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BIOLOGICAL SAFETY PLAN

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Section 1:Introduction

In September 1986, the Occupational Safety and Health Administration (OSHA) was petitioned by various unions representing health care employees to develop a standard to protect workers from occupational exposure to Bloodborne diseases. In response, OSHA issued 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens," to protect workers, students and visitors from anticipated exposures to Bloodborne pathogens that include human bodily fluids potentially contaminated with the human immunodeficiency virus (HIV), hepatitis C virus (HCV), the hepatitis B virus (HBV), or other Bloodborne pathogens (see Appendix A for a "List of Bloodborne Pathogens"). Generally, the standard reflects published guidelines from the Centers for Disease Control and Prevention (CDC), which include the guidelines for Standard Blood & Body Fluid Precautions, or Universal Precautions.

This Biological Safety Plan is designed to describe the federal standard as well as provide information on how the standard is to be implemented at the University. Should clarification of terminology or abbreviations be necessary, please refer to Appendix G.

The requirements in this document apply to

- All Nova Southeastern University laboratory workers.
- Hosted visitors, students, patients, participating guests, contract laborers, and supplemental personnel.
- Workers of other firms working at locations where NSU has management control of specific biohazards.
- Workers who volunteer to provide emergency first aid.

1.1 Scope

Any biological work performed at NSU involving agents of known or potential pathogenicity for humans, animals, or plants must be conducted in a manner that affords protection to workers, students, animals and the surrounding community and environment. The Environmental and Health Safety Office (EHS) has established this Biological Safety Plan (BSP) to ensure that adequate administrative and operational protection measures are in place. The NSU Biological Safety Plan, which creates the Institutional Biological Safety Committee (IBC), was developed in order to set forth the responsibilities of all parties involved in obtaining and using biological hazards, recombinant DNA, or working in a patient care setting at NSU.

The Institutional Biological Safety Committee (IBC) is responsible for the following:

a. State the training required by all individuals who work with biological hazardous compounds and/or wastes.
b. Development of an exposure control plan.
c. Advise of rights and responsibilities under federal and state law for all individuals working with hazardous biological agents.
d. Prescribe the use of medical surveillance and preventive procedures such as health histories and vaccinations.

e. Provide staff, students and faculty with a reference so as to assist in the safe handling of pathogenic agents by staff, students and faculty.
f. Establish engineering controls, administrative and procedural controls, and safe work practices for activities involving the handling of blood and Bloodborne pathogens.
g. Prescribe the use of warning labels and signs to identify hazards,
h. Provide information on zoonotic diseases transmissible from animal to man.
i. Provide information on the proper treatment and disposal of wastes.
j. State the steps to be taken in the case of spills or other emergencies.
k. Provide guidance for the control and prevention of person-to-person or patient-to-healthcare worker infections in human clinical activities.

1.2 Definitions

See Appendix G for definitions.

1.3 Bloodborne Pathogens

Exposure to Bloodborne pathogens may occur in occupational settings where there is contact with materials potentially contaminated with human bodily fluids (e.g., blood) or Bloodborne pathogens. Individuals at risk shall take steps to protect themselves from exposure. The risk of infection following contact with contaminated equipment or blood varies depending on the type of infectious agent and the extent of actual exposure to the individual.

The likelihood of an infection occurring from an accidental Bloodborne exposure depends on a number of factors, including, but not limited to:

a. The probability that the material (e.g., blood) was contaminated.
b. The health status of the individual.
c. The efficiency of the transmission.

The source of material involved in an accidental Bloodborne exposure may be tested for specific Bloodborne contaminants such as HIV, HBV, and HCV. Appropriate medical evaluation or treatment shall be sought whenever an exposure occurs or is thought to have occurred.

The individual's health status plays a key factor in how an individual responds to an exposure. Pre-existing diseases, the use of medication, compromised immunity, and pregnancy are factors to consider when determining how the individual may respond to an exposure.

The efficiency of the transmission depends upon the type of wound, severity of exposure, infectious dose, routes of infection, and the ability of the organism to produce disease. Listed in Appendix A are human Bloodborne pathogens, morbidity and mortality information, incubation periods, and sources. The specimen sources are from humans unless otherwise specified, i.e. rodents.

Section 2:Responsible NSU Personnel

Nova Southeastern University is responsible for providing a safe working environment for all University activities and for compliance with all applicable federal, state, and local regulations concerning the use of biological agents, biological toxins, and recombinant DNA. University responsibilities include the establishment and support of an Institutional Biological Safety Committee (IBC), and a Biosafety Officer.

2.1 Chairperson and the Institutional Biological Safety Committee (IBC)

a. Ensure that the IBC is properly constituted and fulfills its requirements under the appropriate regulations, rules, etc.
b. Ensure that all members of the IBC are adequately trained in appropriate containment practices, secondary containment procedures, and accidental spill containment procedures to fulfill their responsibilities as members of the IBC.
c. Advise the President, Provost, Deans, and Department Chairs on matters related to biohazards and biosafety with their respective areas of responsibility.
d. Develop, recommend, and implement policies and procedures for biological risk assessment and biological risk reduction throughout the University.
e. Develop emergency plans for the containment and resolution of accidental spills and other related emergencies with an emphasis on risk reduction, personnel protection, and environmental protection.
f. Oversee all clinical, research and teaching activities involving biohazardous agents including review and approval prior to initiation, annual reviews and updates, reviews of laboratory safety equipment and procedures, and certification of compliance with all applicable rules and regulations governing the use of biohazardous materials.
g. As an agent of the University, ensure that all principal investigators, clinic managers and laboratory supervisors are sufficiently trained in appropriate containment practices, secondary containment procedures, accidental spill containment, and are knowledgeable regarding their responsibilities as principal investigators, managers and lab supervisors.
h. Advise and provide technical expertise, whenever possible, to the Biosafety Officer on matters regarding biosafety.
i. Conduct investigation of violations or problems and to make recommendations to the Dean for the resolution of continued non-compliance or serious infractions.

2.2 Biosafety Officer

a. Conduct periodic inspections of laboratories and clinics to ensure compliance with established containment procedures.
b. Investigate laboratory and clinic accidents and report problems, violations and injuries or illnesses associated with bio-hazardous research activities to the IBC.
c. Develop and implement emergency plans for handling accidental spills and personnel contamination.
d. Provide advice and assistance to the IBC, laboratory supervisors, clinic managers and Principal Investigators concerning containment procedures and practices, laboratory

security, recommended laboratory containment equipment, rules, regulations, and other matters as may be deemed necessary.

e. Provide oversight and assurance that laboratory safety containment equipment is functioning properly including field testing and certification, where appropriate, of all biosafety cabinets.
f. Serve as a member of the IBC.

2.3 Environmental Health & Safety Office

a. Provide industrial hygiene and safety support for all laboratory operations.
b. Ensure that all applicable regulations, standards and guidelines from the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), and the Department of Transportation (DOT) are met.
c. Assist in the receipt and shipment of all biological agents coming to or leaving the facility, including training of shipping regulations and packaging requirements.
d. Oversee the transport and disposition of all infectious waste in compliance with all applicable federal, state, and local ordinances.
e. Assist, as necessary, in the emergency response, cleanup, and decontamination of biological spills and accidents.
f. Assist the BSC and NSU Employee and Student Health Services in developing and reviewing an "exposure determination list" which includes, but is not limited to, the following:
    - A list of all job classifications in which *all* employees may have contact with blood or other potentially infectious materials on a routine basis;
    - A list of job classifications in which *some* employees have potential occupational exposure;
    - A list of all tasks and procedures or groups of closely related tasks and procedures in which the potential for occupational exposure exists and that are performed by employees in job classifications in which *some* employees have occupational exposure.
g. Provide advice and assistance to Occupational Health Services (OHS) in order to acquire personnel health histories, medical evaluations, vaccinations or other needed testing.
h. Suspend any operation causing an excessive and/or unnecessary biological hazard as rapidly and as safely as possible, and subject the situation to an expeditious resolution by the IBC.
i. Ensure compliance with the Centers for Disease Control (CDC) Select Agent Registration regulations as described in 42 C.F.R. 73 and with other regulations as they are applicable.

2.4 Infectious Diseases Review Panel

a. Review instances of HIV, HBV, HCV or other Bloodborne pathogens, TB and other serious infectious diseases in students, researchers, and healthcare professionals, to identify exposure-prone procedures and to determine those circumstances, if any, under

which a student, researcher, or healthcare professionals who are infected may perform such procedures.

b. Recommend to the Dean and the IBC, infectious disease control policies and procedures to ensure the health and safety of all patients, staff, students and faculty of NSU.
c. Recommend to the Dean and the IBC, policies and procedures to ensure NSU compliance with all federal, state and local statues, regulations, procedures and principles relating to TB, HIV, HBV, HCV and other significant pathogens.
d. Identify tasks that carry the risk for transmission and the employees or occupational groups that are involved.
e. Review and contribute annually, or as necessary to the update of the Biological Safety Plan which contains the Bloodborne Pathogen Exposure Control Plan, and the TB Exposure Control Plan.

2.5 Research and Sponsored Programs (RSP)

a. Provide the necessary liaison between Principal Investigators, the IBC, granting agencies, and regulatory agencies.
b. Serve as the Office of Record for documentation involving the IBC.
c. Provide all necessary documentation, forms, regulatory guidelines and regulations, etc. to Principal Investigators.

2.6 Laboratory Animal Resources (LAR)

a. Provide appropriate animal husbandry and care that meets or exceeds federal, state, and local requirements and specifications.
b. Ensure that animal housing systems are designed and utilized in a manner that will minimize the potential exposure of other animals or personnel to potentially biohazardous agents.
c. Develop and implement, in cooperation with the Principle Investigator, the Biosafety Officer, and the IBC, specific standard operational procedures, in adherence to the ABSL classification of the agent being used addressing animal care, research procedures, and procedures in case of accident or equipment failure.
d. Ensure that all animal care personnel are adequately trained and aware of the potential risk associated with each agent.
e. Develop, in cooperation with the institutional Biosafety Officer, emergency plans for handling accidental spills, personnel exposures, unintentional animal exposure, equipment failure, etc.

2.7 Principal Investigator, Clinic Managers and Laboratory Supervisor

a. Ensure compliance with appropriate National Institute of Health guidelines and all conditions stated in the protocol approved by the Institutional Biological Safety Committee (IBC).
b. Review proposed laboratory work to identify potential hazards (risk assessment).

c. Submit protocol applications, including safety procedures, for all activities or modifications of activities involving biohazardous materials and obtain approval by the IBC prior to initiation of the activities or modifications.
d. Ensure that all laboratory and healthcare staff, and students, are trained in the accepted procedures in; laboratory practices, containment methods, disinfectant and disposal practices, and required actions in the event of an accidental spill.
e. Ensure compliance with all shipping requirements for biological agents and toxins.
f. Ensure proper handling and disposal of all infectious wastes as outlined in this plan.
g. Request immunizations for laboratory personnel when working with biological agents for which there is an effective vaccine available.
h. Maintain all biosafety equipment in appropriate operating condition. Decontaminate laboratory equipment prior to maintenance or disposal.
i. Maintain records of microorganisms and toxins used in the laboratory and biosafety cabinets.

2.8 Laboratory and Healthcare Staff

a. Conduct no activities under the clinic or research protocol until the protocol is approved by the IBC and appropriate training is completed.
b. Follow all procedures and containment methods established for activities conducted.
c. Properly utilize all laboratory protective equipment including proper clothing, personal protective equipment, and containment devices.
d. Report all accidents and spills to the Principal Investigator, clinic manager, laboratory supervisor or the Biosafety Officer as soon as possible.
e. Report unsafe conditions to the Principal Investigator, clinic manager, laboratory supervisor, the Biosafety Officer, or the IBC.

Section 3:Employee Exposure Assessment

OSHA states that all employees, students, and faculty who have duties which potentially expose them to blood or potentially infectious material or are determined to have a reasonable anticipated risk of exposure to Bloodborne pathogens and are acknowledge in this Plan.

As required by OSHA, exposure evaluations will be performed in accordance with a categorization scheme based on the potential of job-related tasks leading to exposure. The three categories used are as follows:

Category 1 —
Duties and tasks that involve occupational exposure to blood, body fluids, or tissues.

Category 2 —
Duties and tasks that involve no occupational exposure to blood, body fluids or tissues, but employment may require performing unplanned Category 1 procedures.

Category 3 —
Duties and tasks that involve no occupational exposure to blood, body fluids or tissues and Category 1 tasks are not a condition for employment.

3.1 Jobs in which all employees will have occupational exposure to Bloodborne pathogens

1. Medical Doctors	5. Physician Assistants
2. Dentist	6. Technologists (Clinical)
3. Nurses	7. Technicians (Clinical)
4. Nurses' Aides	8. Mortuary Workers

3.2 Jobs in which some employees may have occupational exposure to Bloodborne pathogens

1. Ph.D.s	5. Engineering Staff
2. Post Doctoral Fellows	6. Animal Caretakers
3. Research Technicians	7. Security
4. Housekeeping Staff	8. Messenger

3.3 Job Duties that may lead to Exposure from Bloodborne Pathogen

Phlebotomy and injections - Handling blood specimens and other body fluid specimens	X-rays of open wounds	Venipuncture
Surgical procedures	Cleaning, maintaining and sterilizing instruments	Biopsy and human tissue pathological analysis
Catheterizations, cauterizations, lacerations	Housekeeping tasks - toilets, floors, emptying infectious wastes	Patient examination, including emergency first aid
Contact with saliva with the possibility of blood present	Housekeeping and laundry - blood-soaked linens	Diagnostic or therapeutic procedures involving patient bodily fluids
Clinical laboratory assays or tests involving potentially-infectious materials	Cell, tissue or organ culture	Blood culture
Cell separation	Research procedures involving potentially-infectious material	Animal injection with human pathogens
Embalming.	Disposal or storage of body fluid or tissue specimens	Transporting blood or related products
Cleaning blood spills	Repairing and cleaning contaminated equipment	Certain laboratory repair work, e.g., plumbing

Section 4:Risk Assessment and Management

Risk Assessment is an important responsibility at all levels and is shared throughout the University. Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an infectious agent, and the probable consequences of such an infection.

While the IBC, animal care committees, biosafety officers, and laboratory animal caretakers share in the responsibility, the Principal Investigator or laboratory supervisor is ultimately responsible for safety within the laboratory. An integral part of the Principle Investigator (PI) or laboratory supervisor responsibility is to conduct a review of proposed work to identify potential hazards (risk assessment) and to adopt appropriate safety procedures before initiation of the experiments (risk management).

It is the researchers, clinicians, and technicians who perform work with biohazards who are perhaps the most important component of the biosafety program. It is these individuals who are responsible for incorporating the biosafety requirements and safety precautions into all facets of their work.

A risk assessment/ management matrix has been prepared to illustrate key elements of the process (see below). Relevant sections providing additional details are indicated within the matrix. Information on the routes of exposure is included at the end of this section.

The five P's of risk assessment and management are:

Pathogen – hazardous biological agent.
Procedures – proposed experimental manipulations and safe work practices.
Personnel – appropriate training and skills.
Protective equipment – protective clothing and safety equipment.
Place – laboratory design.

Consider the five P's in each facet of laboratory work. Properly conducted, risk assessment can help prevent exposure to biohazards and minimize the potential for laboratory acquired infection.

Prior planning prevents poor performance.

Table A: Risk Assessment and Management Matrix

	Risk Assessment	Risk Management
Pathogen	• Agent classification (See Appendix C) • Routes of infection • Infectious disease process • Virulence, pathogenicity, quantity, concentration, incidence in community, presence of vectors	Registration of agents with ▪ IBC ▪ Biosafety Officer ▪ State of Florida - infectious agents ▪ CDC - selected agents ▪ FDA/NIH - human gene therapy
Procedures	• Aerosol risk: centrifuging, blending, shaking,etc. • Percutaneous risk: needles, syringes, scalpels, etc. • Splash/ splatter risk: pipetting, microbial loops, etc.	• Standard Operating Procedures with safety practices • Adherence to basic biosafety principles • Label areas and equipment • Conduct inspections to review practices
Personnel	• Host immunity ▪ Neoplastic disease ▪ Infection ▪ Diabetes, Lupus, etc. • Immunization • Post-exposure prophylaxis • Open wound, non-intact skin, eczema, dermatitis	• Safety training • Demonstrate proficiency with techniques • Prompt reporting of exposure incidents • Investigation/ review of incidents /spills, etc to prevent reoccurrence
Protective equipment	Protection (containment) for: • Aerosols • Droplets/splatter • Sharps	• Personal protective equipment (PPE) ▪ Respirators - HEPA ▪ Face protection - mask and safety glasses ▪ Gown or lab coat ▪ Gloves • Biological safety cabinets (BSC's) • Centrifuge safety buckets/ rotors
Place - laboratory facility	• Risk group/ biosafety level requirements • Aerosol risk • Restricted access	• Basic lab - door, sink, surfaces, eyewash • Labels • Containment laboratory with directional airflow

4.1 Hazardous Characteristics of an Agent

The principle hazardous characteristics of an agent are: its capability to infect and cause disease in a susceptible human and/or animal host, its virulence as measured by the severity of disease, and the availability of preventive measures and effective treatments for the disease. The World Health Organization (WHO) has recommended an agent risk group classification for laboratory use that describes four general risk groups based on the following principle characteristics and the route of transmission of the natural disease.

The principle characteristics to be considered are the following:

a. Pathogenicity of the organism.
b. Mode of transmission and host range of the organism.
c. Local availability of effective preventive measures.
d. Local availability of effective treatment.

The four risk groups and the basis for each classification are as follows:

Risk Group 1	Agents not associated with disease in healthy adult humans. (No or low individual and community risk) A microorganism that is unlikely to cause human or animal disease.
Risk Group 2	Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. (Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be serious hazard to laboratory workers, the community, livestock or the environment.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. (High individual risk but low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. (High individual risk and high community risk) A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

See Appendix B for more information on each risk group.

4.2 Routes of Exposure

In order for biological agents to cause disease, they must first enter or invade the body in sufficient numbers. Routes of entry for biological agents include oral, respiratory, parenteral, mucous

membrane, and/or animal contacts (bites, scratches). Once inside the body, biohazard agents must meet other requirements to cause disease; they must colonize and establish in body cells, tissues and/or organs, overcome the body's natural defense mechanisms and mutate or adapt to body changes. Other factors contribute to an individual's susceptibility to the disease process. These include age, immunological state, occupation, physical and geographic environment, and predisposing conditions (such as alcoholism, pregnancy and diseases such as diabetes).

It is difficult to determine a minimum infectious dose when discussing biohazard agents. The same dose of a pathogen may produce none to minimal disease symptoms in one individual but may cause serious or even fatal disease in another. There are microorganisms for which it is thought one organism entering the body is sufficient to invade and promote the disease process; the bacteria that causes tuberculosis is an example. For many pathogens, 10 to 100 or more organisms must enter the body to cause infection leading to disease.

Illustration 1: Route of Transmission for Biological / Infectious Agents

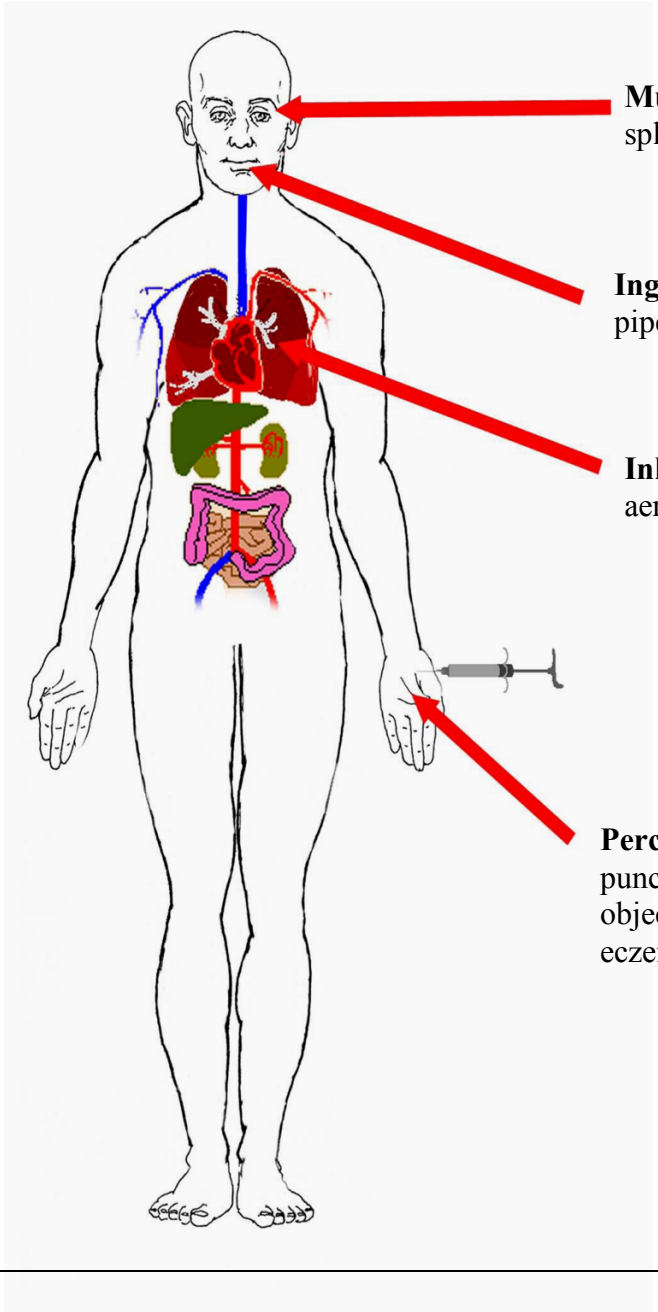


Table B: Protection for the Routes of Biological Exposure

Route of Exposure	Activity	Protection
Mucous membrances - eyes, nose or mouth	Splash and splatter generation	Face protection using full-face shield, mask or safety glasses, biosafety cabinet, protective shields and standard laboratory practices
Ingestion - mouth	Mouth pipetting, eating, drinking, smoking	Mechanical pipettors, standard laboratory practices
Inhalation - breathing in aerosols (<5µm)	Aerosols generated from centrifuge leaks, spills, pipetting, etc.	Biosafety cabinet, sealed rotors or canisters for centrifuges, HEPA-filtered respirator, safety containment equipment, and standard laboratory practices
Percutaneous	Puncture of skin with contaminated sharp object, needlestick, animal scratch, bite, or through exposure of non-intact skin from wounds, eczema or dermatitis.	Use extreme precautions with sharps, use plastic instead of glass, use animal restraints, bite resistant gloves, dispose immediately of rigid leak proof needlebox, water-proof bandages, standard laboratory practices
Contact - indirect transmission	Unwashed hands, touching of mucous membranes with contaminated hands from work surfaces	Decontaminate work surfaces, wash hands, avoid touching face with hands, do not apply cosmetics in laboratory

4.3 Biosafety Levels

The CDC and NIH have established biosafety levels for work with biohazardous materials in the publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). Each of the four biosafety levels (BSL) requires a specific combination of laboratory practices and procedures, safety equipment, and laboratory facilities. These combinations are set forth by risk group below:

Table C: Risk Groups and Management Combinations

Risk Group	Biosafety Level (BSL)	Laboratory Type	Laboratory Practices	Safety Equipment - Primary Barriers	Facilities - Secondary Barriers
1	BSL Level 1 Basic	Basic teaching, Research	Standard Laboratory Practices	None	Open bench top
2	BSL Level 2 Basic	Diagnostics, Research	BSL -1 plus protective clothing, biohazard sign, limited access	BSC's Class I or II or other containment devices used for manipulation of agents; PPE, coats; gloves and face protection	BSL - 1 plus: autoclave
3	BSL Level 3 Containment	Special Diagnostics Research	BSL - 2 plus special clothing, controlled access, directional airflow, decontamination of all waste	BSC's Class I or II and/or other primary devices for all activities; PPE; respiratory protection as needed	BSL -2 plus: Physical separation from access corridors; exhausted air not recirculated; negative airflow into laboratory
4	BSL Level 4 Maximum containment	Dangerous Pathogens	BSL - 3 plus airlock entry, shower exit, special waste disposal	Class III Biosafety cabinet or positive pressure suits in conjunction with Class II biosafety cabinets, double-ended autoclave, filtered air	BSL - 3 plus: Separate building or isolated zone; dedicated supply/ exhaust, vacuum , and decon systems

The assignment of an agent to a biosafety level for laboratory work must be based on a risk assessment which is to be conducted by the PI or laboratory supervisor when the project is proposed and reported to the NSU Research Director. Such an assessment will take the risk group as well as other factors into consideration in establishing the appropriate biosafety level. However, if particular experiments require the generation of high-concentration aerosols, then Biosafety Level 3 may be more appropriate to provide the necessary degree of safety, since it ensures superior containment of aerosols in the laboratory workplace. The Biosafety level assigned for the specific work to be done is therefore driven by professional judgment based on a risk assessment (agent and procedures), rather than by automatic assignment of a laboratory biosafety level according to the particular risk group designation of the pathogenic agent to be used.

The minimum facility requirements at the four biosafety levels are as follows:

Table D: Biosafety Levels and Minimum Facility Requirements

	Biosafety Levels			
	1	2	3	4
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation				
- Inward air flow	No	Desirable	Yes	Yes
- Controlled ventilating system	No	Desirable	Yes	Yes
- HEPA - filtered air exhaust	No	No	Yes/ No[b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	----
Anteroom with shower	No	No	Yes /No[c]	No
Effluent treatment	No	No	Yes /No[c]	Yes
Autoclave				
- on site	No	Desirable	Yes	Yes
- in lab room	No	No	Desirable	Yes
- double-doored	No	No	Desirable	Yes
Biosafety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring[d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic
[b] dependent upon location of exhaust
[c] dependent upon agent(s) used in the laboratory
[d] Examples: windows, closed-circuit TV, two-way communication

Thus, the assignment of a biosafety level takes into consideration the organism used, the facilities available, the equipment and practices and procedures required to conduct work safely in the laboratory.

Section 5:Signs and Labels

5.1 Wall Signs

A Laboratory Safety Information card must be completed and posted at the entryway to all laboratories to provide information on the materials handled inside the laboratory as well as the name and phone numbers of the principal investigator or other responsible person.

5.2 Biosafety Level

Entryways to research and clinical areas that handle BL2 materials, human blood or other potentially infectious materials must be posted with a BL2 biohazard sign that contains the universal biohazard symbol, the legend “Biohazard” and the term BL2.

Entryways to research areas that handle BL3 material must be posted with a similar sign replacing the term BL2 with BL3.

5.3 Door Signs

HIV and HBV research laboratories and production facilities; laboratories working with certain infectious agents that require special provisions for entry (e.g. vaccination); and BL2+ and BL3 laboratories must have a biohazard door sign posted on all access doors. The sign includes the international biohazard symbol, bears the legend "Biohazard", and identifies the name of the infectious agent, any special entrance requirements, and the name and phone numbers of the principal investigator or any other responsible persons. The following elements must be included on the door sign:

Illustration 2: Biohazard Door Sign

BIOHAZARD

ADMITTANCE TO AUTHORIZED PERSONNEL ONLY

The door signs shall be fluorescent orange-red (or predominantly so) with lettering or symbols in a contrasting color.

5.4 Labels and Color-coding

Inside the facility, warning labels shall be affixed to containers of medical waste, refrigerators, freezers, incubators, and centrifuges containing BL2 or BL3 agents, human blood or "other potentially infectious material." Other equipment such as waterbaths, sonicators, and biological safety cabinets do not require a permanent biohazard label if decontaminated after each use. In these situations, a biohazard label should be temporarily posted on the equipment while in use with human blood, other potentially infectious materials, or an infectious agent.

Warning labels shall also be affixed to other containers used to store, transport or ship BL2 or BL3 agents, human blood or "other potentially infectious material". (Note: Shipping blood and "other potentially infectious material" not suspected of harboring an infectious agent may not require the biohazard warning label, just the diagnostic specimen label). Labels required must have the international biohazard symbol and bear the legend "Biohazard"

The labels shall be fluorescent orange-red (or predominantly so) with lettering or symbols in a contrasting color. Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or any other method that prevents their loss or unintentional removal.

The use of warning labels may be waived if any of the following occurs:

a. Waste is placed in red bags or red containers;
b. Containers of blood, blood components, or blood products are labeled as to their contents and have been released for transfusion or other clinical use; or
c. Individual containers of blood or "other potentially infectious materials" are placed in a labeled secondary container during storage, transport, shipment or disposal.

5.5 Labeling Equipment Sent Out for Repair or Disposal

Contaminated and potentially contaminated equipment sent out for repair or disposal must be decontaminated as thoroughly as possible. Affix a tag to the equipment indicating when the equipment was decontaminated, what disinfectant was used, and the name of the person who performed the decontamination. Thorough decontamination of highly technical or sensitive equipment or equipment with limited access to contaminated areas may not be possible.

Decontaminate the equipment to the degree possible (flushing lines or wiping down the exterior) and affix a label to the equipment before sending it out for repair. The label must indicate what portions of the equipment remain contaminated and include the biohazard symbol as well as the legend "Biohazard". The label must convey this information to all affected workers (service representatives, manufacturer, etc.).

Section 6:Principles of Biosafety

6.1 Containment

The term **containment** is used in describing safe methods for handling or maintaining 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 people and the outside environment to potentially hazardous agents. The three elements of containment include **laboratory safety practices and techniques**, **safety equipment** and **facility design**.

Containment includes primary containment, the protection of personnel and the laboratory environment from exposure to biohazardous agents, and secondary containment, the protection of the environment outside of the laboratory from exposure to biohazardous agents. Primary containment is possible through good laboratory techniques and the proper use of appropriate safety equipment. Secondary containment is provided by a combination of facility design and operational practices.

1. Laboratory Safety Practices and Techniques

The most important element of containment is strict adherence to standard safety practices and techniques. Persons working with infectious agents or infected 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 PI or laboratory supervisor is responsible for providing or arranging for appropriate training of personnel.

Each laboratory should develop Standard Operating Procedures (SOP) that identify specific hazards that will or may be encountered as well as specific practices and procedures designed to minimize or eliminate risks. Personnel should be advised of special hazards and should be required to read and to follow the required practices and procedures.

Standard Laboratory Practices include, but is not limited to, the following:

a. Laboratory doors are kept closed when experiments are in progress.
b. Work surfaces are decontaminated daily and after each spill of viable material.
c. All contaminated liquids or solid wastes are decontaminated before being disposed of or otherwise handled.
d. Mechanical pipetting devices are used; mouth pipetting is prohibited.
e. Eating, drinking, smoking, storing of food and applying cosmetics are not permitted in the work area.
f. Persons must wash their hands after handling viable materials or animals and before they leave the laboratory.
g. All procedures must be carefully performed to minimize the creation of aerosols.
h. An insect and rodent control program is in effect.

When standard laboratory practices are not sufficient to control the hazard associated with a particular agent or laboratory procedure, additional measures may be needed. Laboratory

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

2. Safety Equipment (Primary Barriers)

Safety equipment includes biological safety cabinets, enclosed hoods and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The Biological Safety Cabinet (BSC) is the principle engineering control used to provide containment of infectious splashes or aerosols generated by many laboratory procedures. Safety equipment may include items for personal protection such as respirators, face shields, and safety glasses. Personal Protective Equipment (PPE) is often used in combination with other safety equipment when working with biohazardous agents.

3. Facility Design (Secondary Barriers)

The design of a facility is important in providing a barrier to protect people working inside and outside the laboratory and to protect people or animals in the community from infectious agents that may be accidentally released in the laboratory. Facilities must be commensurate with the laboratory's function and the recommended biosafety level for the agent being manipulated.

Laboratory design minimal standards include, but are not limited to, the following:

a. The laboratory should be designed so that it is easily cleaned.
b. Bench tops should be impervious to water and resistant to acids, alkalis, organic solvents and moderate heat.
c. Each laboratory should contain a hand washing sink.
d. If the laboratory has windows that open, they should be fitted with screens.
e. An autoclave for decontamination of infectious laboratory wastes should be available in the same building with the laboratory.

The need for a recommended secondary barrier(s) will depend on the risk of transmission of specific agents. As the risk for aerosol transmission increases, higher levels of primary containment including 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 airflow, air treatment systems to decontaminate or remove agents from exhaust air, controlled access zones, airlocks at laboratory entrances, or separate buildings or modules for isolation of the laboratory.

6.2 Biosafety Levels

1. Biosafety Level 1

Biosafety Level 1 is suitable for experiments involving agents of no known or of minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns of the building. Work is generally conducted upon open bench tops and special containment equipment is not required or generally used. Laboratory personnel have

specific training in the procedures conducted in the laboratory and are supervised by personnel with general training in laboratory science. Level I practices, safety equipment and facilities are those appropriate for undergraduate and secondary educational training and teaching laboratories and for other facilities working with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans or not known to colonize in humans.

Note however, that many agents not ordinarily associated with disease processes or colonization in humans are opportunistic pathogens and may cause infection for the young, the aged and for immuno-suppressed or immuno-incompetent individuals. Live vaccine strains which have undergone multiple passages should not be considered avirulent.

Including the minimally required standard laboratory practices and facility design, it is strongly recommended that individuals wear a laboratory coat, gown or uniform when participating in Level 1 experiments. Further, contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable container which is sealed before leaving the lab.

Special containment equipment is generally not required for manipulations of agents assigned to Biosafety Level 1.

2. Biosafety Level 2

Biosafety Level 2 is similar to Level 1 and is suitable for experiments involving agents of moderate potential hazard to personnel and the environment. It differs in that laboratory personnel have specific training in handling pathogenic agents, access to the laboratory is limited when experiments are being conducted and that procedures involving large volumes or high concentrations are conducted in BSCs or other physical containment equipment. Level 2 practices, equipment and facilities are those which are applicable to clinical, diagnostic, teaching and other facilities working with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. [The Hepatitis agents (Hepatitis A, Hepatitis B, Hepatitis non A-non B), the Salmonellae, and Toxoplasma spp, are representative of micro-organisms assigned to this containment level.] Primary hazards to personnel working with these agents relate to accidental auto-inoculation or ingestion of infectious materials. Procedures with high aerosol potential may predictably and significantly increase the risk of exposure and must be conducted in primary containment equipment or devices.

Special Practices

a. Laboratory coasts, gowns or uniforms must be worn in the laboratory but must NOT be worn in non-laboratory areas when soiled or contaminated.
b. Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in durable, leak proof containers which are sealed before being removed from the laboratory.
c. The laboratory supervisor will assure that only persons who have been advised of the potential hazard and met any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.

d. When infectious materials or infected animals are present in the laboratory or animal rooms, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors and on other items (i.e. equipment, containers, materials) as appropriate to indicate the presence of viable infectious agents.

Illustration 1: Biohazard Warning Sign

BIOHAZARD

ADMITTANCE TO AUTHORIZED PERSONNEL ONLY

Biosafety Level: _____
Responsible Investigator: _____
In case of emergency call: _____
Daytime phone: _____Home phone: _____
Authorization for entrance must be obtained from the Responsible Investigator.

e. Access to the Laboratory is limited by the laboratory supervisor or PI when experiments are being conducted. In general, persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. Persons at increased risk may include children, pregnant women and individuals who are immunodeficient or immunosuppressed. The lab manager or lab supervisor has the final responsibility for assessing each individual circumstance and determining who may enter or work in the laboratory.
f. Animals not involved in the experiment being performed are not permitted in the lab.
g. The use of hypodermic needles and syringes is restricted to gavage, parental injection and aspiration of fluids from laboratory animals and diaphragm vaccine bottles. Hypodermic needles and syringes are not used as a substitute for automatic pipetting devices in the manipulation of infectious fluids. Serial dilutions of infectious agents should not be done in diaphragm bottles with needles and syringes because of the hazards of autoinoculation and of aerosol exposure. Cannulas should be used instead of sharp needles whenever possible.
h. If activities of lesser biohazard potential are conducted in the laboratory concurrently with activities requiring Biosafety Level 2, all activities will be conducted at Biosafety Level 2.
i. Gloves should be worn for all procedures requiring the handling of infectious materials or infected animals.
j. All spills, accidents and overt or potential exposures to infectious materials must be immediately reported to the laboratory supervisor. A written record must be prepared and maintained. Appropriate medical evaluation, surveillance and treatment must be provided.

k. Safety or operational instructions which identify known and potential hazards and which specify practices and procedures to minimize or eliminate such risks should be prepared or adopted as necessary. Personnel must be advised of special hazards and are required to read and follow standard practices and procedures.

Containment Equipment

Biological safety cabinets (Class I, II, or III) or other appropriate personal protective or physical containment devices are used whenever:

a. Procedures with a high potential for creating aerosols are conducted. These may include centrifugation, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient, intranasal inoculation of animals and harvesting infected tissue from animals or eggs.
b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

Laboratory Facility

It is recommended that to use plastic-backed absorbent toweling over a bench top work surface.

3. Biosafety Level 3

Biosafety Level 3 is suitable for experiments involving agents of high potential risk to personnel and the environment. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. Access to the laboratory is controlled by the lab supervisor or PI. The laboratory has special engineering and design features and physical containment equipment and devices. All procedures involving the manipulation of infectious material are conducted within biological safety cabinets or other containment devices or by personnel wearing appropriate personal protective clothing. Level three practices, safety equipment and facilities are those which are applicable to clinical, diagnostic, teaching, research or production facilities working with indigenous or exotic agents which may cause serious and potentially lethal infections.

If activities of lesser biohazard potential are conducted in the laboratory concurrently with activities requiring Biosafety Level 3, all work will be conducted at Biosafety Level 3.

Special Practices

a. Laboratory clothing that protects street clothing (i.e. solid front or wrap-around gowns, scrub suits, coveralls, etc.) must be worn in the laboratory. FRONT- BUTTON

LABORATORY COATS ARE UNSUITABLE. Laboratory clothing is not to be worn outside of the laboratory and must be decontaminated before being laundered.

b. All contaminated materials shall be decontaminated within the generating laboratory.
c. The laboratory supervisor or PI will assure that only persons, who have been advised of the potential biohazard, meet any specific entry requirements (e.g., immunization) and comply with all entry and exit procedures may enter the laboratory or animal room.
d. When infectious materials or infected animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors and on other items (i.e., equipment, containers, materials) as appropriate to indicate the presence of viable infectious agents.
e. Access to the laboratory is controlled by the laboratory supervisor or PI and is restricted to persons whose presence is required for program or support needs. Persons, who are at increased risk if acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. Persons at increased risk may include children, pregnant women and individuals who are immunodeficient or immunosuppressed. The lab supervisor or PI has the final responsibility for assessing each individual circumstance and determining who may enter or work in the laboratory.
f. Animals and plants not related to the experiment being conducted are not permitted in the laboratory.
g. The use of hypodermic needles is restricted to gavage, parenteral injection and aspiration of fluids from lab animals and diaphragm vaccine bottles. Hypodermic syringes are not used as a substitute for automatic pipetting devices in the manipulation of infectious fluids. Serial dilutions of infectious agents should not be done in diaphragm bottles with syringes due to the potential for autoinoculation and aerosol exposure.
h. Gloves worn when handling infectious materials or animals should be aseptically removed and autoclaved with other laboratory wastes before being disposed of.
i. All spills, accidents and overt or potential exposures to infectious materials must be immediately reported to the laboratory supervisor. A written report must be prepared and maintained. Appropriate medical evaluation, surveillance and treatment must be provided.
j. Safety or operational instructions which identify known and potential hazards and which specify practices and procedures to minimize or eliminate such risks should be prepared or adopted. Personnel should be advised of special hazards and must read and follow required practices and procedures.
k. Molded surgical masks or respirators are worn in rooms containing infected animals.
l. All activities involving infectious materials are conducted in biological safety cabinets or other physical containment devices. No work in open vessels is conducted on the open bench.
m. The work surfaces of biological safety cabinets and other containment equipment are decontaminated when an experiment is finished. The use of plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets facilitates clean up following the completion of activities.
n. Baseline serum samples should be collected and stored for all laboratory and other at-risk personnel. Additional serum specimens must be collected in cases of known or suspected exposure.

Biosafety Equipment

Biological safety cabinets or other physical containment equipment for devices are used for all procedures and manipulations involving infectious material.

Laboratory Facilities

The following additional precautions should be taken in laboratories with experiments designated as Biosafety Level 3:

a. The surfaces of walls, floors and ceilings are water resistant and can be easily cleaned. Openings in these surfaces are sealed or capable of being sealed to facilitate decontaminating the area.
c. A foot or elbow-operated hand washing sink is provided near each laboratory exit door.

d. Windows in the laboratory are closed and sealed.
e. An autoclave for decontamination of laboratory wastes is available within the laboratory. Infectious wastes which must be removed to another area in the same building for decontamination must be held and transported in a covered, leak proof container.
f. The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Separation is provided by either a double-door change room and shower or an airlock or other access facility which requires passage through two sets of doors to enter the laboratory. Access to the laboratory area is designed to prevent entrance of free-living arthropods.
g. Access doors to the laboratory are self closing and locking.
h. An exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry area. The building exhaust system can be used for this purpose if the exhaust air is not recirculated to any other area of the building. Personnel must verify that proper directional airflow (into the laboratory) is achieved. However, air within the laboratory can be recirculated. The exhaust air from the laboratory is discharged directly to the outside or through the building exhaust system so that it is dispersed away from occupied buildings and air intakes. The exhaust air from the laboratory that does not come from the biological safety cabinet can be discharged to the outside without being treated.
i. In laboratories which have supply air systems, the supply air and exhaust air systems are interlocked to assure inward airflow at all times
j. The HEPA-filtered exhaust air from Class I or Class II biological safety cabinets should be discharged directly to the outside or through the building exhaust system. Air may be recirculated within the laboratory only after it has been filtered through tested and certified cabinet exhaust HEPA filters. Exhaust air from Class III biological safety cabinets is to be discharged to the outside through a building exhaust air system. It is recommended that these cabinets be connected to this system to avoid any interference with the air balance of the cabinet or building exhaust system.
k. Biological safety cabinets must be certified yearly.

6.3 Animal Specifications

Ideally, facilities for laboratory animals used for studies of infectious or noninfectious disease should be physically separated from other activities such as animal production and quarantine, clinical laboratories and especially from facilities that provide patient care. Animal facilities should be designed and constructed to facilitate cleaning and housekeeping. A "clean corridor/dirty corridor" layout is very useful in reducing cross contamination. Floor drains should be installed in animal facilities only on the basis of clearly defined needs. If floor drains are installed, the drain trap should always contain water. This section describes three combinations of practices, safety equipment and facilities for experiments on animals infected with agents which produce or may produce human infection. These combinations provide increasing levels of protection to personnel and to the environment and are recommended as minimal standards for activities involving infected laboratory mammals.

The minimum standard practices for activities involving infected laboratory animals include, but is not limited to the following:

a. Doors to animal rooms are to be self-closing and are kept closed when experiments are in progress.
b. Work surfaces are decontaminated following use or spills of viable materials.
c. Eating, drinking, smoking and storing food are not permitted in animal rooms.
d. Personnel shall wash their hands after handling viable cultures and animals and before leaving the animal room.
e. All procedures are carefully conducted to minimize the creation of aerosols.
f. An insect and rodent control program is in effect.

Additionally, minimum design features include, but is not limited to, the following:

a. The animal facility shall be designed and constructed to facilitate cleaning and housekeeping.
b. A hand washing sink shall be available in the room where infected animals are housed.
c. If the animal facility has windows that open, they shall be fitted with screens.
d. It is recommended, but not required that the animal facility be provided with inward directional airflow and that exhaust air be discharged to the outside without being recirculated to other rooms.

The minimum standards apply to all animal biosafety levels.

1. Animal Biosafety Level 1

Special Practices

Bedding materials from cages used for animals infected with agents transmissible to humans are decontaminated--preferably by autoclaving--before being discarded. Cages used for animals

infected with agents transmissible to humans are washed and/or rinsed with water, heated to at least 180ºF for at least 20 minutes.

The wearing of laboratory coats, gowns or uniforms in the animal room is recommended. It is further recommended that laboratory coats worn in the animal room not be worn in other areas.

Biosafety Equipment

Special containment equipment is generally not required for animals infected with agents assigned to Biosafety Level 1.

2. Animal Biosafety Level 2

Special Practices

a. Cages shall be autoclaved before bedding is removed and before they are cleaned and washed.
b. Laboratory coats, gowns or uniforms shall be worn in the animal room but must not be worn elsewhere.
c. Surgical-type masks shall be worn by all personnel entering animal rooms housing nonhuman primates.
d. Access to the animal room is restricted by the laboratory or animal facility supervisor to personnel who have been advised of the potential hazard and who need to enter on an approved basis when experiments are in progress. In general, persons who may be at increased risk of acquiring infection or for whom infection might be unusually hazardous are not allowed in the animal room. Persons at increased risk may include children, pregnant women and individuals who are immunodeficient or immunosuppressed. The lab supervisor or PI has the final responsibility for assessing individual circumstances and determining who may enter or work in the animal room.
e The laboratory supervisor will assure that only persons who have been advised of the potential hazard and meet any specific requirements (e.g., immunization) may enter the animal room.
f. Hazard warning signs, incorporating the universal biohazard warning symbol are posted on access doors to animal rooms when materials containing or animals infected with agents assigned to Biosafety Level 2 or higher are present. The hazard warning sign should identify agent(s) in use, list the name of the laboratory supervisor or other responsible person(s) and indicate any special conditions for entry into the animal room (e.g., immunization, respirators).
g. Gloves are worn by personnel handling animals when the hazard of contact infection exists. Forceps should be used when handling and inoculating small laboratory animals to further reduce exposures of personnel to bites, scratches or unnecessary contact with infected animals.
h. All waste from the animal rooms is appropriately decontaminated-- preferably by autoclaving--before being disposed of. Infected animal carcasses are autoclaved before being disposed of in sealed, leak proof containers.

i. The use of hypodermic needles and syringes is restricted to gavage, parenteral injection or aspiration of fluids from laboratory animals and diaphragm bottles. Serial dilutions of infectious agents should not be done in diaphragm bottles with needles and syringes because of the hazards of autoinoculation and of aerosol exposure. Canulas should be used instead of sharp needles whenever possible.
j. If floor drains are provided, the drain trap is always filled with water.

Containment Equipment

Biological safety cabinets, other physical containment devices and/or personal protective devices (e.g. respirators, face shields) are used whenever procedures with a high potential for creating aerosols are conducted. These may include necropsy of infected animals, harvesting of infected tissues or fluids from animals or eggs, intranasal inoculation of animals and manipulations of high concentrations or large volumes of infectious materials.

Animal Facilities

In addition to minimal requirements, an autoclave to decontaminate infectious waste should be available in the same building with the animal facility.

3. Animal Biosafety Level 3

Special Practices

a. Cages are autoclaved before bedding is removed and before they are cleaned and washed.
b. Warp-around or solid-front gowns or uniforms are worn by personnel entering the animal room. Front-button laboratory coats are unsuitable. Protective gowns must remain in the animal room and must be decontaminated before being laundered.
c. Surgical-type masks or other respiratory protection devices are worn by personnel entering rooms housing animals infected with agents assigned to Biosafety Level 3.
d. Access to the animal room is restricted by the supervisor or other responsible person to personnel who have been advised of the potential hazard and who need to enter on a program or service basis when experiments are in progress In general, persons who may be at increased risk of acquiring infection or for whom infection might be unusually hazardous are not allowed in the animal room. Persons at increased risk may include children, pregnant women and individuals who are immunodeficient or immunosuppressed. Supervisor or other responsible person has the final responsibility for assessing individual circumstances and determining who may enter or work in the animal room.
e. The laboratory supervisor or other responsible person will assure that only persons who have been advised of the potential hazard and meet any specific requirements (e.g. immunization) may enter the animal room.
f. Hazard warning signs, incorporating the universal biohazard warning symbol are posted on access doors to animal rooms when materials containing, or animals infected with, agents assigned to Biosafety Level 2 or higher are present. The hazard warning sign should identify the agent(s) in use, list the name of the animal room supervisor or other

responsible person (s) and indicate any special conditions of entry into the animal room (e.g. immunizations, respirators).

g. Gloves are worn by personnel when handling infectious agents and animals. Gloves should be removed aseptically and autoclaved with other animal room wastes before being disposed of or reused.
h. All wastes from the animal room are autoclaved before being disposed of. All animal carcasses are disposed of as biohazardous waste.
i. The use of hypodermic needles and syringes is restricted to gavage, parenteral injection or aspiration of fluids from laboratory animals and diaphragm bottles. Serial dilutions of infected agents should not be done in diaphragm bottles with needles and syringes because of the hazards of autoinoculation and of aerosol exposure. Cannulas should be used instead of sharp needles whenever possible.
j. If floor drains are provided, the drain trap is always filled with water.
k. If vacuum lines are provided, they shall be protected with HEPA filters and liquid traps.
l. Boots, shoe covers or other protective footwear and disinfectant foot baths are provided and used when indicated.

3.2. Biosafety Equipment

a. Personal protective clothing and equipment or other physical containment devices are used for all procedures and manipulations of infectious materials or infected animals.
b. Infected laboratory animals are housed in partial containment caging systems such as open cages place in ventilated enclosures, solid wall and bottom cages covered by filter bonnets or other equivalent primary containment systems.

3.3. Animal Facilities

a. The animal facility should be designed and constructed to facilitate cleaning and housekeeping and should be separated from areas which are open to unrestricted personnel traffic within the building. Separation shall be provided by an airlock or other access device which requires passage through two sets of doors to gain access to the animal room by a double door change room and shower.
b. A foot- or elbow-operated hand washing sink is provided near each animal room exit door.
c. Windows in the animal room are closed and sealed.
d. The animal room is provided with a ventilation system which creates an inward directional flow of air and assures that exhaust air is discharged directly to the outside or through the building exhaust system without being recirculated to any other area of the facility. Air within the animal room may be recirculated.
e. An autoclave for decontamination of wastes is available within the animal room or animal facility. Materials to be autoclaved outside the animal room are transported in a covered leak proof container.
f. The surface, of walls, floors and ceilings are water resistant and easily cleaned. Openings in these surfaces are sealed or capable of being sealed to facilitate fumigation or space decontamination.

g. In animal facilities which have supply air systems, the supply air and exhaust air systems are electrically or mechanically interlocked to assure inward air-flow at all times.
h. The exhaust air from Class I or Class II biological safety cabinets can only be recirculated within the animal room after appropriate filtration through tested and certified cabinet exhaust HEPA filters.
i. Biological safety cabinets must be certified yearly.

Section 7:Engineering and Work Practice Controls

Engineering, work practice controls, and personal protective equipment, as outlined in this Biological Safety Plan will be used to eliminate or reduce employee exposure to Bloodborne Pathogens hazards.

The Biological Safety Plan will be reviewed and updated at least annually, and when necessary to reflex new or modified tasks and procedures, and to reflect new or revised employee positions that affect occupational exposure. The review will also document the consideration and implementation of changes in technology and safer needle devices that reduce or eliminate exposure.

The PI or supervisor is responsible for the implementation and development of site-specific procedures and policies, and the annual review and update of each laboratory Plan.

The Office of Environmental Health and Safety is available to assist with the development of the exposure control plan, employee training and other consultative roles as related to the OSHA standard.

7.1 Universal / Standard Precautions

Universal (or what is now often referred to as Standard Precautions) is a simple approach to infection control and will be used with all blood or other potentially infectious materials (OPIM). Universal Precautions were developed by the Centers for Disease Control to help prevent the transmission of Bloodborne diseases in the work place. Under these precautions, all human blood, human body fluids, secretions and excretions, and other potentially infectious materials (OPIM) are considered infectious for HIV, HBV, HCV and other Bloodborne diseases. Therefore, all human blood and OPIM are treated as though they are infectious and precautions are taken accordingly.

OPIM includes the following:

- Body fluids-semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead)
- Blood products and blood components, albumin, factors 8 and 9, immune globulin
- Human cells or tissue cultures, and HIV or HBV containing culture medium or other solutions,
- Blood, organs and other tissues from experimental animals infected with Bloodborne pathogens or OPIM
- Human cells, cell lines, cell strains, tissue cultures, cell media,
- Non-human primate cells, cell lines, cell strains, tissue cultures, cell media

7.2 Work Practice Controls

Work practice controls are physical or mechanical means of isolating or removing Bloodborne hazards from the work area. Engineering and work practice controls are used to eliminate or minimize exposure to employees. Where occupational exposure remains after institution of these controls, personal protective equipment will be used.

1. Handwashing

NSU provides readily accessible hand washing facilities in areas where blood or other potentially infectious materials are handled. Hands and other body surfaces shall be washed immediately and thoroughly if contaminated with blood or other body fluids.

a. After removal of personal protective gloves, employees shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water.
b. When hand washing facilities are not immediately available, NSU will provide either antiseptic cleanser in conjunction with clean cloth/paper towels, antiseptic towelettes, or waterless disinfectant such as alcohol based gels. If these alternatives are used, then the employees shall wash their hands with soap and running water as soon as feasible. More information on hand washing can be found on the CDC website at www.cdc.gov/handhygiene

2. Sharps Injury Prevention

NSU employees and students shall take precautions to prevent injuries during the use or disposal of needles, scalpels, broken glass, dental wires and other sharp instruments.

a. To prevent needle stick injuries, needles shall not be recapped / resheathed by hand, purposely bent or broken by hand, clipped, sheared, removed from disposable syringes, or otherwise, manipulated by hand. Used needles shall not be removed from disposable syringes, unless no feasible alternative can be demonstrated. In these instances where non-disposable syringes are used, needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

b. Used, disposable syringes with needles, needles from evacuated blood collection systems, scalpel blades, and other sharp items shall be placed in puncture-resistant containers for disposal; the puncture-resistant containers shall be located as close as practical to the work area. Large-bore reusable needles shall be placed in a puncture-resistant container for transport to the reprocessing area.

c. Broken glassware, which may be contaminated, shall not be picked up directly with the hands. It shall be picked up using mechanical means such as a brush and dustpan, tongs, cotton swabs or forceps.
d. Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are closeable, puncture resistant, leak proof on sides and bottom and labeled or color coded. Sharps disposal containers should be examined weekly to ensure proper function.

e. During use, containers for contaminated sharps shall be: easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries); maintained upright throughout use; and replaced routinely and not be allowed to overfill. **Fill only ¾ full prior to closing container.** All containers will have an open closing mechanism until such time as the container can be closed out and disposed of.
f. When moving containers of contaminated sharps from the area of use, the containers shall be: Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport or shipping; placed in a secondary container if leakage is possible. The second container shall be closeable; constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and labeled or color coded.
g. Once sharps containers containing contaminated waste have been closed, they should be placed in a medical waste box for disposal.
h. A guide for the proper selection and use of sharps containers can be found at the following website:

http://www.cdc.gov/niosh/sharps3.html

3. Food and Drink

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses is prohibited in areas where there is reasonable likelihood persons will be subjected to occupational exposure. Food and drink shall not be stored in refrigerators, freezers, or cabinets where blood or other potentially infectious materials are stored or in other areas of possible contamination.

4. Specimen Handling and Processing

All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, and aerosolization of these substances.

a. Mouth pipetting/suctioning is prohibited.
b. When working with open specimen containers, or a risk of aerosolization, spraying or splashing is present (such as when removing or replacing specimen containers toppers or snap lids), facial mucous membrane protection shall be used.

i. Perform these procedures in a Class I, II, or III, biological safety cabinet whenever possible.
ii. Use gauze or absorbent tissues to minimize spraying when opening potentially infectious specimen tube tops.

c. Specimens of blood or other potentially infectious materials shall be placed in a closeable, leak-resistant container that is appropriately labeled prior to being stored or transported. Each individual specimen container need not be labeled with the biohazard symbol or color coded as long as it is recognizable as a specimen, and standard or universal precautions are in effect within the immediate processing area.
   i. If outside contamination of the primary container is likely, then a second leak-resistant container that is labeled shall be placed over the outside of the first and closed to prevent leakage during handling, processing, storage, or transport.
   ii. If puncture of the primary container is likely, it shall be placed within a leak-resistant, puncture-resistant secondary container.
d. Centrifuges will have closable lids and rotor specimen cups must have lids to prevent aerosolization during centrifugation.

5. Housekeeping

Proper and routine cleaning and decontamination of work areas is an integral part of preventing environmental transmission of Bloodborne pathogens. The Principal Investigator or supervisor will ensure work areas will be maintained in a clean and sanitary condition.

Work surfaces and equipment will be cleaned and decontaminated at the completion of procedures, as soon as possible after contact with blood or OPIM, and at the end of the work shift if they may have been contaminated during the shift. Additionally, a written schedule for cleaning and methods of decontamination based on the location, type of surface to be cleaned, type of soil present, and the tasks or procedures done in the area will be maintained.

1. Appropriate Disinfectant

Cleaning of contaminated work surfaces after completion of procedures is required to ensure that employees are not unwittingly exposed to blood or OPIM remaining on a surface. Appropriate disinfectants include a diluted bleach solution and EPA registered tuberculocides (List B), and products registered against HIV/HBV (List D). OSHA Instruction CPL 2-2.69 (Nov. 19, 2001) does not include 70% alcohol among "appropriate disinfectants" and thus, it may not be used as the sole disinfectant.

Under this standard, OSHA has interpreted that, to decontaminate contaminated work surfaces, either an EPA-registered tuberculocidal disinfectant or an EPA-registered disinfectant labeled as effective against human immunodeficiency virus (HIV) and hepatitis B virus (HBV) is appropriate. Disinfectants with such HIV and HBV claims can be used, provided surfaces are not contaminated with agents or concentration of agents for which higher level (i.e., intermediate-level) disinfection is recommended. In addition, as with all disinfectants, effectiveness is governed by strict adherence to the label instructions for intended use of the product.

The lists of the EPA Registered products are available from the EPA Website. The EPA list contains the primary registrants' products only. The same formulation is frequently repackaged and renamed and distributed by other companies. These renamed products will not appear on the list, but their EPA Registration number must appear on the label.

The following is just a sample of some commercially available disinfectants, and is not meant to be a comprehensive list.

- Bleach (Clorox) Solution (5.25% available chlorine in a 1/10 or 1/100 dilution in water)
- CiDecon Detergent Disinfectant (Decon Laboratories, Inc.)
- BDD Backdown (Decon Laboratories)
- Cavicide (Metex Research Corp.)
- Process NPD (Steris Corp.)
- Sani-Cloth (PDI)
- Dispatch Hospital Cleaner Disinfectant (Caltech Industries)
- Amphyl (Reckitt Benckiser)
- Envirocide (Metex Research Corp.)

Any of the above mentioned products are considered effective when used according to the manufacturer's instructions provided the surfaces have not become contaminated with agents or volumes of concentrated agents for which a higher level of disinfection is recommended.

7.3 Personal Protective Equipment

Multidisciplinary clinical and research procedures conducted at NSU requires that personal protective equipment (protective clothing and safety apparatus/equipment) be used to protect the employee, students and researchers from contact with infectious, toxic and corrosive agents, excessive heat, cold, fire and other physical hazards. Suitable Personal Protective Equipment (PPE) also protects the experiment from contamination. The extent and kind of clothing and equipment to be selected for any particular activity depends upon the clinical and research operations and levels of risk associated with the procedure. While PPE is an important component of any biological safety plan, PPE is used with the understanding that PPE serves as a second line of defense. Good laboratory techniques, procedures and appropriate laboratory equipment are the primary barriers against potential exposure to hazardous agents.

For additional information you are urged to consult the Biosafety Officer. In the event the Biosafety Officer does not have a listing of the kind of protective devices you are seeking, contact the EHS.

1. Laboratory Clothing

A commonly used PPE item within the laboratory is special clothing. Both reusable and disposable clothing is available. Whichever is used, it must be durable, designed to provide protection and prevent exposure of the skin to harmful agents, as well as be compatible with the methods of decontamination employed.

Laboratory clothing serves to protect the wearer, the experiment, and environment against contamination. If proper precautions are not taken, contaminated clothing may carry infectious materials outside the laboratory and into other work areas, cafeterias, or the home. Infectious agents can remain viable on cotton and wool fabrics and be disseminated from these fabrics.

Some additional points:

a. Overt exposure to agents at all level of risk should be followed by immediate decontamination of the PPE and change into clean PPE to protect the worker, the experiments and the environment.
b. Provisions should be made for PPE to be provided to visitors and maintenance or security personnel, if applicable.
c. PPE worn within the laboratory should not be worn outside the facility to the library, cafeteria, or other places accessible to the public.
d. Personnel should be encouraged to use disposable facial tissues instead of personal handkerchiefs.
e. PPE should be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.
f. All PPE should be decontaminated before being sent to the laundry or discarded. Treat contaminated areas of PPE with an appropriate disinfectant. Lab coats with extensive contamination may be placed in a biohazard bag and autoclaved.
g. Do not take PPE home to launder; select a laundry service that follows universal precautions.
h. Change PPE as soon as feasible whenever it is compromised, soiled or torn.
i. Wear appropriate sizes and keep an adequate supply of PPE available in the laboratory.
j. Wash hands whenever PPE is removed.
k. Do not touch door handles, elevator buttons, telephones, computers or other clean surfaces or items with gloved hands.
l. Wear closed-toe shoes and long pants to guard against skin contamination or chemical exposure. Do not wear sandals or shorts in the laboratory.

2. Gloves

Gloves should be comfortable and of sufficient length to prevent exposure of the wrist and forearm. Depending upon intended use, the composition and design of the glove may vary to provide the desired level of flexibility, strength, impermeability, and resistance to penetration by sharp objects, as well as protection against heat and cold. Quality assurance is an important consideration. No one glove can be expected to be satisfactory for all intended uses. Gloves may be fabricated of cloth, leather, natural and synthetic rubbers, or plastics.

New formulations of synthetic rubber and plastic continue to be developed as research makes varied and changing demands on the protective capabilities of gloves. Changing applications lead to improved capabilities of impermeability, strength, flexibility, tactile sense and control. Within even the modest laboratory, the glove applications may be such that no less than four or five types of protective gloves need to be stocked and used.

Disposable (single use) gloves provide a barrier between infectious agents and the skin. Glove use is a basic precept of preventing infectious agent transmission. Breaks in the skin barrier of the hand (damaged cuticles, scrapes, micro-cuts, dermatitis, etc.) are common.

EHS can provide information on gloves needed for various tasks, such as working with animals, dry ice, heat, acids, etc. See Appendix C: Glove Selection Chart.

Considerations for the selection and use of gloves:

a. Gloves are not 100% leak proof; change gloves periodically and when soiled and always wash hands after removing gloves or other PPE.
b. Gloves will not prevent needle sticks or other puncture injuries.
c. Check gloves for visible tears before use.
d. Avoid wetting examination gloves as water or disinfectants will encourage wicking and leaking.
e. Do not reuse examination gloves; discard contaminated gloves in a biohazard bag immediately after use.
f. Double glove or use household utility gloves when cleaning spills. Household utility gloves may be decontaminated and reused (replace when compromised.)

Gloves shall be removed and hands washed before exiting the laboratory. Use the one glove method, or an appropriate secondary container, when transporting materials through common use areas.

The following outlines the recommended procedure for removing gloves:

a. Grip the outside of one glove at wrist with the other gloved hand, pull glove off and gather in palm of gloved hand.
b. Place index or middle finger of the ungloved hand on wrist of gloved hand, slide finger under the glove opening and pull glove off inside out.
c. When removing PPE, remove lab coat or solid front gown first, then remove gloves (aseptically), remove face protection last to avoid touching your face with contaminated hands.
d. If wearing double gloves, remove outer gloves before removing lab coat or solid front gown.

3. Shoes

Shoes worn in the laboratory must be closed-toe. Protective shoes are required for certain work activities. When working with infectious agents it is advisable to wear shoe covers, which can be decontaminated (autoclaved) before disposal, over street shoes. For work in tissue culture laboratories it may be necessary to change from street shoes to specific laboratory shoes for protection of cultures from contamination.

In certain animal facilities, NSU requires personnel to wear overshoes to protect the animals in containment areas. Similarly, people who work with animals and do cage washing are required to wear protective shoes.

4. Gowns, Lab Coats, Jumpsuits, Aprons and Other Protective Clothing

Gowns, lab coats and jumpsuits protect the wearer's clothing and skin from contamination. As with all PPE, the type of clothing needed depends on the task being performed and the degree of exposure anticipated. Solid front wrap-around clothing offers better protection than pull-over type clothing or clothing with front closures.

Lab coats are not 100% leak proof. Change protective clothing when soiled, and always wash your hands after removal. Lab coats or other protective clothing will not prevent needle sticks or other punctures. Spills and splashes occur most often in the chest or lap area.

The contaminated surface must not be touched during removal of a front closing jacket or lab coat. The contaminated portion often ends up in the wearer's face during removal of pullover clothing. Many workers prefer not to button up front closing jackets, which leaves street clothing exposed. If front closing jackets must be worn, strict measures shall be implemented to assure the clothing is closed at all times when performing procedures or tasks that may cause exposure.

Long sleeved garments with snug fitting cuffs are preferred over open or short sleeves. Snug fitting cuffs prevent splashes, splatters and aerosols from making contact with exposed skin on the lower arms. Longer single-use gloves can be pulled over snug fitting cuffs to seal out any infectious materials.

Plastic, vinyl or rubber aprons are usually worn over other protective clothing when extra protection is desired. Aprons are necessary for protection against liquids spilling or splashing on clothing. It is recommended that appropriate aprons be worn to protect against the potential harmful effects of liquid waste. Aprons may also be used to provide protection from steam and hot water in locations such as animal handling facilities, autoclave rooms and laboratory glass-washing rooms.

Table E: Properties of Protective Clothing Materials

Materials	Properties					
	Strength	**Chemical Resistance**	**Flammability**	**Static Properties**	**Comfort**	**Uses**
Cotton	Fair durability	Degraded by acids; binds	Special treatment for flame	No static problems	Comfortable, lightweight	Lab coats
Modacrylic	Resistant to rips and tears but less so than polyamide fibers; abrasion-resistant but less so than nylon or polyester	Resistant to most chemicals	In direct flame, fabric shrinks to resist flame penetration; will not melt or drip; self-extinguishing; rapidly dissipates when source of ignition is removed	Has antistatic properties	Comfortable, soft, and resilient; easy to clean; has soil release properties	Lab coats
Nylon	Exceptionally strong and abrasion resistant	Not water absorbent	Melts when heated; requires flame retardant	Static buildup possible; requires antistatic agent	Lightweight	Lab coats
Plastic	Usually reinforced at points of strain; will not stick together, peel, crack, or stiffen	Resistant to corrosive chemicals	Can be ignited by flammable solvents and others in event of static discharge	Accumulates considerable charge of static electricity	Lightweight	Aprons, sleeve protectors, boots
Polyolefin	Resistant to rips and tears	Excellent chemical resistance; low binding for chemicals	High melting point; flame-resistant	Good static dissociation	Lightweight; good permeability; limited moisture absorbency; wearer perspiration may cause discomfort	Bouffant caps
Polypropylene	Strong	Resistant to most chemicals; oxygen and light-sensitive	Low melting point; requires flame retardant	Static buildup; requires antistatic agent	Lightweight	Aprons
Rayon	Fairly durable			Degraded by acids; binds some chemicals		Lab coats

5. Face and Eye Protection

Protection of the face and eyes is of prime importance in laboratories due to the potential for foreign material, both liquid and solid, to splash on the head, face and eyes or contact lenses. A variety of face shields, head covers/hoods, protective goggles, and lenses are available from safety supply houses. The selection is dependent upon materials of construction, fit, comfort, and compatibility with the work and the overall facial area requiring protection.

Some of the considerations for selection and use of face and eye protections are indicated below:

a. Face shields and hoods protect the face and the neck from flying particles and sprays of hazardous material; however, they do not provide basic eye protection against impacting objects.
b. Shields should cover the entire face, permit tilting back to clean the face if desired, and be easily removed in the event of an accident.
c. If an eye hazard exists in a particular operation or experiment, the soundest safety policy would be to require that eye or face protection, or both, be worn at all times by all persons entering or working in the laboratory.
d. Contact lenses do not provide eye protection. It is recommended that contact lenses not be worn when working around chemicals, fumes, and other hazardous material and dust particles since these items may become trapped in the space between the contact lens and the cornea. When contact lenses are worn, eye protection, such as tight fitting goggles, must be worn.

6. Respiratory Protection

Protection of the respiratory system is a major concern of any biological safety program because infectious organisms can readily enter the human body through the respiratory tract. The possibility of this occurring depends on the type and infectious dose of the particular organism. For some, as few as one to ten organisms, when inhaled, may cause infection. Particles with an effective aerodynamic diameter of between 0.5 and 5.0 μm (the respirable fraction) are most effective at penetration and retention in the deep pulmonary spaces. Particles larger than 5 micrometers are generally trapped in the upper respiratory tract and eventually cleared or swallowed.

Engineering controls, such as the use of biological safety cabinets, should always be considered as a first line of defense against respiratory infection when working with infectious organisms. Respirators should only be considered as a second line of defense when additional controls are determined to be needed after feasible engineering controls have been put into place. Respirators vary in design, application, and protective capability. Respirators can be placed into two categories: (1) air purifying and (2) supplied air.

By far, the most commonly used respirators in laboratories are air purifying respirators. These protect by purifying the existing breathing air through a filter (for particulates) or cartridge (for gases and vapors). Standard air purifying respirators are ½ mask, full face, or powered air purifying respirators (PAPR). Air purifying respirators are to be set on the proper cartridge selection to filter out the contaminant. Dust masks that have been approved by NIOSH are also considered to be air purifying respirators. These are ranked by their filtering efficiencies and by whether they can be used in an environment containing oil aerosols.

Approved dust masks will have one of the following designations – N95, N99, N100, R95, R99, R100, P95, P99, or P100. Proper selection of cartridges and respirators is very important and should not be made without input from EHS. New regulations concerning respirators require initial and annual training and fit-testing, and well as medical surveillance of all respirator wearers.

Please make sure that EHS is notified whenever the use of a respirator is being considered. The Safety Officer Respirator Administrator can assist in evaluating the procedure, selecting the proper respirator, and provide the required training and fit testing. The Employee Health Officer must also be notified so that medical surveillance and clearance can be issued prior to wearing the respirator.

7. Selection of PPE

Use the following PPE to minimize exposure via mucous membrane OR non-intact skin:

a. For face protection, wear safety glasses and a mask, or a chin length face shield whenever splashing, splattering or droplets may be anticipated (any work with liquids on the open bench). An impact resistant face shield should be used when operating the autoclave. Impact resistant face shields will protect the user's face against splatters of hot liquids or broken glass fragments.
b. Gloves and a lab coat are worn to protect the skin and clothing from contact with potentially infectious materials. Wear gloves that are long enough to extend over the sleeves of the lab coat and cover wrists. Consider double gloving when working with cultures of infectious agents or handling spills. Thicker household utility gloves can be worn for cleaning blood or BL2 spills. Utility gloves can be decontaminated and reused until the integrity of the glove is compromised. Temperature resistant gloves should be worn to protect hands from physical damage when working with very hot (autoclave) or cold (liquid nitrogen tank, -70°C freezer) materials.
c. Sleeve covers are worn over lab coat and gown sleeves to provide protection to the sleeves and wrists from contamination when working in the biological safety cabinet. Disposable sleeve covers have tight fitting grips at both ends.
d. Waterproof bandages are worn to cover any wounds or non-intact skin before gloving. It is preferred to double glove when skin is damaged or non-intact. Inform your supervisor of any severe skin conditions or wounds. Avoid working with BL2, BL3 or other potentially infectious materials if non-intact skin cannot be adequately covered.
e. Solid front gowns provide more protection to clothing and skin than lab coats. Solid front gowns are worn for high hazard infectious agent work. The tight fitting cuffs of the gown help to minimize wrist contamination.
f. Impervious lab coats, gowns or aprons are worn when heavy contamination or soiling is likely.
g. Head covers are worn to protect the hair and scalp from splatter or droplets when working with heavy contamination or when contact with the head is likely. When choosing a head cover make sure it is impervious to liquids (some head covers are not impervious).
h. Shoe covers are worn over the shoes to protect shoes from contamination when working in heavily contaminated areas (such as large spills, crime scenes, morgues, cadaver dissection areas, surgical operation areas).
i. Gowns, head and shoe covers also help keep contaminants from entering the sterile area in clean rooms and surgical suites.

Use the following PPE to minimize exposure via cuts, slices, or scratches:

a. Kevlar gloves and sleeves are cut resistant and will help guard against slices, scratches or cuts, but will not prevent direct puncture or needlestick injuries.
b. Steel mesh gloves also protect against slices, cuts, and scratches but will not eliminate punctures.
c. Neoprene and other abrasive resistant gloves are cut resistant, but significantly reduce dexterity.

Use the following PPE to minimize exposure via aerosols:

a. HEPA filtered respirators (air purifying or powered air purifying) are worn to prevent exposure to potentially infectious aerosols when cleaning spills of concentrated infectious material or responding to centrifuge incidents.

7.3 Biological Safety Cabinets (BSCs)

Biological Safety Cabinets (BSCs) are designed to protect the operator, the laboratory environment and work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing infectious agents, such as primary cultures, stocks and diagnostic specimens. Aerosol particles are created by any activity that imparts energy into a liquid or semi-liquid material, such as shaking, pouring, stirring or dropping liquid onto a surface or into another liquid. Other laboratory activities, such as streaking agar plates, inoculating cell culture flasks with a pipette, using a multichannel pipette to dispense liquid suspensions of infectious agents into microculture plates, homogenizing and vortexing infectious materials, and centrifugation of infectious liquids, or working with animals, can generate infectious aerosols. Aerosol particles of less than 5 microns in diameter and small droplets of 5–100 microns in diameter are not visible to the naked eye. The laboratory worker is generally not aware that such particles are being generated and may be inhaled or may cross-contaminate work surface materials. BSCs, when properly used, have been shown to be highly effective in reducing laboratory-acquired infections and cross-contaminations of cultures due to aerosol exposures. BSCs also protect the environment.

Over the years the basic design of BSCs has undergone several modifications. A major change was the addition of a high-efficiency particulate air (HEPA) filter to the exhaust system. The HEPA filter traps 99.97% of particles of 0.3 microns in diameter and 99.99% of particles of greater or smaller size. This enables the HEPA filter to effectively trap all known infectious agents and ensure that only microbe-free exhaust air is discharged from the cabinet. A second design modification was to direct HEPA-filtered air over the work surface, providing protection of work surface materials from contamination. This feature is often referred to as product protection. These basic design concepts have led to the evolution of three classes of BSCs. The type of protection provided by each BSC is described in the table below.

NOTE: HORIZONTAL AND VERTICAL OUTFLOW CABINETS ("CLEAN-AIR WORK STATIONS") ARE **NOT** BIOLOGICAL SAFETY CABINETS AND SHOULD NOT BE USED AS SUCH.

Table F: Comparison of Biosafety Cabinet Characteristics

BSC Class	Face Velocity lfpm*	Airflow Pattern	Applications	
			Nonvolatile Toxic Chemicals and Radionuclides	Volatile Toxic Chemicals and Radionuclides
I	75	In at front; exhausted through HEPA to the outside or into the room through HEPA	YES	YES
II, A1	75	70% recirculated to the cabinet work area through HEPA; 30% balance exhausted through HEPA back into the room or to the outside through a canopy unit	YES	NO
II, B1	100	30% recirculated, 70% exhausted. Exhaust cabinet air must pass through a dedicated duct to the outside through a HEPA filter	YES	YES
II, B2	100	No recirculation; total exhaust to the outside through hard-duct and a HEPA filter	YES	YES
II, A2	100	Same as II, A1, but has 100 lfpm intake air velocity and plenums are under negative pressure to room; exhaust air is can be ducted to the outside through a HEPA filter	YES	YES
III	N/A	Supply air is HEPA filtered. Exhaust air passes through two HEPA filters in series and is exhausted to the outside via a hard connection	YES	YES

* lfpm - linear feet per minute

1. Class I Biological Safety Cabinet

The figure below provides a schematic diagram of a Class I BSC. Room air is drawn in through the front opening at a minimum velocity of 0.38 m/s (~1.3 feet/s). It passes over the work surface and is discharged from the cabinet through the exhaust duct. The directional flow of air whisks aerosol particles that may be generated on the work surface away from the laboratory worker and into the exhaust duct. The front opening allows the operator's arms to reach the work surface inside the cabinet while he or she observes the work surface through a glass window sash. The window sash can also be fully raised to provide access to the work surface for cleaning or other purposes.

In a Class I BSC, the air from the cabinet is exhausted through a HEPA filter:

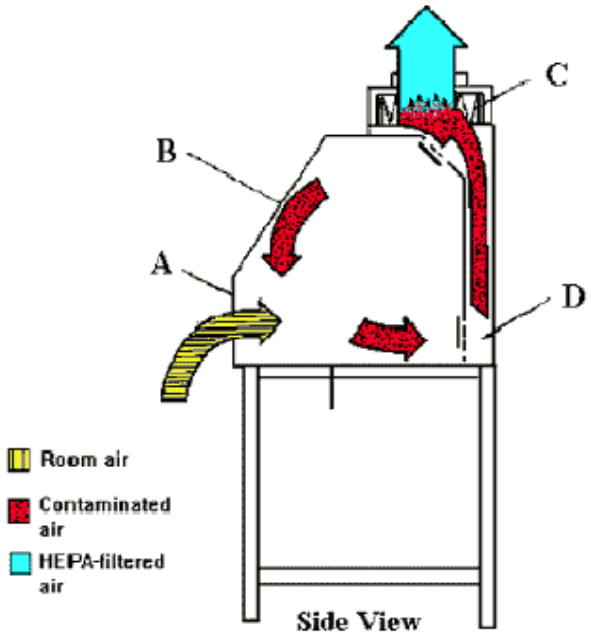
1. Into the laboratory and then to the outside of the building through the building exhaust;
2. To the outside through the building exhaust; *or*
3. Directly to the outside.

The HEPA filter may be located in the exhaust plenum of the BSC or in the building exhaust. Some Class I BSCs are equipped with an integral exhaust fan, whereas others rely on the exhaust fan in the building exhaust system.

The Class I BSC was the first recognized BSC and, because of its simple design, is still in wide use throughout the world. It has the advantage of providing personnel and environmental protection and can also be used for work with radionuclides and volatile toxic chemicals. Because unsterilized room air is drawn over the work surface through the front opening, it is not considered to provide consistently reliable product protection. The Class I BSC is mainly used today to hold equipment (centrifuge, small fermenters, harvesting equipment) or for procedures that may generate aerosols (cage dumping, culture aeration or tissue homogenization).

Illustration 3: Class I Biological Safety Cabinet

Legend
A – Front Opening C – Exhaust HEPA filter
B – Sash D – Exhaust Plenum



2. Class II Biological Safety Cabinet

As the use of cell and tissue cultures for the propagation of viruses and other purposes grew, it was no longer considered satisfactory for unsterilized room air to pass over the work surface. The Class

II BSC was designed not only to provide personnel protection but also to protect work surface materials from contaminated room air. Class II BSCs, of which there are four types (A1, A2, B1 and B2), differ from Class I BSCs by allowing only air from a HEPA-filtered (sterile) supply to flow over the work surface. The Class II BSC can be used for working with infectious agents in Risk Groups 2 and 3. Class II BSCs can be used for working with infectious agents in Risk Group 4 when positive-pressure suits are used.

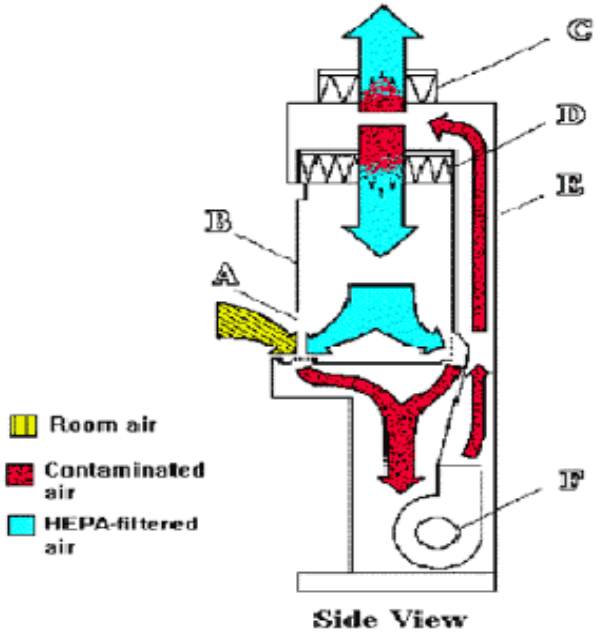
a. Class II - Type A1 biological Safety Cabinet.

For a Class II Type A1 biological safety cabinet, an internal fan draws room air (supply air) into the cabinet through the front opening and into the front intake grill. The inflow velocity of this air should be at least 0.38 m/s at the face of the front opening. The supply air then passes through a supply HEPA filter before flowing downwards over the work surface. As the air flows downwards it "splits" about 6 –18 cm (2.4 – 7 inches) from the work surface, one half of the downwards flowing air passing through the front exhaust grill, and the other half passing through the rear exhaust grill. Any aerosol particles generated at the work surface are immediately captured in this downward airflow and passed through the front or rear exhaust grills, thereby providing the highest level of product protection. The air is then discharged through the rear plenum into the space between the supply and exhaust filters located at the top of the cabinet. Owing to the relative size of these filters, about 70% of the air recirculates through the supply HEPA filter back into the work zone; the remaining 30% passes through the exhaust filter into the room or to the outside.

Air from the Class IIA1 BSC exhaust can be recirculated to the room or discharged to the outside of the building through a thimble connection to a dedicated duct or through the building exhaust system. Recirculating the exhaust air to the room has the advantage of lowering building fuel costs because heated and/or cooled air is not being passed to the outside environment. A connection to a ducted exhaust system also allows some BSCs to be used for work with volatile radionuclides and volatile toxic chemicals.

Illustration 4: Class II, Type A1 Biological Safety Cabinet

Legend:
A – Front Opening
B – Sash
C – Exhaust HEPA filter
D – Supply HEPA filter
E – Common Plenum
F - Blower



b. Class II - Type A2 vented to the outside, B1 and B2 Biological Safety Cabinet

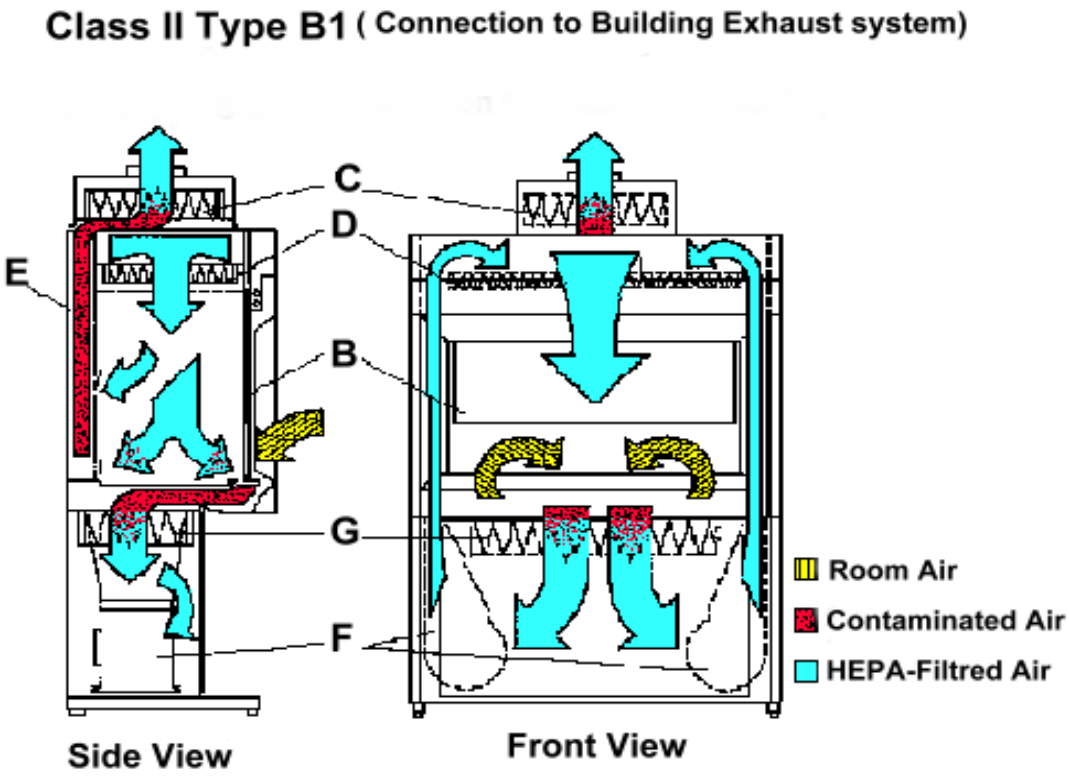
Class IIA2 vented to the outside, IIB1 and IIB2 BSCs are variations of the type IIA1. Each variation allows the BSC to be used for specialized purposes. These BSCs differ from one another in several aspects: the air intake velocity through the front opening; the amount of air recirculated over the work surface and exhausted from the cabinet; the exhaust system, which determines whether air from the cabinet is exhausted to the room, or to the outside, through a dedicated exhaust system or through the building exhaust; and the pressure arrangements (whether cabinets have biologically contaminated ducts and plenums under negative pressure, or have biological contaminated ducts and plenums surrounded by negative pressure ducts and plenums).

For Class II, Type B1 BSC, connection of the cabinet exhaust to the building exhaust air system is required.

Illustration 5: Class II, Type B1 Biological Safety Cabinet

Legend:

A – Front Opening	D – Supply HEPA filter
B – Sash	E – Negative Pressure Exhaust Plenum
C – Exhaust HEPA filter	F – Blower
	G – HEPA filter for supply air



Complete descriptions of the various Class IIA and IIB BSCs can be obtained from manufacturers' brochures and the BMBL.

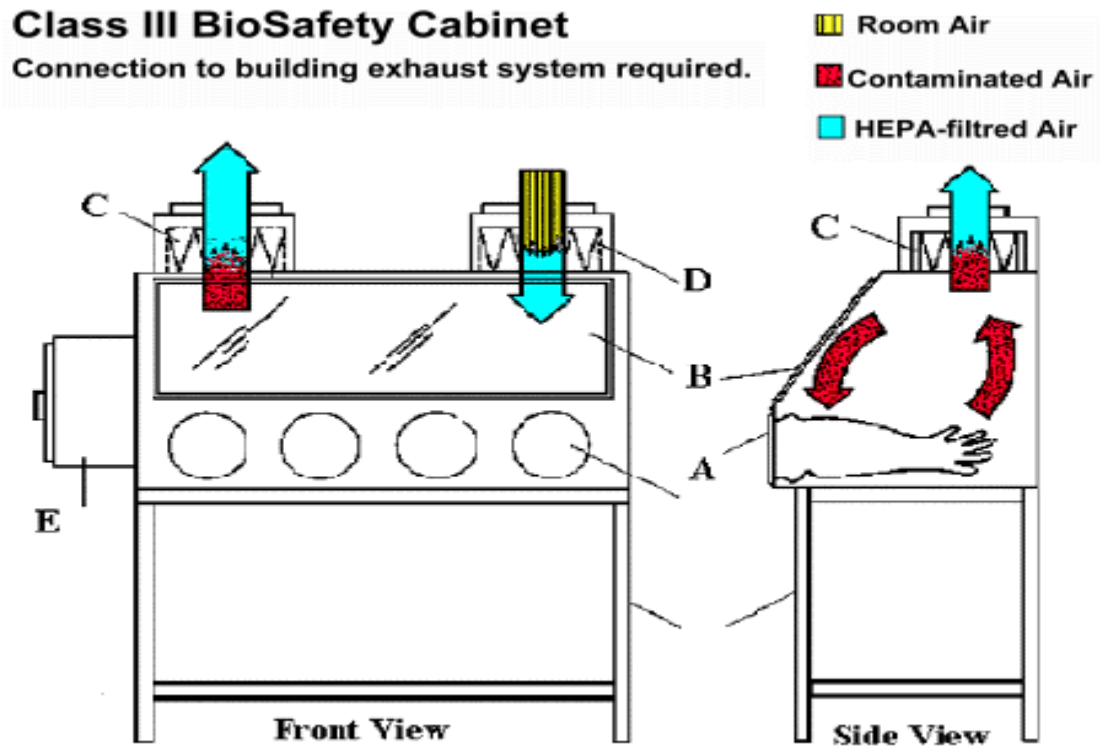
3. Class III Biological Safety Cabinet

Class III BSC provides the highest level of personnel protection and is used for Risk Group 4 agents. All penetrations are sealed "gas tight." Supply air is HEPA-filtered and exhaust air passes through two HEPA filters. Airflow is maintained by a dedicated exhaust system exterior to the cabinet, which keeps the cabinet interior under negative pressure (about 124.5 Pa). Access to the work surface is by means of heavy duty rubber gloves, which are attached to ports in the cabinet. The Class III BSC should have an attached pass-through box that can be sterilized and is equipped with a HEPA-filtered exhaust.

The Class III cabinet may be connected to a double-door autoclave used to decontaminate all materials entering or exiting the cabinet. Several glove boxes can be joined together to extend the work surface. Class III BSCs are suitable for work in Biosafety Level 3 and 4 laboratories.

Illustration 6: Class III Biological Safety Cabinet

Legend:
A – Glove ports with O-ring for attaching arm-length gloves to cabinet
B - Sash
C - Exhaust HEPA filter
D - Supply HEPA filter
E - Double ended autoclave or pass-through box.



With a Class III BSC, a chemical dunk tank may be installed which would be located beneath the work surface of the BSC with access from above. The cabinet exhaust needs to be hard connected to an independent dedicated exhaust system. The exhaust air must be double HEPA filtered or HEPA filtered and incinerated.

4. Selection of a Biological Safety Cabinet

A BSC should be selected primarily in accordance with the type of protection needed: product protection; personnel protection against Risk Group 1–4 microorganisms; personnel protection against exposure to radionuclides and volatile toxic chemicals; or a combination of these. See Table E: Comparison of Biological Safety Cabinet Characteristics above which shows which BSC is recommended for each type of protection. Refer also to this Table for those BSCs that can be used with nonvolatile and volatile or toxic chemicals.

5. Using Biological Safety Cabinet in the laboratory

a. Location

The velocity of air flowing through the front opening into a BSC is about 0.45 m/s. At this velocity the integrity of the directional air inflow is fragile and can be easily disrupted by air currents generated by people walking close to the BSC, open windows, air supply registers, and opening and shutting doors. Ideally, BSCs should be situated in a location remote from traffic and potentially disturbing air currents. Whenever possible a 30-cm (~ 1 foot) clearance should be provided behind and on each side of the cabinet to allow easy access for maintenance. A clearance of 30–35 cm above the cabinet may be required to provide for accurate air velocity measurement across the exhaust filter and for exhaust filter changes.

b. Operators

If BSCs are not used properly, their protective benefits may be greatly diminished. Operators must be careful to maintain the integrity of the front opening air inflow when moving their arms into and out of cabinets. Arms should be moved in and out slowly, perpendicular to the front opening. Manipulations of materials within BSCs should be delayed for about 1 min after placing hands and arms inside to allow the cabinet to adjust and to "air sweep" the surface of the hands and arms. The number of movements across the front opening should also be minimized by placing all necessary items into the cabinet before beginning manipulations.

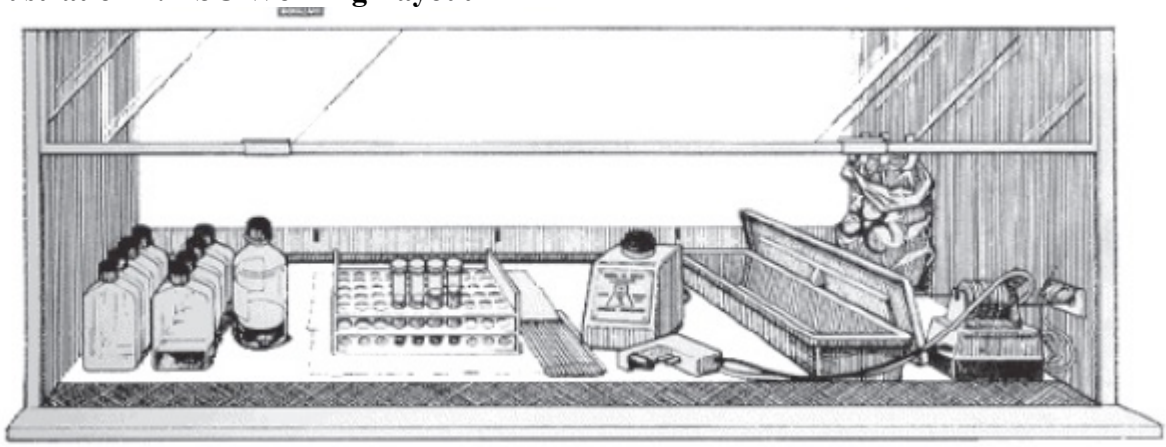
c. Material placement

The front intake grill of Class II BSCs must not be blocked with paper, equipment or other items. Materials to be placed inside the cabinet should be surface-decontaminated with 70% alcohol. Work may be performed on disinfectant-soaked absorbent towels to capture splatters and splashes. All materials should be placed as far back in the cabinet, towards the rear edge of the work surface, as practical without blocking the rear grill. Aerosol-generating equipment (e.g. mixers, centrifuges, etc.) should be placed towards the rear of the cabinet. Bulky items, such as biohazard bags, discard pipette trays and suction collection flasks should be placed to one side of the interior of the cabinet. Active work should flow from clean to contaminated areas across the work surface.

The autoclavable biohazard collection bag and pipette collection tray should not be placed outside the cabinet. The frequent in-and-out movement needed to use these containers is disruptive to the integrity of the cabinet's air barrier, and can compromise both personnel and product protection.

An example of a typical layout for working "clean to dirty" can be demonstrated for a Class II BSC. Clean cultures (left) can be inoculated (center); contaminated pipettes can be discarded in the shallow pan and other contaminated materials can be placed in the biohazard bag (right). This arrangement is reversed for left-handed persons.

Illustration 7: BSC Working Layout



6. Operation and Maintenance

Most BSCs are designed to permit operation 24 hours per day, and investigators find that continuous operation helps to control the levels of dust and particulate materials in the laboratory.

A "thimble" or "canopy hood" is designed for use with the Class IIA1 and IIA2 vented to the outside. The thimble fits over the cabinet exhaust housing, sucking the cabinet exhaust air into the building exhaust ducts. A small opening, usually 2.5 cm in diameter, is maintained between the thimble and the cabinet exhaust housing. This small opening enables room air to be sucked into the building exhaust system as well. The building exhaust capacity must be sufficient to capture both room air and the cabinet exhaust. The thimble must be removable or be designed to allow for operational testing of the cabinet. Generally, the performance of a thimble-connected BSC is not affected much by fluctuations in the airflow of the building. Class II A1 and II A2 BSCs exhausting to the room or connected by thimble connections to dedicated exhaust ducts can be turned off when not in use.

Class IIB1 and IIB2 BSCs are hard-ducted, i.e. firmly connected without any openings, to the building exhaust system or, preferably, to a dedicated exhaust duct system. The building exhaust system must be precisely matched to the airflow requirements specified by the manufacturer for both volume and static pressure. Certification of hard-duct connected BSCs is more time-consuming than that for BSCs that recirculate air to the room or which are thimble-connected. Class II B1 and II B2 BSCs must have airflow through them at all times to help maintain room air balance. Cabinets should be turned on at least 5 min before beginning work and after completion of work to allow the cabinet to "purge", i.e. to allow time for contaminated air to be removed from the cabinet environment.

All repairs made on BSCs should be made by a qualified technician. Any malfunction in the operation of the BSC should be reported and repaired before the BSC is used again.

7. Ultraviolet Lights

Ultraviolet lights are not required in BSCs. If they are used, they must be cleaned weekly to remove any dust and dirt that may block the germicidal effectiveness of the light. Ultraviolet light intensity should be checked when the cabinet is recertified to ensure that light emission is appropriate. Ultraviolet lights must be turned off while the room is occupied, to protect eyes and skin from inadvertent exposure.

8. Open Flames

Open flames should be avoided in the near microbe-free environment created inside the BSC. They disrupt the airflow patterns and can be dangerous when volatile, flammable substances are also used. To sterilize bacteriological loops, microburners or electric "furnaces" are available and are preferable to open flames.

9. Spills

A copy of the laboratory's protocol for handling spills should be posted, read and understood by everyone who uses the laboratory. When a spill of biohazardous material occurs within a BSC, clean-up should begin immediately, while the cabinet continues to operate. An effective disinfectant should be used and applied in a manner that minimizes the generation of aerosols. All materials that come into contact with the spilled agent should be disinfected and/or autoclaved.

10. Certification

The functional operation and integrity of each BSC should be certified to current performance standards at the time of installation and annually thereafter by qualified technicians, according to the manufacturer's instructions. Evaluation of the effectiveness of cabinet containment should include tests for cabinet integrity, HEPA filter leaks, down-flow velocity profile, face velocity, negative pressure/ventilation rate, air flow smoke pattern, and alarms and interlocks. Optional tests for electrical leaks, lighting intensity, ultraviolet light intensity, noise level and vibration may also be conducted. Special training, skills and equipment are required to perform these tests and it is highly recommended that they are undertaken by a qualified professional.

11. Cleaning and Disinfection

All items within BSCs, including equipment, should be surface-decontaminated and removed from the cabinet when work is completed, since residual culture media may provide an opportunity for microbial growth. The interior surfaces of BSCs should be decontaminated before and after each use. The work surfaces and interior walls should be wiped with a disinfectant that will kill any microorganisms that might be found inside the cabinet. At the end of the work day, the final surface decontamination should include a wipe-down of the work surface, the sides, back and interior of the glass. A solution of bleach or 70% alcohol should be used where effective for target organisms. A second wiping with sterile water is needed when a corrosive disinfectant, such as bleach, is used. It is recommended that the cabinet is left running.
If not, it should be run for 5 min in order to purge the atmosphere inside before it is switched off.

12. Decontamination

BSCs must be decontaminated before filter changes and before being moved. The most common decontamination methods are by fumigation with formaldehyde gas or vaporized hydrogen peroxide. BSC decontamination should be performed by a qualified professional.

13. Personal Protective Equipment

Personal protective clothing should be worn whenever using a BSC. Laboratory coats are acceptable for work being performed at Biosafety Levels 1 and 2. Gloves should be pulled over the wrists of the gown rather than worn inside. Elasticized sleeves can be worn to protect the investigator's wrists. Masks and safety glasses may be required for some procedures.

14. Alarms

BSCs can be equipped with one of two kinds of alarm. Sash alarms are found only on cabinets with sliding sashes. The alarm signifies that the operator has moved the sash to an improper position.

Corrective action for this type of alarm is returning the sash to the proper position. Airflow alarms indicate a disruption in the cabinet's normal airflow pattern. This represents an immediate danger to the operator or product. When an airflow alarm sounds, work should cease immediately and the laboratory supervisor should be notified. Manufacturers' instruction manuals should provide further details. Training in the use of BSCs should cover this aspect.

7.4 Laboratory Equipment

Since aerosols are important sources of infection, care should be taken to reduce the extent of their formation and dispersion. Hazardous aerosols can be generated by many laboratory operations such as blending, mixing, grinding, shaking, stirring, sonicating and centrifuging of infectious materials. Even when safe equipment is used, it is best to carry out these operations in an approved biological safety cabinet whenever possible. The use of safety equipment is no assurance of protection unless the operator is trained and uses proper techniques. Equipment should be tested regularly to ensure its continued safe performance.

1. Centrifugation

Accidents from improper use of centrifuges and associated equipment are less frequent than from use of pipettes, and syringes and needles. However, if they do occur, aerosols are created, and the possibility of causing multiple infections is considerably greater. Centrifuges may have been responsible for many laboratory illnesses in which causes of the accidents were categorized as "unknown".

A mechanical failure, such as a broken drive shaft, a faulty bearing, or a disintegrated rotor, can produce not only aerosols but also hazardous fragments at great velocity. These fragments, if they escape the protective bowl of the centrifuge, could produce traumatic injury to personnel. Risk of mechanical failure can be minimized by meticulous observance of the manufacturers' instructions.

Even a well-functioning centrifuge is capable of producing biohazardous aerosols. However, aerosols can be avoided by observing sound laboratory practices and using appropriate centrifuge safety equipment and containment cabinets as described below.

Centrifugation of biohazards should be:

a. performed in a centrifuge that is contained within a specially designed biological safety cabinet or
b. if no such centrifuge is available, an **aerosol containment device** must be used. Aerosol containment devices include sealed canisters which fit in the centrifuge bucket or covers for the centrifuge bucket, heat sealed tubes or sealed rotor bowls.

Activities such as filling centrifuge tubes, removing cotton plugs and rubber caps on tubes after centrifugation, removing the supernatant and re-suspending the pellet can release aerosols into the environment. Centrifuge tubes and bottles should be filled and opened in a biological safety cabinet. Do not fill tubes to the point that the rim of the closure becomes wet with culture or specimen. Special attention needs to be given when filling tubes to be placed in fixed angle centrifuge.

Screw caps, or other tight-fitting skirted caps that fit outside the rim of the centrifuge tube are safer to use than plug-in closures. Some fluid usually collects between a plug-in closure and the rim of the tube. Even screw-capped bottles are not without risk; if the rim is soiled and seals imperfectly, some fluid will escape down the outside of the tubes. Aluminum foil should never be used to cap centrifuge tubes containing toxic or biohazards because these light-weight caps often become detached or ruptured during handling and centrifuging. When centrifuging biohazards, including clinical specimens, do not use cotton plugs; instead, tight-fitting tabbed or hinged caps made of plastic or rubber, screw caps, or other tight-fitting plastic or metal closures.

The aerosol containment device must be removed from the centrifuge and opened in the biological safety cabinet. These devices often have clear tops to alert the operator to problems such as broken or leaking tubes prior to opening.

The greatest hazard associated with centrifuging biohazards is created when a **centrifuge tube breaks**. The frequency of use, maximum g-force exposure, washing, etching, abrasion, method of storage, etc., affect the life expectancy of glass centrifuge tubes and bottles.

The stresses developed during these processes are cumulative in Pyrex glass despite its excellent chemical resistance. When used with proper adapters and cushions, it can withstand moderate speeds. Corex glass has four to six times the strength of conventional glass, greater resistance to alkalies and acids, resists scratching and etching, and is unaffected by temperatures up to 300° C. In proper adapters, Corex tubes may be used at relatively high speeds. Before using glass centrifuge tubes, eliminate those with cracks, severe etching or scratches, and chipped rims. Plastic tubes and bottles resist breakage but are not indestructible. Plastic containers may begin to show

signs of deterioration after several runs as a result of the interaction of centrifugal forces, chemical effects from samples and cleaning solutions, and autoclaving cycles of heat and pressure. Deterioration may appear as crazing, cracking or spotting. Tubes showing these signs should be used only at low speeds, used as storage containers, or discarded. Some plastics are subject to chemical interaction with samples being processed. For complete specific information, the principal investigator or laboratory supervisor should refer to the material compatibility data provided by the manufacturers of centrifuge equipment.

Proper balancing of the centrifuges is important. Care must be taken to ensure that matched sets of safety devices and adapters do not become mixed. If the components are not inscribed with their weights by the manufacturer, colored stains can be applied for identification to avoid confusion. The basic concern is that the centers of gravity of the tubes are equidistant from the axis of rotation. To illustrate the importance of this, two identical tubes containing 20 g of mercury and 20 g of water, respectively, will balance perfectly on the scales; however, their performance in motion is totally different, leading to violent vibration with all its attendant hazards.

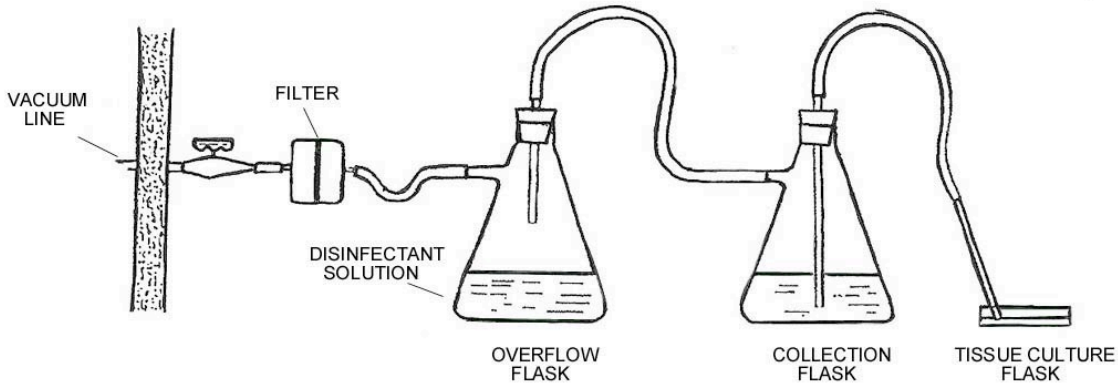
2. Vacuum Line Chemical Traps and Filters

Vacuum line chemical traps and filters prevent suction of infectious and non-infectious materials into the vacuum lines.

When using vacuum line chemical traps, be sure to add full strength chemical disinfectant to chemical trap flasks and allow the aspirated fluids to complete the dilution. (For example: Start with 100-ml household chlorine bleach, aspirate 900-ml fluids and discard.)

Contact the Biosafety Officer for information regarding vacuum line filters. Vacuum line filters shall be examined and replaced if clogged or if liquid makes contact with the filter. Used filters shall be discarded in the medical waste stream.

Illustration 8: Remove Culture Media



3. Pipetting Aids

A pipetting aid must always be used for pipetting procedures. Mouth pipetting is strictly forbidden.

The importance of pipetting aids cannot be overemphasized. The most common hazards associated with pipetting procedures are the result of mouth suction. Oral aspiration and ingestion of hazardous materials have been responsible for many laboratory-associated infections.

Pathogens can also be transferred to the mouth if a contaminated finger is placed on the suction end of a pipette. A lesser known hazard of mouth pipetting is the inhalation of aerosols caused by suction. The cotton plug is not an efficient microbial filter at negative or positive pressure, and particles may be sucked through it. Violent suction may be applied when the plug is tightly packed, resulting in the aspiration of plug, aerosol and even liquid. The ingestion of pathogens is prevented by the use of pipetting aids.

Aerosols can also be generated when a liquid is dropped from a pipette on to a work surface, when cultures are mixed by alternate sucking and blowing, and when the last drop is blown out of a pipette. The inhalation of aerosols unavoidably generated during pipetting operations can be prevented by working in a biological safety cabinet.

Pipetting aids should be selected with care. Their design and use should not create an additional infectious hazard and they should be easy to sterilize and clean. Plugged (aerosol-resistant) pipette tips should be used when manipulating microorganisms and cell cultures.

Pipettes with cracked or chipped suction ends should not be used as they damage the seating seals of pipetting aids and so create a hazard.

4. Homogenizers, Shakers, Blenders and Sonicators

Domestic (kitchen) homogenizers are not sealed and release aerosols. Only equipment designed for laboratory use should be used. Their construction minimizes or prevents such release. Stomachers, which are now available for use with large and small volumes, may also produce aerosols.

Sonicators may release aerosols. They should be operated in biological safety cabinets or covered with shields during use. The shields and outsides of sonicators should be decontaminated after use.

5. Disposable Transfer Loops

The advantage of disposable transfer loops is that they do not have to be sterilized and can therefore be used in biological safety cabinets where Bunsen burners and micro-incinerators would disturb the airflow. These loops should be placed in disinfectant after use and discarded as contaminated waste.

6. Lyophilizers

Specimens shell-frozen in ampoules are dried on a vacuum manifold or in a chamber-type drier at low negative pressure. If the glass neck of the ampoule is sealed off while the ampoule is still under vacuum, it may cause implosion, either during the sealing or later when the evacuated ampoule is being opened. To avoid this, after drying is completed, and before sealing is done, bring the pressure within the ampoule back to normal by gradually introducing dry nitrogen, avoiding turbulent disturbance of the dry product.

The narrow or constricted neck of the ampoule is contaminated if the specimen is allowed to run down the wall of the neck during filling. Subsequently, when the ampoule is sealed with a torch, the dried material on the wall becomes charred or partially decomposed; residues of this material may adversely affect the dried material when it is reconstituted. To avoid this, a syringe with a long cannula or a Pasteur-type pipette should be used to fill the vial. Do not allow the delivery end of the cannula or pipette to touch the neck of the vial.

All ampoules used for freeze-drying of cultures, toxins, or other biohazardous material should be fabricated of Pyrex-type glass. This type of glass requires a high-temperature torch using an air-gas or oxygen-gas mixture for sealing. These hard glass ampoules are much less apt to form gas bubbles that burst inwardly during sealing under vacuum than the soft glass ampoules and are more resistant to breakage during handling and storage.

The filling of ampoules and vials with infectious specimens, the subsequent freeze-drying, and sealing or closing of ampoules and vials in the preparation of dry infectious specimens should be performed in a biological safety cabinet. The same is true for the preparation of ampoules and vials containing liquid specimens not subject to freeze-drying.

Safety precautions to be taken will depend on the agents, equipment, and containment available. Therefore, before initiating this procedure, the principal investigator or laboratory supervisor should work out the protocol for each machine in consultation with the Biosafety Officer.

7. Microtome / Cryostat

Due to the very sharp blade and the nature of the materials used with the microtome/cryostat, training is essential in the use of the equipment and in the hazards of the materials used with the equipment. Users should be informed of the need to prevent cuts and scrapes as well as protect the eyes, nose, mouth and skin from exposure to the materials being used. New personnel must be trained in the proper use and maintenance of the equipment, and demonstrate proficiency prior to use.

If using human tissue, microtome/cryostat users are required to attend Bloodborne Pathogens training. Fixatives take time to penetrate tissue; the fixatives may not inactivate pathogens deep in the tissue. Freezing and drying do not inactivate most pathogens, so, as with fixative use, the pathogens that may be present in the tissue should be considered capable of causing infection.

Never retrieve samples, change blades, or clean equipment by hand with the blade in place; always use appropriate engineering controls (i.e. forceps, tweezers, dissecting probes, and small brushes). When using and maintaining microtomes/cryostats remember the following:

a. Always keep hands away from blades.
b. Use extreme caution when aligning blocks, the blocks may be close to the blades. If available, make sure block holder is in locked position when loading/aligning blocks.
c. Use knife-edge protectors/guards. Do not leave knife-edges that may extend beyond microtome knife holder unprotected.
d. Keep blocks wet when in the microtome to minimize airborne shavings during slicing.
e. Use brushes to clean/brush equipment.
f. Use engineering controls such as forceps when removing or changing the blade.
g. Dislodge stuck blocks using mechanical means such as forceps and/or dissecting probes.
h. Wear appropriate PPE such as a lab coat or gown, mask, safety glasses or goggles, surgical grade Kevlar gloves that provide dexterity and cut protection, and examination gloves to protect against biohazards.
i. When changing blades, wear stainless steel mesh gloves to provide additional protection from cuts and scrapes.
j. Avoid freezing propellants that are under pressure as they may cause splattering or droplets of infectious materials.
k. Decontaminate equipment on a regular schedule using an appropriate disinfectant.
l. Consider trimmings and sections of tissue as contaminated and discard in the appropriate waste stream.
m. Do not move or transport microtome with knife in position.
n. Do not leave knives out of containers when not in use.
o. Do not leave motorized microtomes running unattended.

When purchasing new units the available safety features should be taken into consideration prior to deciding on a manufacturer or model. Some available safety features to take into consideration are:

a. Auto-decontamination cycle.
b. Easy blade release for installing and changing blades.
c. Retractable knife/blade to permit safe entry into chamber for cleaning, retrieving specimens, etc.
d. Disposable blades.

8. Miscellaneous Equipment

Water baths used to incubate, or test infectious substances should contain a disinfectant. For cold water baths, 70% propylene glycol is recommended. Sodium azide should not be used as a bacteriostatic because it creates a serious explosion hazard.

Deep freeze, liquid nitrogen, dry ice chests and refrigerators should be checked, cleaned out periodically to remove any broken ampoules, tubes, etc. containing infectious material followed by decontamination. Use rubber gloves and respiratory protection during this cleaning. All infectious or toxic material stored in refrigerators or deep freezers should be properly labeled. Security measures should be commensurate with the hazard.

The degree of hazard represented by contaminated liquid nitrogen reservoirs will be largely dependent upon the infectious potential of the stored microorganisms, their stability in liquid nitrogen, and their ability to survive in the airborne state. Investigations suggest that storing tissue culture cell lines in containers other than sealed glass ampoules might result in potential inter-contamination among cell lines stored in a common liquid nitrogen repository.

Care must be exercised in the use of membrane filters to obtain sterile filtrates of infectious materials. Because of the fragility of the membrane and other factors, such filtrates cannot be handled as noninfectious until culture or other tests have proved their sterility.

Shaking machines should be examined carefully for potential breakage of flasks or other containers being shaken. Screw-capped durable plastic or heavy walled glass flasks should be used. These should be securely fastened to the shaker platform. An additional precaution would be to enclose the flask in a plastic bag with or without an absorbent material.

Laboratory personnel should never work alone on an extremely hazardous operation.

Section 8: Disinfectants and Sterilization

A basic knowledge of disinfection and sterilization is crucial for biosafety in the laboratory. Since heavily soiled items cannot promptly be disinfected or sterilized, it is equally important to understand the fundamentals of cleaning prior to disinfection (precleaning). In this regard, the following general principles apply to all known classes of microbial pathogens.

Specific decontamination requirements will depend on the type of experimental work and the nature of the infectious agent(s) being handled. The generic information given here can be used to develop both standardized and more specific procedures to deal with biohazard(s) involved in a particular laboratory. Contact times for disinfectants are specific for each material and manufacturer. Therefore, all recommendations for use of disinfectants should follow manufacturers' specifications.

8.1 Definitions

Many different terms are used for disinfection and sterilization. The following are among the more common in biosafety:

Antimicrobial: An agent that kills microorganisms or suppresses their growth and multiplication.

Antiseptic: A substance that inhibits the growth and development of microorganisms without necessarily killing them. Antiseptics are usually applied to body surfaces.

Biocide: A general term for any agent that kills organisms.

Chemical germicide: A chemical or a mixture of chemicals used to kill microorganisms.

Decontamination: Any process for removing and/or killing microorganisms. The same term is also used for removing or neutralizing hazardous chemicals and radioactive materials.

Disinfectant: A chemical or mixture of chemicals used to kill microorganisms, but not necessarily spores. Disinfectants are usually applied to inanimate surfaces or objects.

Disinfection: A physical or chemical means of killing microorganisms, but not necessarily spores.

Microbicide: A chemical or mixture of chemicals that kills microorganisms. The term is often used in place of "biocide", "chemical germicide" or "antimicrobial."

Sporocide: A chemical or mixture of chemicals used to kill microorganisms and spores.

Sterilization: A process that kills and/or removes all classes of microorganisms and spores.

8.2 Cleaning laboratory materials

Cleaning is the removal of dirt, organic matter and stains. Cleaning includes brushing, vacuuming, dry dusting, washing or damp mopping with water containing a soap or detergent. Dirt, soil and organic matter can shield microorganisms and can interfere with the killing action of decontaminants (antiseptics, chemical germicides and disinfectants).

Pre-cleaning is essential to achieve proper disinfection or sterilization. Many germicidal products have antimicrobial activity only on pre-cleaned items. Pre-cleaning must be carried out with care to avoid exposure to infectious agents. Materials chemically compatible with the germicides to be applied later must be used. It is quite common to use the same chemical germicide for pre-cleaning and disinfection.

8.3 Chemical germicides

Many types of chemicals can be used as disinfectants and/or antiseptics. As there is an ever-increasing number and variety of commercial products, formulations must be carefully selected for specific needs.

The germicidal activity of many chemicals is faster and better at higher temperatures. At the same time, higher temperatures can accelerate their evaporation and also degrade them. Particular care is needed in the use and storage of such chemicals in tropical regions, where their shelf-life may be reduced because of high ambient temperatures.

Many germicides can be harmful to humans or the environment. They should be selected, stored, handled, used and disposed of with care, following manufacturers' instructions. For personal safety, gloves, aprons and eye protection are recommended when preparing dilutions of chemical germicides.

Chemical germicides are generally not required for regular cleaning of floors, walls, equipment and furniture. However, their use may be appropriate in certain cases of outbreak control. Proper use of chemical germicides will contribute to workplace safety while reducing the risk from infectious agents. As far as possible, the number of germicidal chemicals to be used should be limited for economic reasons, inventory control and to limit environmental pollution.

Commonly used classes of chemical germicides are described below, with generic information on their applications and safety profiles. Unless otherwise indicated, the germicide concentrations are given in weight/volume (w/v).

8.4 Ethanol as Disinfectant

Solutions of 70% ethanol are no longer recommended for disinfection of work surfaces, such as on benches or in biosafety cabinets. A solution of 70% ethanol must be made up regularly to maintain potency, and becomes ineffective within seconds when spayed on work surfaces, necessitating extended exposure times. Although a good skin disinfectant, it also dries out skin and gloves (vinyl and latex), actually increasing permeability and risk of infection. There is

increased risk of explosion and fire hazard when ethanol is used in biosafety cabinets in the amounts and exposure times that are required for effectiveness. Concentrations of ethanol below 70% are not sporocidal, and a 100% concentration of ethanol may actually preserve some microorganisms.

8.5 Appropriate Disinfectants per OSHA

Cleaning of contaminated work surfaces after completion of procedures is required to ensure that employees are not unwittingly exposed to blood or OPIM remaining on a surface. Appropriate disinfectants include a diluted bleach solution and EPA registered tuberculocides (List B), sterilants (List A) and products registered against HIV/HBV (List D).

8.6 Autoclaves and Indicators

1. Steam Sterilization

Steam sterilization of materials is a dependable procedure for the destruction of all forms of microbial life. Steam sterilization generally denotes heating in an autoclave utilizing saturated steam under a pressure of approximately 15 pounds per square inch (psi) to achieve a chamber temperature of at least 121ºC (250ºF) for a minimum of 15 minutes. The time is measured after the temperature of the material being sterilized reaches 121ºC (250ºF).

Physical controls such as pressure gauges and thermometers are widely used but are considered secondary methods of sterilization. The use of appropriate biological indicators at locations throughout the autoclave is considered the best indicator of sterilization. The biological indicator most widely used for wet heat sterilization is a *Bacillus stearothermophilus* spore suspension or strip.

2. Chemical Indicators

a. Chemical Color Change Indicators

Chemical indicators for steam autoclaving change colors after being exposed for a few minutes to normal autoclave operating temperatures of 121ºC (250ºF). Hence, chemical indicators can give a quick visual reference for heat penetration inside the hood. Chemical indicators should be positioned near the center of each load and toward the bottom front of the autoclave.

Caution: Most chemical indicators can only be used to verify that your autoclave has reached normal operating temperatures for decontamination; they have no time factor. Chemical indicators alone are not designed to prove that organisms are actually killed during a decontamination cycle.

b. Tape Indicators

Tape indicators are adhesive backed paper tape with heat sensitive, chemical indicator markings. Commonly used heat sensitive markings include diagonal stripes (autoclave tape) and/or the word

"sterile." These markings only appear when the tape has been exposed for a few minutes to normal autoclave decontamination temperatures.

Caution: Tape indicators can only be used to verify that your autoclave has reached normal operating temperatures for decontamination; they have no time factor. Tape indicators alone are not designed to prove that organisms are actually killed during a decontamination cycle.

3. Biological Indicators

Biological indicators are designed to demonstrate that an autoclave is capable of killing microorganisms. Only *Bacillus stearothermophilus* spores can be used to monitor the effectiveness of steam autoclaves.

Typical biological indicator systems consist of a vial with spore strips or a small glass ampoule of growth medium with spores and indicator dye. Refer to manufacturer's instructions for usage. The biological is removed from a load after it has been autoclaved. Then the biological indicator is incubated at 56ºC (132.8ºF) for up to three days. A control vial, which is not autoclaved, should remain clear without evidence of turbidity (no growth). If the autoclaved biological indicator is turbid (cloudy, indicating growth) the autoclave did not function properly. Notify your supervisor if this occurs.

4. Autoclave Procedures

Never autoclave FLAMMABLE, REACTIVE, CORROSIVE, TOXIC or RADIOACTIVE MATERIALS.

Always wear safety glasses, goggles or face shield, lab coat or apron, and heat-protective non-asbestos gloves when opening door or removing item(s) from autoclave. When using a steam autoclave, remember the following:

- Open doors slowly; beware of a rush of steam.
- Open door only after chamber pressure returns to zero. Leave door open for several minutes to allow pressure to equalize and for materials to cool.
- Do not mix loads which require different exposure times and exhaust.
- Materials that will melt (e.g., plastic lab wear) and block chamber exhaust drain should be placed in a shallow stainless steel autoclave pan.

5. Autoclave Packaging and Treatment

Materials contaminated with infectious materials must be collected in the appropriate containers and sterilized or disinfected before disposal. Specific requirements for handling, sterilizing, and disposing infectious waste must be followed.

6. Liquids containing Biohazardous Agents

When handling liquids containing biohazardous agents, collect the liquids in leak-proof containers such as flasks or bottles.

When steam sterilization is utilized, liquid waste containers designed to withstand autoclaving temperatures must be used. To allow pressure equalization, they should not be sealed.

7. Solids Containing Biohazardous Agents

Non-sharp, solid laboratory waste (e.g., empty plastic cell culture flasks, Petri dishes, empty plastic tubes, gloves, wrappers, absorbent tissues) which may be, or is known to be, contaminated with infectious material must be collected in autoclavable bags. If this waste is not autoclaved immediately, it must be stored in autoclavable bags displaying the biohazard-warning symbol.

Autoclavable bags should be used for solid, non-sharp, infectious waste only and disposed of appropriately. They should not be used for the collection of other solid hazardous or non-hazardous waste that may require other treatment or disposal methods.

For laboratories generating large volumes of agar gel in disposable Petri dishes and tubes requiring sterilization, such waste should be collected in an autoclavable plastic pail in the laboratory. Autoclavable bags filled with plastic ware containing agar gel tend to leak fluids during and after the sterilization process. The pail will contain the liquids released by the agar gel.

8. Sterilization and Disinfection

Employ steam sterilization procedures to inactivate the biological agents. Autoclaving (steam sterilization) is the preferred (and generally regarded as the most reliable) method of sterilizing biological waste. Depending on the volume of waste to be sterilized, it may be necessary to extend the duration of exposure to high temperature steam under pressure. However, steam sterilization is generally not recommended for laboratory waste contaminated with or containing a combination of viable biological agents and significant amounts of hazardous chemical or radioactive materials.

Containers of liquid waste must be placed in an autoclavable tray or pan of sufficient capacity to contain all liquid in the event of vessel failure or breakage inside the autoclave chamber. Use extreme caution when handling autoclaved liquids since they are hot and may boil over.

Autoclavable bags of solid waste should be gently closed (but not sealed airtight) to allow steam penetration before they are placed into the autoclave chamber.

Section 9: Biological Spills

Any biological spill that occurs in the laboratory can generate aerosols in the air that may be potentially hazardous especially if the spill occurs outside the biosafety cabinet. If infectious microorganisms are spilled that should have been contained in a biosafety level 3 cabinet this may be serious as the aerosols can be transmitted throughout the laboratory. In the event of a large spill and to reduce the exposure risk, employees should leave the area immediately. The room should be closed for at least 30 minutes to allow for the aerosols to be ventilated out before reentering to perform the clean-up of the spill. The use of absorbent liners on bench tops when working, helps absorb the spill and reduce exposure. All spills are to be reported to the immediate supervisor or Biosafety Officer.

A biological spill kit should contain the following:

- Concentrated disinfectant or 10% chlorine bleach.
- Package of paper towels.
- Forceps for broken glass.
- Gloves – nitrile or latex and rubber.
- Several biohazardous bags.

Table G: Biological Spill Disinfectant Usage

Disinfectant	Disinfectant Level	Bacteria	Lipo-phil. Viruses	Hydro-phil Viruses	M. tuberculosis	Fungi	Comments
Alcohols (ethyl and isopropyl) 70%	Intermediate	+	+	-	+/-	+	Not sporicidal; evaporates quickly so that adequate contact time may be achieved, high concentrations of organic matter diminish effectiveness; flammable.
Phenolics 1/20 Lysol™	Intermediate	+	+	+/-	+	+	Not sporicidal; phenol penetrates latex gloves; eye / skin irritant; remains active upon contact with organic soil; may leave residue.
Glutaraldehyde (2-5%)	High	+	+	+	+	+	Used to sterilize surgical instruments that can not be autoclaved; strong odor; sensitizer; use with adequate ventilation. Not for use on environmental surfaces.
Quaternary Ammonium (0.5-1.5%)	Low	+	+	-	-	+/-	May be ineffective against Psuedomonas and other gram – bacteria; recommendation limited to environmental sanitation (floors, walls). Low odor, irritation.
Iodophors (30-1,000 ppm iodine)	Intermediate	+	+	+	+/-	+/-	Inactivated by organic matter.
Chlorine 1/10	Intermediate	+	+	+	+/-	+	Not sporicidal; inactivated by organic matter, fresh solutions of hypochlorite (chlorox) should be

							prepared weekly; corrosive; irritating to eyes and skin.

Biological spills are handled differently depending upon the type of spill. The recommended procedure for handling each spill type will be briefly outlined in Sections 9.1 through 9.5 below.

9.1 Spills inside a Biosafety Cabinet

- Leave the cabinet turned on and put on gloves and a gown.
- Spray 10% bleach on the walls and working surfaces. Leave for 20 minutes
- Soak up the spill and disinfectant with paper towels and discard in a biohazard container.
- Drain the catch basin, and lift the exhaust grill to wipe all contaminated surfaces.
- Wash exposed surfaces thoroughly with water after the clean-up procedure; wash hands, and dispose of gown.

9.2 Spills on the Body

- Remove the contaminated clothing.
- Wash the exposed area for one minute with soap and water.
- Report the spill to the supervisor and seek medical attention if necessary.

9.3 Biosafety Level 1 and 2 Organism Spills

- Wear disposable gloves and gown, add disinfectant to the spill and cover with paper towels.
- Let the spill soak for 20 minutes.
- Pick up the paper towels carefully and discard into a biohazardous bag.
- Use a forceps and remove the broken glass and dispose of in a sharps container.
- Add more disinfectant to the spill area and wipe with fresh paper towels.
- Discard all spill materials in a biohazardous container, and wash hands with disinfectant soap.

9.4 Biosafety Level 3 Organism Spill

- Alert employees of the spill, hold your breath and evacuate the area.
- Close the doors to the affected area and post a warning sign.
- Call 911 and notify the Biosafety Officer.
- Be ready to report the location of the spill and all relevant information to the emergency personnel when they arrive.

9.5 Blood and Body Fluids Spills

- Universal precautions must be used when dealing with blood and body fluid spills.
- Disposable materials shall be used to clean up the spill and discarded into the biohazardous containers.
- All broken glass must be picked up with forceps or tongs and not by hand.

9.6 Spill Reporting

All spill incidents must be reported immediately to the supervisor or the Biosafety Officer. A short written summary must be submitted to determine the root cause of the spill and what appropriate measures need to be taken to prevent this incident from reoccurring. The report must include the date and time of the spill, the location, the identity of any injured employees and whether any corrective action was taken.

Section 10: Biological Waste

Infectious and regulated medical waste is defined as any waste material that is capable of producing disease in humans from pathogenic organisms. The laboratory supervisor and the Biosafety Officer are responsible for the management of infectious waste materials that are generated in the clinical and research laboratories which includes the safe handling and disposing of this waste. Personnel are to be trained in the correct procedure for biohazardous waste disposal and inexperienced or untrained personnel are not to manage the disposal of infectious waste. The disposal of biological waste is highly regulated and costly, thus it must be segregated properly from other types of waste.

The following are sources of infectious waste:

- Microbiological – discarded cultures of microorganisms.
- Human blood, blood products and certain body fluids as defined by OSHA.
- Pathological wastes – human tissue or anatomical wastes.
- Contaminated sharps- needles, blades, contaminated pipettes and microscope slides.
- Materials from an infectious spill.
- Any waste contaminated by or mixed with infectious waste.

10.1 Segregating Biohazardous Waste

The proper manner for managing your biohazardous waste is to correctly segregate the biohazardous waste at the time of generation. It may be difficult or expensive to dispose of biohazardous waste that is mixed, and the following guidelines may be used when segregating your waste.

a. Do not combined biohazardous waste with hazardous chemical or radioactive waste.
b. Keep sharps separate from biological waste.
c. If the different type of waste are mixed, try to treat the mixtures are follows:
d. Decontaminate the biohazardous component of the biohazardous/radioactive waste and discard as radioactive waste.
e. If safe to perform, decontaminate the biohazardous component of the biohazardous/ hazardous chemical waste and discard as chemical waste.

10.2 Handling and Storage

All infectious waste must be stored in the appropriate containers as soon as it is generated. These containers must be correctly labeled with the international "biohazard" symbol.

Illustration 9: International Biohazard symbol

1. Biohazardous Bags

Biohazardous Bags are disposable red bags labeled with the biohazard symbol and the words "Biohazardous Waste" and used for the disposal of solid biohazardous waste. The bags must have the strength to pass the 165-gram dart impact test as prescribed by the Standard D 1709-85 of ASTM and certified by the manufacturer. This will prevent the bags from ripping, tearing or bursting under normal usage.

The red bags should be contained in a secondary labeled container at all times to prevent infectious spills. When red bags are removed from the secondary container, they must be securely tied for storage. The secondary container must be rigid, leak-proof, puncture-resistant and have a tight fitting lid that is closed at all times except when adding waste to the container.

Secondary containers that are reusable must be washed and decontaminated.

2. Sharp Containers

Sharp Containers are to be used for the disposal of any devices that have rigid corners, edges and capable of cutting or piercing. Examples are blades, needles, microscope slides, syringes and pipettes. A Sharp container must be rigid and puncture-resistant and labeled with the words "Sharps Waste" or the international biohazard symbol and "Biohazard."

When sealed the sharp containers must be leak resistant and cannot be reopened. Sharp containers must be kept upright and placed close to the work area. Sharp containers are to be filled about ⅔ full, closed, taped and ready for pick-up.

3. Storage of Biohazardous Waste

Biohazardous waste storage areas must physically be secured in lock areas.

Biohazardous waste can be disposed of in two ways – red bags can be autoclaved if this service is available and then disposed of as regular waste or transferred off the premises by a registered hauler for disposal. An alternative method for the disposing of infectious liquids can be down the sewer system but these liquids have to be disinfected with 10% bleach and this form of disposal has to be approved and comply with state regulations.

Biohazardous waste may not be stored for more than 7 days.

Section 11: Shipping of Biological Material

All institutions are to ensure that the packaging and shipping of biological materials must be performed in a way that will prevent the contents from leaking and the package will arrive at its destination in good condition.

The governmental agencies that enforce regulations for the shipping of biological materials include the CDC, the US Department of Transportation (DOT), and the International Air Transport Association (IATA). IATA is the trade association of the world's airlines whose regulations are tailored to United Nations technical instructions. IATA regulations **must** be followed for all shipments by air.

11.1 Criteria

Before shipment, biological materials are packaged, labeled and documented according to one of two categories relating to their hazard: (1) lower risk or (2) higher risk.

1. Lower Risk Category

The lower risk category includes, but is not limited to:

a. Diagnostic specimens - any human material shipped for purposes of diagnosis for other than the presence of a pathogen.
b. Biological products - products derived from living organisms that are used for prevention, treatment, or diagnosis of disease in humans.
c. Microorganisms not known or reasonably anticipated to cause disease in humans. IATA Packing Instruction 650 applies to these shipments. (Biosafety Level 1)

IATA Packing Instruction 650 applies to shipments of biological materials in the lower risk category.

2. Higher Risk Category

The higher risk category includes, but is not limited to:

a. Infectious substance - substances known, or reasonably expected to contain microorganisms known or reasonably expected to cause disease in humans or animals, including material containing a Biosafety Level 2, 3, or 4 organism. This category also includes specimens being shipped for initial or confirmatory testing for pathogens.

IATA Packing Instruction 602 applies to shipments of biological materials in the higher risk category.

3. "What about human blood and body fluids?"

In a clinical laboratory, human blood and body fluids must be treated as infectious for HIV, Hepatitis B and C, and other Bloodborne pathogens. For shipping purposes the situation is not as clear cut. Human blood and body fluids must be shipped as an infectious substance (higher risk material-use Packing Instruction 602) if it is being sent for purposes of pathogen-testing or if it is known or reasonably expected that the sample contains Biosafety Level 2, or higher. **However**, if the none of the above criteria for designation as an infectious substance apply, the shipper may send the sample using Packing Instruction 650 (for lower risk materials) provided that the rationale for making this decision are documented as part of the laboratory's SOPs. The rationale for using the package instructions 650 for lower risk materials are that specimens are not sent for pathogen testing and the infectious status is unknown.

In either case, the international "BIOHAZARD" symbol must be affixed to the outside of the package.

Table H: IATA Packaging Instructions

	602 (Higher Risk Materials)	650 (Lower Risk Materials)
Drop Test	Packaging unit must withstand 9 meter drop test and bear UN marking.	1.2 meter drop test; no UN marking required.
Responsible Person Info	Name, phone of sender, consignee, and 'responsible person', emergency phone on outer package.	Same, except 'Responsible person' not required.
Consignee Arrangement	Prior arrangement with consignee required.	Package and air waybill states: 'Diagnostic Specimen (Biological Product) packed in compliance with IATA Packing Instruction 650'.
Outer Package Label	Outer package shows shipping and technical name of material, UN I.D. number, and 'Infectious Substances' label.	If package contains material covered by OSHA Bloodborne Pathogens Standard, the Biohazard Symbol appears on package.
Shipper's Declaration	Shipper's 'Declaration of Dangerous Goods' required.	No Declaration required.
Shipment Means	Amounts greater than 50 ml. (liquids) or 50 gm. (solids) shipped 'Cargo Only'. 4 liter or 4 kg. total limit per package.	Primary containers have a volume or weight limit of 500 ml. or 500 gm. for liquids and solids, respectively. 4 liter (liquids) or 4 kg. (solids) limit on total shipment size for cargo and passenger aircraft.

11.2 Packaging

All biological materials including diagnostic specimens that may contain an etiologic agent must be packaged in containers that are leak-proof, shock resistant, can withstand pressure changes, and other conditions incident to ordinary handling and transportation. The specimen contents should not leak to the outside of the shipping container, thus the primary container must be sealed to prevent such an occurrence.

1. Volume not exceeding 50 ml

Requirements for packaging for biological materials of a volume not exceeding 50 ml are as follows:

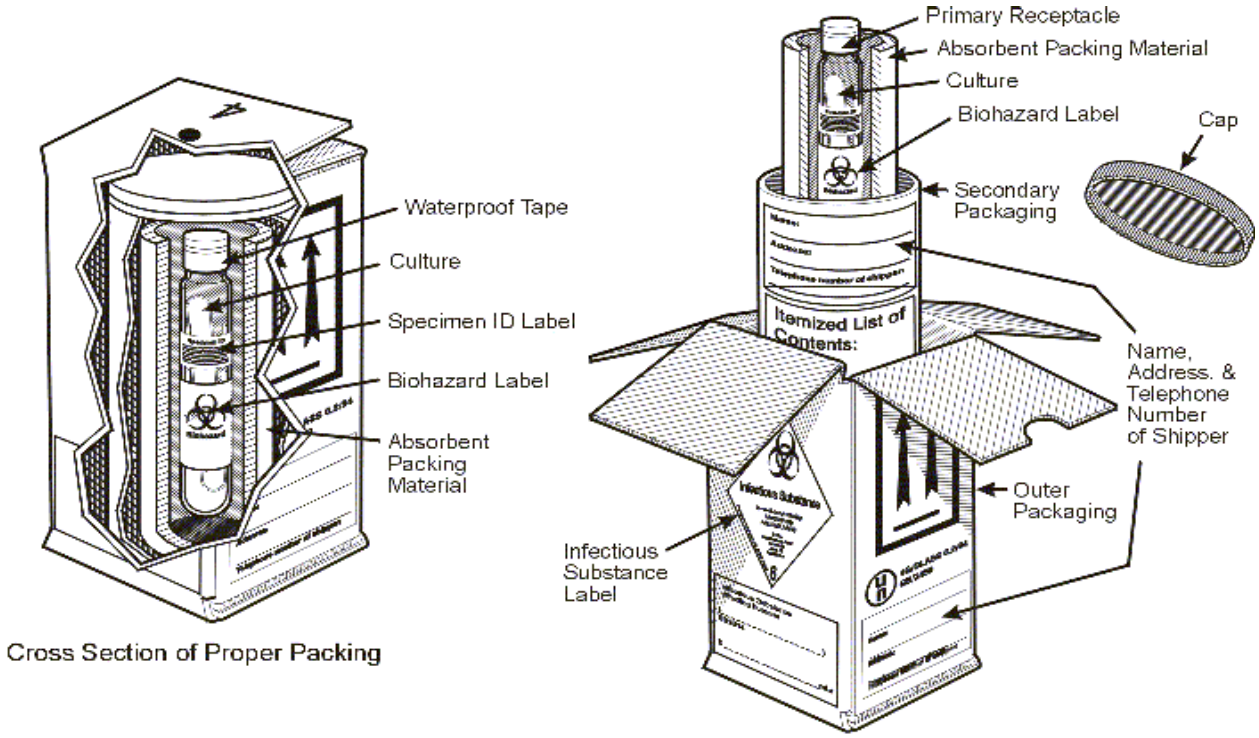
b. Use watertight primary containers as shown for biological materials.
c. This primary container is to be placed in a secondary, durable watertight container thus preventing leakage of the biological materials to the outside of the package.
d. Several primary containers may be enclosed in a single secondary container as long as the total volume of the biological materials does not exceed 50 ml.
e. To prevent leaking, place absorbent non-particulate material such as paper toweling in the spaces around the primary and secondary containers.
f. Use enough absorbent material to absorb the entire contents of the primary container(s) in the event of breakage or leakage.
g. Place the primary and secondary containers in a shipping container constructed of cardboard, corrugated fiberboard or any other material of equal strength.
h. If the package contains dry ice, see the instructions below.

2. Volume greater than 50 ml

For biological materials of a volume greater than 50 ml, follow the same packaging requirements as outlined above for smaller volumes. In addition, ensure that there is adequate absorbent material between the primary and secondary containers as well as between the outer shipping packages.

Each primary container must no hold more than 1000 ml of biological material. More than one primary container with volumes of 1000 ml may be used, but the overall volume for the shipping package may not exceed 4000 ml.

Illustration 10: Packing and Labeling Infectious Substances



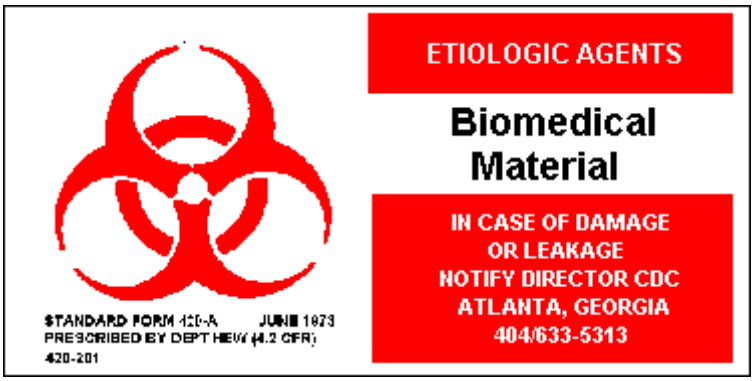
3. Packaging with Dry Ice

If dry ice is to be used, it should be placed between the secondary and shipping containers. When using dry ice, place enough shock absorbent material inside the shipping container so that the secondary container does not become loose inside the outer container as the dry ice sublimates.

11.3 Labeling

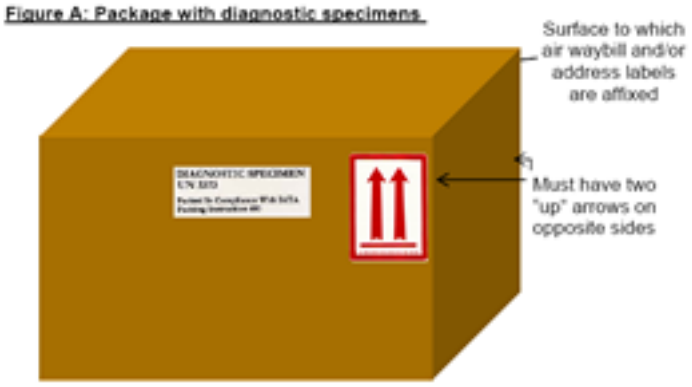
The outer shipping package for biological materials must bear a special label when being shipped or transported.

Illustration 11: Required Shipping Label for Biological Materials



The following two diagrams illustrate which labels are required to be placed on the outer surfaces of shipping packages that contain biological materials with or without dry ice.

Illustration 12: Diagnostic specimen packaging without dry ice labeling. (See below)



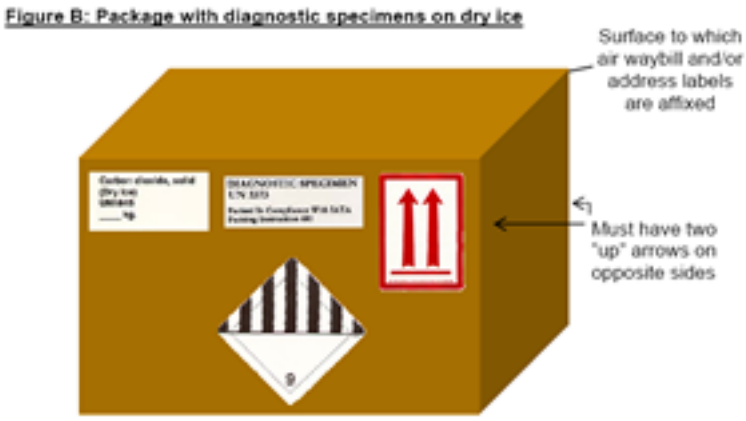


Illustration 13: Diagnostic specimen packaging with dry ice labeling (See above)

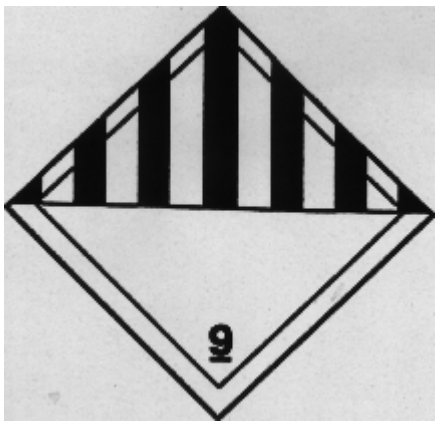
11.4 Transportation

1. Specific Carriers (FedEx or UPS)

Shipments sent either internationally or domestically by air must conform to the International Air Transport Association (IATA) Dangerous Goods Regulations. A receipt of shipment notice is not required since the shipment is traceable through the specific carrier. When using private carriers, the following is also required for shipment:

a. Place the appropriate labels to the outer shipping containers for packages containing dry ice and/or infectious substances as shown below.
b. Contact the specific carrier's dangerous goods agent prior to shipment for any additional packaging and labeling requirements.

Illustration 14: Placards



Dry Ice

Infectious Substances

2. Damaged Packages

When there is evidence of leakage or any other damage to packages bearing an Etiological Agents/Biomedical Material label, the carrier must promptly isolate the package and notify the Director, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road N.E., Atlanta, Georgia 30333, by telephone (404) 639-3883 or 633-5313.

3. Notice of Delivery

In the event that a package sent by a laboratory is not received by the recipient within 5 days following the anticipated delivery of the package, the sender must notify the Director, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Atlanta, Georgia 30333 or by telephone (404) 639-3883 or 633-5313.

11.5 Importation / Exportation of Etiologic Agents

Importation of infectious agents is governed by federal regulation. In general, an importation permit is required for any infectious agent known to cause disease to man that may include but is not limited to bacteria, viruses, rickettsia, parasites, yeasts and molds. In some instances, a biological agent which is suspected of causing human disease may also require a permit.

Importation permits are issued by the U.S. Public Health Service (USPHS) only to the importer, who must be located in the United States. This permit with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the USPHS Division of Quarantine and Release by U.S. Customs.

In some instances, a Letter of Authorization may be issued by the Centers for Disease Control and Prevention (CDC) after a review of the "Application to Import an Etiological Agent". This letter is issued and effective for two years for materials that are judged to be non-infectious. Non-infectious items include, but are not limited to, formalin fixed tissues, sterile cell cultures, clinical materials such as human blood, serum, plasma, urine, cerebrospinal fluid, and other tissues or materials of human origin when there is no evidence or indication that such materials contain an infectious agent.

Importation permits and Letters of Authorization are issued by the CDC, Import Permit Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, Ga. 30333.

11.6 Training Requirements

All employees involved in the shipping of biological materials must be trained in shipping regulations and requirements. Training is conducted upon hire. For air shipping, employees are required to have additional training every two years and for ground transportation the requirement is every three years. All records of training are to be documented and maintained.

Section 12: Medical Surveillance Program

12.1 Employee / Student Health Services

NSU Employee / Student Health Services serve as vital components of the Biological Safety Plan by helping to protect the health and safety of employees, students and authorized visitors in clinics, research and teaching laboratories. The primary objective of the medical surveillance program is prevention, and early detection of work-related health effects. This is achieved through training, periodic evaluations and immunizations. The major services provided include: pre-placement examinations for designated personnel, immunizations and serum banking for designated personnel, periodic monitoring evaluations, exit evaluations, maintenance of employee occupational health records, response to exposures, epidemiology, and considerations for other special medical situations.

12.2 Immunizations and Tuberculosis Surveillance

Employees, students and authorized visitors will be offered immunizations and/or skin tests as indicated for the situation, including, but not limited to the following:

a. Tuberculin skin testing (PPD), repeated annually or as recommended for the situation (i.e. work exposure to TB). Skin tests will be interpreted and managed following the most current CDC guidelines.
b. Tetanus vaccine will be administered every 10 years or post-injury if needed per CDC Guidelines.
c. Administration of rabies vaccine, if indicated, by possible animal contact.
d. Administration of the hepatitis B vaccine, if indicated, by exposure to human tissues or body fluids.
e. Administration of the varicella vaccine, if indicated, by immunization status in relation to possible occupational exposure.

12.3 Periodic Surveillance

Periodic surveillance exams may include an annual review and update of health histories and/or an annual review and update of immunizations and TB skin tests, as needed.

A periodic surveillance exam is designed to:

a. Detect changes in an individual's health that might indicate the need for a change in job placement or in the work process.
b. Educate individuals with regard to health promotion and disease prevention.
c. Detect evidence of exposure to infectious agents, and/or exposures to chemical toxins or other physical hazards.

12.4 Employee Health Records

Health records obtained from employees, students and authorized visitors will be kept confidential and maintained in a secure location. Access to records will be limited to authorized personnel per state and federal law. Records will not be released to anyone without the individual's written consent, except in situations required by law.

All medical and exposure records shall be maintained for the duration of the individual's stay, plus 30 years.

12.5 Responses to Exposures

Personal exposures to infectious agents can arise from a variety of incidents, including exposure to aerosols, splashes of liquid into mucous membranes or broken skin, percutaneous injury and animal scratches or bites. In the event of any incident of this type involving infectious materials, the immediate response should be directed towards life saving. Any bleeding should be controlled, and if possible, the wound(s) should be thoroughly cleaned with hot soapy water and a disinfectant solution.

For select agents and toxins, the CDC has defined an occupational exposure as:

> "Any event which results in any person in a registered entity facility or lab not being appropriately protected in the presence of an agent or toxin. This may include reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potential infectious materials that may result from the performance of a person's duties. For example, a sharps injury from a needle being used in select agent or toxin work would be considered an occupational exposure."

Any exposure incident involving infectious materials should be reported to the Employee/ Student Health Services. If exposure occurs after 5:00 p.m. or on a weekend or holiday the employee/student should go to the nearest Hospital Emergency Room, if indicated, for wound care or tetanus update. The employee/student should report to NSU Health Services as soon as possible on the next working day.

NSU Health Services provider can be reached by calling 262-4100.

An Injury Report Form must also be completed for reporting to Worker's Compensation and Insurance. These exposures should be reported immediately to EHS for reporting to the CDC as required by law.

1. Disease Outbreak Evaluations

In the event of a disease outbreak:

a. Exposure will be documented.

b. Physical examinations will be done as indicated.
c. Serum samples will be collected and stored as indicated.
d. Lab tests will be done as indicated.
e. Appropriate treatment will be given or referral made as needed.

12.6 Other Special Medical Considerations

1. Allergies

Individuals with histories of allergies, specifically animal allergies, will be evaluated and advised of the potential health risk of animal exposure.

2. Reproductive Concern

Employees and authorized visitors will be advised to inform NSU Employee/ Student Health Services staff if they are pregnant or are considering pregnancy, so that they can be counseled on work related risks and can consider work assignment modification to avoid exposure to specific hazards.

Section 13: Bloodborne Pathogens Exposure Control Plan

13.1 Purpose

While Florida law allows mandatory testing of a source patient in the event of an accidental exposure, it requires institutions to have written procedures that protect the rights of both source patients and exposed health care workers.

13.2 Definitions

Specific definitions for purposes of this section are as follows:

Hazardous Body Fluids: Hazardous body fluids include blood, bloody fluids, and other body fluids which are known or assumed to be associated with the transmission of Bloodborne pathogens.

Source Patient: The source patient is from whom the health care worker sustained an exposure of hazardous body fluids.

13.3Exposure Risk Classifications

1. Blood Exposure Risk Classifications

a. High Risk: Includes exposure to both large volumes of blood and blood with a known high titer of a Bloodborne pathogen.
b. Increased Risk: Includes exposure to either large volumes of blood or blood with a known high titer of a Bloodborne pathogen.
c. No Risk: Includes neither exposure to large volumes of blood nor blood with a known high titer of a Bloodborne pathogen.

2. Skin Exposure Risk Classifications

a. Increased Risk: Exposure involving a known high titer of a Bloodborne pathogen, prolonged contact over an extensive area, and/or an area in which skin integrity is visibly compromised.

13.4 Treatment of Exposed Health Care Worker / Student

Immediate treatment is provided to the health care worker at the site where the injury occurred. Immediate treatment consists of the following:

a. Clean exposed area with soap and water for at least 15 minutes.
b. Flush mucous membranes with water or saline for at least 15 minutes.

After immediate treatment is completed, the exposed health care worker /student should call 954-262-4100 for employees/faculty members or page 954-262-5404 for students/residents to speak

with the NSU Exposure Coordinator, who will counsel the individual and refer him/her for appropriate care.

13.5 Early Treatment of Exposures

The exposed health care worker / student must fill out an "Injury Report" form and blood samples are to be obtained prior to administration of any treatment.

13.6 Confidentiality of Lab Results

Lab work drawn on an exposed health care worker is identified by an encoded number and not his or her name. The encoded numbers are known only to the exposed health care worker and the designated Exposure Coordinator.

13.7 Costs for Lab Studies

The exposed health care worker /student is not responsible for the laboratory bills related to the accidental exposure occurring during work duties. NSU is responsible for the cost of all exposure-based lab studies on NSU students. Residents, medical school staff and all other NSU employees file under worker's compensation.

Section 14: Tuberculosis Exposure Control Plan

14.1 Purpose

The purpose of the Tuberculosis Control Plan is to reduce the potential of transmission of pulmonary *Mycobacterium tuberculosis* from person to person and to detect tuberculosis exposures (and possible disease contractions) to staff by utilizing a screening process set forth in recommendations by the Center for Disease Control and Prevention in "The Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings" (also referred to as the 2005 Guidelines). These CDC Guidelines replace the 1994 Guidelines and address recent changes in health care practice and settings, re-evaluate the risk assessment process, and establish screening and testing procedures for tuberculosis.

14.2 Hierarchy of Control Measures

Below is the designated hierarchy of control measures available to address potential TB exposure:

1. Use of administrative measures to reduce the risk of exposure to persons with suspected or confirmed infectious TB.
2. Use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei.
3. Use of personal respiratory protective equipment.

14.3 Scope

The plan covers all patients, classified employees, staff, faculty, medical staff, and educational appointees (including students and volunteers) of NSU.

14.4 Risk Assessment for Health Care Workers / Students

An initial risk assessment to evaluate the risk of TB transmission will be done by NSU Employee Health Services with the assistance of EHS. This assessment will cover all parts of the facility including all clinics where TB patients may receive care; where cough-inducing procedures may be performed; and where individual groups of health care workers work throughout the facility.

The purpose of this assessment is to provide guidance on controls to be taken, and frequency of staff screening for exposure to tuberculosis. Each specific area and occupational category will be classified as low, medium or potential ongoing transmission (high) risk based on the factors outlined below. Reference the 2005 Guidelines for all occupational categories that will be included in the risk assessment. Risk assessments and health care worker exposure will be reviewed annually.

Table I: TB Risk Assessment

Low Risk	Applies to settings in which persons with TB disease are not expected to be encountered, and therefore, exposure to *M. tuberculosis* is unlikely. It is highly unlikely health care workers will be exposed to persons with TB disease or to clinical specimens that might contain *M.tuberculosis*.
Medium Risk	Applies to settings in which the risk assessment has determined health care worker or student will or will possibly be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.
High Risk (or potential ongoing transmission)	Applies to any setting (or group of health care workers or students) where there is evidence that suggests person-to-person (e.g., patient-to-patient, patient–to-health care worker, health care worker-to-patient, health care worker-to-health care worker) transmission of *M. tuberculosis* in a setting during the preceding year. Evidence of person-to-person transmission of *M. tuberculosis* includes, but is not limited to, the following: 1) clusters of TST or BAMT conversions, 2) health care worker confirmed TB disease, 3) increased rates of TST or BAMT conversions, 4) unrecognized TB disease in patients or health care workers, or 5) recognition of an identical strain of *M. tuberculosis* in patients or health care workers with TB disease identified by DNA fingerprinting.

The frequency of risk assessment and skin testing will be determined on the basis of the most recent risk assessment. Low risk groups will be assessed upon employment and reassessed only if exposure occurs, medium risk groups every 12 months, and potential ongoing (high) risk groups as often as necessary but no less than 2 years.

Representatives of the EHS will inspect the facility, review data, and make recommendations regarding changes in the TB Exposure Control Plan at least annually or as necessary to update the plan in response to documented nosocomial transmission of TB.

Following each risk assessment, the IBC, in conjunction with other appropriate health care workers will review all TB Control policies to assure that they are effective and meet current needs.

1. Analysis of Health Care Workers TB Skin Test Screening Data

Results of employee TB (PPD) testing will be kept in a retrievable aggregate database. To identify areas where the risk of occupational PPD test conversion may be increasing, PPD test conversion rates for each area will be compared to rates in areas without occupational exposure

to active TB and to previous rates in the same area. PPD conversion rate will be calculated as follows:

$$\% \text{ Conversion} = \frac{A}{A+B} \times 100$$

A = # health care workers with new positive skin tests in each area or group
B = # health care workers with negative skin tests in each area or group

Any time a cluster of PPD test conversions is noted, further evaluation is indicated.

The frequency of PPD testing is determined by the risk assessment. Areas in which cough-inducing procedures are performed on patients who may have active TB will, at a minimum, be considered intermediate risk.

2. Review of Patient Medical Records

The medical records of patients diagnosed with active TB will be reviewed for the risk assessment and to determine whether any employee exposures occurred.

3. Case Surveillance

Data on the number of active TB cases among patients and health care workers will be collected, reviewed and used to:

a. Identify the number of isolation rooms required.
b. Recognize clusters of nosocomial transmission.
c. Assess the level of potential occupational risk.
d. Monitor drug susceptibility characteristics of *M. tuberculosis* isolates.

4. Observation of Infection Control Practices

Compliance is considered to be a standard of performance and will be included in the annual performance evaluation for all employees with potential for exposure. Recommended practices are stated in this plan, copies of which are located in each department in the safety manual.

Recommended strategies for monitoring of compliance include, but are not limited to:

a. Follow-up of any report of an employee's failure to comply with the required protective measures will be the responsibility of the employee's supervisory staff.
b. Follow-up of problems identified through informal reports, complaints from staff, quality assurance or safety reports, minutes from committees, employee questionnaires, staff logs, and comments received during evaluation of education and training programs will be the responsibility of the affected department's supervisory staff.
c. Noncompliance will be reported to the IBC and to the employee's immediate supervisor for evaluation and follow-up.
d. Significant issues will be forwarded to the IBC.

5. Administrative Controls

a. Initial assessment

Patients will be assessed for possible infectious TB at the site of initial presentation (Emergency Center, Outpatient clinics, Observation areas, etc.) following the procedure for handling suspected TB patients. Health care workers who are the first points of contact should ask the following questions which will help recognize and detect patients with signs and symptoms suggestive of TB:

- Have you had a cough for 2 or more weeks?
- Has this cough been productive of sputum? Is it blood stained?
- Have you had fever, night sweats, unintentional weight loss, lethargy or weakness?
- Do you or any of your family have TB now, or a history of TB?
  - At this time, it should be determined if a patient is a member of a high risk group.
  - For those patients whose assessments indicate suspected infectious TB, follow established TB protocol for proper actions.

b. Physician Referral

Referring physicians or facilities should be questioned as to the patient's possible TB status, in order to facilitate the patient's admission into appropriate isolation and care.

c. Bacteriologic Screening

Florida Department of Health will be notified of all positive AFB direct smears and cultures.

d. Management of Pediatric Patients with Known or Suspected Infectious TB

Pediatric patients with suspected or confirmed TB should be evaluated for potential infectiousness on the basis of symptoms: sputum AFB smears, radiologic findings, and other criteria. Those with cavitary pulmonary or laryngeal TB should be placed in Airborne Infection Precautions until they are determined to be non-infectious.

Parents and relatives of pediatric patients suspected of having TB should be assessed as soon as possible for the presence of TB and should be asked to wear an N95 respirator at all times when in the facility until their status is known. Parents should have chest x-rays and PPD tests placed and it should be documented that they are not considered to be infectious before they may discontinue use of a N95 respirator.

e. Management of Patients with Suspected Tuberculosis in Ambulatory Care Settings and Emergency Centers

Place patient with suspected infectious TB in Airborne Infection Isolation in separate negative pressure room or demistifier tent if available. If separate waiting/exam room is unavailable or if patient requires transportation to ancillary departments, patient should wear a N95 respirator.

i. Schedule patient to minimize exposure to other patients.
ii. Patients should be instructed to use cough etiquette by covering their mouth with tissues if it is necessary for them to clear respiratory secretions, and to then reapply the N95 respirator. Patients should also be told how to dispose of the tissues in appropriate waste receptacle.
iii. If patients are known to be non-compliant with TB medications, institute Airborne Infection Precautions until they are documented to be non-infectious.
iv. Patients with previously diagnosed TB infections should be considered to be infectious until the physician determines otherwise.

f. Tuberculin Skin Testing

i. Administration of tuberculin test (Mantoux):

- 0.1 ml of PPD will be injected into either the volar or dorsal surface of the arm.
- Anergy panels should be ordered in addition to PPD testing for immunocompromised patients where TB is suspected.
- Tuberculin is injected just beneath the surface of the skin.
- Discrete, pale elevation of the skin 6-10 mm should be produced.

ii. Reading of the skin test

- Trained personnel will read the test between 48-72 hours and record results on the appropriate form which will then be placed in the patient's chart.
- Presence or absence of induration is to be assessed, (not redness or erythema), and should be recorded in millimeters.

g. Treatment Guidelines

Patients who have confirmed active TB or are considered highly likely to have active TB should be started on appropriate treatment promptly, according to current guidelines.

While the patient is in the hospital, anti-tuberculosis drugs will be administered by directly observed therapy, in which a health care worker observes the patient ingesting the medications. All patients should be discharged on outpatient directly observed therapy. Arrangements for this will be made in collaboration with the Florida Department of Health.

h. Cough - Inducing Procedures

Cough-inducing procedures should not be performed on patients who may have infectious TB unless absolutely necessary. These cough-inducing procedures include endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments (including pentamidine therapy), and bronchoscopy. Other procedures that may generate aerosols, e.g. irrigation of TB abscesses, homogenizing or lyophilizing tissue, are also included in these recommendations.

All cough inducing procedures performed on patients who may have infectious TB should be performed using local exhaust ventilation devices, e.g. booths, or if that is not feasible, in a negative air flow room that meets TB ventilation requirements (i.e. airborne infection isolation rooms). Health care workers should wear a N95 respirator present in rooms where cough-inducing procedures are being performed on patients who have, or are at high risk of having infectious TB.

After completion of cough-inducing procedures, patients with known or suspected TB should remain in the airborne infection isolation room or enclosure and not return to common waiting areas until coughing subsides. They should be given tissues and instructed to cover their mouth and nose when coughing. If they must recover from their sedatives or anesthesia following procedures such as bronchoscopy, they should be monitored in a separate airborne infection isolation room, and not in recovery rooms with other patients.

Before the booth, enclosure, or room is used for another patient, adequate time should be allowed to pass so that any droplet nuclei that have been expelled into the air are removed. This time will vary according to the efficiency of the ventilation of filtration used, but is generally 20 minutes.

If performing bronchoscopy in positive pressure rooms, such as operating rooms, if unavoidable, TB infection should be ruled out before the procedure. If bronchoscopy is being performed for diagnosis of pulmonary disease on patients that may have infectious TB, it should be performed in a room that meets TB isolation ventilation requirements.

Before prophylactic aerosolized pentamidine therapy is initiated, all patients should be screened for active TB. Screening should include medical history, PPD, and chest x-ray. Before each subsequent aerosolized pentamidine treatment, patients should be screened for symptoms suggestive of TB. If such symptoms are elicited, a diagnostic evaluation for TB should be initiated.

For patients with suspected or confirmed active TB, it is preferable to use oral instead of aerosolized, prophylaxis for pneumocystic pneumonia if clinically practical.

The Florida Department of Health should be notified for contact investigation prior to discharge; especially when children are in the household.

i. Other Infection Control Measures

Any required infection control measures must be followed to ensure compliance with the OSHA standards and/or current guidelines for preventing the transmission of *M. tuberculosis*.

j. Engineering Controls

To prevent nosocomial transmission, patient rooms and areas where patients with suspected or confirmed TB are treated should be at negative pressure to adjacent areas, have at least 6 air changes per hour, be directly exhausted to the outside or have air recirculated through a HEPA filtration system with 99.7% filtration. Patient isolation rooms are required to have negative pressure relative to the surrounding areas.

Monitoring of isolation rooms for negative pressure when used for TB isolation should be done routinely, per current guidelines or standards. Further, HEPA filters should be monitored and changed routinely, per current guidelines or standards. The need for supplemental ventilation or air cleaning will be periodically reassessed as a part of the risk assessment.

k. Respiratory Protection

In the following circumstances, health care workers should wear a NIOSH approved high efficiency particulate air (HEPA) respirator or an approved N-95 respirator:

i. when entering rooms housing patients with suspected or confirmed infectious TB
ii. when performing high risk procedures on patients who have suspected or confirmed infectious TB. Examples of these include administration of aerosolized medications, bronchoscopy, sputum induction, endotracheal intubation and suctioning procedures, and autopsies.
iii. emergency medical response personnel or others who must transport, in a closed vehicle, an individual with suspected or confirmed infectious TB.

Qualitative or quantitative fit testing must be performed for each respirator wearer. The results of such fit testing must be maintained in a retrievable aggregate database. Medical surveillance will be performed on all potential HEPA respirator wearers.

Other guidelines in the use of respiratory protection include, but are not limited to, the following:

i. Disposable HEPA respirators should be discarded per hospital policy current guidelines.
ii. Multi-user reusable HEPA respirators should be cleaned and filters checked and/or changed per hospital policy or current guidelines.
iii. Designated user reusable HEPA respirators should be cleaned and filters checked and/or changed per hospital policy or current guidelines.
iv. HEPA respiratory wearers should perform check to insure proper fit prior to each use.
v. Facial hair that interferes with the seal of the mask must be removed.

Please reference CDC Guidelines for more detailed information on the use and selection of respiratory protection.

l. Health Care Workers / Student Tuberculosis Screening Program

Health care workers / students should have a two-step Tuberculin Skin Test or a single BAMT infection with *M. tuberculosis* test upon employment and at appropriate intervals as determined by NSU Employee/Student Health Services. The 2005 Guidelines introduce the term “tuberculin skin tests” (TSTs) which is used to include optional testing systems in addition to the purified protein derivative (PPD). All health care workers or students with a history of a positive skin test should either have a chest x-ray on employment or when they initially convert to a positive skin test.

Below are basic guidelines for the screening program:

i. Individuals with a previous history of positive TB skin test should not continue to undergo skin testing. However, a baseline chest x-ray should be on file in the employee's health record.
ii. Health care workers or students who previously received BCG vaccine as a child should receive a baseline TB skin test. If positive, the employee should have a chest x-ray.
iii. Tuberculin PPD is not contraindicated for pregnant employees.
iv. Health care workers with immunosuppression should follow guidelines employed by the NSU Employee/Student Health Services. Because these individuals may be at higher risk for acquisition of TB and rapid progression to active disease, voluntary reassignment to lower risk areas may be advisable.

m. Health Care Workers with TB Infection or Active Disease

Health care workers with baseline positive or newly positive TST or BAMT result should receive one chest radiograph to exclude a diagnosis of TB disease. Such health care workers should be excluded from the workplace and should be allowed to return to work when the following criteria have been met:

i. Three consecutive sputum samples collected in 8–24-hour intervals that are negative, with at least one sample from an early morning specimen (because respiratory secretions pool overnight);
ii. The person has responded to anti-tuberculosis treatment that will probably be effective (can be based on susceptibility results); and
iii. The person is determined to be non-infectious by a physician knowledgeable and experienced in managing TB disease.

Health care workers with infectious TB should notify NSU Employee/ Student Health Services and be excluded from work until documented to be noninfectious and substantial improvement in symptoms. Clearance from Student and Employee Health is required to return to work. NSU Employee/ Student Health Services will monitor compliance with medications. Noncompliant health-care workers should be excluded from work until therapy is re-instituted and the individual assessed to be noninfectious.

Health care workers with TB at sites other than the lung or larynx usually do not need to be excluded from work if concurrent pulmonary TB has been excluded. (except exuding skin lesions).

All information provided by health care workers regarding their health status shall be treated confidentially.

n. Education and Training

All health care workers should receive initial employment and annual education about TB that is appropriate to their job category.

NSU will provide to each new employee during new employee orientation information about the methods of transmission and prevention of tuberculosis infection. NSU will also provide the same information to existing employees who did not receive it at orientation.

For NSU students, NSU will provide information on preventing tuberculosis infection and the modes of transmission, the use of infection control procedures, and the laws governing communicable diseases such as tuberculosis. Schools within the NSU will assist in the educational efforts by providing relevant information about infection control and transmission.

NSU employees who are involved in patient care, share the airspace of patients, and/ or participate in research that could put them at risk of transmission must be informed by NSU about tuberculosis infection.

Examples of information to be included in the educational effort as appropriate include:

a. The basic concepts of tuberculosis transmission, stages of the disease, the signs and symptoms of tuberculosis and the role of PPD testing.
b. The potential for occupational exposure to patients with infectious tuberculosis, its prevalence in the community and facility, and the role of isolation of patients.
c. The principles and practices of infection control that reduce the risk of transmission.
d. The principles of preventive therapy for latent infection.
e. The responsibility of the employee to seek medical evaluation for signs and symptoms of tuberculosis or possible conversion to infectious tuberculosis.
f. The importance of notifying NSU if diagnosed with infectious tuberculosis.
g. The responsibility of NSU to maintain confidentiality for the employee and/or student with tuberculosis.
h. The higher risk posed by tuberculosis infection in individuals who are immunocompromised and the significance of multiple drug resistant tuberculosis in such patients.
i. The responsibility of health care workers to be non-infectious before return to work.

Section 15: Hepatitis B Vaccination & Post-Exposure Follow-up

HBV vaccination shall be offered at no cost to all employees occupationally exposed to blood or other potentially infectious materials in the normal course of their duties. It shall be made available after the required training and within 10 working days of initial assignment to job duties that put the employee at risk of exposure to a Bloodborne pathogen. NSU shall not make participation in a prescreening program a prerequisite for receiving the hepatitis B virus vaccine.

1. Vaccine Acceptance

Employees at NSU who accept to receive the hepatitis B vaccine shall be sent to a designated healthcare provider within 10 working days of their acceptance in writing. The form shown in Appendix D of this Plan, or a similar form, may be used for this purpose. A post vaccine titer will be offered two months after completion of the third dose.

2. Vaccine Declination

NSU shall assure that employees, who decline to accept hepatitis B vaccination offered by the employer, sign the declination statement as worded in the example in Appendix D of this Plan. Employees who initially decline the vaccine but who later elect to receive it may then have the vaccine provided at no cost. The employee shall complete a new form in Appendix D, sign the "Acceptance" portion of the form, and follow the "Vaccine Acceptance" procedures. Copies of the Acceptance/Declination form should be kept on file as a confidential medical record by the department or supervisor.

3. Healthcare Professional's Written Opinion – HBV Vaccine

The employee's supervisor shall obtain and provide to the employee, a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation. This opinion shall be limited to the following information:

a. Whether or not the HBV vaccine is indicated; and
b. If the employee has received the initial inoculation of vaccine.

4. Post exposure Evaluation and Follow-up

In the event of a Bloodborne pathogen exposure or suspected exposure, the individual (Employee, Student or Non-employees as defined in this Plan) should immediately notify his/her supervisor or Department official of the incident. The CDC recommends that the exposed individual seek treatment with 1-2 hours after initial exposure, especially if the HIV status of source individual is unknown. Because timely treatment is essential, the provider should be called ahead of time to be advised of the employee's emergent condition. All Bloodborne pathogen exposures are to be reported to the Coordinator in the EHS.

15.1 Employee Exposure Protocol

In the event of a Bloodborne pathogen exposure or suspected exposure to an employee, the following is applicable:

a. The supervisor, in conjunction with the employee, shall complete an Injury Report which is available from the EHS.
b. If the exposure occurred as a result of contact with a contaminated sharp including sharps injuries involving primates (needlestick, scalpel cut, etc.), then the employee and their supervisor must also complete Injury Report Form.
c. For work related exposures, the employee may seek treatment with any state licensed healthcare provider. The employee, Department Supervisor, or Department of Human Resources shall provide the following information to the evaluating physician, or at the physician's request.
d. Blood from the exposed employee should be collected as soon as possible after the exposure incident for the determination of baseline HIV, HBV, or HCV status.
    i. If the employee consents to baseline blood collections, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.
    ii. Any blood sample taken must maintain the confidentiality of the employee's identity. A unique alphanumeric identifier, and not the employee's name, is recommended to be placed on the sample tube.
o. Supervisors must ensure that employees who do not wish to seek treatment for a potential Bloodborne pathogen exposure sign a statement to that effect. Employees who decline treatment have 2 options:
    i. That they do not wish to seek medical treatment or consultation and they do not consent to have a sample of their blood drawn and held, or tested at this time. That they do not wish to seek medical treatment or consultation, but they wish to have a blood sample drawn and the serum held for 90 days.
    ii. They may not have this sample tested unless they seek medical consultation.
i. Follow-up of the exposed employee should include antibody or antigen testing, counseling, illness reporting, and safe and effective post-exposure prophylaxis according to current U.S. Public Health Service recommendations for medical practice.
    i. For updated U.S. Public Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post-exposure Prophylaxis Centers for Disease Control (CDC) Morbidity and Mortality Weekly Report (MMWR) (RR09); 1-17 (2005, September 30) and updated US Public Health Service recommendations for the management of occupational exposures to blood and other fluids that might contain human immunodeficiency virus (HIV) go to:

        http://www.osha.gov/SLTC/Bloodbornepathogens/postexposure.html

    ii. For updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-exposure Prophylaxis Center for Disease Control (CDC) Morbidity and Mortality

Weekly Report (MMWR) (RR-11); 1-42 (2001, June 29) as well as updated and consolidated recommendations for the management of health-care personnel (HCD) go to:

http://www.osha.gov/SLTC/Bloodbornepathogens/postexposure.html

f. The source individual's blood should be tested as soon as feasible. If the worksite already has a sample specimen of the source individual, then the state of Florida does not require the source individual's consent prior to testing. If a specimen must be obtained from the source individual, then an informed consent form must be obtained (See Appendix E).
g. Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual. When the source is already known to be infected with HBV, HIV, or HCV, then testing for the source individual's known HBV, HIV, or HCV status need not be repeated.

HEALTHCARE PROFESSIONAL'S WRITTEN OPINION – POST EXPOSURE: For each evaluation under this section, the employing department shall obtain and provide to the exposed employee a copy of the evaluating healthcare professional's written opinion within 15 days of receipt. The written opinion shall be limited to the following information:

a. Whether the hepatitis B virus vaccination is indicated for an employee, and if the employee has received such vaccination.
b. A statement that the employee has been informed of the results of the medical evaluation and that the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.
c. Any other findings and diagnoses shall remain confidential, and shall not be included in the written opinion report.
d. The treating healthcare professional shall provide this written opinion report at the request of an authorized NSU representative.

15.2 Students

Students who have had significant contact from a contaminated needle or who have had contamination to an open wound or mucous membrane are to follow the specific guidelines and procedures for students as outlined in the Needlestick Policy.

15.3 Non-Employees

Non-employees may choose their medical provider for post-exposure evaluation. Non-employees should report the exposure to their own institution or employer for reimbursement according to the policies and procedures of their institution.
The sponsoring NSU department will report all incidents involving sharps or suspected Bloodborne pathogen exposures sustained by persons to the EHS.

15.4 Simian Herpes B virus

Individuals working with primates who have been exposed either through a bite, scratch, sharps injury, or mucous membrane exposure to the Simian Herpes B virus should follow the protocol established by the Department of Laboratory Animal Resources (DLAR) and seek immediate medical treatment.

The National B Virus Resource Center can provide information on the most current management of this type of exposure. The Center's contact information is noted below:

National B Virus Resource Center
Viral Immunology Center
Georgia State University
50 Decatur Street
Atlanta Georgia 30303

PH (lab): 404-651-0808
FAX (lab): 404-463-9951

Section 16: Information & Training

Each department shall ensure that all individuals with occupational exposure participate in a training program for prevention of Bloodborne pathogen exposure. Those individuals include: research personnel, clinicians, custodial services personnel, NSU security department personnel, students, residents, physicians, or any other persons working within the institution. NSU employees are required to attend the Bloodborne Pathogen Safety Awareness course offered by the Environmental Health & Safety Office or take the web-based course

16.1 Safety-Bloodborne Pathogens Training

This course covers the required content for compliance with the State of Florida and OSHA Bloodborne Pathogen Standard. Research personnel are also required to attend the Basic Biological Safety course.

16.2 Training frequency

Training shall be provided at the time of initial assignment to tasks where occupational exposure may take place. Annual refresher training is to be taken within 1 year of the employee's previous training.

NSU shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

16.4 Training content

Material appropriate in content and vocabulary to educational level, literacy, and language background of employees shall contain the following elements:

a. A summary of this Exposure Control Plan and explanation of its contents and where to obtain an accessible copy of this plan, as well as awareness of the State of Florida and OSHA regulations;
b. A general explanation of the epidemiology and symptoms of Bloodborne diseases;
c. An explanation of the modes of transmission of Bloodborne pathogens;
d. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;
e. An explanation of the use and limitations of practices that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;
f. Information on the types, proper use, locations, removal, handling, decontamination and/or disposal of personal protective equipment;
g. An explanation of the basis for selection of personal protective equipment;
h. Information on the Hepatitis B vaccine, including information on its efficacy, safety, method of administration and the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

i. Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;
j. An explanation of the procedure to follow if an exposure incident occurs including the method of reporting the incident and the medical follow-up that will be made available. Also information on the post exposure evaluation and follow-up that the institution is providing for exposed individuals; and
k. An explanation of the signs and labels and/or color-coding.

16.5 Additional Training for Employees in HIV or HBV Research Laboratories

Employees in HIV or HBV clinical and research laboratories shall receive the following training in addition to the above training requirements:

a. The principal investigator or supervisor shall ensure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.
b. Department supervisors shall assure that employees have experience in the handling of human pathogens or tissue cultures prior to working with HIV or HBV.
c. A training program shall be provided to employees with no prior experience in handling human pathogens, before handling any infectious agents.

Additional requirements for training may be found in the latest edition of *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* which can be accessed on the CDC website at:

http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

16.6 Fulfilling the Training Requirements

Health care personnel, clinical, or research employees with likely occupational exposure to Bloodborne pathogens may fulfill the training requirements as follows (BBPC = Basic Bloodborne Pathogens Course):

Table J: Minimum Training Requirements

Employee Type	Potential Exposure to Bloodborne Pathogens	Training Courses Required
Research	Medium	Bloodborne Pathogens Safety Basic Biological Safety
Clinical/Dental	Medium	Bloodborne Pathogens Safety
Ancillary	Low	Bloodborne Pathogens Safety
Laboratory Animal Resources	Medium	Bloodborne Pathogens Safety Basic Biological Safety
Safety Specialist/ Manager	Medium	Bloodborne Pathogens Safety Basic Biological Safety

16.7 Alternative Training

Training provided by groups outside of Environmental Health & Safety Office is acceptable if the specifications noted below are fulfilled:

a. Only training that is provided by a U.S. institution and meets the curriculum requirements.
b. Copies of this Exposure Control Plan must be made available for review during alternative training.
c. Documentation of alternative training must be maintained by the requesting department. Training records must meet the requirements.

Section 17: Recordkeeping

This section outlines the records required to be maintained and retained by the University.

17.1 Medical Records

Each department shall maintain or have access to medical records for each employee with an occupational exposure for at least the duration of employment plus 30 years. These records shall include:

a. The name and Social Security Number of the employee.
b. The employee's Hepatitis B vaccination status including the dates of all the Hepatitis B vaccinations and medical records relative to the employee's ability to receive vaccination or the circumstances of an exposure incident.
c. A copy of all results of physical examinations, medical testing, and follow-up procedures as they relate to the employee's ability to receive vaccination or to post exposure evaluation following an exposure incident in accordance with OSHA 29 CFR 1910.1020, Access to Employee Exposure and Medical Records.
d. A copy of the healthcare professional's written opinion form**.**

17.2 Availability

Medical records are made available to the subject employee or anyone with written consent of the employee.

17.3 Confidentiality

The employer department(s) maintaining medical records activity shall ensure that employee medical records:

a. Are secured from unauthorized use and confidentially maintained.
b. Are not disclosed or reported to any person within or outside the workplace except as required by this section or as may be required by law.
c. Meet the NSU health information records storage requirements.

17.4 Training records

Records of training performed by Environmental Health & Safety Office will be retained in the Environmental Health & Safety Office for at least 3 years.

The training records shall include the following:

a. Dates of the training sessions;
b. The contents or summary of the training sessions;
c. The names and job titles of all persons conducting the training session;
d. The names and job titles of all persons attending the training session.

Employee training records are provided to the employee or their supervisor within 15 working days of a written request.

17.5 Monitoring Employee Compliance

Each department shall establish a mechanism to monitor employee compliance with Standard or Universal Precautions based on the level of exposure. Each department shall also define a system of disciplinary action for employee noncompliance with the requirements set forth in this Plan. Accurate written records of any disciplinary action shall be maintained in the employee's file.

APPENDIX A

List of Bloodborne Pathogens.[a,b,c]

Disease/Agent(s)	Common Names	Risk	Incubation	Sources
Serum Hepatitis/Hepatitis B Virus	Hepatitis B (42 nm), Hepadnavirus dsDNA	6-10% infection 1-2% fatal	11 weeks	Blood, semen, saliva, cerebral spinal fluid
Transfusion Hepatitis/Hepatitis C Virus	Hepatitis C, Non A, Non B (40-60 nm), Flaviviridae (ss RNA)	0.5-1% fatal	7 weeks	Blood, serum
AIDS: Retroviridae(100 nm) (Oncornavirus - RNA)	HIV-1, LAV (formally HTLV III)	< 0.5% infection, 100% fatal	Adults: 8 years Infants: 2 years	Blood, serum, saliva, tears, urine, breast milk, amniotic fluid, cerebral spinal fluid
	HIV-2 (West Africa) HTLV IV	<8.9% infection 100% fatal	Unknown	Blood, serum, saliva, tears, urine, breast milk, amniotic fluid, cerebral spinal fluid
Leukemia/Lymphomas Human T-Lymphotropic Virus (HTLV)	Retroviridae (Oncornavirus 100 nm), HTLV I	18-49% infection	Unknown	Blood
	HTLV II	52% Infection	Unknown	Blood
	HTLV V	Unknown	Unknown	Blood
Transmissible spongiform encephalopathies (CJD)	Creutzfeldt-Jakob Disease	30 cases per million	10-15 yrs.	Neurological and brain tissues, corneal spinal cord, transplant tissues
Kuru (50-300 µm)	Kuru Disease	Unknown	10-30 yrs.	Spinal cord, brain
Hemorrhagic fever: Marburg virus	Filovirus-ss RNA: (900 x 80 nm) MBG	22% fatal	4-16 days	Rodents, bodily fluids
Ebola virus	EBO	53-88% fatal		Rodents, bodily fluids
Argentine hemorrhagic fever	Junin virus (arenavirus: ss RNA-130 x 20 nm)	15% fatal	7-14 days	Rodents, bodily fluids, cerebral spinal fluid
Bolivian hemorrhagic fever	Machupo virus (ss RNA) Arenavirus 130 x 20 nm	18% fatal	7-14 days	Rodents, bodily fluids

Venereal syphilis/ Treponema pallidium	Bacterial spirochete (6 --15 x 0.1-0.2 µm)	14.6 per 100,000 cases	10-90 days	Bodily fluids

[a] Hunt, D.L., "Human Immunodeficiency Virus Type 1 and Other Bloodborne Pathogens," *Laboratory Safety: Principles and Practices*, 2nd ed, Fleming, Richardson, Tulis, Vesley, Eds. (American Society of Microbiology, 1995) pp. 33-66.

[b] Jahrling, Peter, "Marburg Virus, Ebola Virus, and the Arenaviruses," *Manual of Clinical Microbiology*, 4th ed, Lennette, Balows, Hausler, and Shadomy , Eds. (American Society of Microbiology, 1985) pp. 796-804.

[c] Swenson, P.D., "Hepatitis Viruses," *Manual of Clinical Microbiology*, 5th ed, Balows, Hausler, Herman, Isenberg and Shadomy, Eds. (American Society of Microbiology, 1991) pp. 959-983.

APPENDIX B

Classification of Human Etiologic Agents on the Basis of Hazard

This appendix includes those biological agents known to infect humans as well as selected animal agents that may pose theoretical risks if inoculated into humans. Included are lists of representative genera and species known to be pathogenic. Mutated, recombined, and non pathogenic species and strains are not considered. Non infectious life cycle stages of parasites are excluded.

This appendix reflects the current state of knowledge and should be considered a resource document. The list includes the more commonly encountered agents and is not meant to be all-inclusive. Information on agent risk assessment may be found in the Agent Summary Statements of the CDC/NIH Biosafety in the Microbiological and Biomedical Laboratories. Further guidance on agents not listed in this Appendix may be obtained through: Centers for Disease Control and Prevention, Biosafety Branch, Atlanta, Georgia 30333, Phone: (404) 639 3883, Fax: (404) 639 2294; National Institutes of Health, Division of Safety, Bethesda, Maryland 20892, Phone: (301) 496 1357; National Animal Disease Center, U.S. Department of Agriculture, Ames, Iowa 50010, Phone: (515) 862 8258.

Risk Group 1 (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. No or low individual and community risk. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis*.

Those agents not listed in Risk Groups (RGs) 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. Moderate individual risk: low community risk.

Risk Group 2 (RG2) Bacterial Agents Including Chlamydia	
• **Acinetobacter baumannii** (formerly Acinetobacter calcoaceticus) • **Actinobacillus** • **Actinomyces pyogenes** (formerly Corynebacterium pyogenes) • **Aeromonas hydrophila** • **Amycolata autotrophica**	• **Helicobacter pylori** • **Klebsiella** all species except K. oxytoca (RG1) • **Legionella** including L. pneumophila • **Leptospira interrogans** all serotypes • **Listeria** • **Moraxella**

- **Archanobacterium haemolyticum** (formerly Corynebacterium haemolyticum)
- **Arizona hinshawii** all serotypes
- **Bacillus anthracis**
- **Bartonella henselae, B. quintana,B. vinsonii**
- **Bordetella** including **B. pertussis**
- **Borrelia recurrentis, B. burgdorferi**
- **Burkholderia** (formerly Pseudomonas species) except those listed in RG3
- **Campylobacter coli, C. fetus, C. jejuni**
- **Chlamydia psittaci, C.trachomatis, C. pneumoniae**
- **Clostridium botulinum, Cl.chauvoei , Cl. haemolyticum , Cl. histolyticum, Cl. novyi. Cl. septicum, Cl. tetani**
- **Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale**
- **Dermatophilus congolensis**
- **Edwardsiella tarda**
- **Erysipelothrix rhusiopathiae**
- **Escherichia coli** all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including **E. coli O157:H7**
- **Haemophilus ducreyi, H.influenzae**
- **Mycobacterium** (except those listed in RG3) including **M. avium complex, M. asiaticum, M. bovis BCG vaccine strain, M. chelonei, M. fortuitum, M. kansasii, M. leprae, M. malmoense, M. marinum, M. paratuberculosis, M. scrofulaceum, M. simiae, M. szulgai, M. ulcerans, M. xenopi**
- **Mycoplasma** , except **M. mycoides** and **M. agalactiae** which are restricted animal pathogens
- **Neisseria gonorrhoeae, N. meningitidis**
- **Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum , N. transvalensis**
- **Rhodococcus equi**
- **Salmonella** including **S, arizonae, S. cholerasuis , S. enteritidis , S. gallinarum pullorum, S. meleagridis, S. paratyphi, A, B, C, S. typhi, S. typhimurium**
- **Shigella** including **S. boydii, S. dysenteriae, type 1, S. flexneri, S. sonnei**
- **Sphaerophorus necrophorus**
- **Staphylococcus aureus**
- **Streptobacillus moniliformis**
- **Streptococcus** including **S. pneumoniae, S. pyogenes**
- **Treponema pallidum, T. carateum**
- **Vibrio cholerae, V. parahemolyticus , V. vulnificus**
- **Yersinia enterocolitica, Y. pseudotuberculosis**

Risk Group 2 (RG2) Fungal Agents

- **Blastomyces dermatitidis**
- **Cladosporium bantianum , C. (Xylohypha) trichoides**
- **Cryptococcus neoformans**
- **Fonsecaea pedrosoi**
- **Microsporum**
- **Paracoccidioides braziliensis**

• **Dactylaria galopava (Ochroconis gallopavum)** • **Epidermophyton** • **Exophiala (Wangiella) dermatitidis**	• **Penicillium marneffei** • **Sporothrix schenckii** • **Trichophyton**

Risk Group 2 (RG2) Parasitic Agents	
• **Ancylostoma** human hookworms including **A. duodenale , A. ceylanicum** • **Ascaris** including **A. lumbricoides suum** • **Babesia** including **B. divergens, B. microti** • **Brugia** filaria worms including **B. malayi , B.timori** • **Coccidia** • **Cryptosporidium** including **C. parvum** • **Cysticercus cellulosae (hydatid cyst, larva of T. solium)** • **Echinococcus** including **E. granulosis, E. multilocularis, E. vogeli** • **Entamoeba histolytica** • **Enterobius** • **Fasciola** including **E. gigantica, E. hepatica** • **Giardia** including **G. lamblia** • **Heterophyes** • **Hymenolepis** including **H. diminuta, H. nana** • **Isospora**	• **Leishmania** including **L.braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana, L. peruvania, L. tropica** • **Loa loa** filaria worms • **Microsporidium** • **Naegleria fowleri** • **Necator** human hookworms including **N. americanus** • **Onchoerca** filaria worms including **O. volvulus** • **Plasmodium** including simian species, **P. cynologi, P. falciparum, P. malariae, P. ovale, P. vivax** • **Sarcocystis** including **S. sui hominis** • **Schistosoma** including **S, haematobium, S. intercalatum, S. japonicum, S. mansoni, S. mekongi** • **Strongyloides** including **S. stercoralis** • **Taenia solium** • **Toxocara** including **T. canis** • **Toxoplasma** including **T. gondii** • **Trichinella spiralis** • **Trypanosoma** including **T. brucei brucei, T. brucei gambiense, T.brucei rhodesiense, T. cruzi** • **Wuchereria bancrofti filaria worms**

Risk Group 2 (RG2) Viruses	
• Adenoviruses, human all types	• Orthomyxoviruses

- Alphaviruses (Togaviruses) Group A Arboviruses
    - Eastern equine encephalomyelitis virus
    - Venezuelan equine encephalomyelitis vaccine strain TC 83
    - Western equine encephalomyelitis virus
- Arenaviruses
    - Lymphocytic choriomeningitis virus (non neurotropic strains)
    - Tacaribe virus complex
    - Other viruses as listed in the reference source
- Bunyaviruses
    - Bunyamwera virus
    - Rift Valley fever virus vaccine strain MP 12
    - Other viruses as listed in the reference source Calciviruses
- Coronaviruses
- Flaviviruses (Togaviruses) Group B
    - Arboviruses Dengue virus serotypes 1, 2, 3, and 4
    - Yellow fever virus vaccine strain 17D
    - Other viruses as listed in the reference source Hepatitis A, B, C, D, and E viruses
- Herpes viruses except Herpesvirus simiae (Monkey B virus) (see Risk Group 4)
    - Cytomegalovirus
    - Epstein Barr virus
    - **Herpes simplex** types 1 and 2
    - **Herpes zoster**
    - Human herpesvirus types 6 and 7
    - Influenza viruses types A, B, and C
    - Other tick borne orthomyxoviruses as listed in the reference source
- Papovaviruses
    - All human papilloma viruses
- Paramyxoviruses
    - Newcastle disease virus
    - Measles virus
    - Mumps virus
    - Parainfluenza viruses types 1, 2, 3, and
- Respiratory syncytial virus Parvoviruses Human parvovirus (B19) Picornaviruses Coxsackie viruses types A and B Echoviruses all types
- Rhinoviruses all types Poxviruses -- all types except Monkeypox virus **(see Risk Group 3)** and restricted poxviruses including Alastrim, Smallpox, and Whitepox
- Reoviruses -- all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)
- Rhabdoviruses
    - Rabies virus -- all strains
- Vesicular stomatitis virus laboratory adapted strains including VSV Indiana, San Juan, and Glasgow
- Togaviruses (see Alphaviruses and Flaviviruses)
    - Rubivirus (rubella)

Risk Group 3 (RG3) Agents

RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. High individual risk; low community risk.

Risk Group 3 (RG3) Bacterial Agents Including Rickettsia	
• **Bartonella** • **Brucella** *including* **B. abortus,B. canis, B. suis** • **Burkholderia (Pseudomonas) mallei B. pseudomallei** • **Coxiella burnetii** • **Francisella tularensis**	• **Mycobacterium bovis** *(except BCG strain, see RG2 Bacterial Agents),* **M. tuberculosis** • **Pasteurella multocida** *type B "buffalo" and other virulent strains* • **Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R. siberica, R. tsutsugamushi, R. typhi (R. mooseri)** • **Yersinia pestis**

Risk Group 3 (RG3) Fungal Agents	
• **Coccidioides immitis** *(sporulating cultures; contaminated soil)*	• **Histoplasma capsulatum, H. capsulatum var. duboisii**

Risk Group 3 (RG3) Viruses and Prions	

• Alphaviruses (Togaviruses)--Group A Arboviruses
  o Semliki Forest virus
  o St. Louis encephalitis virus
  o Venezuelan equine encephalomyelitis virus (except the vaccine strain TC 83, see RG2)
  o Other viruses as listed in the reference source
• Arenaviruses
  o Flexal
  o Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
• Bunyaviruses
	• Poxviruses
	  o Monkeypox virus
	• Prions
	  o Transmissible spongioform encephalopathies (TME) agents (Creutzfeldt Jacob disease and kuru agents)(contact Biological Safety for containment instruction)
	• Retroviruses

○ Hantaviruses including Hantaan virus ○ Rift Valley fever virus • Flaviviruses (Togaviruses)--Group B Arboviruses ○ Japanese encephalitis virus ○ Yellow fever virus ○ Other viruses as listed in the reference source (consult OSEH)	○ Human immunodeficiency virus (HIV) types 1 and 2 ○ Human T cell lymphotropic virus (HTLV) types 1 and 2 ○ Simian immunodeficiency virus (SIV) • Rhabdoviruses ○ Vesicular stomatitis virus

Risk Group 4 (RG4) Agents

RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. High individual and community risk.

Risk Group 4 (RG4) -- Bacterial Agents
None

Risk Group 4 (RG4) -- Fungal Agents
None

Risk Group 4 (RG4) -- Parasitic Agents
None

Risk Group 4 (RG4) -- Viral Agents	
• Arenaviruses ○ Guanarito virus ○ Lassa virus ○ Junin virus ○ Machupo virus	• Arboviruses ○ Tick borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring summer encephalitis viruses

o Sabia • Bunyaviruses (Nairovirus) o Crimean Congo hemorrhagic fever virus • Filoviruses o Ebola virus o Marburg virus • Flaviruses (Togaviruses) -- Group B	• Herpesviruses (alpha) o Herpesvirus simiae (Herpes B or Monkey B virus) • Paramyxoviruses o Equine morbillivirus • Hemorrhagic fever agents and viruses as yet undefined

Animal Viral Etiologic Agents in Common Use

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents is associated with disease in healthy adult humans; they are commonly used in laboratory experimental work. A containment level appropriate for RG1 human agents is recommended for their use. For agents that are infectious to human cells, e.g., amphotropic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.

Animal Viral Etiologic Agents in Common Use	
Adenoviruses • Aian adenovirus, including CELO virus • Bovine adenovirus • Canine adenovirus • Equine adenovirus • Baculoviruses • Coronaviruses o Bovine coronavirus o Canine coronavirus o Equine coronavirus o Feline coronavirus • Herpesviruses o Bovine herpesvirus	• Shope papilloma virus • Simian virus 40 (SV40) • Paramyxoviruses o Bovine parainfluenza o Bovine respiratory syncytial virus o Canine distemper virus o Canine parainfluenza • Parvoviruses o Bovine parvovirus o Canine parvovirus o Equine parvovirus o Porcine parvovirus • Retroviruses

○ Canine herpesvirus ○ Channel catfish herpesvirus ○ Equine herpesvirus ○ Feline herpesvirus ○ Herpesvirus ateles ○ Herpesvirus saimiri ○ Murine cytomegalovirus ○ Pseudorabies virus ○ Papovaviruses • Bovine papilloma virus ○ Polyoma virus	○ Avian leukosis virus ○ Avian sarcoma virus ○ Bovine leukemia virus ○ Feline leukemia virus ○ Feline sarcoma virus ○ Gibbon leukemia virus ○ Mason Pfizer monkey virus ○ Mouse mammary tumor virus ○ Murine leukemia virus ○ Murine sarcoma virus • Rat leukemia virus

CDC Select Agents and Toxins

HHS Non-Overlap Select Agents and Toxins	
• Crimean-Conco haemorragic fever virus • ***Coccidiodes posadasii*** • Ebola viruses • Cercopithecine herpesvirus 1 (Herpes B Virus) • Lassa Fever virus • Marburg virus • Monkeypox virus • ***Rickettsia prowasekii*** • ***Rickettsia rickettsii*** • South American haemorrhagic fever viruses ○ Junin ○ Machupo	• Tick-borne encephalitis complex (flavi) viruses ○ Central European tickborne encephalitis ○ Far eastern tickborne encephalitis ○ Russian spring and summer enephalitis ○ Kyasanur forest disease ○ Omsk hemorrhagic fever • Variola major virus (Smallpox virus) • Variola minor virus (Alastrim) • Yersinia pestis • Abrin • Conotoxins • Diacetoxyscripenol

○ Sabia ○ Flexal ○ Guanarito	• Ricin • Saxitoxin • Shiga-like ribosome inactivating proteins • Tetrodotoxin

Listed Plant Pathogens	
• **Liberobacter africanus** • **Liberobacter asiaticus** • **Peronosclerospora phillippinensis** • **Phakopsora pachyrhizi** • Plum Pox Potyirus	• **Ralstonia colanacearum race 3, biovar 2** • **Schlerophthora rayssiae var zeae** • **Synchytrium endobioticum** • **Xanthomonas oryzae** • **Xylella fastidiosa** (citrus variegated chlorosis strain)

USDA High Consequence Livestock Pathogens and Toxins (Non-overlap Agents and Toxins)	
• Akabane virus • African swine fever virus • African horse sickness virus • Avian influenza virus (highly pathogenic) • Blue tongue virus (exotic) • Bovine spongiform encephalopathy agent • Camel pox virus • Classical swine fever virus • ***Cowdria ruminantium (Heartwater)*** • Foot and mouth disease virus • Goat pox virus • Lumpy skin disease virus	• Japanese encephalitis virus • Malignant catarrhal fever virus (Exotic) • Menangle virus • ***Mycoplasma capricolumi M.D38/M.mycoides capri*** • ***Mycoplasma mycoides mycoides*** • Newcastle disease virus (WND) • Peste Des Petits Ruminants virus • Rinderpest virus • Sheep pox virus • Swine vesicular disease virus • Vesicular stomatitis virus (Exotic)

High Consequence Livestock Pathogens and Toxins/Select Agents (Overlap Agents)	
• **Bacillus anthracis** • **Brucella abortus** • **Brucella melitenis** • **Brucella suis** • **Burkholderia malleii (formerly Pseudomonas mallei)** • **Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)** • Botulinum neurotoxin producing species of Clostridium • **Coccidioides immitis**	• **Coxiella burnetti** • Eastern equine encephalitis virus • Hendra virus • **Francisella tularensis** • Nipah Virus • Rift Valley fever virus • Venezuelan equine encephalitis virus • Botulinum neurotoxin • **Clostridium perfringens** epsilon toxin • Shigatoxin • Staphylococcal enterotoxin • T-2 Toxin

Plant Biosafety Level Criteria

Research involving recombinant DNA containing plants, plant associated microorganisms, and small animals shall be conducted in accordance with - "Physical and Biological Containment for Recombinant DNA Research Involving Plants" as contained in the latest copy of the document Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) published by the National Institutes of Health (NIH).

NCI Classification Scheme for Oncogenic Agents

The National Cancer Institute (NCI) has prepared minimum safety guidelines for research involving oncogenic viruses which are designed to protect the laboratory worker and his/her experiments, to minimize hazards to anyone else who might enter the laboratory area, and to insure the safety of the surrounding community. NCI strongly recommends that the guidelines be practiced in all research laboratories where oncogenic viruses are present.

It is assumed that oncogenic viruses vary in their potential hazard to man. Criteria have been developed to identify oncogenic viruses of moderate and high risk. All other oncogenic viruses are considered low risk. The criteria are not absolute, but are subject to modification as research continues.

In addition to the listed criteria, the extent to which there is prior experience with the virus without indication of any harmful effect on man must also be considered when evaluating risk. Listed below are some known low risk and moderate risk oncogenic agents, respectively.

In general, low risk oncogenic viruses may be handled at Biosafety Level 1 and moderate risk oncogenic viruses may be handled at Biosafety Level 2. All viruses of human or primate origin must be handled at Biosafety Level 2, 3 or 4.

Low Risk Oncogenic Viruses	
• Rous sarcoma	• Rat leukemia
• SV 40	• Hamster leukemia
• CELO	• Bovine leukemia
• Ad7 SV40	• Dog sarcoma*
• Polyoma	• Mason Pfizer monkey virus
• Bovine papilloma	• Marek's
• Rat mammary tumor	• Guinea pig herpes
• Avian leukosis	• Lucke (Frog)
• Murine leukemia	• Adenovirus
• Murine sarcoma	• Shope fibroma
• Mouse mammary tumor	• Shope papilloma
	*Although listed by NCI, it is questionable whether a dog sarcoma virus has been isolated.

Criteria for Moderate Risk Oncogenic Viruses

A. Suspected oncogenic virus isolate from man.

B. Virus that transforms human cells in vitro, as evidenced by a morphological and/or functional alteration that is transferred genetically.

C. Virus that produces cancer without the aid of experimental host modification in either a subhuman primate at any age or across another mammalian species barrier in juvenile or adult animals.

D. A genetic recombinant between an animal oncogenic virus and a microorganism infectious for man shall be considered moderate risk until its oncogenic potential for man is determined.

E. Any concentrated oncogenic virus or infectious transforming viral nucleic acid.

Moderate Risk Oncogenic Viruses	
• Ad2 SV40 • FeLV • HV Saimiri • EBV • SSV	• GaLV • HV ateles • Yaba • FeSV

Criteria for High Risk Oncogenic Viruses

A virus proved to induce cancer in man shall be classified as high risk until it's complete hazard potential can be determined. At the present time, there are no known oncogenic viruses classified as high risk.

APPENDIX C

GLOVE SELECTION CHART

Gloves	Usage	Comments	Recommended for	Not recommended
Latex (Natural rubber) low cost	Incidental contact	Good for biological and water-based materials. Poor for organic solvents. Little chemical protection. Can puncture holes. Can cause or trigger latex allergies	Weak Acids, Weak bases, alcohols, aqueous solutions	Oils, greases and organics
Nitrile (synthetic rubber) low cost	Incidental contact	Good for solvents, oils, greases, and some acids and bases. Clear indication of tears and breaks. Good alternative for those with latex allergies	Oils, greases, acids, caustics, aliphatic solvents	Aromatic solvents, many ketones, esters, many chlorinated solvents
Butyl (synthetic rubber)	Extended contact	Good for ketones and esters. Poor for gasoline, aromatic, and halogenated hydrocarbons	Aldehydes, ketones, esters, glycol ethers, polar organic solvents	Aliphatic, aromatic and chlorinated solvents
Neoprene (synthetic rubber) medium cost	Extended contact	Good for acids, bases, alcohols, fuels, peroxides, hydrocarbons, and phenols.	Oxidizing acids, bases, alcohols, aniline, phenol, glycol ethers	Chlorinated solvents
PVA (poly-vinyl alcohol)	Specific use	Good for aromatic and chlorinated solvents. Poor for water-based solutions	A wide range of aliphatic, aromatic and chlorinated solvents, ketones	Acids, alcohols, bases, water
PVC (poly-vinyl chloride)	Specific use	Good for acids, bases, oils, fats, peroxides, and amines. Good resistance to abrasions. Poor for most organic solvents	Strong acids and bases, salts, other aqueous solutions, alcohols, glycol ethers	Aliphatic, aromatic and chlorinated solvents, aldehydes, ketones.
Viton (Fluoro-elastimer)	Extended use	Good for chlorinated and aromatic solvents. Good resistance to cuts and abrasions. Poor for ketones.	Aromatic, aliphatic and chlorinated solvents, and alcohols	Some ketones, esters, amines
Silver Shield(laminate)			Wide range of solvents, acids and bases	

APPENDIX D

NOVA SOUTHEASTERN UNIVERSITY
HEPATITIS B VIRUS (HBV) VACCINE ACCEPTANCE OR DECLINATION FORM

Acceptance Statement

I, the undersigned, acknowledge that my employer, Nova Southeastern University has offered the hepatitis B virus (HBV) vaccine to me at no cost. I have been informed of the biological hazards that exist in my workplace, and I understand the risks of exposure to blood or other potentially infectious materials involved with my job.
I wish to receive the hepatitis B virus vaccine.

_____ _____ _____
Employee's name (printed) Employee's signature Badge Number

_____ _____ _____
Department Supervisor / Witness signature Date

NOTE: If you accept to receive the hepatitis B vaccine, you must report to the designated medical provider within 10 working days of signing this form.

Declination Statement

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine at no charge to myself. However, **I decline hepatitis B vaccination at this time.** I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

All my questions regarding the risk of acquiring hepatitis B virus, and the hepatitis B virus vaccination process, have been answered to my satisfaction.

_____ _____ _____
Employee's name (printed) Employee's signature
Badge Number

_____ _____ _____
Department Supervisor / Witness signature
Date

Retain a copy of this document in Employee's medical record for 30 years after termination of employment

APPENDIX E

CONSENT FORM FOR TESTING

_____ My initials indicate that I have been given verbal and written educational information for HIV, HBV and HCV antibody testing.

Name _____ ID# _____

CONSENT FOR SEROLOGICAL TESTING FOR HIV, HBV and HCV ANTIBODIES
I have been informed that a sample of my blood will be drawn and tested to detect HIV, HBV and HCV antibodies. I have been informed of the purpose and potential uses of the test. By my signature below, I hereby acknowledge that I have read, or have had read to me, this information regarding HIV, HBV and HCV antibody testing. I have been given the opportunity to ask questions and any questions have been answered to my satisfaction. I acknowledge that I have given consent for performance of this blood test to detect HIV, HBV and HCV antibodies. I hereby release (laboratory name here) from any liability or claims arising from the reporting of the results of my test to authorized persons.

_____	_____
Signature of Patient/Responsible Party	Relationship if Not Patient
_____	_____
Witness	Second Witness (If Telephone Consent)
_____	_____
Date	Time

REFUSAL OF SEROLOGICAL TESTING FOR HIV, HBV and HCV ANTIBODIES
I have read the previous consent and have been adequately informed regarding HIV, HBV and HCV antibody testing. I have decided not to consent to testing. I hereby release (laboratory name here) from any liability or claims that I may have resulting from my refusal to HIV, HBV and HCV antibody testing. If a health care provider has a significant exposure to blood or body fluid from me or equipment used on me, and if I or my next-of-kin or legal guardian refuse to consent to HIV, HBV and HCV antibody testing, and a sample of my blood is available, the sample shall be tested for the presence of infectious diseases.

_____	_____
Signature of Patient/Responsible Party	Relationship if Not Patient
_____	_____
Witness	Second Witness (If Telephone Consent)
_____	_____
Date	Time

APPENDIX F

POST- EXPOSURE FOLLOW-UP

Laboratory name
Laboratory address

__/__/__

Dear

Regarding your incident on (date), as we informed you, the source (patient) testing results are:

Hepatitis B surface antigen: Nonreactive
Hepatitis C antibody: Nonreactive
HIV (AIDS testing): Negative

Results of your blood tests drawn on are:

Hepatitis B surface antibody: Reactive- You are immune to Hepatitis B.
Hepatitis C antibody: Nonreactive
HIV 1/HIV 2 (AIDS testing): Nonreactive

You declined follow-up blood tests.

We recommend follow up blood testing for you on the following date (s).
6 weeks due:_____ 3 months due:_____ 6 months due:_____

You will be reminded when due.

Please contact (Employee Health or a physician) if any questions or any of the following symptoms occur: Low grade fever, Swollen glands, Unexplained rash or Weight loss, Malaise or Night sweats.

Contact at ___-___-____, for additional help.

This information is being provided to you as a result of a confidential medical evaluation and follow-up for a reported blood borne pathogen exposure.

The source results are made available to you according to federal regulation. Under applicable laws and regulations, you may not further disclose their identity and infectious status.

Confidential Report
Consistent with Federal Register, Bloodborne Pathogens- (29 CFR 1910.1030).

Healthcare Professional Signature: _____Date: _____

APPENDIX G

Glossary

Biohazardous materials	Materials that are not capable of self replication and that are the components of biological agents that present a real or potential risk of causing illness or injury to humans, plants, or animals.
Biohazard	Any biological material, or a component thereof, that presents a real or potential risk of illness or injury to humans, plants, or animals.
Biological safety cabinet	An apparatus used for the ventilation control of infectious agents or other biologically derived molecules. These cabinets are divided into three classes by design and containment and cleanliness capability: Class I cabinets, which are most suitable for Safety Level 1 and some Safety Level 2 and 3 containment, are similar to a conventional laboratory hood having an open-face, negative-pressure design. Class II (i.e., laminar-flow) cabinets utilize a HEPA filter in an overhead diffuser to reduce contamination in the cabinet, and are effective in protecting operators from research materials and in protecting research materials from external contamination. Class III cabinets are hermetically sealed enclosures for the handling of extremely hazardous materials at Safety Level 4.
Blood	Human blood, human blood components, and products made from human blood. The term "human blood components" includes plasma, platelets, and serosanguinous fluids (e.g., exudates from wounds). Also included are medications derived from blood, such as immune globulins, albumin, and factors 8 and 9, (OSHA CPL 2-2.44D).
Bloodborne pathogens	Microorganisms that are present in human blood and that can cause diseases in humans; while HBV, HCV and HIV are specifically identified in the standard, the term includes any pathogenic microorganism that is present in human blood or other potentially infectious material (OPIM) and can infect and cause disease in persons who are exposed to blood containing the pathogen. Pathogenic microorganisms can also cause diseases such as malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, adult T-cell leukemia/lymphoma (caused b y HTLV-I), HTLV-I associated myelopathy, diseases associated with HTLV-II, and viral hemorrhagic fever, (OSHA CPL 2-2.44D).
CDC	The Centers for Disease Control and Prevention. Agencies of the Public Health Service.
CFR	Code of Federal Regulations.
Contaminated	The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry	Laundry that has been soiled with blood or other potentially infectious materials or that may contain sharps.
Contaminated Sharps	Any contaminated object that can penetrate the skin. This includes, but is not limited to, needles, scalpels, broken glass, broken capillary tubes and exposed ends of dental wires.
Decontamination	The use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
Engineered controls	Controls (e.g., sharps disposal containers, self- sheathing needles) that isolate or remove a pathogen hazard from the workplace.
HBV	Hepatitis B virus.
HBsAB	Hepatitis B surface Antibody
HBsAG	Hepatitis B surface Antigen
HCV	Hepatitis C virus.
Handwashing Facilities	Locations that provide an adequate supply of running potable water, soap, and single-use towels or hot-air drying machines.
Hepa Filters	High-efficiency particulate air filters
HIV	Human immunodeficiency virus
HIV and HBV Research Laboratories	This refers to a laboratory which produces or uses research laboratory scale amounts of HIV or HBV. Although research laboratories may not have the volume found in production facilities, they deal with solutions containing higher viral titers than those normally found in patient's blood. Academic research laboratories are included in this definition.
IATA	International Air Transportation Association
NIH	National Institutes of Health, an agency of the Public Health Service.
Occupational exposure	Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of a worker's duties.
Other potentially infectious materials (OPIM)	Human bodily fluids, (e.g., semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures; any body fluid that is visibly contaminated with blood; and all bodily fluids in situations where it is difficult or impossible to differentiate between bodily fluids. Any unfixed tissue or organ (other than intact skin) from a human (living or dead).

	HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV, HBV or other human pathogens.
Parenteral Exposure	Exposure occurring as a result of piercing the skin barrier (e.g., subcutaneous, intramuscular, intravenous routes) through such events as needlesticks, bites, cuts, and abrasions. This definition includes human bites that break the skin, which are most likely to occur in violent situations such as may be encountered by security personnel in emergency rooms or psychiatric wards, (OSHA CPL 2-2.44D).
Pathogen	Any agent (usually living) capable of producing disease.
PEP	Post Exposure Prophylaxis
Personal protective equipment (PPE)	Specialized clothing or equipment worn by a worker for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.
Production facility	A facility engaged in industrial-scale, large-volume or high-concentration production of microorganisms.
Regulated biohazardous waste	Liquid or semi-liquid blood or other potentially infectious materials or contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed. Includes items that are caked with dried blood or other potentially infectious materials and which are capable of releasing these materials during the handling of contaminated sharps, pathological waste, or microbiological wastes containing blood or other potentially infectious materials.
Research Laboratory	A laboratory producing or using small but significant amounts of HIV, HCV, or HBV. Research laboratories may produce high concentrations of HIV, HCV, or HBV but not in the volume found in production facilities.
Sharps	Any objects that can penetrate the skin, including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed metal edges such as dental wires.
Sharps Container	Made of a variety of products from cardboard to plastic. Each sharps container must be either labeled with the universal biohazard symbol and the word "biohazard" or be color-coded red. Sharps containers must be rigid, break-resistant, closable, puncture resistant, and leakproof on sides and bottom. Sharps containers must be able to be closed in such a manner as to be completely sealed.

Source Individual	Any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients, clients in institutions for the developmentally disabled, trauma victims, clients of drug and alcohol treatment facilities, residents of hospices and nursing homes, human remains, and individuals who donate or sell blood or blood components.
Sterilize	The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.
TB	Mycobacterium Tuberculosis
Universal precautions	An approach to infection control in which all human blood and certain human bodily fluids are treated as if known to be infectious for HIV, HBV, and other Bloodborne pathogens.
Worker	An individual employed in a workplace.
Work practice controls	Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting the recapping of needles by a two-handed technique).