3.18. Shipment of Biological Materials

3.18.1. General Information

Anyone who prepares or ships packages containing biological or infectious substances (human or animal pathogens) or biological substances containing recombinant or synthetic DNA, must attend a training class before providing a package for transport by commercial carrier. The U.S. Department of Transportation (DOT) and the International Air Transport Association (IATA) regulate shipment of human and animal pathogens. The regulations are complex and exacting. They require that researchers who prepare infectious materials for shipment receive periodic training (every 2 years). In addition, packages must be marked and labeled exactly as the regulations specify, and packaging materials must have been tested and certified to withstand certain durability and pressure tests. Cardboard boxes in which supplies have been received cannot be used to ship infectious materials. Recent events have led to greater scrutiny for compliance with these regulations. Training is also required when receiving and signing for packages containing infectious substances. Please contact IUEHS Biosafety for your respective campus for assistance with packaging and shipping biohazardous material and for information regarding required training.

3.18.2. Permits

Permits are required from the Centers for Disease Control and Prevention (CDC) to import or transport 1) any microorganism that causes disease in humans; 2) biological materials, such as blood and tissues, when known or suspected to contain an infectious agent; 3) live insects, such as mosquitoes, known or suspected of being infected with any disease transmissible to humans; and 4) any animal known or suspected of being infected with any disease transmissible to humans. Importation permits are issued only to the importer, who must be located in the U.S. The importation permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the U.S. Public Health Service Division of Quarantine and release by U.S. Customs. Transfers of previously imported material within the U.S. also require a permit. IUEHS Biosafety for the respective campus must be notified prior to submission of application for permit and are available to assist through the permitting process.

Application for the permit should be made at least 10 working days in advance of the anticipated shipment date. Further information and application forms may be obtained by calling the CDC at (404) 639-3235, or through the CDC website at http://www.cdc.gov/od/eaipp/

Permits are required from the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) for importation or domestic transport of agents infectious to livestock; and of biological reagents containing animal, particularly livestock, material (this includes tissue culture media containing growth stimulants of bovine origin such as calf serum). Further information and application forms may be obtained by calling the USDA/APHIS at (301) 734-4401, or http://www.aphis.usda.gov/animal_health/permits/.

Permits are also required from the USDA/APHIS for **interstate movement, importation, or release into the environment (i.e., field tests)** of genetically engineered organisms that are **plant pests**, or that contain portions (plasmids, DNA fragments, etc.) of **plant pests.** Application should be made at least 120 days in advance of the anticipated release or shipment date. IUEHS Biosafety for the respective campus must be notified prior to the submission of application for permit and are available to assist through the permitting process.

Information and application forms may be obtained by calling the USDA/APHIS at (301) 734-4401, or through the APHIS web site at http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology.

Facility registration and completion of the CDC/USDA Form 2 are required by the CDC prior to transfer of **select agents and toxins** (42 CFR Part 73). If proposed research involves the use of any agents listed in Appendix A the PI must contact IUEHS Biosafety for your respective campus immediately to initiate the registration process. It is strictly forbidden to use, transport, or possess any of the agents listed without an active registration. Your IUEHS Biosafety will assist you with obtaining approval for research involving Select Agents and should be your first contact if your research designs include Select Agents.

A validated license is required by the Department of Commerce for **export** of certain microorganisms and toxins (listed in 15 CFR Part 774) to all destinations. Investigators wishing to ship these items must contact the IU Export Control Office for assistance in meeting these requirements (export@iu.edu). .

3.18.3. Packaging

Various carriers (FedEx, UPS, Postal Service or others) have different requirements for packaging and labeling infectious substances. In addition, various agencies such as the International Air Transport Association (IATA), and the Department of Transportation (DOT) have developed guidelines and procedures to facilitate the safe shipment of infectious substances. Therefore, it is important to check with the carrier you have chosen to determine their specific requirements for shipping infectious agents. In addition to the materials listed above that require permits, the following materials are likely to require special packaging and/or labeling:

- Infectious Substance: a viable microorganism, or its toxin, which causes or may cause disease in humans. DOT requires shippers of infectious substances to attend training every 2 years.
- Diagnostic Specimen: any human or animal material including blood, tissue, and tissue fluids, shipped for the purpose of diagnosis.
- Biological Product: a product for human or veterinary use, such as vaccines and investigational new drugs.

The basic component of all shipping requirements, with various minor modifications, is triple packaging, as follows:

- A primary container that contains the specimen;

- A secondary container that contains the primary container and packaging capable of absorbing the specimen; and
- An outer rigid shipping container that contains the secondary container and other material.

3.18.4. Genetically Modified Microorganisms (GMOs)

The International Air Transport Association's Dangerous Goods Regulations (50th ed.) states that:

- GMOs of Category A agents must be shipped as Category A.
- GMOs of Category B agents must be shipped as Category B.
- If a GMO is not classified as Category A or B it would be classified as UN 3245 Category 9

3.18.5. Human Clinical Materials

The OSHA Bloodborne Pathogens Standard requires that all packages containing human blood and other potentially infectious materials be labeled with the universal biohazard symbol or color-coded. Various carriers may have additional requirements. For more information regarding OSHA Bloodborne Pathogens Standard and the handling of blood and OPIM refer to the Indiana University Bloodborne Pathogens Exposure Control Plan.

3.18.6. On-Campus Transport Between Laboratories or Buildings

When moving infectious substances between labs or buildings on campus, the following minimum procedures must be followed:

- Sample must be in sealed primary container. Utilize plastic containers whenever possible.
- Place primary container in sealed secondary container, with absorbent (paper towels) between primary and secondary container suitable for the volume transported.
- If dry ice is needed, the secondary container should be placed in an outer container, with the dry ice placed between the secondary and tertiary container (never place dry ice in a sealed container).
- Place biohazard label on outer container.