

Institutional Biosafety Committee MANUAL

GEORGIA SOUTHERN UNIVERSITY

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A Step by Step Guide to Applying to the IBC

1. Read and review the *Biosafety Manual* found at <http://academics.georgiasouthern.edu/research/IBC.htm>

2. Determine if you have to apply to the IBC by going to the IBC website to review the types of research that do require IBC approval. The types of research which require IBC approval can be found at:
<http://academics.georgiasouthern.edu/research/IBC.htm>

- 3. Determine the biosafety level** you believe your project involves
- For further information on biosafety levels, please see [page 8](#) of the **IBC Manual**.

4. Select the appropriate forms for either approval or exempt approval by the IBC. To determine which forms you need, go to the following website:
<http://academics.georgiasouthern.edu/research/IBC.htm>
And follow the links to the required forms.

Forms required for application to IBC:

- Application for Research Involving Biohazardous Materials
- Appropriate SOP forms for the biosafety level of your research
- Appropriate Laboratory Audit forms for the biosafety level of your research

Forms required for exempt application to IBC:

- Application for Research with rDNA that is Exempt Under CDC/NIH Guidelines

5. Include:

- Certificate of completion for the mandatory on-line training course, Chemical Specific Right to Know Training
- Any other necessary documents that will present the most complete case for research to be conducted
- Letter of Approval from Collaborating Institutions, if applicable

6. Complete mandatory on-line training. All applicants must complete this training and provide the certificate of completion with their application. The training can be completed at the following website:

<http://www.usg.edu/ehs/training/chemical/>

7. Submit all application materials to: ORSSP, PO Box 8005, or 2021 Veazey Hall, Georgia Southern University, Statesboro, GA 30460

8. For questions, or assistance at any time, call 912-478-5465, or you may wish to review the IBC website located at http://academics.georgiasouthern.edu/research/compliance_ibc.htm

Use of Biohazardous Materials in Research

Biosafety Manual

*(This manual was adapted from materials provided by Georgia State University (J. Owens)
and the Medical College of Georgia (P. Chandler).*

SECTION I - Responsibilities

- Principal Investigator, Laboratory Director, or Supervisor
 - Department Heads
 - Institutional Biosafety Committee
 - Compliance Officer
 - Environmental Safety Officer
 - The University
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A. Principal Investigator, Laboratory Director, Instructor or Supervisor

Developing and maintaining a healthy and safe work environment depends on the day-to-day supervision of investigative practices by personnel with a positive safety attitude. The principal investigator (PI), laboratory director, project supervisor, or teaching supervisor is responsible for complying fully with Georgia Southern University, State, and Federal rules, regulations, and/or standards. The principal investigator and/or laboratory supervisor shall:

1. Determine the known or potential biohazards associated with the proposed experiments. For recombinant DNA (rDNA) experiments, the PI shall not initiate or modify those experiments requiring approval of the Institutional Biosafety Committee (IBC) until that proposed research or modification has received approval from the IBC and has met all other requirements of the appropriate governing local, state and/or federal agencies.
2. Submit a Biohazardous Research Registration Form (Appendix A) as requested by the Compliance Officer/IBC or otherwise required by applicable guidelines, regulations, or standards.
3. Provide personnel or students under his/her supervision with knowledge of biohazards to which they may be exposed and safety procedures to be followed. This is to be accomplished by:

- a. The PI being knowledgeable of good laboratory safety practice and demonstrating a positive safety attitude.
 - b. Making available to the laboratory staff copies of the procedures that describe potential biohazards and the precautions to be taken. These procedures and other information addressing biosafety-related issues should be produced in the form of a standard operating procedure (SOP) for the work.
 - c. Providing laboratory staff with documented formal and informal instruction and training in the practices and techniques required to ensure safety and in the procedures for dealing with accidental spills, personnel contamination, and other laboratory accidents.
 - d. Informing the laboratory staff of the reasons and provisions for any precautionary medical practices (e.g. physical examinations, serum collection, and vaccinations).
 - e. Supervising the performance of the staff to ensure that required safety practices and techniques are employed.
4. Report in writing to the Environmental Safety Officer any accident, exposure of personnel, suspected illness, release from containment of biohazardous agents, and significant problems pertaining to the operation and implementation of containment practices and procedures.
 5. Ensure physical examinations and other medical surveillance of personnel when required by the nature of the experiments.
 6. Ensure the integrity of the physical containment (e.g. biological safety cabinets) and biological containment (e.g. purity and genotypic and phenotypic characteristics).
 7. Maintain knowledge of and adhere to the permit requirements of federal and state agencies for interstate and international movement of biohazardous agents.

B. Department Heads

Department Heads have the following responsibilities:

1. To ensure that prior to initiation of work, each investigator or laboratory director using a biohazardous agent files an Application for Research Involving Biohazardous Materials with the IBC through the Compliance Officer and that approval has been granted prior to the initiation of the research.

2. To ensure that students have had instruction in safety procedures in teaching laboratories or field situations where biohazardous agents are used.
3. To determine that appropriate facilities and safety equipment are available for proposed research or instruction involving biohazardous agents.
4. To provide leadership in laboratory safety at the management level in the department.

C. Institutional Biosafety Committee

Georgia Southern University's Institutional Biosafety Committee (IBC) serves to advise the Provost on policies pertaining to biohazardous research, teaching, and service activities. The committee recommends standards under which biohazardous activities should be conducted and reviews projects involving biohazardous materials. The composition of the IBC is specified in the NIH "Guidelines for Research Involving Recombinant DNA Molecules", which can be found at http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm. Other specific responsibilities include:

1. Review for appropriateness and adequacy the containment levels and safety measures proposed and/or used in research and teaching.
2. Assess the adequacy of containment facilities for Biosafety Level 1 or 2 agents and rDNA molecules as required by NIH or other funding or regulatory agencies.
3. Develop with the Compliance Officer and Environmental Safety Officer informational and training seminars and workshops on biohazards for the Georgia Southern University community.
4. Periodically review biohazardous research being conducted at Georgia Southern University in conjunction with the Compliance Officer and the Environmental Safety Officer to ensure that the requirements of the University, funding sources, and regulatory agencies are being fulfilled.
5. Recommend to the University Administration appropriate sanctions for non-compliance with biosafety standards, guidelines, or regulations.

D. Compliance Officer

Georgia Southern University's Compliance Officer has responsibility for the daily administration of standards set by the IBC and acts as the agent of the committee in their implementation. Other responsibilities include, as resources allow:

1. Receiving completed Applications for Research Involving Biohazardous Materials for preliminary screening and assignment to the IBC or special subcommittee thereof for review.
2. Arranging for initial and periodic inspections of laboratories by the used in biohazardous research to ensure that standards set by the IBC are followed and acting to ensure compliance with IBC standards in individual laboratories.
3. Providing technical advice to PIs and to the IBC on research safety procedures.
4. Organizing and conducting informational and training seminars and workshops on biohazards for the GSU community.
5. Arranging with the appropriate health service for appropriate medical surveillance of personnel working with certain biohazardous agents or as required by the IBC.
6. Providing technical advice to the University regarding biohazard safety needs and requirements for projects involving the renovation or construction of laboratory or other facilities in which biohazards will be used.
7. Providing guidance to the IBC to ensure that approved protocols and committee procedures are compliant with local, state and federal regulations governing research involving biohazardous materials.

E. Environmental Safety Officer

Georgia Southern University's Environmental Safety Officer shares responsibility for implementation of the standards set by the IBC and acts as an agent of the committee in their implementation. Other responsibilities include, as resources allow:

1. Providing guidance to the IBC to ensure that approved protocols and committee procedures are compliant with local, state and federal regulations governing research involving biohazardous materials.
2. Conducting initial and periodic inspections of laboratories used in biohazardous research to ensure that standards set by the IBC are followed.
3. Organizing and conducting informational and training seminars and workshops on biohazards for the GSU community.
4. Providing technical advice to PIs and to the IBC on research safety, shipping and biohazardous disposal procedures.
5. Providing technical advice to the University regarding biohazard safety needs and requirements for projects involving the renovation or construction of laboratory or other facilities in which biohazards will be used.

F. Georgia Southern University

Georgia Southern University and its administrative officers are ultimately responsible for the following:

1. Developing and maintaining appropriate policies regarding the conduct of potentially biohazardous research, education, and service activities.
2. Developing mechanisms for ensuring adherence to biosafety policies.
3. Providing the resources necessary for the construction of safe research and teaching facilities and for the implementation of the Biosafety Program.
4. Providing adequate resources for the dissemination of information on biohazards and biosafety procedures, including training programs and workshops.
5. Providing resources for appropriate medical surveillance measures to protect the health and safety of employees.
6. Administering on behalf of the Board of Regents appropriate and sufficient legal protection for faculty and staff members who conduct activities in compliance with appropriate regulations and guidelines.

SECTION II - Biohazardous Research

A. General Definitions

1. **Biohazard** - infectious agents, or parts thereof, presenting a real or potential risk to the well-being of humans, other animals, or plants directly through infection or indirectly through disruption of the environment; and venomous vertebrate or invertebrate animals presenting a real or potential risk to humans.
2. **Biomedical Waste** (as defined by the Georgia Environmental Protection Division in Chapter 391-3-4 section .15 "Solid Waste Management") - Biomedical waste shall mean and include the following:
 - (a) **Pathological waste** - all recognizable human tissues and body parts except teeth which are removed during surgery, obstetrical procedures, autopsy, and laboratory procedures.
 - (b) **Biological waste** - blood and blood products, exudates, secretions, suctionings, and other body fluids which contains free liquids and cannot be or are not directly discarded into a municipal sewer system.
 - (c) **Cultures and stocks of infectious agents and associated biologicals** - includes cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.
 - (d) **Contaminated animal carcasses** - includes body parts, their bedding, and other wastes from such animals which are infected with or which have been exposed to infectious agents, capable of causing disease in humans.
 - (e) **Sharps** - any discarded article that may cause punctures or cuts. Such waste includes, but is not limited to, items such as needles, IV tubing and syringes with needles at-tached, and scalpel blades.
 - (f) **Chemotherapy waste** - any disposable material which has come in contact with cytotoxic/antineoplastic agents (agents toxic to cells) and/or antineoplastic agents (agents that inhibit or prevent the growth and spread of tumors or malignant cells) during the preparation, handling, and administration of such agents. Such waste includes, but is not limited to, masks, gloves, gowns, empty IV tubing bags and vials, and other contaminated materials. The above waste must first be classified as empty

which means such quantity that it is not subject to other federal or state waste management regulations prior to being handled as biomedical waste.

(g) **Discarded medical equipment and parts** - excludes expendable supplies and materials included in paragraphs (a) through (f) of this Rule, which have not been decontaminated, and that were in contact with infectious agents.

3. **Biosafety Level 1 (BSL-1; as defined by the “CDC/NIH Guidelines for Biosafety in Microbiological and Biomedical Laboratories, 4th ed. 1999”)** - suitable for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.
4. **Biosafety Level 2 (BSL-2)** - similar to BSL-1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.
5. **Biosafety Level 3 (BSL-3)** - applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.
6. **Biosafety Level 4 (BSL-4)** - required for work with dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.
7. **Genetic Engineering** - the genetic modification of organisms by recombinant DNA techniques.
8. **Institutional Biosafety Committee (IBC)** - The University Committee appointed by the Provost at Georgia Southern University as specified by NIH in its "Guidelines for Research Involving Recombinant DNA Molecules", which can be found at the following website: <http://oba.od.nih.gov/oba/index.html> . The Committee reviews, approves, and oversees projects involving recombinant DNA as well as other biohazardous research identified in this manual.
9. **Plant Pests** - Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants. (USDA - 7 CFR 340.1)
10. **Regulated Article** - any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 7 CFR 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an

organism whose classification is unknown or any product altered or produced through genetic engineering which the Deputy Administrator (USDA) determines is a plant pest or has reason to believe is a plant pest. (USDA - 7 CFR 340.1)

11. **Restricted Animal Pathogens** - nonindigenous pathogens of domestic livestock and poultry that may require special containment strategies and facilities not generally discussed in this manual.
12. **Risk Group 1 Agents (as defined by the “NIH Guidelines on rDNA, April 2002”)** – agents that are not associated with disease in healthy adult humans (most often aligned with BSL-1 practices).
13. **Risk Group 2 Agents** – agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available (most often aligned with BSL-2 practices).
14. **Risk Group 3 Agents** – agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (most often aligned with BSL-3 practices).
15. **Risk Group 4 Agents** – agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (most aligned with BSL-4 practices).

B. Classification of Biohazardous Research

Georgia Southern University's IBC has identified the following types of research as potentially biohazardous. References used in designating specific classes or agents or biohazardous potential are included as appropriate.

1. **Type I** - In vitro construction and/or propagation, use, or manipulation of recombinant DNA molecules. The process of genetic engineering is covered by regulations or guidelines promulgated by several federal agencies. The IBC is to receive a Biohazardous Research Registration Form for all rDNA projects (covered and exempt) for record purposes. References: "NIH Guidelines for Research Involving Recombinant DNA Molecules"
<http://oba.od.nih.gov/oba/index.html>
2. **Type II** – All laboratory experiments/research involving the use of infectious agents, pathogenic or not, human blood, unfixed human or non-human primate tissues, and human or non-human primate cell lines. References: Occupational Safety and Health Administration, "Occupational Exposure to Bloodborne Pathogens", Federal Register, 56:235:64004-64174, December 6, 1991. Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, 4th edition, April 1999.

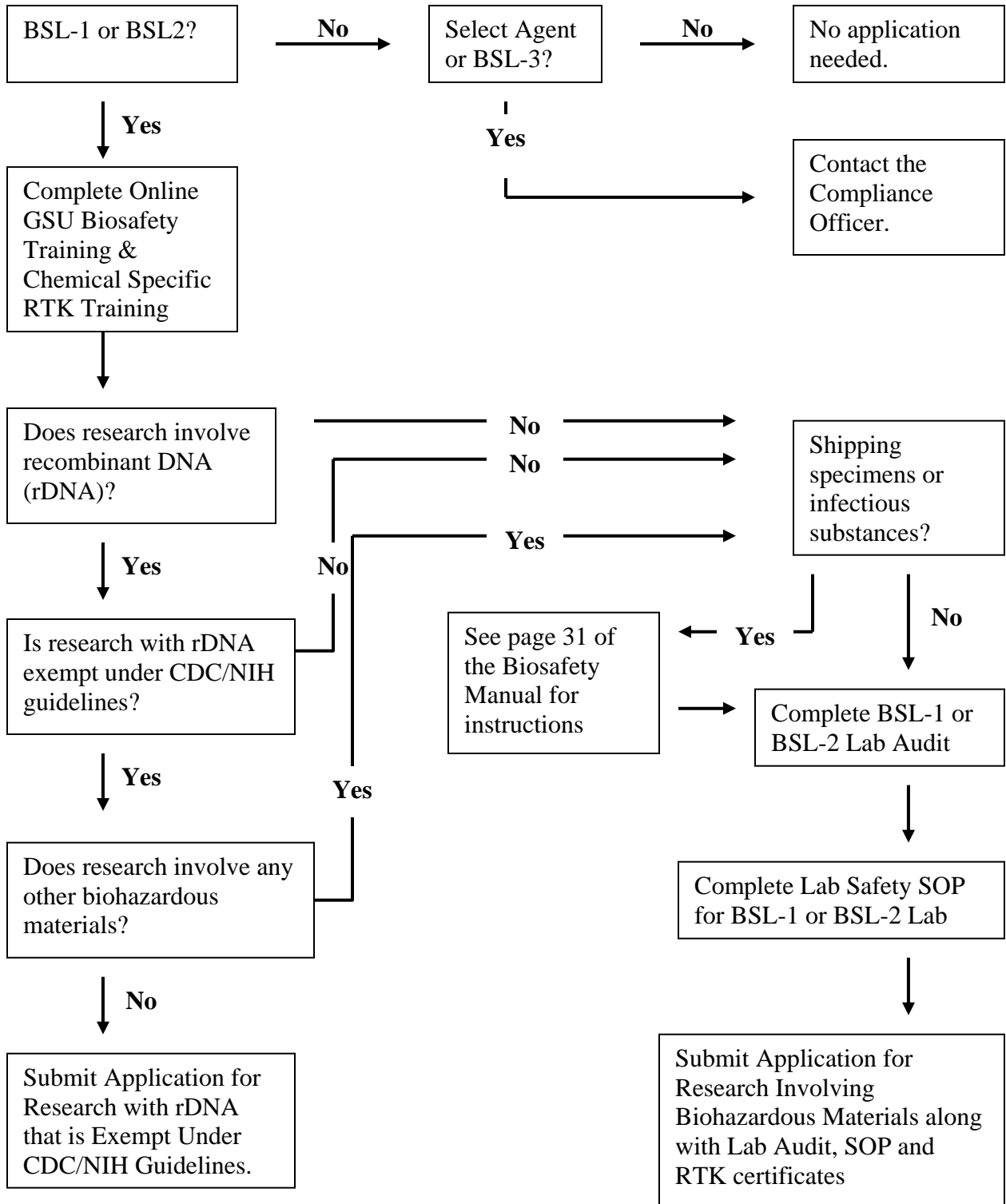
3. **Type III** - Studies Involving Venomous Invertebrates or Vertebrates. Federal and state agencies including but not limited to the United States Departments of Agriculture, Interior, and Health and Human Services and Georgia Departments of Agriculture and Natural Resources restrict the movement of certain species of venomous vertebrates and invertebrates and in special instances specify containment levels.
4. **Type IV** - Experiments Involving the Movement into Georgia of: 1) pathogens that adversely affect plants or animals; 2) any non-indigenous species of plants or animals (including offspring); 3) any indigenous species of plants or animals infected with pathogenic organisms outside the state.
5. **Type V** – Any experiments/research involving “select agents”. The United States Congress expanded the restrictions on potential agents of bioterrorism by enacting the USA PATRIOT Act of 2001. The Act places restrictions on who can possess “select agents” and how the agents are to be protected from unauthorized use. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 promulgated rules (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) to regulate the possession, use, and transfer of “select agents” deemed a threat to public, animal or plant health, or to animal or plant products. The rules and regulations (42 CFR 73) can be found at <http://www.selectagents.gov/> and hard copies are available by contacting the Compliance Officer. A list of the “select agents” is included in Appendix C.

C. Paperwork Flow

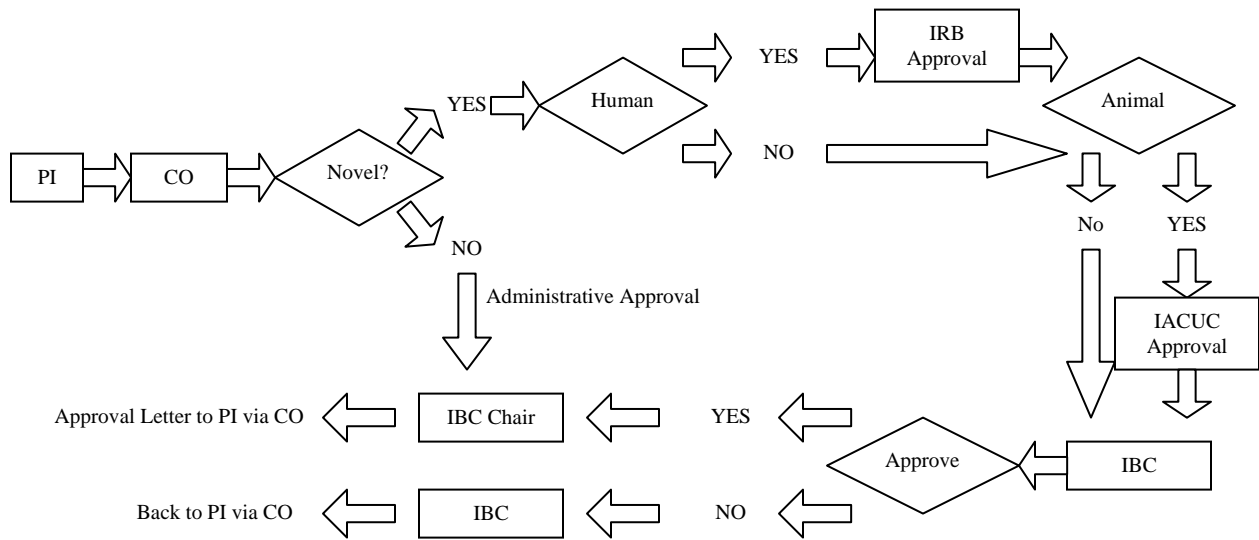
1. Applications and supporting materials are to be submitted by all Georgia Southern University faculty conducting recombinant DNA experiments and/or research involving biohazardous materials. If research involves ONLY EXEMPT recombinant DNA work and no other biohazards, then faculty may submit an Application for Research with rDNA that is Exempt Under CDC/NIH Guidelines. For modifications to existing protocols approved using forms revised AFTER July 2004, faculty should submit an Application for Modification of an Existing IBC-Approved Protocol form.

The following flowchart is provided to help faculty determine which forms are required for IBC approval of NEW projects.

IBC Research Review Flowchart



2. If research involves human subjects or animals in addition to biohazardous materials, then use the following flowchart as a guide to the overall application process to the individual compliance committees. IRB and/or IACUC approval should be obtained BEFORE submission of an application to the IBC. Guidelines and forms for each committee can be accessed at the following link: <http://academics.georgiasouthern.edu/research/>



SECTION III - Biohazardous Waste

It is expected that investigators using biohazardous agents and/or producing biomedical wastes as defined in Section II of this manual will comply with the rules promulgated by the Georgia Environmental Protection Division in Chapter 391-3-4 section .15 "Solid Waste Management". The waste streams generated by biological laboratories should be separated into non-hazardous waste (trash), biohazardous waste, chemical/hazardous waste, and radioactive waste.

A. Georgia Southern University Procedures for handling biomedical wastes on campus

1. Biomedical/biohazardous waste shall be segregated by separate containment from other waste at the point of origin. These wastes, except for sharps, are to be placed in orange or red plastic bags clearly identified with the universal biohazard symbol or clearly marked with the word "BIOHAZARD". The bags are to have strength sufficient to preclude ripping, tearing, or bursting under normal conditions of use.
2. Sharps (needles and syringes, Pasteur pipettes, etc.) must be placed in puncture proof and leak proof containers. The containers are then disposed of by a biomedical waste disposal contractor via the Environmental Safety Officer.

Broken glass can be disposed of in two ways. If it is NOT contaminated with biohazardous agents, the broken glass can be placed in the broken glass containers. If it is contaminated with biohazardous agents, the broken glass must first be decontaminated (autoclaving or chemical disinfection) prior to disposal with broken glass OR it can be directly placed in a biohazardous sharps container and disposed of as biomedical waste.

3. Wastes contaminated with hazardous chemicals, such as animal carcasses preserved with formaldehyde or alcohols, should be collected in leak proof closed containers and disposed of by a hazardous waste disposal contractor. Please contact the Environmental Safety Officer for more details.
4. Liquid biohazardous materials are to be properly inactivated or sterilized prior to disposal in the community sewage treatment system. Garbage disposal units are not to be used with contaminated materials because of the aerosols generated. Chemotherapy waste may not be disposed of in the community sewage; it must be disposed of as hazardous waste.

5. Biomedical wastes may be treated so as to render it non-biomedical wastes. Properly treated wastes may be combined and handled with regular solid wastes. Biomedical wastes may be treated by autoclaving in a recording autoclave. Recording of the temperature during each complete cycle shall be used to assure the attainment of 121°C or 250°F for a time appropriate to assure decontamination of the entire load. Monitoring of the autoclave process through the use of biological or other approved indicators is to be accomplished by the investigator and maintained along with the temperature recording as proof of decontamination.

Several factors affect the steam sterilization process including load size, distribution and compaction, altitude above sea level, and heat penetration. The investigator or personnel responsible for sterilization may have to determine the appropriate time at standard autoclave temperature and pressure for certain loads of biohazardous materials. Barbeito and Gremillion in their article "Microbiological Safety Evaluation of an Industrial Refuse Incinerator" (*Applied Microbiology*. 1968. 16:2:291-95) reported on various times required for autoclaving selected animal carcasses, animal bedding materials, and eggs. With some loads, even extended times did not provide for sterilization.

B. Georgia Regulations

Georgia Department of Natural Resources/Environmental Protection Division - rules on solid waste management covering biomedical waste (391-3-4-.15).

C. Contact Information

1. For biomedical waste, please contact the Georgia Southern University Environmental Safety Officer (912-478-7161).

[\(http://services.georgiasouthern.edu/ess/\)](http://services.georgiasouthern.edu/ess/)

2. For hazardous waste, please contact the Georgia Southern University Environmental Safety Officer (912-478-7161).
3. For radioactive waste, please contact the Georgia Southern University Radiation Safety Officer at 912-478-1151.

SECTION IV – Containment of Biohazardous Research

Please review [CDC/NIH - Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#)

Physical Containment of Experiments

There are different degrees of risk involving biohazardous research which requires different levels of containment. The term "containment" is used in describing safe methods for managing biohazardous agents in the laboratory environment where they are being stored or handled. Primary containment, the protection of personnel and the immediate laboratory environment from exposure, is provided by good technique and the use of appropriate safety equipment that has been properly designed, located, installed, and maintained. Secondary containment, the protection of the environment external to the laboratory from exposure to biohazardous agents, is provided by a combination of facility design and operational practices.

Biosafety Level 1

Biosafety Level 1 (BSL-1) is suitable for working with agents having no known or minimal hazard to laboratory personnel and the environment (including plants and other animals). The laboratory practices and techniques, safety equipment, and physical facilities are those appropriate for undergraduate and secondary educational training and teaching. When assessing the risk of an experiment and determining the appropriate containment level it is important to remember that BSL-1 depends entirely upon good laboratory practice and using agents with no known hazards. The use of standard microbiological practice and techniques is basic for laboratory safety/containment, however, the PI must recognize that special precautions may be needed. Research laboratories in which biological agents are used should be at BSL-2.

A. BSL-1 Standard Microbiological Safety Practices:

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director. Limiting access to control the in/out traffic when experiments are in progress reduces sources of distraction and disturbance, which may result in accidents. Closing laboratory doors during experiments is one method of controlling in/out traffic. This also allows for the exclusion of special category persons (children, immunosuppressed persons, act.) during times of potential exposure.
2. Work surfaces are decontaminated at least once a day and following any spill of viable material. Contaminated equipment must be decontaminated

according to any local, state or federal regulations before it is sent for repair or maintenance or packaged for transport or surpluses.

3. All contaminated liquid and solid wastes are decontaminated prior to disposal. Disposal of biomedical wastes shall be accomplished so as to comply with state and federal laws and regulations, see Section III.
4. Mechanical pipetting devices are used; mouth pipetting is prohibited.
5. Eating, drinking, smoking, and the application of cosmetics are not permitted in the work area. Food may be stored cabinets and refrigerators designated and used for this purpose only. Food storage cabinets and refrigerators should be located outside the work area.
6. Personnel wash their hands after they handle viable materials and animals, after removing gloves, and before leaving the laboratory or animal facility.
7. All procedures are performed carefully to minimize the creation of aerosols. Aerosols may be generated by several routine laboratory procedures and gain entry to lab personnel via inhalation, ingestion, and absorption. Aerosols have been associated with many laboratory acquired infections. They are, however, controllable with the use of safety procedures and containment equipment.
8. Personal protective equipment (PPE) is worn as appropriate when working with viable microorganisms, animals, and chemicals. Laboratory coats, gowns, uniforms, gloves, eye protection, etc. are examples of personal protective equipment.
9. An insect and rodent control program is in effect.

No special safety procedures are identified at BSL-1

Special containment equipment (i.e. biological safety cabinets) is not required; basic teaching laboratories are a good example of facilities typically operating at BSL-1.

Biosafety Level 2

Biosafety Level 2 (BSL-2) is suitable for work involving agents of moderate potential hazard to personnel and the environment (including plants and other animals). The practices, equipment, and laboratory design are appropriate for clinical, diagnostic, teaching, and basic research with a broad spectrum of indigenous moderate-risk agents associated with human disease and/or which may negatively impact the environment. Laboratory procedures which generate aerosols may increase the risk and therefore are to be conducted in a biological safety cabinet and/or other primary containment equipment. BSL- 2 facilities and procedures are those that are basic in

a good quality laboratory working with microorganisms, genetic materials, cell/tissue cultures, and carcinogens.

A. In addition to the BSL-1 Standard Microbiological Safety Procedures, the following Special Practices are implemented:

1. Access to the laboratory is limited or restricted by the laboratory supervisor when work with biohazardous agents is in progress. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal rooms. Keeping laboratory doors closed during experiments is recommended. 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. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections.
2. The principle investigator is responsible for providing training of laboratory personnel in the potential hazards and safety procedures. Knowledgeable personnel work more efficiently and effectively in the laboratory by reducing the risks of accidents that could result in personal injury or loss of research effort. Georgia Law "Public Employee Hazardous Chemical Protection and Right to Know Act of 1988" (The Official Code of Georgia Annotated Section 45-22-8) and the Department of Labor regulations (Chapter 300-3-19) provide requirements for training of employees using hazardous chemicals. This "best practice" should also be applied to biohazards.
3. When research involves working with or storing biohazardous agents in the laboratory a hazard warning sign incorporating the universal biohazard symbol is posted on the access door. The principle investigator is ultimately responsible for informing persons, including emergency personnel, of any special requirement for entering the laboratory.
4. Before leaving the laboratory areas, protective clothing (lab coats, aprons, etc.) is removed and left in the laboratory. This practice helps prevent infectious agents from being carried from the laboratory on contaminated clothing.
5. Animals not involved in the work being performed are not permitted in the laboratory.
6. Special care is taken to avoid contamination of skin and mucous membranes with infectious materials; appropriate personal protective equipment (gloves, goggles, face shield, etc.) should be worn when

handling infected animals or infectious materials. See Section VII on Bloodborne Pathogens and universal precautions.

7. Spills and accidents which result in exposure of people or the environment to infectious materials and/or rDNA molecules are immediately reported to the principle investigator and to the Environmental Safety Officer. Exposure may require medical evaluation, treatment, and surveillance. Accident investigation may assist in the prevention of similar types of accidents in the future.
8. When it is deemed appropriate by the Principle Investigator and/or the IBC, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional samples may be collected periodically. Serum samples are useful for biological monitoring of workplace exposures in the effort to reduce occupational risks. Stored serum samples are used only to compare pre and post occupational exposure of serum components. Any use of stored samples for any purpose other than those associated with occupational exposures requires the informed consent of the individuals and approval of appropriate IRB applications.
9. Laboratory personnel are to read and are responsible for becoming familiar with this Manual and specific standard operating procedures (SOPs) of the laboratory. The Principle Investigator is responsible for providing supplemental safety training and information for personnel in his/her laboratory. NIH rDNA Guidelines and OSHA Bloodborne Pathogens regulations are examples of two federal regulations requiring appropriate biosafety training for laboratory personnel. Since personnel who are trained and use appropriate biosafety procedures are less likely to have lost research time from injuries, providing safety training for personnel is prudent.
10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids for laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
 - a. Only needle-locking syringes or disposable syringe-needle units (i.e. needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather they must be carefully placed in puncture-resistant containers used for sharps disposal.

- b. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
- c. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps.
- d. Disposal of biohazardous materials covered under the Georgia Environmental Protection Division regulations on Biomedical Wastes is to be accomplished according to those regulations. See Section III in this manual.

B. BSL-2 Containment Equipment

Biological safety cabinets (BSC) and other appropriate containment devices are to be used whenever laboratory procedures have a significant potential for creating aerosols of infectious materials or rDNA molecules. Procedures that may create aerosols include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers, inoculating animals intranasally, and harvesting tissues from animals or eggs.

BSCs and other containment devices are to be maintained in good working condition. Certification of BSCs is to be accomplished annually or whenever the BSC is moved or the HEPA filter is changed or major repair accomplished (whenever the contaminated plenum is breeched). Certification of BSCs is conducted by a third party and is coordinated by the Environmental Safety Officer.

C. BSL-2 Laboratory Facilities

Laboratory facilities are similar to those for BSL-1 with the addition of an autoclave (a recording autoclave is required for treating biomedical waste) which is readily available and easily accessible.

Biosafety Levels 3 and 4

Research requiring BSL-3 or BSL-4 facilities is not permitted at Georgia Southern University.

SECTION V – Operation of Laboratory Equipment

Georgia Southern University personnel should not operate equipment that they have not been specifically trained and authorized to use. Operating manuals must be consulted for detailed operating instructions for individual pieces of equipment. Equipment known or suspected of being faulty should not be operated. Mechanically or electrically unsafe equipment should be tagged and reported to the laboratory supervisor.

Autoclaves/Steam Sterilizes

Moist heat, in the form of steam under pressure, is the most dependable medium for the destruction of all forms of microbial life. Autoclaves are instruments, which produce superheated steam under high pressure and are used for two processes: decontamination and sterilization.

Autoclave loads should be routinely checked with appropriate indicators to the adequacy of the sterilization or decontamination (for biomedical wastes) processes. Barbeito and Gremillion in their article "Microbiological Safety Evaluation of an Industrial refuse Incinerator" (*Applied Microbiology*. 1968. 16:2:291-95) reported on various times required for autoclaving selected animal carcasses, animal bedding materials, and eggs. With some loads even extended times did not provide for sterilization. Investigators or personnel responsible for sterilization may have to determine appropriate times and maintain appropriate records of the process.

Autoclaves should receive routine inspections to determine the need for maintenance and repair. Autoclave door gaskets may become distorted if the door is tightly shut for prolonged periods resulting in leaks. Doors should be kept open or loosely closed except when the autoclave serves as a barrier between clean and dirty areas.

Effective decontamination and sterilization by steam depends on the adequacy of circulation of the steam; loads packed tightly may not allow for adequate circulation. The steam must penetrate all packaging materials and contact all surfaces to be decontaminated or sterilized. And, finally the packaging must prevent the recontamination of the sterilized materials. To achieve effective and safe use of the autoclave you must be familiar with and follow laboratory procedures regarding:

1. Types of packaging – autoclavable pan, bag in pan, double bag, etc.
2. Separating into pans/bags for autoclaving in the lab
3. Adding water/germicidal solutions - Do not autoclave radioisotopes or explosive or volatile chemicals without checking with radiation safety, laboratory safety and biological safety.

4. Where possible, use specific autoclaves – "dirty" autoclaves for decontamination and "clean" autoclaves for sterilization and biological media.
5. Proper settings for type of cycle, and type and amount of material. Details of proper operation and settings may be contained in the specific device operation manual. Monitor the autoclave process for proper cycle and length of time. Cycle and time depend on what is being sterilized. For example, liquids would require the use of slow exhaust and while most loads require cycle times of 15 to 30 minutes at 121°C, longer times may be needed to meet the thermodynamic needs of special loads. The decontamination of biomedical waste may regularly require 60 minutes at 121°C.
6. When the cycle is completed care must be taken to wear proper personal protective equipment and to use proper unloading procedures. These include: Personal protective equipment – laboratory coat and apron that resists liquids (i.e. rubber/plastic) gloves that are heat and liquid resistive, and goggles and/or face shield. Procedures – Stand away from the autoclave door when opening to avoid a rush of steam and open slowly; do not move boiling liquids; and allow sufficient cooling time before handling superheated solution (i.e. microbiological culture media) to avoid burns and exploding glass.
7. Spill clean-up procedures should be posted in every autoclave room and followed when a spill occurs.

Biohazard Containment Equipment

Many manipulations of bacterial and viral cultures commonly used in the laboratory generate aerosols of viable organisms. This principle must be remembered when evaluating a person's degree of risk.

Biological Safety Cabinets

Primary biohazard containment devices serve to protect laboratory personnel from exposure to infectious aerosols produced by routine procedures. The biological safety cabinet (laminar flow hood) can be an extremely useful containment device for both personnel and product protection. Please see [CDC/NIH Primary Containment of Biohazards: Selection, Installation, and Use of Biological Safety Cabinets.](#)

Before purchasing a biological safety cabinet, horizontal flow clean bench or a vertical flow clean bench, please contact the Environmental Safety Officer to discuss the most appropriate option.

Centrifuges

Centrifuges are an important tool in the microbiological laboratory and must be treated with respect. Each time you use a centrifuge you make a series of choices: Which centrifuge, which rotor, which tubes and adapters, what speed and for how long. In addition, if you are using infectious agents you must decide on the level of containment and then select the appropriate rotor and tubes. Load the infectious agents inside a biological safety cabinet to prevent aerosol exposure. Your choices will affect both your research and your safety.

Always check your user manual for specific requirements as well as load limitations and speed. Operating procedures for each centrifuge must be established by the laboratory supervisor or principle investigator and followed by each operator. These procedures should follow the information provided in the operation manual and guidelines for centrifugation of infectious agents, chemical hazards and/or radioactive materials. Make sure the load is properly balanced – a minor error may not be a problem at low speed but may be serious at higher speeds.

Centrifuge tubes must be selected with the knowledge of the materials they will contain and the pressures they will be under. Plastic centrifuge tubes should be used whenever possible to minimize breakage. Nitrocellulose tubes should only be used when clear, without discoloration, and flexible. It is advisable to purchase small lots several times a year rather than one large lot. Storage at 4°C extends the shelf life. Nitrocellulose tubes must not be used in angle-head centrifuges.

Tubes to be used in angle-head centrifuges must never be filled to the point that the liquid is in contact with the lip of the tube when it is placed in the rotor, even though the meniscus will be vertical during rotation. When the tube lip is wetted, high G force drives the liquid past the cap seal and over the outside of the tube.

Inspect all centrifuge tubes prior to use. Broken, cracked, or damaged tubes are to be discarded. Capped centrifuge tubes should be used whenever possible.

Carrier Cups and Rotors

It has been estimated that 80% of centrifuge accidents are operator error. The most common operator errors are failure to secure the rotor to the drive shaft; failure to place lid on the rotor; and failure to secure the lid. Additionally it is very important not to run the rotor above its rated maximum and not to overfill it.

Cryogenic Liquids

Cryogenic liquids are gases that have been transformed into extremely cold refrigerated liquids, which are stored at temperatures below minus 90°C (-130°F). They are normally stored at low pressures in specially constructed multi-walled, vacuum-insulated containers.

The hazard potential presented by cryogenic liquids may result from the extreme cold, extreme pressure, which can result from rapid vaporization, and asphyxiation due to the displacement of air.

Appropriate personal protective equipment (heavy leather gloves/gloves for extreme cold, safety shoes, aprons, and eye protection) is to be worn when handling cryogenic liquids or materials preserved in cryogenic liquids.

Lasers

Lasers are a tool of biological research and as such must be used with consideration of applicable safety precautions. Contact the Georgia Southern University Radiation Safety Officer for appropriate guidance in laser safety.

Ultra Violet Light

Under certain conditions of radiation intensity and exposure time UV radiation may kill certain types of microorganisms, its greatest effect is against vegetative forms. UV is not a sterilizing agent except in certain exceptional circumstances. It is used to reduce the numbers of microorganisms on surfaces and in the air. The age of the UV lamp, dust accumulations on the bulb, and other factors that impede direct contact of the UV on the microorganisms contribute to decreased efficacy.

Microwave Ovens

Microwave ovens used in the laboratory may not be used to heat food unless that is the only use of that oven.

When melting agar the following precautions must be taken to prevent explosions: Caps on screw-cap bottles must be completely loosened before heating the bottles in the microwave and wear appropriate personal protective equipment including laboratory coat or apron, heat resistant gloves, and face shield.

Laboratory Vacuum Lines

When laboratory vacuum is used to manipulate biohazard materials, suitable filters and traps are to be used to prevent contamination of the vacuum lines and pumps.

Repair and Maintenance of Equipment and Facilities / New Construction

University employees or outside vendors undertaking facility expansion, equipment repair and maintenance, and general maintenance activities should not be unnecessarily exposed to biological hazards.

New Construction and Renovation – It is expected that new construction and renovation projects involving biohazard laboratories are to be reviewed in the planning stages by the University Environmental Safety Officer in cooperation with the Office of Facilities and other campus support groups.

Repair and Preventive Maintenance – Repair or routine preventive maintenance of mechanical or laboratory equipment in posted biohazard areas should be completed in such a way as not to expose the repair personnel to biohazardous agents.

Removal of equipment – Potentially contaminated equipment is not to be removed from biohazard laboratories for repair, servicing, cleaning or to surplus properties or repair shops or other areas until decontamination and removal of biohazard labels have been performed. The investigator or laboratory supervisor is to certify such equipment as being free of biohazard agents. Service personnel may ask laboratory personnel to sign a waiver stating that the piece of equipment has been appropriately decontaminated.

Biohazard Containment When Conducting Research with Vertebrate Animals

The University Policy on the Care and Use of Laboratory Animals encompasses (1) The Health and Human Services *"Guide for the Care and Use Of Laboratory Animals"* (2) Regulations of the Federal *"Animal Welfare Act"* (3) the NASULGC *"Guide for the Care and Use of Agricultural Animal in Agricultural Research and Testing"* and (4) the *"U.S. Government Principles on the Humane Care and Use of Laboratory Animals"*.

Specific Medical Concerns for Persons Working with Laboratory Animals

Allergy and musculoskeletal injury constitute the primary health risks to individuals using and caring for laboratory animals. Allergies are a significant problem, but can be reduced by providing appropriate protective equipment to affected personnel. Musculoskeletal injuries can be minimized by good laboratory planning, use of transport equipment such as carts, and training in lifting techniques and equipment use.

Infectious diseases may constitute a significant risk depending on the species and health status of animals involved, and the level of exposing animal care personnel. Infectious diseases to which animal care personnel may be at risk include a number of viral infections, such as rabies from random source dogs and lymphocytic choriomeningitis from hamsters and mice. In addition to infections potentially acquired from live animals, cell cultures, animal tissues and excreta can serve as sources of zoonoses. Careful monitoring and quarantine of any animals with potential viral or bacterial infections is a crucial part of quality assurance in animal care programs. Particular care must be taken in facilities handling nonhuman primates as these animals are most prone to carry infections which are known to cause serious disease in humans, for example Herpesvirus simiae (Herpes B) and tuberculosis. Routine periodic mycobacterial skin testing of humans and associated nonhuman primates is essential.

Animal bites and scratches are hazards common to animal facility personnel. All cases should be documented by filing an incident report and recording in an incident log. Tetanus immunizations should be routinely administered every ten years and at the time following a potential exposure such as an animal bite.

Working with Infectious Agents and Laboratory Animals:

Agents which are potentially infective from animals to humans or humans to animals (zoonoses) and when used with experimental animals should be handled according to principles outlined in the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories". Four general levels of applying biosafety practices are described in this publication for activities involving infectious disease work with experimental animals. These four combinations of practices, safety equipment, and facilities are designated Animal Biosafety Levels 1, 2, 3, and 4 (ABSL-1, etc.). Specific containment and management practices for each situation must be developed by the Principal Investigator with consultation from the Biosafety Officer and the designated Attending Veterinarian. When appropriate, the biosafety management practices should be incorporated into the standard operating procedures for animal care management and included in the personnel training program.

In general, most infectious disease studies with animals are handled at Biosafety level 2, with most exceptions being agents with true aerosol transmission capability (level 3) and certain blood-borne hemorrhagic fever agents (level 4). Exotic, non-indigenous foreign animal diseases (level 5) may require specialized containment and facilities to prevent animal to animal transmission and spread to native animal populations.

Safety Equipment for Animal Care (primary and secondary barriers)

Laboratory coats, gowns, or uniforms are worn while in the animal room. Gloves are worn when handling infected animals and when skin contact with infectious material is possible. This protective clothing is removed before leaving the animal facility. The animal facility is designed and constructed to facilitate cleaning and housekeeping. Supplies and equipment are stored outside of the animal room area whenever possible. A handwashing sink is available in the room where the infected animals are housed.

Exhaust air is discharged to the outside without being recirculated to other rooms, and it is recommended that the direction of air flow is toward the inside of the room. An autoclave for decontaminating waste should be available in the building with the animal facility.

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

Biohazard Containment for Plants

The principal purpose of plant containment is to avoid unintentional transmission of recombinant DNA containing plant genome, including nuclear or organelle hereditary material; the release of recombinant DNA derived organisms associated with plants; the release of non-indigenous species; or the release of plant pathogens/pests associated with research at Georgia Southern University Facilities.

The containment principles used in this section of the biosafety manual are based on the recognition that the organisms to which they apply pose no health threat to human or higher animals unless deliberately modified to do so, and that the intent of containment is to minimize the possibility of unanticipated deleterious effects on organisms and ecosystems outside the experimental facility.

The intentional release of genetically engineered organisms and products which are or are believed to be plant pests is regulated under CFR Parts 330 and 340 by the Animal and Plant Health Inspection Service, United States Department of Agriculture. Biological pesticides and certain field trials are regulated by the United States Environmental Protection Agency. In each case of proposed intentional release, the investigator(s) shall submit appropriate information on anticipated environmental impacts (as submitted to USDA, EPA, or other Federal or State regulatory Agency) for review by the Georgia Southern University IBC.

It is the responsibility of the Investigator to obtain any necessary permits for transport and/or work with regulated organisms/products. A copy of the permit is to be provided to the Compliance Officer.

Laboratory experiments with biohazardous plant materials are to be conducted in a BSL-2 laboratory.

Greenhouse Biological Containment Practices.

Greenhouse containment practices involve a combination of biological and physical measures.

Biological containment practices are intended to be used in association with facility design and facility/experimental operational procedures.

Effective Dissemination of Plants by Pollen or Seed can be Prevented by One or More of the following:

1. Preventing insect mediated pollination by appropriate insect control measures within the greenhouse.
2. Covering reproductive structures to prevent pollen dissemination at flowering and seed dissemination at maturity.
3. Removing reproductive structures, employing male sterile strains, or terminating the experiment and harvesting the plant material prior to the reproductive stage.
4. Ensuring that the experimental plants flower at a time of year when non cross-fertile plant is flowering within the normal pollen dispersal range of the experimental plant.
5. Ensuring that no cross-fertile plant is growing within the experimental plant's known pollen dispersal range.

Facilities - definitions.

The term 'greenhouse' refers to a permanent structure with walls, roof, and floor designed and utilized principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

The term 'greenhouse facility' includes the actual greenhouse rooms or compartments for growing plants plus all immediately contiguous hallways and headhouse areas and is considered part of the confinement area.

SECTION VI – Universal Blood and Body Fluid Precautions

The following are the key elements, which can be used at Georgia Southern University to control occupational exposures to bloodborne pathogens. All blood and body fluids must be considered as potentially infectious and personnel are to use appropriate protective measures to prevent exposure.

Personnel Practices

Hand-washing:

- When hands become contaminated with blood or body fluids
- When gloves are removed
- Before going to lunch, breaks, or home

Contaminated Needles and Other Sharps:

- DO NOT recap, bend, or break used needles
- Discard needles & sharps in appropriate "Sharps" containers
- Transport reusable sharps in leak-proof puncture-resistant container
- Use mechanical device (forceps) to place contaminated broken glass into appropriate containers for autoclaving

Personal Protective Equipment for Blood or Body Fluid Contact

- Gloves when touching blood or body fluids, mucous membranes, or non-intact skin
- Gloves when handling items or surfaces soiled with blood or body fluids
- Gloves when performing vascular access procedures (phlebotomy)
- Appropriate gowns or aprons when splashes or soiling of skin or clothing with blood or body fluids is likely
- Masks and goggles, or face shield during procedures likely to generate splashes of blood or body fluids into the mouth, nose, or eye

Environmental Controls

General Housekeeping:

- Maintain work area in clean and sanitary condition
- Decontaminate work surfaces after procedures and when contaminated
- Remove any protective work surface coverings when contaminated

Blood or Body Fluid Spills:

- Soak up spills with absorbent material (paper towels)
- Decontaminate area with appropriate disinfectant
- Dispose of contaminated material appropriately

Biomedical Wastes:

- Are to be disposed of according to State of Georgia Regulations

Transport:

- Consider all laboratory specimens of human or animal origin as potentially infectious
- Use leak proof containers for laboratory specimens
- Place container in a sealable secondary container for transport

Exposures to blood or body fluids via broken skin or needle sticks or mucous membrane contact:

- Wash affected area immediately and apply first aid
- Contact the Georgia Southern University Environmental Safety Officer at 912-478-5234. Please note the Georgia Southern University Student Health Center can not treat employees if the employee wants the injury to be covered under Workers' Compensation. Additionally, the Student Health Center does not have the capability to treat most potentially lethal exposures. After receiving emergency treatment at an appropriate facility, the injured employee should have their supervisor complete a Workers' Compensation First Report of Injury Form.
- Report injury to Compliance Officer.

OSHA Bloodborne Pathogen Regulations

<http://www.osha.gov/SLTC/bloodborne pathogens/index.html>

State of Georgia Bloodborne Pathogen Code/Law

http://www.legis.state.ga.us/legis/2003_04/gacode/31-12-13.html

SECTION VII – Experiments Prohibited at Georgia Southern University

Experiments using any organism or agent that is prohibited by any federal or state agency from importation into Georgia are prohibited.

Experiments using agents or organisms that require containment facilities (e.g. BSL-3 or BSL-4) or equipment that are not available at Georgia Southern University are prohibited.

SECTION VIII – Transporting Biohazardous Materials

Georgia Southern University personnel packaging biohazardous material for shipment or transport must follow appropriate state and federal regulations. Federal rules require that anyone wishing to ship biological materials or dry ice must first have shipping training (see Appendix E). The process for training at Georgia Southern University is currently under review. Until this process is finalized, you should contact the Office of Research Services and Sponsored Programs Compliance Coordinator for assistance if you are going to package biological materials or dry ice for shipment or fill out a Declaration for Dangerous Goods form.

SECTION IX – Spills of Biohazardous Materials

Primary responsibility for preventing or containing and cleaning up laboratory spills remains with the Principal Investigator or laboratory supervisor. Laboratory protocols should be carefully designed to prevent biological, chemical and/or radiation spills.

When accidents occur that involve the mishandling or escape of biohazardous materials, the principal investigator or laboratory supervisor is to be notified immediately. Spills of high risk organisms (certain Class 2 and all Class 3 or higher agents) should be reported to the Environmental Safety Officer during normal working hours or to the Georgia Southern University Police at the emergency telephone number after normal working hours by the principal investigator or laboratory supervisor. The Georgia Southern University Police will contact the Environmental Safety Officer for appropriate response. All employees and/or students have an obligation to themselves and their colleagues to report accidents immediately in order to minimize potential hazard.

When a biohazardous spill also involves radioactivity, cleanup procedures may have to be modified. The extent of the modification will depend on the level of radiation and the nature of the isotope involved. The Radiation Safety Officer should be called during normal working hours, or the Georgia Southern University Police at all other times.

The following guidelines are intended to assist the principal investigator, laboratory supervisor, and other responsible individuals who may be involved in the cleanup of biological spills.

BIOHAZARD SPILLS INSIDE BIOLOGICAL SAFETY CABINETS (BSC)

The occurrence of a spill in a biological safety cabinet poses less of a problem than a spill in an open laboratory as long as the spilled material is contained in the biological safety cabinet. Decontamination of the work zone can usually be effected by direct application of concentrated liquid disinfectants along with a thorough wipe down procedure. Gaseous decontamination may be required to clean-up the interior sections of the cabinet.

- A. Chemical decontamination procedures should be initiated immediately while the biological safety cabinet continues to operate. Continuing the operation of the cabinet helps to prevent the escape of contaminants.
- B. Wearing protective gloves, spray or wipe walls, work surfaces, and equipment with an appropriate decontaminating solution. A disinfectant detergent, such as Wescodyne or Environ has the advantage of detergent

action on extraneous organic substances which may interfere with the microbicidal activity of the disinfectant.

- C. Flood tray top, drains pans, and catch basins below work surface with decontaminating solution and allow to stand for 30 minutes, or as directed by the manufacturer's specifications.
- D. Drain excess decontaminating solution from tray and drain pans into cabinet base. Lift out tray and removable exhaust grille work. Clean the top and bottom (underside) surfaces using a sponge or clean cloth soaked in decontaminant solution. Following the cleaning process, replace the tray and grille work in their proper position. Place gloves and sponge or cloth in autoclave pan and autoclave these items.
- E. Drain decontaminating solution from cabinet base into appropriate container and autoclave according to standard procedures.
- F. If gaseous decontamination of the cabinet's interior sections is needed, call the Environmental Safety Officer.

BIOHAZARD SPILLS OUTSIDE BIOLOGICAL SAFETY CABINETS

The procedure to be used in cleaning up of spills involving microorganisms will depend on the amount of material spilled and the degree of laboratory containment required.

If individuals believe that their outer garments have been contaminated, they should remove their clothing in the laboratory area and place them in an autoclave or a container for autoclaving. They should change into clean clothing in a non-contaminated area.

Special care in decontamination may be necessary if a spill goes under or between fixed furniture or behind base moldings (floor/wall), or if floor penetrations are involved.

Minor Spills (less than 10 ml and generating little aerosol) on equipment, laboratory benches, walls, or floors:

- A. Warn all personnel not essential for spill containment to stay clear of the contaminated area. This may be accomplished verbally or, when appropriate, by posting warning signs on the doors.
- B. Thoroughly wash hands and other apparently contaminated areas with soap and water. Put on clean surgical gloves or latex disposable gloves.
- C. Cover the spill area with paper towels soaked in appropriate decontamination solution. (See Appendix D)

- D. Wipe up the spill with the soaked paper towels and place the used towels in an autoclave pan and autoclave.
- E. Pour decontaminating solution around and on the area of the spill. Let stand for 20 minutes then wipe up with paper towels. Place gloves and paper towels in autoclave pan and autoclave.
- F. Wash hands and other apparently contaminated areas again with soap and water.

Major Spills (more than 10 ml or with considerable aerosol; additional precautions should be considered for Class 3 and above agents):

- A. Close laboratory doors and post warning signs to prevent others from entering the laboratory.
- B. Wash hands and other apparently contaminated areas with soap and water.
- C. Report the accident to the Supervisor and to the Biosafety Officer.
- D. If personal clothing is contaminated, remove all outer clothing and place it in autoclave or container for autoclaving. Put on clean garments.
- E. Leave the laboratory for 30 minutes to allow dissipation of aerosols created by the spill.
- F. Upon returning to the laboratory to start decontamination, check to see if laboratory doors are closed and appropriate signs are displayed. Put on gloves. Respirators or other safety equipment may be required, depending on the microorganism involved. Check with the Principal Investigator, Laboratory Supervisor, or Environmental Safety Officer.
- G. Pour a decontamination solution (See Appendix D) around the spill and allow this solution to flow into the spill. Paper towels soaked with decontamination solution may be used to cover the area. Do not pour decontamination solution directly onto the spill in order to avoid additional release of aerosols.
- H. Let decontamination solution – microorganism mixture stand for 30 minutes or longer to allow adequate contact time.
- I. Using autoclave dust pan and squeegee transfer all contaminated materials to deep autoclave pan, cover with suitable cover, and autoclave according to standard directions.

- J. Place dust pan squeegee in an autoclavable bag and autoclave according to standard directions.
- K. Remove gloves and other contaminated garments and place them in an autoclave container for autoclaving.
- L. Thoroughly wash hands, face, and other apparently contaminated areas.

Special care in decontamination may be necessary. The Principal Investigator and/or the Environmental Safety Officer may require the collection of sample cultures to determine that the area has been effectively decontaminated.

APPENDIX A

Georgia Southern University

Institutional Biosafety Committee Protocol Application Forms:

- Application for Research/Teaching Involving Biohazardous Materials (including rDNA)
- Application for Research/Teaching with rDNA that is EXEMPT under CDC/NIH Guidelines
- Application for Modification of an Existing IBC-Approved Protocol

Applications are available at

http://academics.georgiasouthern.edu/research/forms_compliance.html#IBC

APPENDIX B

Supplementary Application Materials: Safety Standard Operating Procedures (SOP) and Laboratory Self Audit Forms

Supplementary materials are available at

http://academics.georgiasouthern.edu/research/forms_compliance.html#IBC

APPENDIX C

Select Agents and Toxins

APHIS Plant Pathogens, HHS Select Infectious Agents & USDA High Consequence Livestock Pathogens/Toxins

Viruses

1. African horse sickness virus ³
2. African swine fever virus ³
3. Akabane virus ³
4. Avian influenza virus (highly pathogenic) ³
5. Blue tongue virus (exotic) ³
6. Camel pox virus ³
7. Cercopithecine herpesvirus 1 (Herpes B virus) ²
8. Classical swine fever virus ³
9. Crimean-Congo haemorrhagic fever virus ²
10. Eastern equine encephalitis virus ⁴
11. Ebola viruses ²
12. Foot and mouth disease virus ³
13. Goat pox virus ³
14. Japanese encephalitis virus ³
15. Lassa fever virus ²
16. Lumpy skin disease virus ³
17. Malignant catarrhal fever virus ³
18. Marburg virus ²
19. Menangle virus ³
20. Monkeypox virus ²
21. Newcastle disease virus (VVND) ³
22. Nipah and Hendra complex viruses ⁴
23. Peste des petits ruminants virus ³
24. Plum pox potyvirus ¹
25. Rift Valley fever virus ⁴
26. Rinderpest virus ³
27. Sheep pox virus ³
28. South American haemorrhagic fever viruses [(Junin, Machupo, Sabia, Flexal, Guanarito)] ²
29. Swine vesicular disease virus ³
30. Tick-borne encephalitis complex (flavi) viruses [Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)] ²
31. Variola major virus (Smallpox virus) and Variola minor (Alastrim) ²
32. Venezuelan equine encephalitis virus ⁴
33. Vesicular stomatitis virus (exotic) ³

Prion

1. Bovine spongiform encephalopathy agent ³

Toxins

1. Abrin ²
2. Botulinum neurotoxins ⁴
3. *Clostridium perfringens* epsilon toxin ⁴
4. Conotoxins ²
5. Diacetoxyscirpenol ²
6. Ricin ²
7. Saxitoxin ²
8. Shigatoxin and Shiga-like ribosome inactivating proteins ⁴
9. Staphylococcal enterotoxins ⁴
10. Tetrodotoxin ²
11. T-2 toxin ⁴

Bacteria

1. *Bacillus anthracis* ⁴
2. Botulinum neurotoxin producing species of *Clostridium* ⁴
3. *Brucella abortus* ⁴
4. *Brucella melitensis* ⁴
5. *Brucella suis* ⁴
6. *Burkholderia mallei* ⁴
7. *Burkholderia pseudomallei* ⁴
8. *Coxiella burnetii* ⁴
9. *Cordaria ruminantium* (Heartwater) ³
10. *Francisella tularensis* ⁴
11. *Liberobacter africanus*, *Liberobacter asiaticus* ¹
12. *Mycoplasma capricolus*/M. F38/*M. mycoides capri* (contagious caprine pleuropneumonia agent) ³
13. *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia agent) ³
14. *Ralstonia solanacearum* race 3 biovar 2 ¹
15. *Rickettsia prowazekii* ²
16. *Rickettsia rickettsii* ²
17. *Xanthomonas oryzae* pv. *oryzicola* ¹
18. *Xylella fastidiosa* (citrus variegated chlorosis strain) ¹
19. *Yersinia pestis* ²

Fungi

1. *Coccidioides immitis* ⁴
2. *Coccidioides posadasii* ²
3. *Peronosclerospora philippinensis* ¹
4. *Phakopsora pachyrhizi* ¹
5. *Sclerophthora rayssiae* var. *zeae* ¹
6. *Synchytrium endobioticum* ¹

Exemptions

The following agents or toxins are exempt if the aggregate amount under the control of a principal investigator does not, at any time, exceed:

- 0.5 mg of botulinum neurotoxins
- 5 mg of *Staphylococcal* enterotoxins
- 100 mg of abrin, *Clostridium perfringens* epsilon toxin, conotoxin, ricin, saxitoxin, shigatoxin, shiga-like ribosome inactivating protein, and tetrodotoxin
- 1,000 mg of diacetoxyscirpenol and T-2 toxin

The following agents or toxins are also exempt:

- Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable select agent organisms or nonfunctional toxins.
- The vaccine strains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), Venezuelan Equine encephalitis virus vaccine strain TC-83.

The medical use of toxins for patient treatment is exempt.

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

1. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.
2. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the listed toxins if the nucleic acids: a) are in a vector or host chromosome; b) can be expressed *in vivo* or *in vitro*; or c) are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.
3. Listed viruses, bacteria, fungi, and toxins that have been genetically modified.

Other Restrictions

1. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to the listed agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
2. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of listed toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

¹ APHIS Plant Pathogen

² HHS Select Infectious Agent

³ USDA High Consequence Livestock Pathogen or Toxin

⁴ USDA-HHS Overlap Agent

APPENDIX D

Liquid Disinfectants and Biohazardous Material Spill Checklists

Laboratory personnel should be familiar with the various disinfectants that will effectively kill the biohazardous agents being used. The following information is provided to assist in your selection of appropriate disinfectants.

Alcohols – Ethyl and Isopropyl are good disinfectants for the vegetative forms of bacteria and lipoviruses.

Ethyl Alcohol

Use Dilution: 70-95%

Inactivates: vegetative bacteria and Lipoviruses, has variable results with non-lipoviruses and is ineffective with bacterial spores.

Other Characteristics: flammable, eye irritant, and toxic (TLV – 1000 ppm)

Isopropyl Alcohol

Same as for Ethyl Alcohol except the TLV = 400 ppm.

Chlorine Compounds – The germicidal effect of chlorine compounds is dependent upon the release of hypochlorous acid and is therefore dependent upon the available chlorine. Allow a contact time of from 10 to 30 minutes.

Use Dilution: 500 ppm available chlorine is recommended for vegetative bacteria and most viruses. Chlorine solutions that are neutral or slightly acidic and with a concentration of approximately 2500 ppm are needed for effectiveness against bacterial spores. Undiluted common household bleach (Clorox) is alkaline with a pH of 8 or greater. Household bleach typically contains 5.25% sodium hypochlorite for 52500 ppm available chlorine.

Other Characteristics: Chlorine compounds are corrosive to metals; leave a residue; irritate the skin, eyes, and respiratory tract, and are toxic. Chlorine compounds are also rapidly inactivated by organic matter. While chlorine compounds are not generally recommended for routine use, undiluted household bleach is frequently used with biological spills.

Iodophors – The germicidal effect of iodophors is dependent on the free iodine released from the compound in which it is contained. Allow a contact time of 10 to 30 minutes.

Use Dilution: 25 to 1600 ppm of available iodine. Solutions containing 75 to 150 ppm are generally recommended.

Inactivates: vegetative bacteria, fungi and viruses. There is poor activity against bacterial spores.

Other Characteristics: Although iodophors are less harmful to man than chlorine compounds they can irritate the skin and eyes. Iodophors are corrosive (less than chlorine), they leave a residue and may stain. Iodophor stains, however, can be readily removed with solutions of sodium thiosulfate ($\text{Na}_2\text{S}_2\text{O}_3$). As with the chlorine compounds, iodophors are rapidly inactivated by organic matter. One advantage is that iodophors have a built-in indicator. As long as the solution is brown or yellow it is still active.

Phenolic Compounds – These are effective against vegetative bacteria (including mycobacterium tuberculosis), fungi, and lipoviruses. Effectiveness against nonlipid viruses is variable depending on the virus. The phenols are ineffective against bacterial spores.

Use Dilutions: 1.0 – 5.0% Solutions containing 0.5 – 2.0% phenol are effective against lipoviruses.

Other Characteristics: Phenols are corrosive and may leave a sticky, gummy residue. Phenolic compounds are irritating to the skin and eyes and are relatively toxic – Phenol TLV for skin is 5 ppm.

Quaternary Ammonium Compounds – The efficacy of Quaternary Ammonium compounds still generates considerable controversy. Quats are effective in destroying ordinary vegetative bacteria and lipid containing virus but are not effective against pseudomonas, proteus and other gram-negative bacilli. Also, Quats are not effective against bacterial spores at the usual use concentrations of 1:750.

Use Dilutions: 0.1 to 2.0%

Other Characteristics: Quats are surface-active compounds which possess the useful property of lowering the surface tension of the solution. Other advantages include being nontoxic, odorless, nonstaining, noncorrosive to metals and stable. If used at recommended concentrations, Quats are nonirritating.

NOTE: Quaternary Ammonium compounds are rapidly inactivated by organic matter.

Formaldehyde Solutions – Formaldehyde in a 5-8% concentration is an effective liquid decontaminant which inactivates vegetative bacteria, bacterial spores, lipid and nonlipid viruses and fungi.

Use Dilutions: 5.0-8.0%

Other Characteristics: The odor and irritating (skin and eyes) and toxic features (TLV = 1.0 ppm) of formaldehyde solutions reduce the desirability of this solution for general use. Formaldehyde solutions are active in the presence of organic matter and do not corrode metal.

Checklist
BIOHAZARD SPILL PROCEDURES FOR INSIDE BIOLOGICAL
SAFETY CABINETS (BSC)

1. KEEP THE BSC ON
2. PUT ON PROTECTIVE GLOVES.
3. SPRAY/WIPE WALLS, WORK SURFACES, AND EQUIPMENT WITH DECONTAMINATING SOLUTION
4. FLOOD TRAY TOP, DRAIN PANS, AND CATCH BASINS WITH DECONTAMINATING SOLUTION
5. ALLOW TO STAND FOR 30 MINUTES (or Manufacturer's recommendation)
6. DRAIN EXCESS SOLUTION INTO CABINET BASE
7. LIFT OUT TRAY AND REMOVABLE EXHAUST GRILLE WORK
8. CLEAN TOP AND BOTTOM SURFACES WITH SPONGE/CLOTH SOAKED IN DECONTAMINATING SOLUTION
9. REPLACE TRAY AND GRILLE WORK
10. PLACE GLOVES, SPONGE, CLOTH, ETC. IN AUTOCLAVE PAN
11. DRAIN DECONTAMINATING SOLUTION FROM CABINET BASE INTO AUTOCLAVABLE CONTAINERS
12. AUTOCLAVE.
13. IF GASEOUS DECONTAMINATION IS NEEDED, CALL THE BIOSAFETY OFFICE.

Please post this checklist near the biosafety cabinet.

Checklist
BIOHAZARD SPILL PROCEDURES FOR OUTSIDE BIOLOGICAL SAFETY
CABINETS (BSC)

Minor spills (<10 ml)

1. WASH HANDS AND OTHER APPARENTLY CONTAMINATED BODY PARTS WITH SOAP AND WATER.
2. POST WARNING TO KEEP NON-ESSENTIAL PERSONNEL FROM SPILL AREA.
3. PUT ON PROTECTIVE GLOVES.
4. COVER SPILL AREA WITH PAPER TOWELS SOAKED IN DECONTAMINATING SOLUTION.
5. WIPE UP SPILL WITH SOAKED PAPER TOWELS
6. PLACE USED TOWELS IN AUTOCLAVE PAN.
7. POUR DECONTAMINATING SOLUTION AROUND AND ON SPILL AREA.
8. LET SOLUTION STAND FOR 30 MINUTES. (or Manufacturer's recommendation)
9. WIPE UP WITH PAPER TOWELS.
10. PLACE PAPER TOWELS AND GLOVES IN AUTOCLAVE PAN.
11. WASH HANDS WITH SOAP AND WATER.
12. AUTOCLAVE.

Please post this checklist in the laboratory.

Checklist
BIOHAZARD SPILL PROCEDURES FOR OUTSIDE BIOLOGICAL SAFETY
CABINETS (BSC)

Major Spills (>10ml, high potential for aerosol, or any Class 3 or higher agent)

1. WASH HANDS AND OTHER APPARENTLY CONTAMINATED BODY PARTS WITH SOAP AND WATER.
2. POST WARNING SIGNS AND CLOSE LABORATORY DOOR.
3. REPORT SPILL TO SUPERVISOR AND BIOSAFETY OFFICER.
4. IF CLOTHING IS CONTAMINATED, REMOVE ALL OTHER GARMENTS.
5. PLACE CONTAMINATED CLOTHING IN AUTOCLAVE CONTAINER.
6. PUT ON CLEAN GARMENTS.
7. LEAVE LABORATORY FOR 30 MINUTES.
8. CHECK TO SEE THAT LABORATORY DOORS ARE CLOSED AND WARNING SIGNS DISPLAYED UPON RETURNING TO LAB.
9. PUT ON NEEDED PERSONAL PROTECTIVE EQUIPMENT
10. PLACE PAPER TOWELS SOAKED IN DECONTAMINATION SOLUTION OVER THE SPILL.
11. POUR DECONTAMINATION SOLUTION AROUND SPILL – ALLOW SOLUTION TO FLOW INTO SPILL. **DO NOT POUR DECONTAMINATION SOLUTION DIRECTLY INTO SPILL**
12. LET STAND FOR AT LEAST 30 MINUTES (or Manufacturer's recommendation)
13. TRANSFER CONTAMINATED MATERIALS TO AUTOCLAVE CONTAINER USING AUTOCLAVABLE DUST PAN AND SQUEEGEE.
14. PLACE DUST PAN AND SQUEEGEE IN AUTOCLAVE CONTAINER.
15. REMOVE GLOVES AND OTHER CONTAMINATED GARMENTS AND PLACE IN AUTOCLAVE CONTAINER.
16. WASH FACE, HANDS, AND OTHER APPARENTLY CONTAMINATED BODY PARTS.
17. AUTOCLAVE ALL MATERIALS THAT REQUIRE AUTOCLAVING.

Please post this checklist in the laboratory.

APPENDIX E

Georgia Southern University

**Shipment of Biological Materials
and Dry Ice Manual**

Georgia Southern University

Shipment of Biological Materials & Dry Ice Manual

*Many thanks and credit to:
Andy Glode & David Gillum, University of New Hampshire - Office of Environmental Health and Safety
and Jeff Owens, Georgia State University*

*Updated on
February 17, 2004*

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I. Introduction

The Georgia Southern University Institutional Biosafety Committee (IBC) has adopted this manual to assist in the shipment of biological materials and dry ice. This document includes information about how to properly classify, package, mark and label your shipment. This manual also describes the training requirements necessary to ship biological materials and dry ice.

Shipped biological specimens, infectious agents and other biological materials are regulated by governmental and non-governmental, consensus development organizations. Penalties for non-compliance with the rules are significant and could result in the following fines:

- Up to \$250,000 and up to a year jail sentence for individuals.
- Up to \$500,000 per incident for organizations.

Several agencies regulate the shipment of biological materials including:

- International Air Transport Association (IATA).
- US Department of Transportation (DOT).
- US Public Health Service (PHS).
- Occupational Health and Safety Administration (OSHA).

Infectious substances and other dangerous goods must always be transported according to the appropriate regulations. Carrying dangerous goods by hand, for example in a vial in your pocket or in luggage, is strictly prohibited. IATA/DOT regulations cover your checked luggage, materials you carry on, or materials you carry in your pockets when you board an airplane. Persons who violate IATA regulations are subject to fines and criminal prosecution.

IATA regulations are commonly encountered since they regulate materials transported by air and are generally the most restrictive. For these reasons, this guide pays special attention to IATA procedures.

II. Training Requirements

Federal rules require that anyone wishing to ship biological materials or dry ice must first have shipping training. If you are going to package biological materials or dry ice for shipment or fill out a [Declaration for Dangerous Goods](#) form you must follow the training certification requirements outlined below.

1. **Read this manual.** This manual will provide familiarity with the general provisions relating to the regulations and detailed training in the requirements applicable to shipping infectious materials and dry ice.
2. **Contact the Georgia Southern University Environmental Safety Officer for additional assistance.** Training to ensure that you are familiar with the hazards presented by infectious materials; proper handling; and emergency response procedures is currently under

development. Please contact the Environmental Safety Officer for assistance until the new guidelines are in place.

III. Shipping Overview

Follow these steps when shipping biological materials and dry ice.

1. Classify your materials for shipment. See [Section IV](#).
2. Package, mark and label your material(s) appropriately. See [Section V](#).
3. Fill out the [Declaration for Dangerous Goods](#) form. See [Section VI](#).
4. If you are shipping [Select Agents](#), special regulations apply. Consult [Section VII](#).
5. If you plan on importing or exporting biological materials, special regulations apply. Consult [Section VIII](#).

IV. Shipment Types

For shipment purposes, biological materials are categorized into four classes:

- Infectious substances.
- Diagnostic specimens.
- Biological products.
- Genetically modified organisms and micro-organisms.

Read each material section carefully to determine how to classify a material. If you are shipping a biological material that *cannot cause disease*, infectious substance regulations do not apply. **Note:** All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (see [Other Packaging Requirements](#)). All samples preserved with flammable or toxic materials, such as ethanol or formalin, must be shipped appropriately.

The regulations allow for a certain amount of professional judgment when classifying biological materials for shipment. IATA does not apply the “Universal Precautions” definition in regard to infectious materials (where all human blood is treated as potentially infectious). For example, blood collected for routine screening is normally classified for shipment as a *diagnostic specimen*. However, blood collected to verify a diagnosis of HIV should be classified as an infectious substance. Keep this in mind when reading the definitions in the following sections. If you are still not sure how to classify a material for shipment after reviewing the following sections, contact the Environmental Safety Officer at 912-681-5234.

A. Diagnostic Specimens

Diagnostic specimens are human or animal materials that have a relatively low probability of containing pathogens. When these materials are shipped for the purpose of screening, study or diagnosis, they are considered Diagnostic Specimens. These materials include human or animal tissue samples, blood, excreta, etc. Diagnostic specimens are not considered to be a hazardous material by IATA, though the following packaging and shipping requirements apply.

Note: Diagnostic specimens must be shipped as an [Infectious Substance](#) when “the source patient or animal has or may have a serious human or animal disease which can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available.”

1. Packaging

The basic triple packaging concept applies to diagnostic specimens. Purchase packaging for use with diagnostic specimens. Such packaging must comply with IATA Packing Instruction 650. See [Appendix A](#) for packaging suppliers. Be sure to specify if the shipment is a refrigerated sample (ice packs or dry ice).

For diagnostic specimens, the maximum quantity for primary receptacle is 500 mL or 500 g and outer packaging must not contain more than 4 L or 4 kg.

2. Labeling

The sender and recipient’s addresses must be printed and clearly displayed. If packaged with dry ice, a Class 9 diamond label ([Figure 1](#)) must be placed on one side of the outer package. If the package is shipped by air, the following text should appear on the outer container:

“DIAGNOSTIC SPECIMEN PACKED IN COMPLIANCE
WITH IATA PACKING INSTRUCTION 650.”

B. Biological Products

Biological products are defined as biological materials used in the prevention, diagnosis, treatment or cure of diseases in humans or animals and certified by the USDA or FDA. Examples of biological products include certain viruses, therapeutic serums, toxins, antitoxins, vaccines, blood and blood products. Biological products that meet the definition of an infectious material must be shipped as an infectious substance. Biological products that have no or very low probability to produce disease and those packaged for final distribution for

use for personal health care by medical professionals are not subject to special shipping regulations.

C. Genetically Modified Organisms and Microorganisms

Genetically modified organisms or micro-organisms that are dangerous, infectious, or are carried by an animal host are regulated for transportation. For the following guidelines, make sure to distinguish those that apply to *organisms* vs. *microorganisms*.

A genetically modified *microorganism* which meets the definition of an infectious substance must be classified as an infectious substance for transportation. For these materials, follow instructions for shipping an infectious substance.

Genetically modified *microorganisms* which are not infectious substances but which are capable of altering animals, plants or microbiological substances in a way that is not normally the result of natural reproduction can be transported when classified as a Miscellaneous Hazard (Class 9). These materials are packed for shipment in the same way as infectious substances, except there are no specific testing requirements for the packaging; this packaging variation is IATA Packing Instruction 913. You may not be able to purchase packages designed for Packing Instruction 913. In this case, use packages designed for infectious substances (Packing Instruction 605) and use a Class 9 label ([Figure 1](#)). These materials are shipped with the proper shipping name, "Genetically modified micro-organisms" and UN 3245. The maximum allowable quantity per primary receptacle is 100 mL or 100 g. There is no maximum net quantity per package.

Genetically modified *organisms* that are known or suspected to be dangerous to humans, animals or the environment cannot be transported by air. Animals which contain, or are contaminated with, genetically modified *microorganisms* or *organisms* that meet the definition of an infectious substance cannot be shipped by air.

D. Infectious Substances

Infectious substances are materials known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus, microorganism (including its viruses, plasmids, or other genetic elements), proteinaceous infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause infectious disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease, i.e. no or very low, individual or community risk do not have to be shipped as infectious substances.

1. Packaging

The triple packaging concept, explained in Section V, applies to infectious substances. Purchase packaging approved for use with infectious substances. These packages must comply with IATA Packing Instruction 602. See [Appendix A](#) for a list of packaging suppliers. Make sure to specify if you are shipping a refrigerated sample (ice packs or dry ice). The maximum quantity of infectious substance that can be shipped by air in one package is 4 L or 4 kg. The maximum quantity that may be shipped via passenger aircraft is 50 ml or 50 g.

2. Labeling

The sender and recipient's addresses must be printed and clearly displayed. The container should be labeled with the name and telephone number of a person responsible for the shipment. If packaged with dry ice, a Class 9 diamond label ([Figure 1](#)) must be placed on one side of the outer package. The container should be labeled with an infectious substance label ([Figure 2](#)). When shipping over 50 mL or 50 g of infectious substance, you must also put a Cargo Aircraft Label on the outer container ([Figure 3](#)).

When shipping infectious substances by air, you must make advance arrangements with the consignee and the operator to ensure that the shipment can be transported and delivered without delay. In the "[Additional Handling Information](#)" section of the [Shipper's Declaration for Dangerous Goods](#), include the following statement:

"Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made."

There are two proper shipping names for infectious substances:

- Infectious substance, affecting humans (UN 2814); and
- Infectious substance, affecting animals (UN 2900).

If you have any reason to believe the infectious material could affect humans you should ship your material as UN 2814. Infectious materials that can affect humans and animals should be shipped as UN 2814. Infectious materials that can only affect animals should be shipped as UN 2900.

Figure 1.



Figure 2.



Figure 3.



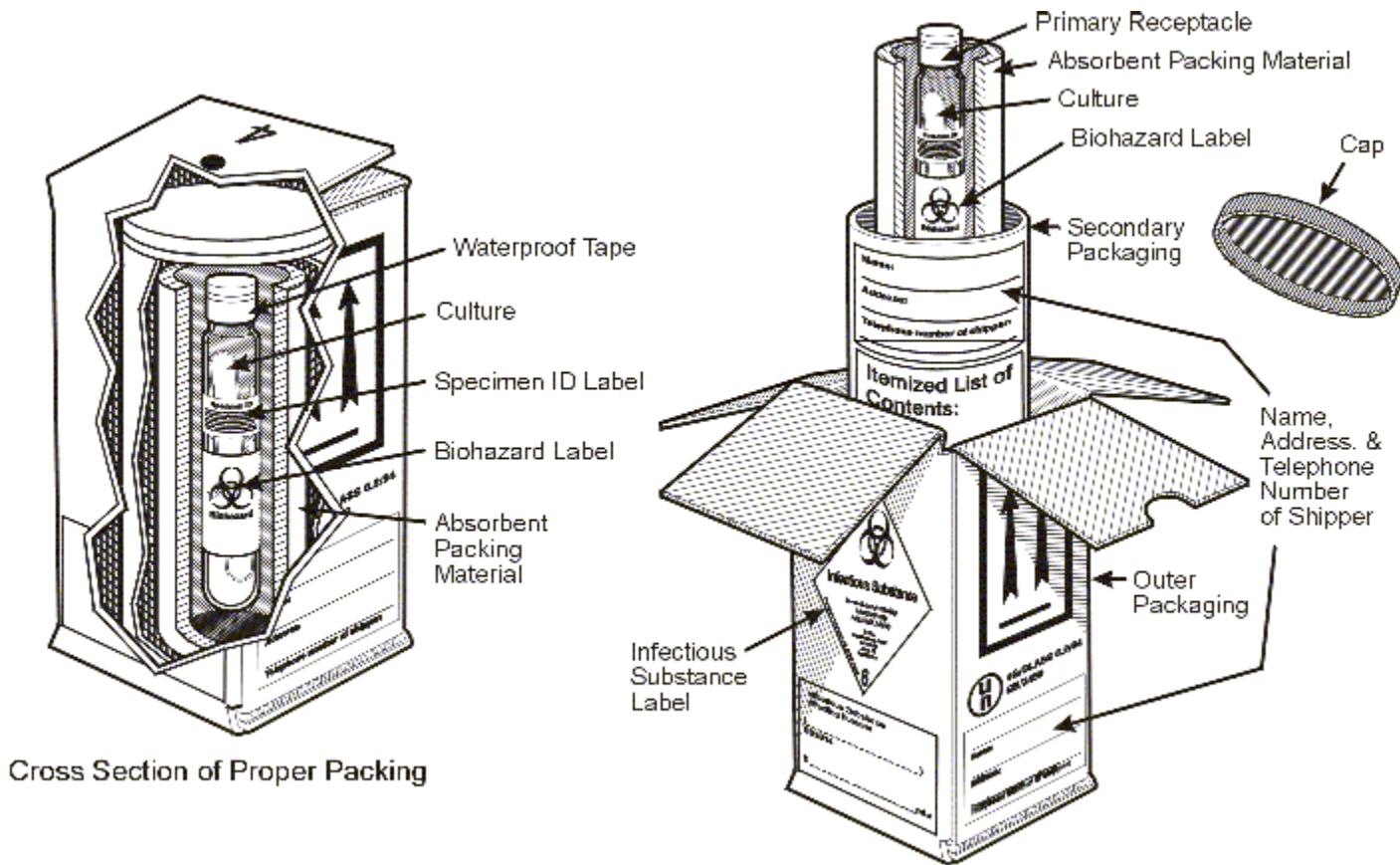
V. Packaging Biological Materials

Potentially hazardous biological materials must be packaged to withstand leakage of contents, shocks, temperature, pressure changes and other conditions that can occur during ordinary handling in transportation. Packaging your material(s) appropriately is accomplished by purchasing certified packaging. Refer to [Appendix A](#) for vendors that can supply certified packaging for biological materials. When ordering, specify what category of material(s) you will be shipping: *infectious substances*, *diagnostic specimens*, *dry ice*, *ice packs*, etc. Different categories have slightly different packaging needs, but all follow the basic triple packaging requirements described below.

A. Triple Packaging

Biological materials must be packaged according to the triple packaging principle depicted in [Figure 4](#). The three elements of triple packaging include: *primary receptacle*, *leak-proof secondary container*, and *durable outer container*. Infectious substances, diagnostic specimens and genetically modified micro-organisms must be packaged in this way, with slight variations.

Figure 4 - Packaging and labeling of biological materials.



Cross Section of Proper Packing

The **primary container** holds the biological material; it must be leak-proof. It must be labeled with the name of the contents. A leak-proof seal, such as a heat seal, skirted stopper or metal crimp, is required. If the container has a threaded lid, it must be secured with waterproof tape. Petri plates cannot be used as primary receptacles. Lyophilized substances can only be shipped in flame sealed glass ampoules or rubber stopped glass vials with metal seals. Packaging purchased for shipping infectious substances or diagnostic specimens usually does not include the primary container.

The **secondary container** holds one or more primary containers, and must also be leak-proof. This container must meet specific United Nations (UN) performance standards. Containers purchased from commercial vendors are designed to meet the necessary standards. If you are shipping any liquid, there must be enough absorbent material in the secondary container to absorb *all* of the liquid in the primary receptacle(s). If multiple primary containers are used, they must be wrapped to prevent contact between them so they do not break during transport.

The **outer container** must be at least 100 mm (4 inches) in the smallest overall external dimension, in order for required markings and labels to fit. The outer package must be of adequate strength for its capacity, mass, and intended use. It must also be certified with a UN specification mark. An **itemized list** of package contents must be included between the outer and secondary container. The outer package should be marked to identify hazardous contents, including the proper shipping name, UN number and net quantity for each substance.

B. Other Packaging Requirements

Overpacks. An overpack can be used to combine several triple packages into one large package. This may be done to save freight charges when shipping multiple samples. Each triple package inside the overpack must be properly marked and labeled. The outside of the overpack must bear the same markings and labels as the triple packages within. If packed with dry ice, the total net quantity of dry ice must be listed on the outer container. The overpack must also be marked with the statement:

“Inner Packages Comply with Prescribed Specifications.”

Ice and Dry Ice. If a shipment includes ice or dry ice, special packaging must be purchased. If shipping with ice, the packaging must be leak-proof. If dry ice is used, the outer packaging must allow for the release of carbon dioxide gas when the solid sublimates. Ice or dry ice must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary container as the refrigerant melts/sublimates. Dry ice is considered a miscellaneous hazard (Class 9) by IATA. Packages containing dry ice must bear a Class 9 label and be marked with the proper shipping name, UN number and net quantity, e.g., Dry Ice, UN1845, 3 KG. Certified packages for dry ice most likely will be pre-labeled and marked. A Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material. Dry ice is included on the Declarations for shipments which include other hazardous materials such as infectious substances.

Liquid Nitrogen. Biological materials can be shipped in liquid nitrogen or dry shippers, which are insulated packages containing refrigerated liquid nitrogen fully absorbed in a porous material. Special packing regulations apply to shipments containing nitrogen. Contact the Environmental Safety Officer if you need to ship materials with liquid nitrogen.

VI. Shipper’s Declaration for Dangerous Goods

A [Declaration for Dangerous Goods](#) form must be completed when shipping infectious substances or genetically modified micro-organisms. A Declaration is not required for shipments in which dry ice is the only hazardous material. Dry ice should be listed on Declarations for shipments containing infectious substances or

genetically modified micro-organisms. A Declaration is not required if you are shipping diagnostic specimens (unless it must be classified as an infectious substance, see [note](#)). The Declaration is included with purchased shipping materials, or provided by the carrier. For Federal Express, these forms must be typed or computer generated. Improperly completed declarations are the most common cause of package refusal.

Refer to the Shipper's Declaration for Dangerous Goods in [Appendix B](#) for an explanation of each section:

- A. Shipper:** Enter your full name, address and telephone number.
- B. Consignee:** Enter full name and address of recipient. When shipping infectious substances, include the text, "Person responsible for the shipment," followed by your name and phone number.
- C. Transport Details:** Indicate here if your shipment is restricted to cargo aircraft only (if it is more than 50 ml or 50 g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.
- D. Shipment Type:** Cross out "radioactive" to indicate you are shipping a non-radioactive substance.
- E. Proper Shipping Name:** Enter the proper shipping name exactly as it appears in [Table 1](#).
- F. Class or Division:** Enter appropriate hazard class as found in Table 1.
- G. UN or ID Number:** Enter appropriate UN number as found in Table 1.
- H. Packing Group:** For dry ice, enter "III" in this column. Biological materials are not assigned packing groups.
- I. Subsidiary Risk:** Leave this column blank.
- J. Quantity and Type of Packaging:** Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages used (usually, "all packed in one fibreboard box."). Do not spell like "fiberboard." If using an overpack, indicate here with "Overpack Used."
- K. Packing Instructions:** Enter appropriate packing instruction number. Refer to Table 1.
- L. Authorization:** Leave this column blank.
- M. Additional Handling Instructions:** Three things are required in this section:
 - 1. The statement "Emergency Contact: Chem-Tel 1(800) 255-3924"
 - 2. The statement "Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made."
 - 3. The statement "Prepared according to ICAO/IATA."
- N. Signature and date.**

Declaration forms must be filled out in triplicate. Keep one copy and supply two to the carrier. Regulations require that you must retain your copy for 375 days. A completed sample declaration is found in [Appendix C](#). Feel free to contact the Environmental Safety Officer with any questions on how to fill out the declaration.

Table 1. Summary of Shipping Information

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Group (PG)	Packing Instruction (PI)	Max. Net qty./pkg. for Passenger Aircraft	Max. Net qty./pkg. for Cargo Aircraft
Infectious substance, affecting humans and possibly animals	Infectious substance, affecting humans (<i>technical name</i>)	UN 2814	6.2	-	602	50 ml or 50 g	4 L or 4 kg
Infectious substance, affecting only animals (not humans)	Infectious substance, affecting animals (<i>technical name</i>)	UN 2900	6.2	-	602	50 ml or 50 g	4 L or 4 kg
Diagnostic or clinical specimen	Diagnostic specimens	UN 3373	-	-	650	4 L or 4 kg	4 L or 4 kg
Dry Ice	Dry Ice or Carbon Dioxide, solid	UN 1845	9	III	904	200 kg	200 kg
Non-infectious, transducing genetically modified <i>micro-organisms</i>	Genetically modified micro-organisms	UN 3245	9	-	913	No limit	No limit

VII. CDC Select Agents

The U.S. Department of Health and Human Services has developed a list of biological agents (see [Appendix F](#)) that have the potential to pose a severe threat to public health. Special regulations apply to the use and transfer of these materials, including registration with the UNH Institutional Biosafety Committee and the Centers for Disease Control and Prevention. If you are planning to, or currently work with, any of the select agents listed below and have not registered, contact the Environmental Safety Officer at 912-681-5234. Specific shipping restrictions apply to these agents (not discussed in this document).

VIII. Importing and Exporting Biological and Infectious Agents

Receiving and sending animals and animal-derived materials, infectious or biohazardous agents, biological toxins, and genetically modified organisms require the approval of federal agencies such as the Centers for Disease Control and Prevention (CDC), the United States Department of Agriculture (USDA), or the US Fish and Wildlife Service (USFWS). Regulations that govern the transfer of biological materials help to minimize or eliminate the possible threats to public health and agriculture.

A. Importation of Infectious Agents

For agents infectious to humans, CDC permit applications are found online at: <http://www.cdc.gov/od/ohs>. These agents include any infectious agent known or suspected to cause disease in humans, unsterilized specimens of human or animal tissues (including blood and other fluids), or vectors including infectious animals, bats, insects, arthropods and snails (see [Appendix F](#) for *HHS Select Infectious Agents*).

B. Importation of Plant/Agricultural Pests

A USDA/APHIS permit is required to import or domestically transfer a plant pest, plant biological agent, or any material that might contain them. Some items that are included are bees, biological control organisms, butterflies and moths, genetically engineered plants and microorganisms, certain fruits and vegetables, noxious weeds, snails and slugs, soil, and wood products (see [Appendix F](#) for *APHIS Plant Pathogens* or *USDA High Consequence Livestock Pathogens or Toxins*). Consult the following web page for more information and permit applications: <http://www.aphis.usda.gov/ppq/permits>.

C. Importation of Fish and Wildlife

For transporting fish, wildlife, or endangered species, use the USFWS form 3-177 and 3-177A found at: <http://forms.fws.gov/display.cfm?number1=100>.

D. Export Guidelines for Infectious Agents of Humans, Animals, Plants, and Related Materials

The export of infectious agents and related materials is governed by the following federal regulation: 15 CFR Parts 730 to 799. An export license is required from the Department of Commerce, when exporting infectious agents of human, plant, and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents. Consult the following web page for specific items and procedures: <http://www.bxa.doc.gov>.

Appendix A – Manufacturers of Certified Shipping Containers for Infectious Substances, Diagnostic Specimens & Dry Ice

Air Sea Atlanta
1234 Logan Circle
Atlanta GA 30318
Phone: 404-351-8600
<http://www.airseaatlanta.com>

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA 15017
Phone: 800-245-2283
<http://www.all-pak.com>

Casing Corporation
P.O. Box 820369
Dallas, Texas 75382
Phone: 800-358-6866
<http://www.casingcorp.com>

CARGOpak Corporation
3215-A Wellington Court
Raleigh, NC 27615
Phone: 800-266-0652
<http://www.cargopak.com>

DG Supplies, Inc.
5 Boxal Drive
Cranbury, NJ 08512
Phone: 800-347-7879
<http://www.dgsupplies.com>

EXAKT Technologies, Inc.
7416 N Broadway Ext.,
Suite E
Oklahoma City, OK 73116
Phone: 800-923-9123
<http://www.exaktpak.com>

HAZMATPAC, Inc
5301 Polk St., Bldg 18
Houston, TX 77023
Phone: 800-347-7879
<http://www.hazmatpac.com>

Inmark, Inc.
220 Fisk Drive S.W.
Atlanta, GA 30336-0309
Phone: 800-646-6275
<http://www.inmarkinc.com>

Polyfoam Packers
Corporation
2320 S. Foster Avenue
Wheeling, IL 60090
Phone: 888-765-9362
<http://www.polyfoam.com>
Therapak Corporation
1440 Arrow Highway, Unit A
Irwindale, California 91706
Phone: 888-505-7377
<http://www.therapak.com>

SAF-T-PAK, Inc.
10807 - 182 Street
Edmonton, Alberta, Canada,
T5S 1J5
Phone: 800-814-7484
<http://www.saftpak.com>

Source Packaging of New
England, Inc.
405 Kilvert St.
Warwick, RI 02886
Phone: 800-200-0366
<http://www.sourcepak.com>

Appendix B – Declaration of Dangerous Goods Guide

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

A					Air Waybill No. Page _____ of _____ pages Shipper's Reference Number (<i>optional</i>):		
B					<i>Area for optional use for company logo name and address</i>		
Two completed and signed copies of this Declaration must be handed to <i>the operator</i>					WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.		
TRANSPORT DETAILS C							
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure					
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY						
Airport of Destination:					Shipment type: (<i>delete non-applicable</i>) NON-RADIOACTIVE RADIOACTIVE D		
NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification					Quantity and type of packing	Packing Inst.	Authorization
Proper Shipping Name	Class or Division	UN or ID No.	Pack-ing Group	Subsidiary Risk			
E	F	G	H	I	J	K	L
Additional Handling Information: Emergency Telephone Number:					M		
I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name, and are classified, packaged, marked, and labeled/placarded, and are in all respects in the proper condition for transport according to the applicable international and national governmental regulations.					Name/Title of Signatory Place and Date Signature <i>(see warning above)</i>		
					N		

Appendix C – Example Declaration Form

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Dr. Joe Germ 123 Science Building Georgia State University Atlanta, GA 30303					Air Waybill No. Page <u> 1 </u> of <u> 1 </u> pages Shipper's Reference Number (<i>optional</i>):		
Consignee Dr. Jane Infection 987 Research Building Anytown University Anywhere, USA					<i>Area for optional use for company logo name and address</i>		
Two completed and signed copies of this Declaration must be handed to <i>the operator</i>					WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.		
TRANSPORT DETAILS							
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure ATL					
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY						
Airport of Destination: ANY					Shipment type: <i>(delete non-applicable)</i> NON-RADIOACTIVE RADIOACTIVE		
NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification					Quantity and type of packing	Packing Inst.	Authorization
Proper Shipping Name	Class or Division	UN or ID No.	Pack- ing Group	Subsi- diary Risk			
Infectious substance, affecting humans (Hepatitis B virus)	6.2	UN2814			50 ml	602	
Dry Ice	9	UN1845	III		3 kg	904	
Additional Handling Information:					Prepared according to ICAO/IATA; prior arrangements as required by IATA Dangerous Goods Regulations 1.3.3.1 have been made.		
Emergency Telephone Number:					ChemTel, 1-800-255-3924		

I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name, and are classified, packaged, marked, and labeled/placarded, and are in all respects in the proper condition for transport according to the applicable international and national governmental regulations.	Name/Title of Signatory:	Dr. Joe Germ, Professor
	Place and Date:	Atlanta, GA 02/15/04
	Signature (see warning above)	

Appendix D – Intent to Ship Hazardous Materials

After reading the *Georgia Southern University Shipment of Biological Materials and Dry Ice Manual*, fill out this form to qualify to ship dangerous materials at Georgia Southern University. The Environmental Safety Officer will review this completed form and upon successful completion and demonstration of knowledge of applicable regulations you will be certified to ship those materials designated on this form.

1. What regulated material(s) might you ship via mail or courier service? List all hazardous materials that you intend to ship. Also, list the mailing service you intend to use.
2. What packaging will you use to ship your material(s)? Include company name and product number for chosen packaging for each material you intend to ship.
3. Check those that should appear on your package:
 - Class 6.2 label
 - Class 9 label
 - Cargo Aircraft label
 - Dry ice, UN 1845, net weight _____ kg
 - Infectious substance, affecting humans (*technical name*), UN 2814, net quantity _____
 - Infectious substance, affecting animals (*technical name*), UN 2900, net quantity _____
 - Name, Address and Phone Number of Shipper
 - Name and Address of Consignee
 - Name and Phone Number of Person Responsible for Shipment
 - "Inner Packages Comply with Prescribed Specifications."
 - Genetically modified micro-organisms, UN 3245, net quantity _____
 - "Diagnostic Specimen Packed in Compliance with IATA Packing Instruction 650"
4. Fill out attached [Declaration for Dangerous Goods](#) form (if your shipments require one). An example of each material you intend to ship must be included in the "Nature and Quantity of Dangerous Goods" section.

I understand the hazards associated with the materials noted above. Also, I understand the shipping requirements for those materials, as outlined in this manual.

Print name:	
Signature:	

Date:	
Please return to Environmental Safety Officer	

Appendix E – Blank Declaration for Dangerous Goods

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper					Air Waybill No.		
					Page _____ of _____ pages		
					Shipper's Reference Number (<i>optional</i>):		
Consignee					<i>Area for optional use for company logo name and address</i>		
Two completed and signed copies of this Declaration must be handed to <i>the operator</i>					WARNING		
TRANSPORT DETAILS					Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.		
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>			Airport of Departure				
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY						
Airport of Destination:							
NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification					Quantity and type of packing	Packing Inst.	Authorization
Proper Shipping Name	Class or Divi- sion	UN or ID No.	Pack- ing Group	Subsi- diary Risk			
Additional Handling Information:							
Emergency Telephone Number:							
I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name, and are classified, packaged, marked, and labeled/placarded, and are in all respects in the proper condition for transport according to the applicable international and national governmental regulations.					Name/Title of Signatory		
					Place and Date		
					Signature <i>(see warning above)</i>		

Appendix F – APHIS Plant Pathogens, HHS Select Infectious Agents & USDA High Consequence Livestock Pathogens/Toxins

Viruses

34. African horse sickness virus ³
35. African swine fever virus ³
36. Akabane virus ³
37. Avian influenza virus (highly pathogenic) ³
38. Blue tongue virus (exotic) ³
39. Camel pox virus ³
40. Cercopithecine herpesvirus 1 (Herpes B virus) ²
41. Classical swine fever virus ³
42. Crimean-Congo haemorrhagic fever virus ²
43. Eastern equine encephalitis virus ⁴
44. Ebola viruses ²
45. Foot and mouth disease virus ³
46. Goat pox virus ³
47. Japanese encephalitis virus ³
48. Lassa fever virus ²
49. Lumpy skin disease virus ³
50. Malignant catarrhal fever virus ³
51. Marburg virus ²
52. Menangle virus ³
53. Monkeypox virus ²
54. Newcastle disease virus (VVND) ³
55. Nipah and Hendra complex viruses ⁴
56. Peste des petits ruminants virus ³
57. Plum pox potyvirus ¹
58. Rift Valley fever virus ⁴
59. Rinderpest virus ³
60. Sheep pox virus ³
61. South American haemorrhagic fever viruses [(Junin, Machupo, Sabia, Flexal, Guanarito)] ²
62. Swine vesicular disease virus ³
63. Tick-borne encephalitis complex (flavi) viruses [Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)] ²
64. Variola major virus (Smallpox virus) and Variola minor (Alastrim) ²
65. Venezuelan equine encephalitis virus ⁴
66. Vesicular stomatitis virus (exotic) ³

Prion

2. Bovine spongiform encephalopathy agent ³

Toxins

1. Abrin ²
2. Botulinum neurotoxins ⁴
3. *Clostridium perfringens* epsilon toxin ⁴
4. Conotoxins ²
5. Diacetoxyscirpenol ²
6. Ricin ²
7. Saxitoxin ²
8. Shigatoxin and Shiga-like ribosome inactivating proteins ⁴
9. Staphylococcal enterotoxins ⁴
10. Tetrodotoxin ²
11. T-2 toxin ⁴

Bacteria

20. *Bacillus anthracis* ⁴
21. Botulinum neurotoxin producing species of *Clostridium* ⁴
22. *Brucella abortus* ⁴
23. *Brucella melitensis* ⁴
24. *Brucella suis* ⁴
25. *Burkholderia mallei* ⁴
26. *Burkholderia pseudomallei* ⁴
27. *Coxiella burnetii* ⁴
28. *Cordaria ruminantium* (Heartwater) ³
29. *Francisella tularensis* ⁴
30. *Liberobacter africanus*, *Liberobacter asiaticus* ¹
31. *Mycoplasma capricolus*/M. F38/*M. mycoides capri* (contagious caprine pleuropneumonia agent) ³
32. *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia agent) ³
33. *Ralstonia solanacearum* race 3 biovar 2 ¹
34. *Rickettsia prowazekii* ²
35. *Rickettsia rickettsii* ²
36. *Xanthomonas oryzae* pv. *oryzicola* ¹
37. *Xylella fastidiosa* (citrus variegated chlorosis strain) ¹
38. *Yersinia pestis* ²

Fungi

1. *Coccidioides immitis* ⁴
2. *Coccidioides posadasii* ²
3. *Peronosclerospora philippinensis* ¹
4. *Phakopsora pachyrhizi* ¹
5. *Sclerophthora rayssiae* var. *zeae* ¹
6. *Synchytrium endobioticum* ¹

Exemptions

The following agents or toxins are exempt if the aggregate amount under the control of a principal investigator does not, at any time, exceed:

- 0.5 mg of botulinum neurotoxins
- 5 mg of *Staphylococcal* enterotoxins
- 100 mg of abrin, *Clostridium perfringens* epsilon toxin, conotoxin, ricin, saxitoxin, shigatoxin, shiga-like ribosome inactivating protein, and tetrodotoxin
- 1,000 mg of diacetoxyscirpenol and T-2 toxin

The following agents or toxins are also exempt:

- Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable select agent organisms or nonfunctional toxins.
- The vaccine strains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), Venezuelan Equine encephalitis virus vaccine strain TC-83.

The medical use of toxins for patient treatment is exempt.

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

4. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.
5. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the listed toxins if the nucleic acids: a) are in a vector or host chromosome; b) can be expressed *in vivo* or *in vitro*; or c) are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.
6. Listed viruses, bacteria, fungi, and toxins that have been genetically modified.

Other Restrictions

3. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to the listed agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
4. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of listed toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

¹ APHIS Plant Pathogen

² HHS Select Infectious Agent

³ USDA High Consequence Livestock Pathogen or Toxin

⁴ USDA-HHS Overlap Agent

