



Alabama State University

## **Institutional Biosafety Committee Biosafety Guidelines for Use of Infectious Agents and Biological Toxins**

ASU requires that all projects involving the use of infectious agents or biological toxins conducted at or supported by this university be registered with and approved by the Institutional Biosafety Committee (IBC) prior to initiation of the project.

### **SPECIFIC AUTHORITY**

Title 29, Part 1910 Code of Federal Regulations Labor

Title 42, Parts 72 & 73 Code of Federal Regulations Public Health

Chapter 64E-16, Florida Administrative Code Biomedical Waste

Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and Prevention (CDC) & National Institutes of Health (NIH)

Guidelines for Research Involving Recombinant DNA Molecules, National Institutes of Health

The Alabama State University acknowledges and credits Florida State University where most of the materials were obtained and modified for ASU purposes.

### **OBJECTIVE**

To prevent the transmission of potentially infectious organisms or toxins to humans, animals, or the environment from ASU operations. This is accomplished through a combination of education, regulatory compliance, adherence to suggested work practices, proper containment, and recommendations on the use of appropriate engineering and administrative control measures. Specific program element objectives are identified below.

1. Bloodborne Pathogens Exposure Prevention: To prevent the transmission of pathogens that may be contained in blood, saliva, other human bodily fluids, and other potentially infectious materials. This is necessary to control the spread of Human Immunodeficiency Virus, Hepatitis viruses, or other similar human pathogens.
2. Recombinant DNA / Biological Safety Level Laboratories: To ensure proper control and containment of potentially infectious organisms that may cause harm to the environment or personnel working in or around these research laboratories. The use of recombinant DNA and its derivatives, as well as other biological materials requiring increased control measures as recommended by the BMBL and as identified by NIH guidelines, is required to be overseen by the ASU Biological Safety Committee.
3. Biomedical Waste Disposal: To ensure adequate sterilization, deactivation, and segregation of materials potentially contaminated with infectious organisms and compliance with packaging, transportation, and disposal of regulated biomedical waste.

4. Etiological Agents: To ensure compliance with the importation of certain infectious agents as identified by the Centers for Disease Control and Prevention (CDC).
5. Select Agents and Toxins: To ensure compliance with heightened security requirements specified for certain biological agents that have been identified as having an increased ability to be used for inappropriate purposes.
6. Occupational Medical Monitoring: To ascertain professional medical opinions that an individual is of sufficient health and physical ability to perform specific occupational activities and/or tasks.
7. Food Safety: To reduce the potential for food-borne induced illnesses through insistence in the utilization of safe food preparation and handling practices.

## **OVERVIEW**

The Biological Safety committee at Alabama State University is responsible for protection of the environment and all individuals that may be exposed to biological agents as a result of Alabama State University (ASU) operations. The scope of this section's responsibilities include programs related to the control of bloodborne pathogens, recombinant DNA, biological safety level determination and facility use, biomedical waste disposal, importation of etiological agents, select agent/toxin control, medical monitoring, and food safety oversight for non-registered entities. Biological Safety section personnel also facilitate, or assist with, University responses to identified biological events that may threaten our community. Faculty, staff, students, and visitors at all ASU facilities and field sites must protect themselves and others by adhering to all applicable federal, state, and local regulations.

## **A. RESPONSIBILITIES**

The Biological Safety committee is responsible for the protection of the environment and all individuals that may be exposed to biological agents as a result of ASU operations. Individuals, or supervisors of personnel working with these types of hazards, are responsible for affording due protection and control against any potential exposures or releases that may result from their actions.

Protection from biohazards is best achieved by preventing the transmission of these materials to the environment and community through the use of standard safety practices and precautions. These safety practices and precautions include prudent measures such as the use of gloves, laboratory coats, eyewear, face shields, biological safety equipment, respirators, and proper hand hygiene. This is especially critical for biological agents or microorganisms that may have the ability to replicate in uncontrolled areas or within individuals that have indirect/direct contact with the materials. The unintentional release of these materials may go unnoticed for long periods, possibly resulting in severe health consequences. Decontamination or treatments intended to eradicate these pathogens following an unintentional release may be very difficult and expensive to perform. The Biological Safety committee works to ensure that established safety precautions and procedures are appropriately followed. This includes, but is not limited to, the safe containment, storage, handling, treatment, and enforce proper disposal of all biological materials generated through ASU operations and procedures. In addition, the Biological Safety committee provides safety training and assistance to all personnel involved in these processes and performs vigilant surveillance and inspections of operations in areas where biological materials are used and stored.

Regulatory compliance issues related to biological safety can be easily overlooked or misinterpreted. The consequences for not adhering to program requirements or specified protocols can result in penalties ranging from small fines to the loss of substantial research funding opportunities for the entire University that may last several years. Therefore, it is imperative that the Biological Safety committee be consulted prior to any operations involving these hazards. This is essential when lead investigators or other personnel in charge of research projects utilizing biological materials are not absolutely certain of the status and control measures required to perform the intended research.

## **Introduction**

The purpose and goal of the Biological Waste Program is to ensure that biological waste is handled in a safe, secure manner, and is disposed of properly. In order to achieve this goal, the University will comply with state rules and regulation regarding Biomedical Waste. The Biological Waste Program has established a convenient and economical policy for the disposal of biological waste for the University.

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## **Definitions**

**Animal contact:** direct physical contact with one or more animals used for research at the University.

**Assistant Secretary:** the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

**Biological waste:** any microorganism containing waste, such as E.coli cloning strains, cell cultures or cell lines. Biological waste includes biomedical waste.

**Biomedical waste:** any solid or liquid waste that presents a threat of infection to humans, including non-liquid tissue, body parts, blood, blood products and body fluids from human and other primates; laboratory and veterinary waste which contain human disease-causing agents; discarded contaminated sharps; and used, absorbent materials or disposable devices contaminated with regulated waste.

*Note: laboratories where any of the above discarded waste that has not been decontaminated is regarded as "biomedical waste".*

**Biomedical sharps bin:** puncture-resistant plastic bin for contaminated glassware or glass sharps.

**Biomedical waste box:** single corrugated box, supplied by contracted waste disposal company.

**Biomedical waste generator:** a facility or person that produces biomedical waste.

**Blood:** human blood, human blood components that include plasma, platelets and wound exudates, and products made from human blood.

**Bloodborne pathogens:** pathogenic microorganisms present in human blood, which can cause disease in humans. Includes the hepatitis B virus (HBV), hepatitis C virus (HCV) and the human immunodeficiency virus (HIV).

**Communication of Hazards to Employees:** use of signs, labels, and a training program to employees on Biohazardous safety.

**Contaminated:** presence or reasonably anticipated presence of blood or other potentially infectious materials (OPIM) on an item or surface.

**Contaminated laundry:** laundry that has been soiled with blood or other potentially infectious materials or may contain sharps.

**Contaminated sharps:** any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

**Decontamination:** use of physical or chemical means to remove, inactivate or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the item or surface is rendered safe for handling, use, or disposal.

**Engineering controls:** controls such as sharp disposal containers, or self-sheathing needles that isolate or remove the hazard from the workplace.

**Exposure determination:** identification of individuals exposed to blood or other potentially infectious materials in the workplace.

**Exposure incident:** specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

**Glass Sharps:** broken glass bottles, containers, pipettes or laboratory ware.

**Hand wash facilities:** a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

**HBV:** hepatitis B virus.

**HIV:** human immunodeficiency virus.

**Methods of compliance:** engineering controls, practices and procedures that are needed to keep the worksite in a clean and sanitary condition. General methods of compliance, which may include specific instructions for a particular area, may be added.

**Needle box:** red, puncture-resistant plastic box for metal sharps, such as needle-syringe units, scalpels and razor blades.

**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 an employee's duties.

**Other potentially infectious materials (OPIM):** including the following human 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 where it is difficult or impossible to differentiate between body fluids; any unfixed tissue from human and HIV/HBV containing culture medium.

**Parenteral:** entry into the body by other means than through the digestive tract such as by piercing mucous membranes or the skin by needle sticks, human bites, cuts or abrasions.

**Personal protective equipment (PPE):** special clothing worn by an employee to protect against a hazard. General work clothes, such as pants, shirts, blouses not provided by the school or department, are not intended to function as protection against a hazard or considered to be personal protective equipment.

**Record keeping:** maintenance of medical and training records.

**Regulated waste:** Biomedical Waste; any solid or liquid waste that may present a threat of infection to humans.

Examples include:

- Non-liquid or semi-liquid tissue and body parts from humans and other primates; laboratory and veterinary waste which contain disease-causing agents; discarded sharps; and blood, blood products and body parts from humans and other primates;
- Or, other potentially infectious materials; contaminated items that would release blood;
- Or other potentially infectious materials in a liquid or semi-liquid state if compressed;
- Items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; and
- Contaminated sharps and pathological and microbiological wastes containing blood or other potentially infectious materials.

**Sharps box:** any strong corrugated box that can be used to package non-contaminated glass sharps. Must be clearly labeled SHARPS and should not be filled no more than  $\frac{3}{4}$  of the way. Once it is filled it must be tightly sealed and disposed of as regular waste.

**Transporter:** contracted licensed waste disposal company moves the biomedical waste away for incineration.

**Universal precautions:** an approach to infection control; a concept that all human blood and certain body fluids are treated as if known to be infectious for HIV, HBV, or other bloodborne pathogens.

**Work practice controls:** controls that reduce the likelihood of exposure by altering the manner in which a task is performed (for instance prohibiting the recapping of needles by a two-handed technique).

**Zoonotic diseases:** diseases transmitted from animals to man

## General Policies

Waste disposal requires well-defined procedures to prevent exposure to pathogens. Improper disposal of biohazardous waste puts everyone at risk as well as jeopardizes the University's waste permits.

In order to prevent unwanted exposure, principal investigators, supervisors, technicians and students must be familiar with current waste disposal procedures for biohazardous materials as well as for chemical and radioactive materials.

This Biological Waste Policy must be accessible to all. Department representatives, laboratory personnel, principal investigators, and or supervisors are responsible for ensuring that all employees are trained and familiar with the Biological Waste Program and that all laboratory procedures conform to these requirements.

### Type of Waste

In order to have an effective Biological Waste Program, the University has organized the biological waste into seven categories:

**General Biohazardous Waste Materials:** General biohazardous waste materials are biological wastes that contain, "biological agent(s) or substance(s) present in or arising from the work environment which presents or may present a hazard to the health or well being of the worker or community." All general biological wastes must be autoclaved or decontaminated by equivalent means to deactivate the biohazardous materials prior to disposal as regular trash.

**Biohazardous Waste Containing Non-Human Pathogens:** Are biological wastes that contain no human pathogen. Biological waste that is considered non-human pathogen-containing waste will be discarded as regular trash after it is autoclaved or decontaminated by equivalent means.

**Biomedical Wastes Containing Human Pathogen:** Are biological wastes that may contain a human pathogen. All waste that may contain human pathogens must be disposed of as biomedical waste.

All biomedical waste must be disposed of within thirty days of generating the waste.

**Biohazardous Sharps:** Are needles, needle-syringe units, scalpels, and razor blades, contaminated or non-contaminated with biological materials, are consider biohazardous sharps. All biohazardous sharps are consider biomedical waste and must be placed into a red, puncture resistant plastic needle box and discarded as biomedical waste.

**Sharps Waste:** Are glassware/glass sharps such as Pasteur pipettes and broken or unbroken glassware. For contaminated glassware/glass sharps, Pasteur pipettes, broken or unbroken glassware must be autoclaved or decontaminated prior to disposal. All sharps wastes must be properly package and labeled prior to disposal as regular trash. However, if the repackaging of sharps for autoclaving presents a risk of infection, sharps may be packaged and disposed as biomedical waste.

**Biohazardous Waste mixed with Hazardous Waste:** Are biological wastes mixed with hazardous waste, as defined in the 40 Code of Federal Regulation (CFR) 261.3. These types of biological waste shall be managed as hazardous waste.

**Biohazardous Waste mixed with Radioactive Waste:** If biological wastes are mixed with radioactive waste; these types of biological waste shall be managed as radioactive waste.

Note that the cost of disposing biological waste mixed with hazardous waste and or radioactive waste is high. Therefore, unnecessary mixing of these forms of waste is highly discouraged.

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### Permit

Biomedical waste generators are required to have a biomedical waste generator permit from the County Health Department. All permits are displayed at waste generation sites.

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### Labeling

Labels and signs bearing a red biohazard warning logo shall be affixed to locations and containers used to store and transport biomedical and biohazardous materials.

The following legend is the biohazardous warning symbol:



The Biohazardous Symbol

This label shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

In addition to the red biohazardous warning logo, biomedical waste generators must affix labels to biomedical waste boxes and biomedical sharps bins with the generator's name, address and the date of

the first day when biomedical waste was generated or the date that the biomedical sharps box was closed and taped.

The Biomedical waste transporter will provide labels for biomedical waste boxes and biomedical sharps bins with the transporter's name, address, registration number and 24 hour telephone number. The waste disposal transport contractor provides all above information on bar code stickers forms for boxes and bins. The waste generator is responsible to make arrangement with the waste transport contractor for waste removal.

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### **Storage**

Indoor storage must be in an access-restricted area and be maintained in a sanitary condition.

For outdoor storage on University campus, please request from your contractor, a locked biomedical waste dumpsters to be placed in a specified site. Example: behind the Life Science Building. To access the biomedical waste dumpster, call the Biological Safety Office.

Both indoor and or outdoor biomedical waste storage must be coordinated with the biomedical waste contractor and the Biological Safety Office. All biomedical waste storage duration must not exceed 30 days for the biomedical waste pick-up schedules. Biomedical waste schedule pick-up for the biomedical waste dumpsters can be arranged with the Biological Safety Committee Chair at 229-4423.

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### **Disposal Procedures for General Biohazardous Waste Materials and Biohazardous Waste Containing Non-Human Pathogens**

General biohazardous waste materials and biohazardous waste containing non-human pathogens must be collected in clear autoclave bag.

Bagged waste must be autoclaved at 121°C, 15 psi for at least 15 minutes.

After autoclaving, the bagged waste should be placed in a non-clear trash bag and disposed as regular trash.

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### **Disposal Procedures for Biomedical Waste Containing Human Pathogens**

Biomedical waste containing human pathogen must be collected in an autoclavable biohazardous label bag.

Bagged waste must be autoclaved at 121°C, 15 psi for at least 15 minutes.

All biomedical waste must be discarded into a lined biomedical waste box.

The maximum gross weight for a 30-gallon biomedical waste box is 50 lbs.

For a 15-gallon biomedical waste box, the maximum gross weight is 40 lbs.

Be sure the bottom of the biomedical waste box is secured with two-inch wide pressure sensitive tape or equivalent.

When the box is full, reaches its maximum gross weight, or waste accumulation approaches the 30 days limit for storage, the biomedical waste box should be sealed.

Be sure that the top of the liner is closed by twisting the bag opening, and tying it in a single knot, or by taping the twisted opening.

Secure the top of the biomedical waste box with a two-inch wide pressure sensitive tape or equivalent.

Label the box with the name of the principal investigator's laboratory, the location of the laboratory, and the date when the waste was first generated.

After the biomedical waste box is sealed and labeled, place the box in a designated biomedical waste dumpster for disposal.

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### **Disposal Procedures for Biohazardous Waste Mixed with Hazardous Waste**

Biohazardous waste mixed with hazardous waste is highly discouraged.

Prior to generating this type of waste, coordinate with the Biological Safety Office at 229-4467/4301.

General biohazardous waste materials, biohazardous waste containing non-human pathogens, or biohazardous waste containing human pathogens mixed with hazardous waste must be collected in a double red biohazardous bag.

As defined in 40 Code of Federal Regulation (CFR) 261.3, these types of biological waste shall be managed as hazardous waste.

When the bag is full, it must be secured by ensuring the top of the bag is closed by twisting the bag opening and tying in a single knot, or by taping the twisted opening.

Clearly label the bag as "Biohazardous Waste Mixed with Hazardous Waste".

Biohazardous waste mixed with hazardous waste should not be placed in the biomedical waste dumpster for disposal.

After the bag is sealed and labeled, a mixed waste pick-up request must be placed and the Biological Safety Office must be notified for disposal.

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### **Disposal Procedures for Biohazardous Waste Mixed with Radioactive Waste**

Biohazardous waste mixed with radioactive waste is highly discouraged.

Prior to generating this type of waste, coordinate with the Biological Safety Office at 229-4467/4301.

General biohazardous waste materials, biohazardous waste containing non-human pathogens, or biohazardous waste containing human pathogens mixed with radioactive waste must be collected in a double red biohazardous bag.

These types of biological waste shall be managed as radioactive waste.

When the bag is full, it must be secured by ensuring the top of the bag is closed by twisting the bag opening, and tying in a single knot or by taping the twisted opening.

Clearly label the bag as "Biohazardous Waste Mixed with Radioactive Waste".

Biohazardous waste mixed with radioactive waste should not be placed in the biomedical waste dumpster for disposal.

After the bag is sealed and labeled, a mixed waste pick-up request must be placed and the Biological Safety Office must be notified for disposal.

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### **Disposal Procedures for Biohazardous Sharps**

Needles must not be re-capped or removed from the syringe.

Biohazardous sharps must be discarded into a red puncture-resistant needle box sharps box.

When needle box reaches  $\frac{3}{4}$  full, close, tape, date, and discard the box as biomedical waste within 30 days from the time the needle box is closed.

After the box is secured and labeled, place the box in designated biomedical waste dumpster or call the Biological Safety Office.

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### **Disposal Procedures for Sharps Waste**

Razor blades and non-contaminated glass sharps are collected in a strong, sturdy cardboard box that is clearly labeled in large print "SHARPS" on the outside of the box on at least two side.

Contaminated glassware/glass sharps, Pasteur pipettes, broken or unbroken glassware must be autoclaved or decontaminated prior to disposal.

When the "sharps" box is  $\frac{3}{4}$  filled, it should be closed, securely taped, and disposed as regular trash. Note that the "SHARPS" labeled must be clearly visible after it is secured with tape.

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### **Enforcement and Penalties**

Anyone in violation of these regulations, who interferes with, hinders, or opposes any employee in the discharge of his duties, is chargeable with a misdemeanor of the second degree.

If any violation occurs, the Department of Health may deny, suspend, or revoke any biomedical waste permit and/or impose an administrative fine up to \$2500/day.

Should you have any questions in regard to the general policies or waste disposal procedures, please call the Biological Safety Office.

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### **Supplies**

The following is a list of common use supplies for biohazardous waste disposal:

1. Autoclavable clear plastic bags
2. Autoclavable red biohazardous bags
3. Autoclavable clear plastic Biohazardous labeled bags
4. Needle boxes: red, puncture-resistant plastic box (for disposal of needle-syringe units, scalpels and razor blades)
5. Two-inch wide pressure sensitive sealing tape for the boxes or equivalent
6. Permanent marker

The following is a list of materials supplied by the licensed waste disposal contractor:

- 15 and 30 gallon biomedical waste box (single corrugated)
- Biomedical bin
- Red biomedical plastic liner

All materials used in biological waste disposal can be purchased from authorized ASU suppliers or vendors.