5.0 TRANSPORTATION AND TRANSFER OF BIOLOGICAL AGENTS

5.1 INTRODUCTION

Biological agents include infectious agents of humans, plants, and animals, as well as toxins that may be produced by microbes or by genetic material potentially hazardous by itself or when introduced into a suitable vector. Etiologic agents and infectious substances are closely related terms that are found in the transfer and transportation regulations. Biological agents may exist as purified and concentrated cultures but may also be present in a variety of materials such as body fluids, tissues, soil samples, etc. Biological agents and the materials that are known or suspected to contain them are recognized by federal and state governments as hazardous materials and their transportation and transfer is subject to regulatory control. Transportation refers to the packaging and shipping of these materials by air, land, or sea, generally by a commercial conveyance. Transfer refers to the process of exchanging these materials between facilities.

5.2 Transportation

Regulations on the transportation of biological agents are aimed at ensuring that the public and the workers in the transportation chain are protected from exposure to any agent that might be in the package. Protection is achieved through (a) rigorous packaging that will withstand rough handling and contain all liquid material within the package without leakage, (b) appropriate labeling of the package with the biohazard symbol and other labels to alert the workers in the transportation chain to the hazardous contents of the package, (c) documentation of the hazardous contents of the package should such information be necessary in an emergency situation, and (d) training of workers in the transportation chain to familiarize them with the hazardous contents so as to be able to respond to emergency situations.

Transportation of select agents is strictly regulated. No individual laboratory is allowed to receive or ship select agent material directly into the laboratory.
5.3 Regulations

- US Public Health Service (USPHS) 42 CFR Part 72. Interstate Transportation of Etiologic Agents. This regulation is in revision to harmonize it with the other U.S. and international regulations. A copy of the current regulation may be obtained from the Internet at:
  http://www.cdc.gov/od/ohs

- Department of Transportation. 49 CFR Parts 171-178. Hazardous Materials Regulations. This regulation applies to the shipment of both biological agents and clinical specimens. Information may be obtained from the Internet at:


- Occupational Health and Safety Administration (OSHA). 29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens. This standard provides minimal packaging and labeling requirements for transport of blood and body fluids within the laboratory and outside of it. Information may be obtained from your local OSHA office or from the Internet:
  http://www.osha.gov

- Dangerous Goods Regulations (DGR). International Air Transport Association (IATA). These regulations provide packaging and labeling requirements for infectious substances and materials, as well as clinical specimens that have a low probability of containing an infectious substance. These are the regulations followed by the airlines. These regulations are derived from the Committee of Experts on the Transport of Dangerous Goods, United Nations Secretariat, and the Technical Instructions for the Transport of Dangerous Goods by air, which is provided by the International Civil Aviation Organization (ICAO). A copy of the DGR may be obtained by calling 1-800-716-6326 or through the Internet at:
  http://www.iata.org, or http://www.who.org

5.4 General Packaging Requirements for Transport of Biological Agents and Clinical Specimens

Annex 3 (Page 23) shows the generalized "triple" (primary receptacle, water tight secondary packaging, and durable outer packaging) packaging required for a biological agent of human disease or materials that are known or suspected of containing them. This packaging requires the "Infectious Substance" label shown in Figure 2 on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the USDOT, USPS, USPHS, and IATA regulations. Clinical specimens with a low probability of containing an infectious agent are also required to be "triple" packaged, but performance tests require only that the package shall not leak after a four-foot drop test.
5.5  **Shipment**

Regulations on the shipment of biological agents are aimed at ensuring that the change in possession of biological materials is within the best interests of the public and the nation. These regulations require documentation of the personnel, facilities, and justification of need for the biological agent in the shipment and subsequent approval of the transfer process by a federal authority. The following regulations fit in this category:

**Importation of Etiologic Agents of Human Disease**

The Centers for Disease Control and Prevention’s Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States. Prior to issuing an import permit, IPP reviews all applications to ensure that entities have appropriate safety measures in place for working safely with these imported materials.

**Inspecting Permittees** IPP may inspect applicants to ensure that the facilities have implemented the appropriate biosafety measures for the infectious biological agent, infectious substance, or vector to be imported.

[http://www.cdc.gov/od/eaipp/forms/Permit to Import Biological Agent or Vector.pdf](http://www.cdc.gov/od/eaipp/forms/Permit to Import Biological Agent or Vector.pdf)

Guidance for completing the CDC PHS import permit can be found on the internet at: [http://www.cdc.gov/od/eaipp/importApplication/](http://www.cdc.gov/od/eaipp/importApplication/).

You can also email to: ImportPermit@cdc.gov

**Importation of Animal and Plant Pathogens**

United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) permits are required for infectious agents of livestock and biological materials containing animal material. Tissue culture materials and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origins are controlled by the USDA due to the potential risk of introduction of exotic animal diseases into the U.S. Further information may be obtained by calling the USDA/APHIS at (301) 734-7834 (see [www.aphis.usda.gov/vs](http://www.aphis.usda.gov/vs)).

U.S. Fish and Wildlife Service permits are required for certain live animals, including bats. Please call 1-800-344-WILD for further information (www.fws.gov).

**Importation of Plant Biological Agents**

7 CFR Part 330. Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage. This regulation requires a permit to import or domestically transfer a plant
pest, plant biological agent, or any material that might contain them. Information can be obtained by calling 301-734-3277 or through the Internet at:
http://www.aphis.usda.gov/ppq/or

Transfer of Select Biological Agents of Human Disease

42 CFR Part 73.16 Transferring or Receiving Select Agents. Facilities transferring or receiving select agents must be registered with the CDC and each transfer of a select agent must be documented. Information may be obtained on the Internet at: http://www.cdc.gov/od/ohs/or

Export of Etiologic Agents of Humans, Animals, Plants and Related Materials

Exports of Infectious Materials
The export of a wide variety of etiologic agents of human, plant, and animal diseases may require a license from the Department of Commerce. Information may be obtained by calling the Department of Commerce Bureau of Export Administration at 202-482-4811 or through the internet at: www.bis.doc.gov/Licensing/.

Contact UTMB Technology Management group for help with information on export licenses and Material Transfer Agreement.

Shipment

For further information on any provision of this regulation contact:

Centers for Disease Control and Prevention
Attn: External Activities Program
Mail Stop F-05
1600 Clifton Road N.E.
Atlanta, GA 30333
Telephone: (404) 639-4418
FAX: (404) 639-2294

For further information on packaging and shipping of a biological material contact:

Environmental Health and Safety
Biological and Chemical Safety
409 772-1781
5.6. **Transportation and transfer of biological material on campus.**

Transport of biological agents on campus, between building, within building, requires that the person transporting the material has knowledge of the agent/material being moved, how to respond to a spill if dropped, and has been provided with appropriate training in the packaging of the agent/material being transported.

All efforts will be made to prevent a spill or aerosol. The outer container needs to be properly surface decontaminated and the agent will never be left unattended while in transit between laboratories. The biohazard level of the agent needs to be respected; you may not take a biohazard agent in a laboratory that is of lower containment specification even if the secondary container is not opened in that laboratory (e.g. BSL3 agents may not be brought into a BSL2 laboratory).

Biological material must be triple packed, primary container that has agent is to be placed inside a leak proof secondary container (this can be a zip sealed plastic bag, a screw top conical tube, a pressure sealed plastic box (i.e. Rubbermaid container) which is then placed in a carrier. The carrier must be labeled with the name of the principal investigator/supervisor responsible for the laboratory and must have a biohazard label when moving a biohazardous agent. The carrier must such that if dropped it will not break or come apart.

Transportation of agents on campus is not regulated but needs to be documented and records kept in the laboratories.

5.7. **Shipment of Select Agents:**

Transfer of select agent material is regulated and must be approved by EHS, laboratories receiving select agent material are approved to do so and follow the proper regulation of select agent possession.

**Note:** **Shipments must be packed by a DOT/IATA trained and certified person.**

**Select agents will be shipped on a Monday, Tuesday or Wednesday only.**

**Shipments are sent and received by EHS**

**Shipments will not occur during the winter holiday season when the University is closed. Black out dates will vary. Contact EHS before arranging shipments in or out of campus.**

5.8 **Internal transfers of Select Agents**

All internal transfers of select agents will be approved the Responsible Official/Alternate Responsible Official. Date and time of transfer will be arranged beforehand and the transfer witnessed by Biological and Chemical Safety.
Classification Flowchart
Example of Packing and Marking for Category A Infectious Substances
(See Packing Instruction 602 for additional requirements)
Notes:

1. The smallest external dimension of the outer packaging must not be less than 100 mm;

2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

Example of Packing and Marking for Category B Infectious Substances
(See Packing Instruction 650 for additional requirements, e.g. drop test)
Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;

2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

Example of Packing and Marking for Exempt Specimens
Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;

2. The outer packaging must be of adequate strength for its capacity, mass and intended use.