaces to reduce the risk of exposure. Laboratory doors shall be self-closing and have locks in accordance with institutional policies.

Biosafety Level 3 practices, safety equipment, and facilities are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. Primary hazards to personnel working with these agents include autoinoculation, ingestion, and exposure to infectious aerosols and droplets.

At Biosafety Level 3, greater emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. For example, all laboratory manipulations must be performed in a BSC or other enclosed equipment. When a procedure cannot be performed in a BSC, a combination of personal protective equipment and other primary containment strategies (e.g., soft wall containment enclosures) are used based on the risk assessment. Loading and unloading of rotors and centrifuge safety cups take place in a BSC or another containment system.

Secondary barriers for this level include everything mentioned for BSL-1 and BSL-2 facilities. They also include controlled access to the laboratory, a specialized ventilation system that minimizes the release of infectious aerosols from the laboratory, anterooms, airlocks, exit showers, and/or exhaust HEPA filtration.

Biosafety Level 4 practices, safety equipment, and facilities are applicable for work with

dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route, and for which there is no available vaccine or therapy. Additionally, agents with a close or identical antigenic relationship to Biosafety Level 4 agents shall also be handled at this level.

The primary hazards to personnel working with Biosafety Level 4 agents are respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets, and autoinoculation. All manipulations of potentially infectious diagnostic materials, isolates, and naturally or experimentally infected animals pose a high risk of exposure and infection to laboratory personnel, the community, and the environment.

The laboratory worker's complete isolation of aerosolized infectious materials is accomplished primarily by working in a Class III BSC or a full-body, air-supplied positive-pressure personnel suit. The Biosafety Level 4 facility itself is generally a separate building or completely isolated zone with complex, specialized ventilation and waste management systems to prevent release of viable agents to the environment.

1.1.6 Animal Facilities

Four animal biosafety levels (ABSLs) are described in the [Biosafety in Microbiological and Biomedical Laboratories 6th Edition](#) (BMBL) for activities involving infectious disease work with experimental vertebrates. These four combinations of practices, safety equipment, and facilities are designated Animal Biosafety Levels 1, 2, 3, and 4; and, in general, the biosafety level recommended for working with an infectious agent in vivo and in vitro is comparable.

One additional Biosafety Level, designated for Animal Biosafety Level 3-Agriculture (ABSL-3Ag) located in Appendix D of the BMBL addresses activities involving the use of hazardous biological agents and toxins designated as High-Consequence Foreign Animal Diseases and Pests by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) in large or loose-housed animals. ABSL-3Ag laboratories are designed so that the laboratory building itself serves as a primary barrier to prevent the unintentional release of these high consequence agents into the environment.

1.1.7 Clinical Laboratories



Clinical laboratories, especially those in healthcare facilities, receive clinical specimens with requests for a variety of diagnostic and clinical support services. Typically, the infectious nature of clinical material is unknown, and specimens are often submitted with a broad request for microbiological examination for multiple agents (e.g., sputa submitted for "routine," acid-fast, and fungal cultures). It is the responsibility of the laboratory director to

establish standard procedures in the laboratory that realistically address the issue of the infectious hazard of clinical specimens.

Except in extraordinary circumstances (e.g., suspected hemorrhagic fever), the initial processing of clinical specimens and identification of isolates from public or animal health clinical laboratories can be done safely at Biosafety Level 2, which is the recommended level for work with bloodborne pathogens such as hepatitis B virus and HIV. The containment elements described in Biosafety Level 2 are consistent with the [Occupational Exposure to Bloodborne Pathogens Standard from the Occupational Safety and Health Administration \(OSHA\)](#), which requires the use of specific precautions with all clinical specimens of blood or other potentially infectious material (Universal Precautions). Additionally, other recommendations specific for clinical laboratories may be obtained from the [Clinical and Laboratory Standards Institute \(CLSI\)](#).



Biosafety Level 2 recommendations and OSHA requirements focus on the prevention of percutaneous and mucous membrane exposures to clinical material. Primary barriers such as BSCs (Class I or II) shall be used when performing procedures that might cause splashing, spraying, or splattering of droplets. BSCs shall also be used for the initial processing of clinical specimens when the nature of the test requested or other information is suggestive that an agent readily transmissible by infectious aerosols is likely to be present (e.g., *M. tuberculosis*), or when the use of a BSC (Class II) is indicated to protect the integrity of the specimen.



The segregation of clinical laboratory functions and limiting or restricting access to such areas is the responsibility of the laboratory director. It is also the director's responsibility to establish standard, written procedures that address the potential hazards and the required precautions to be implemented.

1.1.8 Laboratory Biosecurity

In recent years, with the passing of federal legislation regulating the possession, use, and transfer of biological Select Agents and Toxins with high adverse public health and/or agricultural consequences (DHHS, USDA APHIS Select Agents), a much greater emphasis has been placed in the emerging field of biosecurity. Biosecurity and Select Agent issues are covered in detail in Section VI and Appendix F of [BMBL](#). While biosafety focuses on the protection of personnel, the surrounding community, and the environment from the unintentional release of hazardous biological agents and toxins, the field of laboratory biosecurity is focused on the prevention of the theft, loss, and misuse of hazardous biological agents and toxins, equipment, and/or valuable information by an individual(s) for malicious use. Nonetheless, a successful containment strategy must incorporate aspects of both biosafety and laboratory biosecurity to adequately address the risks present at the facility.

1.1.9 Importation and Interstate Shipment of Certain Biomedical Materials

The importation of etiologic agents and vectors of human diseases is subject to the requirements of the Public Health Service Foreign Quarantine regulations. Companion regulations of the Public Health Service and the [Department of Transportation](#) specify packaging, labeling, and shipping requirements for etiologic agents and diagnostic specimens shipped in interstate commerce.



The U.S. Department of Agriculture (USDA) regulates the importation and interstate shipment of animal pathogens and prohibits the importation, possession, or use of certain exotic animal disease agents that pose a serious disease threat to domestic livestock and poultry. [USDA/APHIS permits](#) are required for both importation and within USA transport of many hazardous biological agents.



1.2 Biological Safety Levels (BSLs)

Biological Safety levels 1, 2, 3, & 4 requirements are provided in [Biosafety in Microbiological and Biomedical Laboratories 6th Edition, 2020](#), HHS publication No. (CDC) 21-1112, by the Centers for Disease Control & Prevention/National Institutes of Health.

1.2.1 Animal Biosafety Levels (ABSL)

Requirements for Animal Biosafety Levels 1, 2, 3, & 4 are available in [Section V of the Biosafety in Microbiological and Biomedical Laboratories 6th Ed](#)



1.3 Risk Group Agents and Institutional Biosafety Committee Review

Please refer to the [Canadian Laboratory Biosafety and Biosecurity Pathogen Safety Data Sheet](#) for classification of agents, and the most up to date information for pathogen safety data sheets.

Please note that Biological Safety Levels are not inherent to an agent but are performance recommendations and shall be chosen after a risk assessment is completed. A proper risk assessment takes into account the characteristics of the agent involved, the activities to be performed, and the environment in which the work will be completed. Therefore, certain agents may be used at different Biological Safety Levels depending upon the circumstances. For instance, human clinical samples from HIV-positive patients may be safely handled in BSL2 containment. Growth of HIV in culture shall be performed in BSL3 containment. Biological Safety Levels may be higher or lower than what is given below for a particular agent depending upon the circumstances of its use.

Pathogen Safety Data Sheets

Important Note: Pathogen Safety Data Sheets (PSDSs) are documents used by individuals working with pathogens in t obtain any other information about infectious diseases, ple [Infectious Diseases](#).



The EHS Biological Safety Officer (BSO) and the University’s Institutional Biosafety Committee (IBC) review all projects involving recombinant or synthetic nucleic acid molecules, infectious disease agents, and agents of concern to livestock and agriculture and will assist you in the risk assessment process. Once the IBC and/or the EHS BSO assigns a Biological Safety Level, it must be adhered to unless new information to warrant a change, in most cases from peer-reviewed literature, is provided. The IBC and/or BSO will review the literature and make an adjustment, if warranted.

2.0 INFORMATION FOR RESEARCHERS

2.1 Project Registration

Northern Arizona University Institutional Biosafety Committee

Many research projects involve work with potentially hazardous biological agents, known infectious disease agents, or biological materials regulated by the federal or state government. Granting agencies require that the university monitor the use of biological hazards, infectious disease agents, and recombinant or synthetic nucleic acid molecules in order for them to release funds to investigators. Therefore, we have developed a registration system to ensure that all biological materials are handled properly and disposed of appropriately. The EHS Office of Biological Safety

administers three registration programs for research, teaching, and clinical laboratories.

The NAU Institutional Biosafety Committee (IBC) reviews all registrations. Approval by the NAU IBC, in writing, is required before ordering or working with any agents. Please contact the EHS BSO for more information.

Fillable registration forms are available on the EHS website at:

<http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety/>

2.1.1 Biological Agent (BA) Registration

Use of the following materials requires that the Principal Investigator completes and submits the biological agent registration document for approval by the EHS Biological Safety Officer. Agents, such as plant pathogens or exotic microorganisms, that are regulated by federal or state agencies (CDC, HHS, DOC, USDA/APHIS, EPA, FDA, DPI, etc.) shall be registered with the EHS Office of Biological Safety by submission of a biological agent registration form. All permits for transport, transfer, import or export of these regulated agents are the responsibility of the Principal Investigator. The NAU Responsible Official (RO) will be responsible for all Select Agent permits. Please allow a minimum of 6 weeks to obtain new federal permits.

Agents characterized at Biosafety Level 1 require registration. These will be expedited and administratively approved barring any complications.

Agents to be used at Biosafety Level 2 (BSL-2) or Biosafety Level 3 (BSL-3):

1. All human, animal, or plant pathogens that require BSL-2 or BSL-3 containment and handling (see previous section: "Agents List") must be registered. Please note that BSL-4 agents may not be stored or used at NAU.
2. Unknown human and animal pathogens must be registered. These are considered BSL-2 until identified.
3. Cell lines or cultures that
 - 1) have been immortalized with a virus (such as EBV or a retrovirus),
 - 2) are known to be tumorigenic in primates (including humans), or
 - 3) are primary human tumor cells.These are considered BSL-2 (or higher in many cases).
4. Human blood or other tissues, when used in research, must be registered.
5. Human blood or other tissue known to be HIV positive or known to contain any human disease-causing agent may require higher containment depending upon the IBC evaluation.

2.1.2 Recombinant or Synthetic Nucleic Acid Molecules (r/s NAM) Registration

All recombinant or synthetic nucleic acid molecules (r/sNAM) projects that involve a recombinant organism (this excludes projects that involve r/sNAM only, i.e., PCR products) require registration with the EHS Office of Biological Safety. All r/sNAM

projects require review and approval from the Institutional Biosafety Committee (IBC), which oversees all research projects and issues involving r/sNAM at NAU. Use of the following requires that the principal investigator complete and submit an r/sNAM registration document.

1. All r/sNAM projects, including the growth of recombinant bacteria for probe isolation (plasmid or phage preparations) require registration. Projects must be registered regardless of where the material came from or who originally constructed it.
2. Projects that are exempt from the NIH Guidelines must also be registered.
3. The development or use of transgenic animals and plants requires registration.

r/sNAM projects are performed at BSL-1, BSL-2, BSL-3 or the corresponding levels for whole plant (BSL-1P, BSL-2P, BSL-3P) or whole animal (BSL-1N, BSL-2N, BSL-3N) work. The EHS Biological Safety Officer, in conjunction with the IBC, will make the final determination.

2.1.3 Acute Toxins (AT) Registration

The use and storage of toxins with a mammalian LD₅₀ of ≤ 100 $\mu\text{g}/\text{kg}$ require registration. For a partial list, see the Toxins Table that follows. Acute toxins may only be ordered following written approval by the BSO or IBC.

2.1.4 Project Amendments

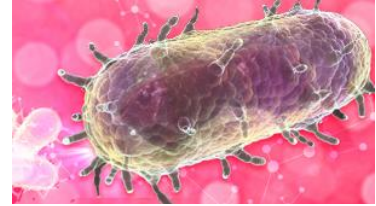
Changes to an existing registration can be done on an amendment form unless said changes result in a dramatic change to the overall project or the containment level.

Typical changes include:

- Addition or deletion of new personnel
- Addition or deletion of new agents (same containment level)
- Minor modifications to the protocol or procedures (final decision to be made by the IBC)

2.1.5 Select Agents and Toxins

The lists of agents and toxins are classified by the Federal government as Select Agents. Any possession, use, transfer or shipment of these materials is strictly controlled by regulation as shown in the weblink below.



[HHS and USDA Select Agents and Toxins](#)
[7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73](#)

Researchers considering work with any of these materials must first contact the NAU Responsible Official for the approvals, permits, clearances and other necessary paperwork. Be aware that government clearance can take as many as 6 months to complete and shall be sought far in advance of any project's proposed start date.

Select Agents and Toxins List

[Print](#)

The following biological agents and toxins have been determined to have the potential to cause death, disease, disability, or to animal and plant products. An attenuated strain of a select agent of the Select Agent Regulations. Here is a list of [excluded agents and toxins](#).

[Download PDF](#)  [PDF - 362 KB]

[HHS and USDA Select Agents and Toxins](#)
[7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73](#)

Failure to comply with these Federal Regulations is punishable by both fines and imprisonment.

2.2 Minors in Research Laboratories or Animal Facilities

Unless enrolled as a Northern Arizona University student, minors are not allowed to work or conduct research in Northern Arizona University research laboratories, greenhouses or animal facilities except as identified specifically below. In addition, minors are prohibited from operating farm machinery or state vehicles and from working in machine shops. All applicable forms can be found on the EHS Forms webpage at <http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Forms/>.

1. All Minors are prohibited from working or conducting research in the following:
 - a. Any laboratory or facility designated as BSL-3, ABSL-3 or higher for recombinant or infectious organisms.
 - b. Any laboratory where Select Agents or explosives are used or stored.
 - c. Any Animal Care Services (ACS) housing or procedure area/lab/facility.
2. Minors are prohibited from working with any of the following materials.
 - a. Radioactive materials or radiation (X-rays)
 - b. Acute Toxins
3. Minors are allowed to work or conduct research in laboratories (not listed in #1 or #2 above) if the following requirements are met in full:

- a. Northern Arizona University EHS Office of Biological Safety Policy titled; **Minors in Research Laboratories or Animal Facilities** (as been read and understood.
- b. **A Minor's Research Proposal Registration Form** is submitted to and approved by the Northern Arizona University Institutional Biosafety Committee which includes:
 - i. A description of the project and all materials
 - ii. A parental consent form
 - iii. A sponsor consent form
- c. Hazard specific safety training is completed by the Principal Investigator/Sponsor with the minor as approved by EHS BSO.
- d. Personal protective equipment, specific to the hazard, is provided to the minor with instructions for use and disposal.
- e. The minor is supervised at all times while in the laboratory.
- f. Hours of work comply with Federal Regulation 29 CFR 570.35.
The laboratory is in full compliance with all applicable Northern Arizona University safety programs and regulations.

2.3 Principal Investigator's Responsibilities During the Conduct of Research

The Principal Investigator shall in accordance with the Institutional Biosafety Committee manual:

1. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
2. Report any significant incident, violation of the NIH *Guidelines*, or any significant, research-related accidents and illnesses immediately by contacting the Biological Safety Officer. Examples of incidents and violations include:
 - a. Overt exposures (exposures that result in direct personnel exposure to biohazards such as injection, spills, splashes, or aerosol inhalation)
 - b. Potential exposures (exposures that have a high risk of exposing personnel to biohazards such as spills, containment failure while working with the agent or equipment failure that may produce aerosols)
 - c. Any exposure (overt or potential) in a BSL-3 laboratory
 - d. Overt exposure in BSL-1 or BSL-2 laboratories
 - e. Any illness that may be caused by the agents used in the laboratory
 - f. Incidents involving the improper disposal of biohazards
3. Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics) and correct procedures or conditions that might result in release of or exposure to biohazards.
4. Limit or restrict access to the laboratory when work with biohazards is in progress; this includes making a determination of who may be at increased risk.
5. Establish policies and procedures to limit access exclusively to those individuals who have been advised of the potential hazards and meet specific entry requirements.

6. Ensure that laboratory personnel are offered, at no cost, appropriate immunizations or tests for the infectious agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine, tuberculosis skin testing).

2.3.1 Reportable Incidents and Violations

Incidents/problems involving biohazards must be immediately reported to the Office of Biological Safety. Examples of reportable significant incidents include but are not limited to:

1. Any overt exposure, such as a needle stick, splash, and contamination due to equipment failure.
2. Any potential exposure in a BSL-3 facility.

A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals or the environment. It shall be noted that waste from recombinant or synthetic nucleic acid research is also considered biohazardous and incidents involving improper disposal of recombinant or synthetic nucleic acids must also be reported. Questions regarding reportable incidents shall be directed to the Office of Biological Safety.



Failure by research personnel to follow federal and institutional regulations, guidelines, policies and/or procedures may also require reporting to the appropriate institutional, local, state and/or federal agencies. Violations may include but are not limited to conduct of new or ongoing research without appropriate federal or institutional registration, review, approval, or oversight.

2.3.2 Institutional Reporting Responsibilities

The Institutional Biosafety Committee is required, by the NIH *Guidelines*, to report to the appropriate University official and to the NIH/OBA within thirty days any significant incidents, violations of the [NIH Guidelines](#), or any significant findings of research-related accidents and illnesses. The IBC will be responsible to determine what actions, if any, are necessary. For example, the IBC may determine the need to make changes to the frequency of laboratory inspections or biosafety containment level of the research, based on results of the incident.

Other IBC reporting requirements (to OBA and other agencies) include but are not limited to:

1. Research involving biohazards conducted without prior IBC approval.
2. Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant or synthetic nucleic acid waste.
3. Changes to research risk that have been initiated without prior approval by IBC.

Some incidents must be reported to OBA on an expedited basis. Spills or accidents in BSL-2 laboratories involving recombinant or synthetic nucleic acids that result in an overt exposure must be immediately reported to OBA. In addition, spills or accidents involving recombinant or synthetic nucleic acids occurring in high containment (BSL-3 or higher) laboratories resulting in an overt or potential exposure must be immediately reported to OBA. The IBC working through the IBC Chair and the BSO will report to the Institutional Official, who, in turn will oversee the report to OBA, any of the above-described incidents.

Institutional violations that will also be reported to the appropriate College or department head may include but are not limited to:

1. Lapses in disclosure approval,
2. Failure to comply with institutional and federal regulations, guidelines, and policies, or
3. Unsafe work practices.

2.4 Biological Waste Disposal Policy

This policy is intended to provide guidance and insure compliance with the NIH/CDC guidelines, [the Arizona Department of Environmental Quality Arizona Administrative Code Title 18, Chapter 13, Article 14 Biohazardous Medical Waste and Discarded Drugs, and restrictions of local jurisdictions.](#)

2.4.1 Categories ([AAC Title 18, Chapter 13, Article 14 Definitions](#))

Infectious/potentially infectious/r/sNAM

- a) Cultures and stocks generated in the diagnosis, treatment, or immunization of a human or animal in any research relating to diagnosis, treatment, or immunization, or the production or testing of biologicals
- b) Research animal wastes
- c) plant pathogens
- d) recombinant or synthetic nucleic acid molecules
- e) human and primate blood, blood products and other body fluids
- f) human and primate pathological wastes: discarded organs, tissues, body parts, cerebral spinal fluid, amniotic fluid, pericardial fluid, pleural fluid, peritoneal fluid
- g) Medical sharps including any material containing or contaminated with any of the above (test tubes, needles*, syringes, tubing, culture dishes, flasks, etc.)



This waste must be inactivated prior to disposal. The preferred method is steam sterilization (autoclaving), although chemical inactivation or

incineration may be appropriate in some cases. Per NAU policy, even autoclaved or otherwise inactivated wastes must be disposed of as biohazardous waste. Storage of non-inactivated waste is restricted to within the generating laboratory. The material may not be stored longer than 24 hours prior to inactivation.

Non-infectious waste

This category includes waste that is not contaminated with any of the biological materials listed in category 1. It includes solid waste and sharps generated in clinical or laboratory settings. Sterile or unopened biomedical materials that require disposal are also considered biological waste and must be treated as such.

IV packs	test tubes	Petri dishes
needles*	razor blades*	tissue culture flasks
syringes	culture dishes	pipettes
scalpels*	flasks	
broken glass and plastic ware**		

This material does not require sterilization prior to disposal.

*must be packaged in plastic sharps boxes.

**must be within a box or other puncture proof container before adding to waste.

Mixed radioactive/biohazardous waste

The biohazardous component of mixed radioactive/biohazardous waste shall be inactivated prior to its release to Radiation Safety for disposal as radioactive waste. Steam sterilization or chemical inactivation shall be employed as above. Although some radioactive materials can be autoclaved safely, please check with the EHS Radiation Safety Officer regarding the best method to employ with any given radionuclide.

Mixed chemical/biohazardous waste

The biohazardous component of mixed chemical/biohazardous waste shall be inactivated prior to its release for chemical disposal. Precautions shall be taken to prevent the generation and release of toxic chemicals during the inactivation process. In general, autoclaving is not recommended because flammable or reactive compounds shall not be autoclaved due to the explosion hazard. Please check with the NAU Chemical Hygiene Officer for guidance regarding certain chemicals.

Animal carcasses and materials

All animal materials must be packaged, shrouded, and delivered to the Vivarium Manager. No animal carcasses or material shall be disposed of as regular trash.



Human remains

Human remains from anatomy labs must be placed in yellow barrels for EHS pick-up.

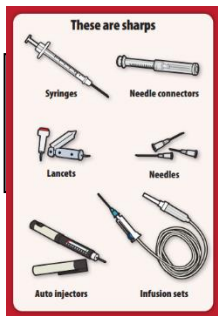
2.4.2 Packaging

Biohazard bags

These are used for the initial collection of certain biological wastes. All biohazard bags must meet impact resistance (165 grams), tearing resistance (480 grams), and heavy metal concentration (<100 PPM total of lead, mercury, chromium and cadmium) requirements. Written documentation (a test report) from the manufacturer regarding these requirements must be on file. Individual departments are responsible for obtaining the appropriate biohazard bags. These bags must be placed in bulk biohazard containers as described within this section.



Sharps



Needles, scalpels, and razor blades must be containerized in red plastic sharps containers. NAU departments are responsible for obtaining their own sharps containers. All other sharps (broken glass and plastic ware, pipettes, etc.) must be containerized in puncture-resistant cardboard boxes. For proper sharps disposal use tongs, tweezers, or a broom and dustpan to pick up sharps and dispose into an appropriate Sharps container. For obtaining Sharps Disposal items contact NAU Supply.

For the step by step instructions on Sharps Disposal, visit the Environmental Health and Safety website under [Biosafety](#).

Containers

All biological waste must be containerized in rigid, leak proof, puncture resistant boxes or plastic tubs/barrels as the terminal receptacle. NAU Departments are responsible for obtaining the appropriate containers from the EHS Hazardous Waste Coordinator.



2.4.3 Labeling

Only manufactured containers with the preprinted universal biohazard symbol and the words "biomedical", "biohazardous", or "infectious" shall be used.

2.4.4 Transport

The transport of biohazardous waste outside of the laboratory (i.e., to an autoclave or incinerator) must be in a closed, leak-proof container that is labeled "biohazard". Only trained personnel may transport biohazardous waste. Labeling may be accomplished by use of a red biohazard bag with the universal biohazard symbol. Only biohazard bags and red plastic sharps containers may be used to transport biological waste to the biohazard waste receptacle. Waste receptacle personnel are instructed not to accept any other type of containers.

Transportation of red-bagged waste must be in closed, leak-proof containers, properly labeled as "biohazards." Movement of regulated/biological waste through public corridors, along carpeted hallways, and on public elevators shall be avoided whenever possible. Any leakage/spills from these containers must be immediately reported to the NAU Office of Biological Safety. Signs must be displayed to prevent tracking of the spills contents to other areas.

2.4.5 Training

All employees who handle biological waste shall be trained regarding its proper handling before they are allowed to handle biological waste.

Training may be accomplished through the NAU Basic Biosafety Training Program (administered by NAU EHS Office of Biological Safety), informally in the lab setting, or through formal training programs set up by individual departments or divisions. For assistance, please call the NAU Biological Safety Officer or Hazardous Waste Coordinator.

According to Arizona Statute (Ch. 64E-16 F.A.C.), records of the training session shall be maintained for each employee, along with an outline of the training program. Training records shall be retained for a period of three (3) years.

2.5 Biological Waste Disposal Containers

The following waste disposal containers for biohazardous or biomedical waste are to be used for teaching and research purposes at Northern Arizona University:
ALL BIOHAZARDOUS WASTE MUST BE TREATED BEFORE DISPOSAL.

2.5.1 Bulk Biohazard Receptacles

The EHS currently provides departments who generate biohazardous and biomedical waste with large receptacles for the disposal of full biohazard bags and sharps containers. Individual departments can contact the EHS Hazardous Waste Coordinator for pickup when containers are full (<https://nau.edu/research/compliance/environmental-health-and-safety/hazardous-waste-management/>).



PLEASE NOTE: PER NAU POLICY, EVEN AUTOCLAVED WASTES MUST BE TREATED AS BIOHAZARDOUS WASTES.

Disposal of biomedical waste in the regular trash or dumpster is prohibited. The Coconino County Landfill does not accept any items that resemble “hazardous materials” and will reject the entire load. In some cases, the individual principal investigator has been made responsible for the costs incurred for sorting and disposal of improperly disposed waste.

2.5.2 Sharps Boxes

NAU is subject to the requirements of [Arizona Administrative Code Rule 18-13-1419](#), Medical Sharps. This regulation requires that a generator who treats biohazardous medical waste on site shall place medical sharps in a sharps container after rendering them incapable of creating a stick hazard by using an encapsulation agent or any other process that prevents a stick hazard.



Red plastic sharps boxes are used for disposal of needles, razor blades, scalpels, and small Pasteur pipettes. Sharps boxes that contain infectious materials must be inactivated by autoclaving the closed box. Only trained staff/research staff shall handle the full sharps boxes. Full sharps containers can be disposed of in the bulk biohazard receptacles described above.

2.5.3 Biohazard Bags



Red plastic biohazard bags shall be used for collection of biohazardous tissue culture items, petri dishes, and other non-sharp items. The biohazardous waste items must be inactivated by autoclaving in biohazard autoclave bags or treatment with bleach within 24 hours of accumulation. After treatment, the bags shall be placed in the bulk containers described above. They may only be transported to the waste receptacle by trained laboratory personnel or by trained staff. Biohazard bags shall never be placed in an area with unrestricted access. Double bagging may be required for waste bags containing significant liquid volumes; however, sufficient absorbent material must also be added to any bag with liquid waste to further help prevent leakage. Full, untreated biohazard bags shall be stored only in the lab where accumulation occurred. Full biohazard bags must be treated within 24 hours. As previously noted, even autoclaved wastes must be disposed of as biohazardous waste.

2.6 Autoclave Use and Testing

Standard operating procedures for autoclave operations and verification can be found in the Northern Arizona University Autoclave Manual on the EHS website at <https://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Standard->

[Operating-Procedures/](#). For additional questions, please contact the Office of Biological Safety.

2.7 Disinfectants

“Disinfectant” refers to an agent that is applied to treat (usually) inanimate objects to eliminate some, but not all microorganisms on the object to make it safer for handling. In contrast, the term “sterilant” refers to an agent that renders items free of all microorganisms. The two are not the same and shall not be confused.

Disinfectants are used in laboratory and chemical settings to 1) treat a surface or an item before or after routine use, or 2) treat a surface or an item after a spill or “contaminating event”.

Because disinfectants are antimicrobial, they may, by their nature, also have a toxic effect to the user. Therefore, Material Safety Data Sheets and other manufacturer’s product information shall be available and thoroughly reviewed before using these products.

There are many different types and formulations of disinfectants. The researcher or clinician shall ensure that the proper product, one that is effective against the specific microorganism being studied, is used.

The FDA regulates those products that are marketed as sterilants or sanitizing agents for medical devices, and has published a list of FDA-Cleared Sterilants and Disinfectants at

<https://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm>.

The EPA regulates moderate and low-level disinfectants under their pesticide regulations. They have published a list of [Selected EPA-registered Disinfectants](#) or the following EPA website for a list of registered disinfectants for particular pathogens: https://search.epa.gov/epasearch/?querytext=disinfectant+list&areaname=&areacontact_s=&areasearchurl=&typeofsearch=epa&result_template=#/

Please contact the Office of Biological Safety for information about any of these lists. Be aware that most disinfectants assume pre-cleaning to remove gross organic/protein prior to use.

Whenever a disinfectant or sterilant is used, proper safety precautions must be followed. Appropriate personal protective equipment (PPE) (e.g., gloves, safety goggles, aprons) must be worn. In addition, these compounds must be used in well-ventilated areas.

Following is a discussion of general categories of disinfectants. Please note that there are several different products and different formulations in each category.

2.7.1 Liquid Disinfectants (Use in accordance with manufacturer's instructions)

Alcohols

The most commonly used alcohols, ethanol and isopropanol, are most effective at concentrations of 70% in water. Both higher and lower concentrations are less effective. Alcohols are active against vegetative bacteria, fungi, and lipid viruses but not against spores. They are only moderately effective against nonlipid viruses. Alcohols are difficult to use as contact disinfectants because they evaporate rapidly and do not penetrate organic matter well. When using alcohols, it is best to clean an object, then submerge it in alcohol for the appropriate time. Alcohols are often used in concert with other disinfectants such as formaldehyde (but see toxicity warning below) or chlorine (2000 ppm chlorine in alcohol). Alcohol is NOT a registered tuberculocidal or HIV listed disinfectant.

Chlorine compounds

The most commonly used and generally effective disinfectant is sodium hypochlorite (common household bleach). However, it is a strong oxidizing agent and therefore can be corrosive to metal. A 1:50 dilution, supplying 1000 ppm available chlorine, using common household bleach is very effective as a general laboratory disinfectant and a 1:10 dilution supplying 5000 ppm available chlorine is effective against spills involving blood or other organic material. Please note that the presence of high concentrations of protein can inactivate the action of chlorine products. Dilute hypochlorite solution must be prepared daily to be maximally effective. There are more concentrated sodium hypochlorite solutions available for industrial use, so please read the product information carefully to determine the proper dilution.

Table 1: Dilutions of Household Bleach



Volume Of Bleach	Volume of Water	Dilution Ratio	% Sodium Hypochlorite	Available Chlorine
Undiluted	0	1:1	5.25	50,000
1	9	1:10	0.5	5,000
1	99	1:100	0.05	500

Hydrogen Peroxide and Peracetic Acid compounds

Peracetic acid is a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil. Peracetic acid removes surface contaminants (primarily protein) on endoscopic tubing. An automated machine using peracetic acid to sterilize medical, surgical, and dental instruments chemically (e.g., endoscopes, arthroscopes) was introduced in 1988. This microprocessor-controlled, low-temperature sterilization method is commonly used in the United States. The sterilant, 35% peracetic acid, and an anticorrosive agent are supplied in a single-dose container. The container is

punctured at the time of use, immediately prior to closing the lid and initiating the cycle.

Formaldehyde

Formaldehyde is a gas that is available either dissolved in water and methanol as a 37% formaldehyde solution, known as formalin, or as a solid, paraformaldehyde, that may be melted to release the gas. Formaldehyde gas is very active against a variety of microorganisms and is used for space decontamination and to decontaminate biological safety cabinets. Formaldehyde dissolved in water is active at 1-8% solutions and can be used to decontaminate hard surfaces. However, because formaldehyde is very irritating at low concentrations (0.1 to 5 ppm) and a known carcinogen, its use as a hard surface disinfectant is limited to situations in which it is particularly needed. Due to its toxic effects, there are no EPA-registered disinfectants that contain formaldehyde.

Glutaraldehyde

Glutaraldehyde is usually supplied as a 20% solution and requires activation by the addition of an alkaline agent prior to use. The activated product may be kept for about two weeks and shall be discarded when turbid. Glutaraldehyde is active against almost all microorganisms, but is toxic, irritating, and mutagenic and shall be used only when necessary. Please follow the manufacturer's guidance when using glutaraldehyde-based products, as there are many different formulations that have been designed for specific uses.

Hydrogen peroxide

Hydrogen peroxide is usually available as a 30% solution. It may be diluted 1:5 for use as a disinfectant. It is active against a wide array of microorganisms. However, it is an oxidizing agent and shall not be used on aluminum, copper, zinc, or brass. Hydrogen peroxide is unstable at high temperatures and in light.

Iodine and Iodophors

Iodine and iodophors, compounds in which iodine is combined with a solubilizing or carrier agent, are general, all-purpose disinfectants with an action similar to that of chlorine products. The appropriate concentration for iodine-containing products is 75 ppm available iodine for disinfecting work surfaces. Concentrations may be much higher for other purposes. Like chlorine compounds, the effectiveness of iodine compounds may be diminished in the presence of protein/organic material. Iodophor compounds that are used for antisepsis (germicide applied to tissue or skin) are not appropriate for use as hard surface disinfectants and vice versa. Please read the product material for appropriate dilutions and applications.

Phenol and phenolic compounds

Phenolic compounds are active at 0.2 to 3% concentrations against all forms of vegetative microorganisms but not against spores. They have only limited effectiveness against nonlipid viruses. There are many common phenol-based

disinfectants and must be used according to the manufacturer's recommendations. Phenol is a hazardous chemical and requires hazard assessment as well as proper PPE selection and use.

Quaternary ammonium compounds

Compounds in this class are active at concentrations of 0.1 - 2%. They are active against vegetative bacteria, lipid viruses, but not against bacterial spores, non-lipid viruses, or tubercle bacilli. These compounds shall be used only when a low-level disinfectant is required.

2.7.2 Disinfectants Bibliography

The following materials were consulted or used in this chapter:

- [*Disinfection, Sterilization, and Preservation*. Fourth edition. 1991. Seymour S. Block ed., Lea & Febiger, Philadelphia](#)
- [*Laboratory Biosafety Manual*. Second edition. 2020. World Health Organization, Geneva.](#)
- [*Laboratory Safety: Principles and practices*. 4th edition. 2006. Diane O. Fleming et al. eds. ASM Press, Washington DC](#)
- [*Manual of Clinical Microbiology*. Fifth edition. 1991. Albert Balows ed., ASM, Washington DC](#)
- [*Prudent Practices in the Laboratory: Handling and disposal of chemicals*. 1995 National Research Council. National Academy Press, Washington.](#)
- [Centers for Disease Control and Prevention \(CDC\). 2016. *Disinfection and Sterilization: Peracetic Acid Sterilization*. Retrieved on 12/8/22](#)
<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/peracetic-acid.html>

2.8 Shipment of Biological Materials

The following regulations apply to the packaging and shipping of biological materials:

- [**U.S. Department of Transportation**, 49 CFR Parts 171-180 and amendments](#)
- [**U.S. Public Health Service**, 42 CFR Part 72, *Interstate Shipment of Etiologic Agents*](#)
- [**U.S. Department of Labor**, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, *Bloodborne Pathogens*](#)
- [**International Air Transport Association \(IATA\)**, *Dangerous Goods Regulations*](#)
- [**U.S. Postal Service**, 39 CFR Part 111, *Mailability of Etiologic Agents, Mailability of Sharps and Other Medical Devices*, and Publication 52, *Acceptance of Hazardous, Restricted or Perishable Matter*](#)
- [**International Civil Aviation Organization**, *Technical Instructions for the Safe Transport of Dangerous Goods by Air*](#)
- [**United Nations**, *Recommendations of the Committee of Experts on the Transportation of Dangerous Goods*](#)

All North American airlines and FedEx, the largest shipper of infectious materials, use the IATA regulation (also referred to as the Dangerous Goods Regulation or DGR) as their standard. Meeting the conditions of this standard will ensure meeting the provisions of the other US regulations.

Please contact the EHS Office of Biological Safety for specific information. Note that for any biological materials for which a state or federal permit or license is required, registration with the EHS Office of Biological Safety is also required.

Any NAU faculty/staff, regardless of job or task, must be trained to package, ship or receive packages of materials/samples classified by regulation as “dangerous goods”. This training is available from EHS. Regulation requires retraining every three years OR whenever the regulations change.

2.9 Laboratory Spills

A spill of biological materials that takes place in the open laboratory may result in the exposure of laboratory personnel to infectious materials and is a serious problem. Every effort shall be taken to prevent spilling materials.

A spill poses less of a problem if it happens inside a biological safety cabinet, provided splattering to the outside of the cabinet does not occur. Direct application of concentrated liquid disinfectant and a thorough wipe down of the internal surfaces of the cabinet will usually be effective for decontaminating the work zone, but gaseous sterilants will be required to disinfect the interior sections of the cabinet and HEPA filter(s) if they become contaminated.

2.9.1 Spill in the Open Laboratory

Advance preparation for management of a spill is essential. Risk assessments should be conducted and a “spill kit” may include the following:

- Red biohazard bag
- Leak-proof containers
- Spill sign to post to prevent access during clean up
- Tong or forceps for sharps
- Paper towels
- Disinfectant and bottle for mixing and application
- Respirators, if necessary
- Nitrile or protective gloves
- Personal protective equipment eye protection or face shield, droplet mask
- Disposable lab coats, gowns, and shoe covers
- Scrubs
- Hand sanitizing wipes
- Dustpan and mini brush
- Absorbent powder or other material



Use the following Spill Steps when responding to a spill outside a biosafety cabinet:

1. Stop and Assess – Remain calm and assess. Call 911 for emergencies.
2. Assessment – Notify people nearby, locate spill kit and notify laboratory manager.

3. What spilled – What is the biological agent, and what disinfectant is needed to kill or denature the agent?
4. Did it splash on you or other surfaces? – Wear gloves to remove contaminated clothing, doff gloves, wash hands (use emergency shower as needed necessary).
5. How much spilled and is there a risk of droplets or aerosols? If >500mL, then evacuate room, doff contaminated clothing, close door, post sign, and keep door closed for 30 minutes for aerosols to settle.
6. Do not remove any contaminated equipment – Do not cross-contaminate other surfaces or areas.
7. Secure Samples – Return containers to upright position, cover plates, when possible.
8. Disinfect gloves, doff, wash hands, and don a fresh pair of gloves. Doff gloves using inside/out method, discard in biohazard bag, wash hands, wrists, and forearms for 20 seconds.
9. Locate spill kit and make sure spill kit has all necessary items.
10. Don appropriate personal protective equipment (e.g., eye protection or face shield, gloves, gown, shoe covers)
11. Sharps removal – DO NOT USE HANDS! Use tongs, or broom and dustpan.
12. Cover, disinfect, and clean up spill – Use paper towels starting around perimeter to center, then pour 10% bleach starting around perimeter to center, wait 20 minutes before removing and discarding into biohazard bag or bin.
13. Doff PPE and wash hands – Apply disinfectant to outsides of gloves, gown, and shoe covers then remove and discard in biohazard bag or bin.
14. Post Biohazard Sign and report spill – Post sign to keep people away from spill and report to lab manager.



Any spill involving recombinant DNA outside containment must be reported to the lab manager and Environmental Health and Safety Biosafety.

If gaseous decontamination of the room is required, contact the Office of Biological Safety.

2.9.2 Exposures

All exposures to a biological agent or chemical require immediate first aid and medical attention. Report to your supervisor and complete an incident report form and a worker's compensation claim within 48 hours.

[Incident Report Form](#)

[Worker's Compensation Form](#)

Skin Exposures:

- Exposure to intact skin:
 - ✓ Wash contaminated area immediately! Use a nearby sink or emergency shower.
 - ✓ Remove all contaminated personal protective equipment and clothing using inside out method, and do not pull contaminated clothing over face and head.
- Exposure to un-intact skin:
 - ✓ Remove personal protective equipment (e.g., gloves) and wash area immediately using nearby sink or shower.
 - ✓ Seek medical attention immediately.



Eye Exposures: All exposures to eyes follow these steps:

- Flush eyes immediately for 15 minutes at an eyewash station or sink. If contact lenses are worn, then remove contact lenses and flush an additional 5 minutes.
- Remove contaminated clothing avoiding head and face.
- Seek medical attention immediately.
- Provide information about biohazard to healthcare provider.



Inhalation or Ingestion Exposures:

- Move to fresh air immediately!
- Call 911 if the person is unconscious or unresponsive.
- Seek medical attention immediately!
- Do not induce vomiting unless instructed by a provider or Poison Center.

2.9.3 Spill in a Biological Safety Cabinet

A spill that is confined to the interior of the biological safety cabinet shall present little or no hazard to personnel in the area. However, chemical disinfection procedures shall be initiated at once while the cabinet ventilation system continues to operate to prevent escape of contaminants from the cabinet.

Check spill kit contents to make sure all items listed on the spill sheet are available, as listed in the section above and follow these steps:

1. Secure samples, when possible, by returning containers to an upright position.
2. Disinfect outsides of gloves using disinfectant located inside the BSC, doff gloves and wash hands thoroughly before donning a fresh pair of gloves. Never wear contaminated gloves outside the BSC!

Note: If disinfectant is not available inside the BSC, then prepare a 10% bleach mixture after donning fresh gloves to clean up spill inside the BSC.

3. Remove broken glass using tongs or forceps and place in a Sharps container located inside the BSC.
4. Cover spill with paper towels inside BSC starting around perimeter and working towards center of spill.
5. Pour 10% bleach mixture on paper towels starting around perimeter towards center. Allow a contact time of 20-minutes.
6. Inspect inside of cabinet for splashes and check drain basin for spill contents. Close drain basin shut off valve to prevent drainage of spill.
7. After 20 minutes, remove paper towels and discard into biohazard bag.
8. Repeat clean up steps above as need to properly clean up spill.
9. Notify lab manager of spill before resuming work.



The above procedure will not disinfect the filters, blower, air ducts, or other interior parts of the cabinet. If the entire interior of the cabinet needs to be sterilized, contact the EHS Office of Biological Safety for the name of the current contractor.

2.10 Biological Safety Cabinets

The following is excerpted from BMBL 6th Edition *Appendix A: Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets*
<https://absa.org/bmbl-6/>

This chapter presents information on the selection, function, and use of biological safety cabinets (BSCs), which are the primary means of containment developed for working safely with infectious microorganisms. BSCs are designed to provide personnel, environment, and product protection when appropriate practices and procedures are followed.

Three kinds of biological safety cabinets, designated as Class I, II, and III, have been developed to meet varying research and clinical needs.



Biological safety cabinets use high efficiency particulate air (HEPA) filters in their exhaust and/or supply systems.

2.10.1 Biological Safety Cabinets (BSCs)

The similarities and differences in protection offered by the various classes of biological safety cabinets are reflected in Table 1. For additional information about hoods watch the following training video produced by Arizona State University: https://www.youtube.com/watch?v=q_C6xq7j-kg&ab_channel=BFCComm

The Class I BSC

This type of cabinet is not for aseptic or sterile technique. The Class I BSC provides personnel and environmental protection, but no product protection. It is similar in air movement to a chemical fume hood but has a HEPA filter in the exhaust system to protect the environment.

The Class II BSC

The Class II (Types A and B) biological safety cabinets provide personnel, environmental, and product protection. Air flow is drawn around the operator into the front grille of the cabinet, which provides personnel protection. In addition, the downward laminar flow of HEPA-filtered air provides product protection by minimizing the chance of cross-contamination along the work surface of the cabinet. Because cabinet air has passed through the exhaust HEPA filter, it is contaminant-free (environmental protection), and may be recirculated back into the laboratory (Type A BSC) or ducted out of the building (Type B BSC).

The Class II, Type A BSC

An un-ducted Class II Type A BSC is not to be used for work involving volatile or toxic chemicals. The buildup of chemical vapors in the cabinet (by recirculated air) and in the laboratory (from exhaust air) could create health and safety hazards. Generally, BSCs are **not** for use with chemicals. Small quantities of chemicals and chemotherapeutic agents may be used in ducted, 100% BSCs.

It is possible to duct the exhaust from a Type A cabinet out of the building. However, it must be done in a manner that does not alter the balance of the cabinet exhaust system, thereby disturbing the internal cabinet air flow. The typical method of ducting a Type A cabinet is to use a “thimble”, or canopy unit, which maintains a small opening (usually 1 inch) around the cabinet exhaust filter housing. The volume of the exhaust must be sufficient to maintain the flow of room air into the space between the thimble unit and the filter housing (contact manufacturers for any additional specifications). The thimble must be removable or be designed to allow for operational testing of the cabinet. The performance of a cabinet with this exhaust configuration is unaffected by fluctuations in the building exhaust system.

“Hard-ducting” (i.e., direct connection) of Class II Type A cabinets to the building exhaust system is not recommended. The building exhaust system must be precisely matched to the airflow from the cabinet in both volume and static pressure. However, fluctuations in air volume and pressure that are common to all building exhaust

systems make it difficult, if not impossible, to match the airflow requirements of the cabinet.

The Class II, Type B1 BSC

Some biomedical research requires the use of small quantities of certain hazardous chemicals, such as carcinogens. The powdered form of these carcinogens shall be weighed or manipulated in a chemical fume hood or a static-air glove box. Carcinogens used in cell culture or microbial systems require both biological and chemical containment.

Type B1 cabinets must be hard-ducted to their own dedicated exhaust system. As indicated earlier, blowers on laboratory exhaust systems shall be located at the terminal end of the ductwork. A failure in the building exhaust system may not be apparent to the user, as the supply blowers in the cabinet will continue to operate. A pressure-independent monitor shall be installed to sound an alarm and shut off the BSC supply fan, should failure in exhaust airflow occur. Since all cabinet manufacturers do not supply this feature, it is prudent to install a sensor in the exhaust system as necessary. To maintain critical operations, laboratories using Type B BSCs shall connect the exhaust blower to the emergency power supply.

The Class II, Type B2 BSC

This BSC is a total-exhaust cabinet; no air is recirculated within it. This cabinet provides simultaneous primary biological and chemical containment.

Should the building or cabinet exhaust fail, the cabinet will be pressurized, resulting in a flow of air from the work area back into the laboratory. Cabinets built since the early 1980's usually have an interlock system installed by the manufacturer to prevent the supply blower from operating whenever the exhaust flow is insufficient. Presence of such an interlock system should be verified; systems can be retrofitted if necessary. A pressure-independent device shall monitor exhaust air movement.

The Class II, Type B3 BSC

This biological safety cabinet is a ducted Type A cabinet. All positive pressure contaminated plenums within the cabinet are surrounded by a negative air pressure plenum. Thus, leakage in a contaminated plenum will be into the cabinet and not into the environment.

The Class III BSC

The Class III biological safety cabinet was designed for work with biosafety level 4 microbiological agents and provides maximum protection to the environment and the worker. It is a gas-tight enclosure with a non-opening view window.

Long, heavy-duty rubber gloves are attached in a gas-tight manner to ports in the cabinet and allow for manipulation of the materials isolated inside. Although these gloves restrict movement, they prevent the user's direct contact with the hazardous

materials. The trade-off is clearly on the side of maximizing personal safety. Depending on the design of the cabinet, the supply HEPA filter provides particulate-free, albeit somewhat turbulent, airflow within the work environment.

2.10.2 Horizontal Laminar Flow “Clean Bench”

Horizontal laminar flow clean air benches are not BSCs. They discharge HEPA-filtered air across the work surface and toward the user. These devices only provide product protection. They can be used for certain clean activities, such as the dust-free assembly of sterile equipment or electronic devices. These benches should never be used when handling cell culture materials or drug formulations, or when manipulating potentially infectious materials. The worker can be exposed to materials (including proteinaceous antigens) being manipulated on the clean bench, which may cause hypersensitivity. Horizontal clean air benches should never be used as a substitute for a biological safety cabinet in research, biomedical or veterinary laboratories and/or applications.

2.10.3 Vertical Laminar Flow “Clean Bench”

Vertical laminar flow clean benches also are not BSCs. They may be useful, for example, in hospital pharmacies when a clean area is needed for preparation of intravenous drugs. While these units generally have a sash, the air is usually discharged into the room under the sash, resulting in the same potential problems as the horizontal laminar flow clean benches.

2.10.4 Operations within a Class II BSC

Laboratory Hazards

Many common procedures conducted in BSCs may create splatter or aerosols. Good microbiological techniques shall always be used when working in a biological safety cabinet. For example, techniques to reduce splatter and aerosol generation will minimize the potential for exposure to personnel from infectious materials manipulated within the cabinet. Class II cabinets are designed so that horizontally nebulized spores will be captured by the downward flowing cabinet air within fourteen inches of travel. Therefore, as a general rule of thumb, keeping clean materials at least one foot away from aerosol-generating activities will minimize the potential for cross-contamination.

The general workflow shall be from “clean to contaminated (dirty)”. Materials and supplies shall be placed in such a way as to limit the movement of “dirty” items over “clean” ones.

Several measures can be taken to reduce the chance for cross-contamination when working in a BSC. Work at least 10” back from the front edge and never cover the front grille. Opened tubes or bottles shall not be held in a vertical position. Investigators working with Petri dishes and tissue culture plates shall hold the lid above the open sterile surface to minimize direct impact of downward air. Bottle or tube caps shall not be placed on the towel. Items shall be recapped or covered as soon as possible.

Open flames are not permitted in the near microbe-free environment of a BSC. On an open bench, flaming the neck of a culture vessel will create an upward air current that prevents microorganisms from falling into the tube or flask. An open flame in a BSC, however, creates turbulence that disrupts the pattern of air supplied to the work surface. When deemed absolutely necessary, touch-plate micro-burners equipped with a pilot light to provide a flame on demand may be used. Internal cabinet air disturbance and heat buildup will be minimized. The burner must be turned off when work is completed. Small electric "furnaces" are available for decontaminating bacteriological loops and needles and are preferable to an open flame inside the BSC. Disposable sterile loops shall be used to eliminate the need for heat or flame.

Aspirator bottles or suction flasks shall be connected to an overflow collection flask containing appropriate disinfectant, and to an in-line HEPA or equivalent filter. This combination will provide protection to the central building vacuum system or vacuum pump, as well as to the personnel who service this equipment. Inactivation of aspirated materials can be accomplished by placing sufficient chemical decontamination solution into the flask to kill the microorganisms as they are collected. Once inactivation occurs, liquid materials can be disposed of appropriately as noninfectious waste.

Investigators must determine the appropriate method of decontaminating materials that will be removed from the BSC at the conclusion of the work. When chemical means are appropriate, suitable liquid disinfectant shall be placed into the discard pan before work begins. Items shall be introduced into the pan with minimum splatter and allowed appropriate contact time as per manufacturer's instructions. Alternatively, liquids can be autoclaved prior to disposal. Contaminated items shall be placed into a biohazard bag or discard tray inside the BSC. Water should be added to the bag or tray prior to autoclaving.

When a steam autoclave is to be used, contaminated materials shall be placed into a biohazard bag or discard pan containing enough water to ensure steam generation during the autoclave cycle. The bag shall be taped shut or the discard pan shall be covered in the BSC prior to removal to the autoclave. The bag shall be transported and autoclaved in a leak-proof tray or pan.

2.10.5 Decontamination

Surface Decontamination

All containers and equipment shall be surface decontaminated and removed from the cabinet when work is completed. At the end of the workday, the final surface decontamination of the cabinet shall include a wipe-down of the work surface, the cabinet's sides and back, and the interior of the glass. If necessary, the cabinet shall also be monitored for radioactivity and decontaminated when necessary. Investigators shall remove their gloves and gowns and wash their hands as the final step in safe microbiological practices.

2.10.6 Engineering Requirements

Ultraviolet Lamps

Ultraviolet (UV) lamps are not required in BSCs. If installed, UV lamps must be cleaned weekly to remove any dust and dirt that may block the germicidal effectiveness of the ultraviolet light. The lamps shall be checked periodically with a meter to ensure that the appropriate intensity of UV light is being emitted. UV lamps must be turned off when the room is occupied to protect eyes and skin from UV exposure, which can burn the cornea and cause skin cancer. Do not depend on UV lamps to disinfect the area.

BSC Placement

The ideal location for the biological safety cabinet is remote from the entry (e.g., the rear of the laboratory away from traffic), since people walking parallel to the face of a BSC can disrupt the air curtain. The air curtain created at the front of the cabinet is quite fragile, amounting to a nominal inward and downward velocity of 1 mph. Open windows, air supply registers, or laboratory equipment that creates air movement (e.g., centrifuges, and vacuum pumps) shall not be located near the BSC. Similarly, chemical fume hoods must not be located close to BSCs.

HEPA Filters

HEPA filters, whether part of a building exhaust system or part of a cabinet, will require replacement when they become so loaded that sufficient air flow can no longer be maintained. Filters must be decontaminated before removal.

Certification of BSCs

All BSCs must be certified (according to a National Sanitation Foundation standard) annually according to NAU policy. Please contact the EHS Office of Biological Safety for the name and phone number of the current contractor performing this service. Prices and quality vary widely, so only BSO approved contractors may be used.

3.0 PROGRAMS

3.1 Occupational Health and Safety (Occupational Health Program)

An Occupational Health and Safety Program is critical to the NAU IACUC. According to the Public Health Service, an occupational health program is required for institutions that employ personnel who have animal contact. The NAU Occupational Health Program is overseen by the NAU Institutional Animal Care and Use Committee (IACUC). Regulations require that the IACUC monitor personnel occupational health programs and training related to animal use at NAU. Occupational health programs must include training in basic safety techniques and information about hazards which will be encountered in each particular job. Hazardous materials must be stored safely and in compliance with MSDS and OSHA regulations. Posted signs must warn of

hazards present. The NAU program is designed to protect all personnel from occupational exposure to conditions that may result in animal related illnesses.

Responsibilities Under the Program

All individuals who engage in animal-related work will participate in the university occupational health program. As the initial step in this program, individuals will complete the "Occupational Health Questionnaire" found at the IACUC website <http://www.nau.edu/research/compliance/animal-care/Certification-Training/>. The University Veterinarian will review the questionnaire, make any comments which may highlight animal work related concerns, and forward the form to health care providers at Campus Health Services. At the discretion of Campus Health personnel, the individual will be scheduled for a brief interview or examination, where potential health-risks will be discussed relative to the individual's health status and job requirements. All individuals who work with animals will be current on their tetanus vaccine. Serology and/or vaccination for rabies, Hepatitis B, toxoplasmosis, measles, and skin testing for tuberculosis may be required for work with certain species or protocols. Vaccination for rabies will be required to work with wild or random-source bats, skunks, and carnivores. Tuberculosis testing will be required for work with all non-human primates. This program is provided at no cost to the employee.

Principle Investigators are responsible for ensuring that all personnel (including employees, students, colleagues, collaborators, and volunteers) involved with their IACUC-approved project are given this program information and that they receive the appropriate immunizations and tests, etc. Investigators who do not respond to requests for registration may have their animal use approval rescinded by the IACUC.

Supervisors are responsible for providing information to animal care technicians, veterinarians, and associated animal workers (e.g., workers in Animal Care Services) who work with animals but are not on a specific research project.

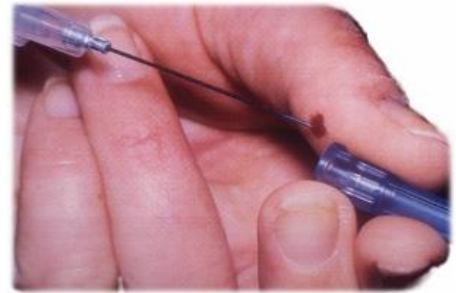
The University Veterinarian and/or health care providers at Campus Health Services will conduct an educational component of the occupational health program as appropriate. Topics to be discussed include zoonoses relative to the protocol, allergy risk, possible risks to immunocompromised individuals, and use of protective equipment and supplies such as gloves, eye protection, masks, lab coats, scrubs, respirators, head covers, boots, and heat resistant gloves chemical resistant gloves.

An animal exposure case involves mucous membrane contact with animal fluids or excreta, ingestion of animal fluids or excreta, bites, scratches, etc. Emergency medical care for minor animal exposure cases is available at Campus Health Services during business hours. For more serious cases or during non-business hours, care is available at the Flagstaff Medical Center Emergency Room. In cases where individuals may be exposed to non-routine or exotic diseases, it is necessary to have emergency care sheets to provide basic information for medical personnel. Such information may include MSDS's, sheets copied from the "Control of Communicable Diseases Manual" (<https://www.apha.org/ccdm>), or monographs written by disease experts. Such sheets

shall be readily available so affected individuals may easily take them when seeking emergency care. MSDS's for chemicals used in laboratories must also be readily available.

3.2 Bloodborne Pathogen Program

In December 1991, [OSHA](#) published the final rule covering occupational exposure to bloodborne pathogens. This was adopted by the state of Arizona and written into the Arizona Administrative Code in January 1993. NAU instituted its program in the spring of 1993.



The rule requires that those who handle human blood or other potentially infectious (human) materials as part of their job duties participate in an employer-generated program. This program shall include development and annual review of a site-specific Exposure Control Plan, annual training regarding exposures, offer of hepatitis B vaccinations free-of-charge, and post-exposure health care services.

Northern Arizona University manages this program through the EHS Office of Biological Safety. The BBP program materials and information is available on our website at <https://nau.edu/research/compliance/environmental-health-and-safety/training/>.

In addition to the program materials, the EHS Office of Biological Safety provides training sessions upon request.

Hepatitis B vaccinations are given by the Campus Health Services. Official program medical records are kept by Campus Health Services, and documentation of vaccination acceptance or declination is maintained by the EHS Office of Biological Safety. There is a requirement that Flagstaff Medical Center staff or other providers send vaccination and post-exposure records to Campus Health Services for record-keeping purposes.

The EHS Office of Biological Safety monitors for NAU compliance by requiring training and vaccination documentation and by confirming BBP participation during the annual laboratory safety inspection, which is conducted in each laboratory annually.

For further information, please call the EHS Office of Biological Safety.

4.0 MEDICAL SURVEILLANCE

4.1 Immunoprophylaxis

Northern Arizona University follows the recommendations of the Centers for Disease Control and Prevention (CDC) and the Public Health Service Advisory Committee for Immunization Practices (ACIP) for vaccination of at-risk personnel.

Currently, NAU has written policies regarding the need for hepatitis B, anthrax, plague, tetanus, rabies, and vaccinia vaccination for certain at-risk personnel. Other vaccinations may be required or recommended, as needed. Particular attention is given to individuals who are or may become immunocompromised, as recommendations for vaccine administration may be different than for immunologically competent adults. Various other factors may be taken into account such as pregnancy, history of allergy, or HIV status.

When considering the need for immunization, a risk assessment will be conducted by the health care provider in conjunction with information regarding the experimental agent provided by the EHS Office of Biological Safety.

4.1.1 [Prophylactic Recommendations for Working with Infectious Agents](#)

For prophylactic recommendations working with infectious agents, please refer to:

- [CDC publication, *Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition](#), and the
- [CDC publication, "Update on Adult Immunization: Recommendations of the Immunization Advisory Committee \(ACIP\)," 1991, *MMWR* vol. 40.](#)

4.1.2 Health Surveillance for Personnel Working with Infectious Agents

A health surveillance program is available for laboratory personnel who use agents that require it. Laboratory personnel should receive immunizations (see chapter entitled "Immunoprophylaxis"), such as hepatitis B vaccination, and medical tests, such as tuberculosis skin testing, when appropriate. The Animal Care and Bloodborne Pathogen Programs (see appropriate chapters) provide for health assessments, risk assessments, medical tests, and immunizations for certain at-risk personnel.

4.1.3 Blood Serum Sampling

For those laboratory personnel working with certain agents under BSL-2 or BSL-3, baseline serum samples may be appropriate (see chapter entitled "Biological Safety Levels"). The collection and maintenance of baseline serum samples provide a tool for monitoring serological changes that may result from the employee's work.

The EHS Office of Biological Safety, with advice from the appropriate health care professional, will provide information regarding the need for, and the frequency of, blood serum sampling on a case-by-case basis. The need for serum sampling will be dependent upon the agent used and the type of research in which an individual is engaged. For example, researchers who work with large quantities of HIV are required to have serum sampling monitored annually and upon accidental exposure.

4.1.4 Health Assessments

The NAU Occupational Health Program provides for pre-placement and other health assessments depending upon the type of work in which an employee will be engaged.

Laboratory personnel who work with agents that are transmitted by aerosol or with certain chemicals or acute toxins may require a respirator at some stage of the research project. The EHS Office of Biological Safety Respiratory Protection Program provides for health assessments that will determine an employee's fitness for respirator use.

The EHS Office of Biological Safety and Occupational Health Program also includes the Hearing Conservation Program, the Asbestos Monitoring Program, as well as the Animal Care Program, discussed in a separate section. Occasionally, researchers who work with infectious agents will require a health assessment based on the requirements of one of these other programs.

5.0 References

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