

GUIDE TO SHIPPING BIOLOGICAL SUBSTANCES AND SUPPORT MATERIALS (SECTION 10 – AUGUSTA UNIVERSITY BIOSAFETY GUIDE)

The following Section is an adapted version of materials originally developed by Andy Glode and David R. Gillum at the University of New Hampshire. The Augusta University Biosafety Office wishes to thank Mr. Glode and Mr. Gillum for their work in producing the original document and their generosity in sharing their document with AU.

This guide includes information about how to properly classify, package, mark and label your biological materials for shipment or extramural transport. This Section also describes the training requirements necessary to ship biological materials and dry ice. Requirements for *intramural* transport are discussed in Section 4.1.5 of the AU Biosafety Guide. Information on the regulations and procedures for transport/shipping of live animals can be found through the Division of Laboratory Animal Services.

Shipped/transported 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 and transport 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).
- United States Postal Service (USPS).

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 and 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 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 protocols; however the DOT standards often reflect those of IATA and also pertain to ground transportation of your materials.

10.1 TRAINING REQUIREMENTS

Federal rules require that anyone wishing to ship biological materials or dry ice must first have shipping training. If you intend to package biological materials or dry ice for shipment, you must complete a special training module, and provide documentation for training to the AU Biosafety Office. AU must be able to document training certification for anyone shipping dangerous goods during regulatory audits. Training consists of:

1. **Read this section of the Biosafety Guide.** This document will provide familiarity with the general provisions relating to the regulations and will direct you to obtain more detailed training in the requirements applicable to shipping biological materials and/or dry ice.
2. **Have a current Biosafety training and bloodborne pathogen training.** This training ensures that you are familiar with hazards presented by infectious materials, proper handling and emergency response procedures.
3. **Complete an DOT/IATA-compliant shipping training module.** This must provide you with a certificate of completion and a copy of this certificate must be submitted to the Biosafety Office. This training is required once every two years. Currently, the Biosafety Office has created online shipping training module that can be accessed through the Desire2Learn, learning Management System. However, the Biosafety Office may accept alternate acceptable forms of training, as long as the content of the class can be documented and complies with the DOT/IATA requirements.
4. **Document your intent to ship or transport biological materials.** The IBC will ask that you document your intent to ship or transport biological materials in your Biosafety Protocol or by generating a shipping Standard Operating Procedure. For shipment of certain High Consequence Dangerous Goods, development of safety and security plans are required by law.

Shipping regulations change frequently so it is necessary to repeat training certification every two years.

10.2 SHIPPING OVERVIEW

Follow these steps when shipping biological materials and dry ice.

1. Classify your materials for shipment/transport. See Section 10.3.
2. Package, mark, and label your material(s) appropriately. See Section 10.4.
3. Fill out the Shipper's Declaration for Dangerous Goods form. See Section 10.5.
4. If you are shipping any Federally regulated materials, including Select Agents, special regulations may apply and/or permits may be required. Consult Section 10.6.
5. If you plan on importing or exporting biological materials, permits may be required. Consult Section 10.7.

10.3 SHIPMENT TYPE

For shipment purposes, biological material will fit into one of the following categories:

- Unregulated biological material;
- Category A infectious substances;
- Category B infectious substances;
- Patient specimens;
- Genetically modified organisms and microorganisms; or
- Regulated Medical/Clinical Waste

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, unless sent by mail (see Section 10.9). Refer to the classification guide to assist with classification of materials (Figure 10.3). **Note:** All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (see Other Packaging Requirements, Section 10.4.2). All samples preserved with flammable or corrosive materials, such as ethanol or formalin, must receive consultation and pre-authorization from the AU Chemical Safety Office (x1-2663) and be shipped appropriately (also please see Section 10.4.2). Materials

which are both biological and radioactive require consultation with and pre-authorization from the Radiation Safety Office (x1-9826).

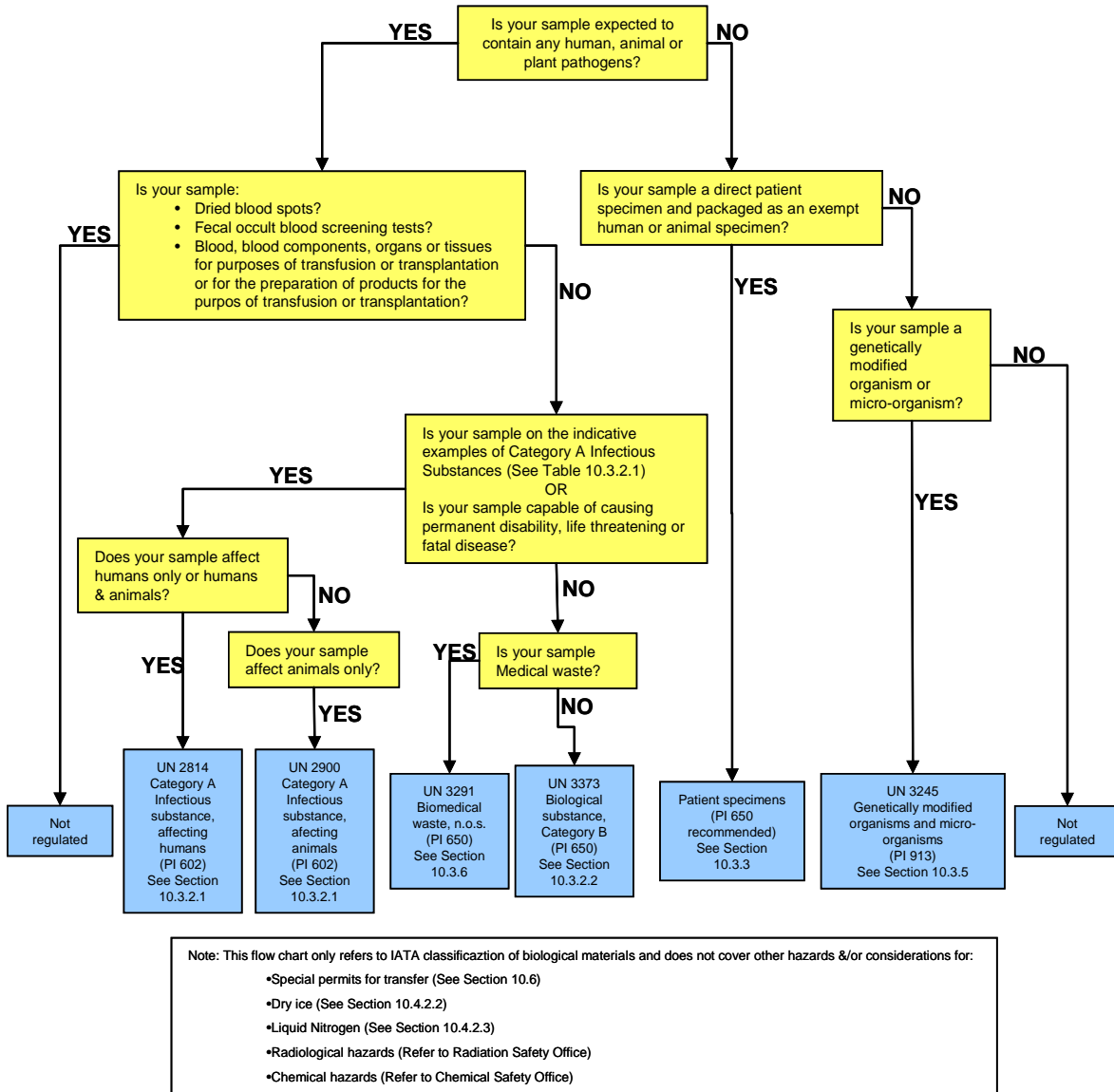
10.3.1 Unregulated Biological Material

The materials listed below are technically not subject to IATA or DOT infectious substance shipping regulations. However, guidance for shipping these materials (*e.g.*, patient specimens, biological products) are found in subsequent sections and these may require a permit for shipment abroad. Please check with the Biosafety Office if you have any questions about these materials. All shipments of blood and blood products must be labeled with a biohazard symbol.

- Substances which do not contain infectious substances or which are unlikely to cause disease in humans or animals;
- Non-infectious biological materials from humans, animals or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA, or other genetic elements;
- Substances containing microorganisms, which are non-pathogenic to humans or animals;
- Substances that have been neutralized or inactivated such that they no longer pose a health risk;
- Environmental samples which are not considered to pose a significant risk of infection;
- Dried blood spots*;
- Fecal occult blood screening tests*;
- An infectious substance, other than a Category A infectious substance (See Section 10.3.2.1), contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment and prevention, or a biological product, when such materials are being transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials;
- Blood or blood components which have been collected for the purpose of transfusion or the preparation of blood products to be used for transfusion or transplantation*;
- Tissues or organs intended for use in transplantation*;
- A material with a low probability of containing an infectious disease or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include foodstuffs and environmental samples (such as water or a sample of dust or mold); or
- A biological product, including an experimental or investigational product or component of a product, subject to federal approval, permit, review or licensing requirements such as those required by the Food and Drug Administration (see, *e.g.*, <http://www.fda.gov/importeddrugs/> or <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>), or the US Department of Agriculture* (see, *e.g.*, http://www.aphis.usda.gov/import_export/index.shtml and http://www.aphis.usda.gov/vs/ncie/fac_imp.html for guidance).

* When mailing these items with the USPS, follow packaging guidelines for non-regulated items. See Section 10.9.

Figure 10.3 The Classification Guide



10.3.2 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 bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease are not subject to biological shipping regulations.

10.3.2.1 Category A Infectious Substances

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease in humans or animals when exposure to them occurs. Category A infectious substances are shipped as infectious substances, affecting humans (UN2814), or infectious substances affecting animals (UN2900). Indicative examples of Category A infectious substances are listed in Table 10.3.2.1.

10.3.2.1.1 Packaging

The triple packaging concept (explained in Section 10.4) applies to Category A infectious substances. Purchase packaging compliant with IATA Packing Instruction 602 as detailed in the IATA Dangerous Goods Regulations (DGR), which is available in the Biosafety Office. See Table 10.3.2.1.1 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.

Table 10.3.2.1. Indicative Examples of Category A Infectious Substances

UN # and Proper Shipping Name	Microorganism
<p style="text-align: center;">UN 2814 Infectious substance affecting humans</p>	<ul style="list-style-type: none"> - <i>Bacillus anthracis</i> cultures - <i>Brucella abortus</i> cultures - <i>Brucella melitensis</i> cultures - <i>Brucella suis</i> cultures - <i>Burkholderia mallei</i> - <i>Pseudomonas mallei</i> - Glanders cultures - <i>Burkholderia pseudomallei</i> - <i>Pseudomonas pseudomallei</i> cultures - <i>Chlamydia psittaci</i> - avian strains cultures - <i>Clostridium botulinum</i> cultures - <i>Coccidioides immitis</i> cultures - <i>Coxiella burnetii</i> cultures - Crimean-Congo hemorrhagic fever virus - Dengue virus cultures - Eastern equine encephalitis virus cultures - <i>Escherichia coli</i>, verotoxigenic cultures - Ebola virus - Flexal virus - <i>Francisella tularensis</i> cultures - Guanarito virus - Hantaan virus - Hantavirus causing hemorrhagic fever with renal syndrome - Hendra virus - Hepatitis B virus cultures - Herpes B virus cultures - Human immunodeficiency virus cultures - Highly pathogenic avian influenza virus cultures - Japanese Encephalitis virus cultures - Junin virus - Kyasanur Forest disease virus - Lassa virus - Machupo virus - Marburg virus - Monkeypox virus - <i>Mycobacterium tuberculosis</i> cultures - Nipah virus - Omsk hemorrhagic fever virus - Poliovirus cultures - Rabies virus cultures - <i>Rickettsia prowazekii</i> cultures - <i>Rickettsia rickettsia</i> cultures - Rift Valley fever virus - Russian spring-summer encephalitis virus cultures - Sabia virus - <i>Shigella dysenteriae</i> type 1 cultures - Tick-borne encephalitis virus cultures - Variola virus - Venezuelan equine encephalitis virus - West Nile virus cultures - Yellow fever virus cultures - <i>Yersinia pestis</i> cultures
<p style="text-align: center;">UN 2900 Infectious substance affecting animals</p>	<ul style="list-style-type: none"> - African swine fever virus cultures - Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus cultures - Classical swine fever virus cultures - Foot and mouth disease virus cultures - Lumpy skin disease virus cultures - <i>Mycoplasma mycoides</i> - Contagious bovine pleuropneumonia cultures - Peste des petits ruminants virus cultures - Rinderpest virus cultures - Sheep pox virus cultures - Goatpox virus cultures - Swine vesicular disease virus cultures - Vesicular stomatitis virus cultures

* This list is not exhaustive. New or emerging pathogens not on the list may meet the criteria to be included in Category A.

Table 10.3.2.1.1. Manufacturers of Shipping Containers for Infectious Substances and Dry Ice

Air Sea Atlanta

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

DG Supplies, Inc.

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

Inmark, Inc.

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

SAF-T-PAK, Inc.

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

All-Pak, Inc.

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

EXAKT Technologies, Inc.

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

JIT Certified, Inc.

1740 Fenpark Drive
Fenton, MO 63026
Phone: 800-962-8636
<http://www.jitcertified.com>

Source Packaging of New England, Inc.

405 Kilvert St.
Warwick, RI 02886
Phone: 800-200-0366
<http://www.sourcepak.com>

CARGOPAK Corporation

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

HAZMATPAC, Inc

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

10.3.2.1.2 Labeling

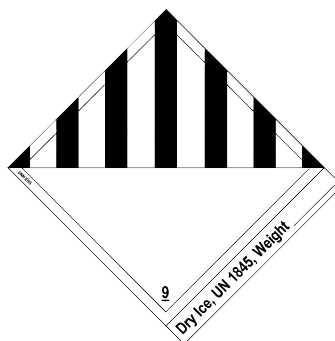
The outer container of a Category A infectious substance shipment must display the following information:

- Sender and recipient's full name and address;
- Infectious substance label (see below);
- "UN2814, Infectious substance, affecting humans" and net quantity or "UN2900, Infectious substance, affecting animals" and net quantity;
- The text "Person responsible: [name, phone number]" You must provide a 24 hr/day, 7 days/week contact for a person who knows what material has been shipped and emergency response information. This should be documented in your shipping/transport SOP;
- Class 9 label (see below), including UN1845 and net weight, if packaged with dry ice; and
- Cargo Aircraft Label (see below), when shipping over 50 mL or 50 g.

Infectious substance
Label



Class 9 Label



Cargo Aircraft Label



10.3.2.2 Category B Infectious Substances

Category B infectious substances are materials that are infectious, but do not meet the standard for inclusion in Category A. Category B infectious substances are assigned to UN3373.

10.3.2.2.1 Packaging

The basic triple packaging concept applies to Category B infectious substances. Purchase packaging that complies with IATA Packing Instruction 650. See Table 10.3.2.1.1 for a list of some packaging suppliers. Be sure to specify if the shipment is a refrigerated sample (e.g., ice packs or dry ice) or will be sent at ambient (room) temperature.

For Category B infectious substances, the maximum quantity of liquid per primary receptacle is 1 liter and outer packaging must not contain more than 4 L or 4 kg.

10.3.2.2.2 Labeling

The outer container of a Category B infectious substance shipment must display the following information:



UN3373 Label

- The sender and recipient’s full name and address;
- The words “Biological Substance, Category B”;
- UN3373 label (see right);
- The text “Person responsible: [*name, phone number*]” You must provide a 24 hr/day, 7 days/week contact for a person who knows what material has been shipped and emergency response information. This should be documented in your shipping/transport SOP; and
- Class 9 label (see Section 10.2.2.1.2), if packaged with dry ice.

10.3.3 Patient Specimens

Patient specimens that have a minimal likelihood of containing pathogens are exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and should be based on the patient’s medical history, symptoms, local conditions and individual circumstances.

If there is more than a “minimal likelihood” that a patient specimen contains pathogens, it must be shipped as a Category A infectious substance (UN2814 or UN2900) or a Category B infectious substance (UN3373).

Patient specimens unlikely to contain pathogens must be prepared for shipment as follows:

10.3.3.1 Packaging

- Leak-proof primary container;
- Leak-proof secondary packaging;
- Fragile primary containers must be wrapped or separated to prevent breakage;
- Absorbent material must be placed between the primary and secondary containers to absorb entire contents so that no liquid release will reach the outer packaging; and
- Outer packaging must be durable enough for its intended use with at least one side 100 mm x 100 mm or larger.

10.3.3.2 Labeling

The outer package must be marked with “Exempt human specimen,” or “Exempt animal specimen.”

10.3.3.3 Dried blood

Special guidance has been provided by the CDC for shipment of dried blood spot specimens which vary from those above. In particular, these should not be packaged in airtight, leak-proof plastic bags because the lack of air exchange in the inner environment of a sealed plastic bag causes heat buildup and moisture accumulation that can damage the dried blood spot test substances. In addition, various chemicals that can adversely affect the test substances in the dried blood spots could leach from these plastics and thus cause incorrect analytical test results. See: <http://www.cdc.gov/od/ohs/biosfty/driblood.htm> for further information.

10.3.4 Biological Products

Biological products are derived from living organisms and manufactured for use in the prevention, diagnosis, treatment or cure of diseases in humans or animals and are certified by the USDA, FDA or other national authority.

Examples of biological products include certain viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, and blood products. Materials which contain incidental blood products, such as fetal calf serum, may also be regulated, particularly internationally. For further information and guidance for shipping biological materials, see:

Food and Drug Administration Guidelines

Importation: <http://www.fda.gov/ora/import/>

Exportation: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>

US Department of Agriculture

Importation/exportation URL: http://www.aphis.usda.gov/import_export/index.shtml

Materials which do not require permits:

<http://www.aphis.usda.gov/biotechnology/submissions.shtml>

Biological products transported for final packaging, distribution, or use by medical professionals are not subject to biological shipping regulations (although international shipments may have importation or exportation standards, See Section 10.7). Biological products that do not meet these criteria must be assigned to UN2814, UN2900 or UN3373, as appropriate.

10.3.5 Genetically Modified Organisms or Microorganisms

Genetically modified organisms (GMO) or microorganisms (GMMO) are organisms and microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMOs and GMMOs that are not infectious but that can alter animals, plants or microorganisms in a way that is not normally the result of natural reproduction are considered a miscellaneous hazard (Class 9) and are assigned to UN3245. GMOs and GMMOs that are infectious must be assigned to UN2814, UN2900 or UN3373.

10.3.5.1 Packaging

These materials are packed for shipment in the same way as Category A infectious substances, except there are no testing requirements for the packaging; this packaging variation is IATA Packing Instruction 913. Packages designed for Packing Instruction 913 may not be available from most vendors. In this case, use packages compliant with Packing Instruction 602.

The maximum allowable quantity per primary receptacle is 100 mL or 100 g. There is no maximum net quantity per package.

10.3.5.2 Labeling

The outer container of a GMO or GMMO assigned to UN3245 must display the following information:

- The sender and recipient's full name and address;
- Class 9 label (See Section 10.3.2.1.2); and
- Genetically modified microorganisms, UN3245, and net quantity.

10.3.6 Regulated Medical Waste

Regulated Medical Waste (also sometimes referred to as Regulated Biomedical Waste or Clinical Waste) is defined differently by many state and federal agencies. Under DOT rules, regulated medical waste (RMW) is a waste or reusable material suspected or known to contain an infectious substance, and is generated in the diagnosis, treatment, immunization, or biomedical research of humans or animals. Regulated Medical Waste (RMW) is assigned UN 3291 and is generally packaged consistently with IATA packing instruction 650 (See Section 10.3.2.2, Category B Infectious Substances for further information about packing instruction 650), although some special exceptions exist in the DOT regulations (49 CFR 173.137 (c) and (d) and 179.197).

AU currently packages all RMW in boxes and carts provided by Stericycle® (See Section 8, Waste Management); which comply with the regulations for packaging and labeling of RMW. Typically, these are transported from AU campus by Stericycle® personnel who have to adhere to the requirements for

transport of these materials, and are generally not transported by most AU personnel in vehicles on public roads. However, special considerations should be made should occasion arise that any regulated medical wastes are to be transported, offered for transport or shipped if these wastes are to be:

- ❖ Transported via vehicles traveling on public thoroughfares (e.g., to AU or to the Stericycle® truck from remote campus locations)
Any material transported under the Regulated Medical Wastes must be in a vehicle dedicated for RMW transport if it may contain agents of Risk Group 2 or higher.
- ❖ Transported outside of campus in containers other than the large Stericycle® boxes or carts (e.g., in sharps containers), which may not have the required markings. These should be appropriately packaged and labeled prior to transport.

Please contact the Biosafety Office (x1-2663, BIOSAFETY@AU.edu) to declare your intention to transport RMW and for further guidance prior to transport.

10.4 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 Table 10.3.2.1.1 for vendors that can supply certified packaging for biological materials. When ordering, specify what type of material(s) you will be shipping: Category A infectious substances, Category B infectious substances, etc. Different categories have slightly different packaging needs, but all follow the basic triple packaging requirements described below.

10.4.1 Triple Packaging

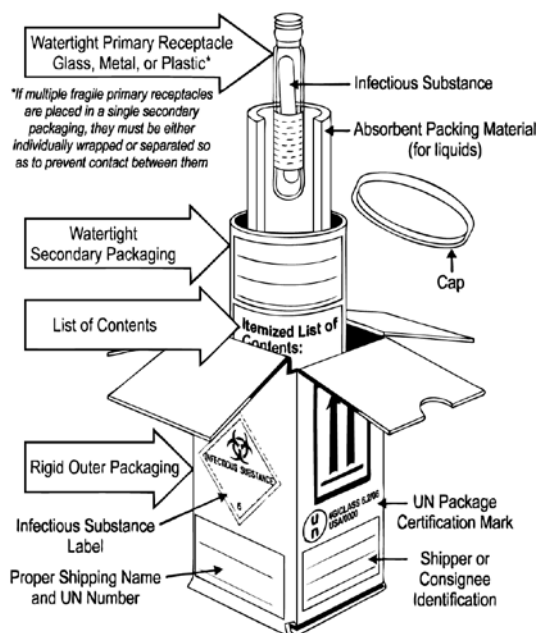
Biological materials must be packaged according to the triple packaging principle. The three elements of triple packaging include: primary receptacle, leak-proof secondary container, and durable outer container. Infectious substances in Category A and B, patient specimens and genetically modified microorganisms must be packaged in this way, with slight variations. An example of triple packaging is illustrated in Figure 10.4.1.

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 (e.g., Parafilm, etc.). 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 usually does not include the primary container.

The **secondary container** holds one or more primary containers, and must also be leak-proof. Secondary containers for all Category A and liquid Category B infectious substances must meet specific pressure test standards when shipping liquids. 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 rigid and have one side that is at least 100 mm X 100 mm, in order for required markings and labels to fit. The outer package must be of adequate strength for its capacity, mass, and intended use. 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, if required.

Figure 10.4.1



Source: Transporting Infectious Substances Safely, US DOT Document PHH50-0079-0706.

10.4.2 Other Packaging Requirements

10.4.2.1 Overpacks

An overpack can be used to combine several triple packages into one large package. This may be done to save on shipping 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 including hazard labels and proper shipping names. The outer container of the overpack must also be marked with the word, "Overpack."

10.4.2.2 Dry Ice

10.4.2.2.1 Hazard Identification

Dry ice is classified by DOT and IATA as a "miscellaneous" hazard, class 9. Dry ice is considered hazardous during transportation for three reasons:

Explosion hazard: Dry ice releases a large volume of carbon dioxide gas as it sublimates. If packaged in a container which does not allow for release of the gas, it may explode, causing potential injury and/or property damage.

Suffocation hazard: a large volume of carbon dioxide gas emitted in a confined space may create an oxygen-deficient atmosphere.

Contact hazard: Dry ice is a cryogenic material that causes severe frostbite upon contact with skin..

Packaging dry ice properly will minimize the risk to personnel transporting the material. The explosion hazard will be eliminated with a package designed to vent gaseous carbon

dioxide. Suffocation and contact hazards will be greatly reduced by labeling the package correctly, so those who come in contact with it will be aware of the contents.

10.4.2.2.2 Packaging Dry Ice

There are five basic requirements for all shipments of dry ice:

- Gas venting:** packages must allow for release of carbon dioxide gas. Dry ice must never be sealed in a container with an airtight seal such as a jar with a threaded lid or a plastic cooler. When transporting in a vehicle, the box should not be placed inside the passenger compartment to prevent carbon dioxide accumulation within the vehicle.
- Package integrity:** a package containing dry ice must be of adequate strength for intended use. It must be strong enough to withstand the loading and unloading normally encountered in transport. It must also be constructed and closed in order to prevent any loss of contents that might be caused by vibration or by changes in temperature, humidity, or altitude.
- Package materials:** do not use plastics that can be rendered brittle or permeable by the temperature of dry ice. This problem can be avoided by using commercially available packages intended to contain dry ice (see Table 10.3.2.1.1).
- Waybill:** the waybill (also referred to as the airbill) must include the statement “Dry ice, 9, UN1845, [number of packages] X [net weight in kilograms]” FedEx has a check box on their waybill to satisfy this requirement (see Figure 10.4.2.2.2A). Airborne Express requires a slightly different format (see Figure 10.4.2.2.2B). Check with your courier to make sure you have made the proper notation on their paperwork.
- Labeling:** the outermost container must be labeled with a hazard class 9 label, UN1845m and net weight of dry ice in kilograms. See Figure 10.4.2.2.2C, below. This must be a specific size (5” x 5”). A full-scale printable version is included in Appendix K.

The image shows a FedEx USA Airbill form. At the top left, it says 'FedEx Express USA Airbill' with a tracking number '839360283475'. The form is divided into several sections: '1 From', '2 Your Internal Billing Reference', '3 To', '4 Express Package Service', '5 Special Handling', '6 Packaging', '7 Payment', and '8 Release Signature'. In the '5 Special Handling' section, there is a checkmark next to 'Dry Ice, 9, UN 1845 1 x 6'. In the '7 Payment' section, there is another checkmark next to 'Dry Ice, 9, UN 1845 1 x 6'. The form also includes fields for 'Sender's Name', 'Company', 'Address', 'City', 'State', and 'ZIP'. At the bottom, there is a 'Try online shipping at fedex.com' button and a 'Questions? Visit our Web site at fedex.com' link.

Figure 10.4.2.2.2A. FedEx Waybill which properly documents 1 box containing 6 kg of dry ice.

Figure 10.4.2.2B. AirBorne Express waybill which properly documents 1 box containing 5 kg of dry ice.

If shipping biological materials with your dry ice, you must comply with the requirements for **both** shipping of biological materials **and** dry ice.

When shipping biological materials and dry ice together:

- Dry ice must be placed **outside** the secondary packaging (See Figure 10.4.2.2D)
- Secure your samples in such a way that when the dry ice sublimates, they will not move freely inside the insulated box. This can be accomplished by wedging your samples in place with cardboard or Styrofoam. Fragile containers such as glass tubes or vials should be wrapped in cushioning material.
- A Shipper's Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material; however, dry ice is included on declarations for shipments that include other hazardous materials such as infectious substances.

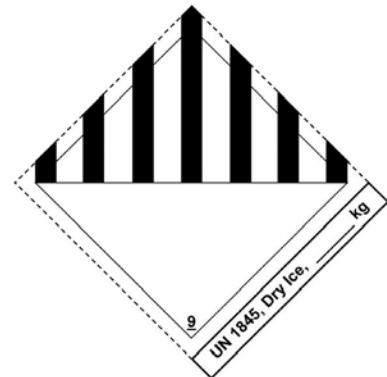


Figure 10.2.2.2C Dry ice label (not to size)

Other issues that you should consider when shipping with dry ice:

- Refer to your package manufacturer's recommendations. Make arrangements with your consignee to make sure your package will be received on its intended delivery date. Take into account local holidays or closings that might delay package receipt.
- Minimize the volume of air to which the dry ice is exposed in order to slow the rate of sublimation. If there is any air space after you fill the package with dry ice, fill it with packing peanuts or other material to reduce the volume of air space.
- Shipments are generally recommended to contain 5-10 pounds (2.27-4.54 kg) of dry ice per 24 hours.

- d. Dry ice shipments can be made with FedEx and DHL. UPS and the U.S. Postal Service have extremely restrictive policies concerning shipments of hazardous materials. Do not ship dry ice with UPS or with the U.S. Postal Service.

10.4.2.3 Liquid Nitrogen

Biological materials can be shipped refrigerated with liquid nitrogen in cryogenic dry shippers, which are insulated packages containing refrigerated liquid nitrogen fully absorbed in a porous material. The dry shippers, themselves, do not contain hazardous materials, do not allow for the build-up of pressure within the container and will not permit the release of any refrigerated liquid nitrogen regardless of the dry shipper's orientation. Properly used, the dry shippers, alone, do not contain free liquid nitrogen, and are not subject to hazardous material regulations by the DOT or IATA. Dry shippers are capable of maintaining cryogenic temperatures normally associated with liquid nitrogen for approximately 24 hours (depending on the manufacturer) without risk of liquid nitrogen spilling. However, be aware, improperly filled dry shippers present a risk of liquid nitrogen leakage and are subject to regulation should spillage occur.

Follow the manufacturer's instructions for filling the dry shipper. Some general practices when filling the dry shipper are:

- a. Wear insulated gloves made for handling liquid nitrogen and a face shield.
- b. Add the liquid nitrogen slowly since a significant volume of nitrogen gas will form as the cold liquid contacts the warm surfaces.
- c. When the liquid level reaches the neck of the dry shipper, stop filling. Replace the cap and set the dry shipper aside for the period specified by the manufacturer to allow the liquid nitrogen to saturate the absorbent.
- d. Repeat steps a-c until the liquid level no longer drops on standing. Special packing regulations apply to shipments containing nitrogen. Contact the Biosafety Office at x1-2663 or BIOSAFETY@mcg.edu if you need to ship materials with liquid nitrogen.

Some manufacturers have empty and full weights for their dry shippers. Dry shippers that will not achieve their full weight may indicate a problem with the absorbent's ability to hold the nitrogen. This may prevent the dry shipper from maintaining the proper cryogenic temperatures during shipment and may damage your samples. Contact the manufacturer to determine if the dry shipper is safe to use.

When you are ready to ship, follow the following steps:

- a. Remove all free liquid nitrogen from the dry shipper before transport.
- b. Wear insulated gloves and a face shield when emptying the dry shipper.
- c. Do not pour liquid nitrogen on to the floor since it could splash on your shoes or legs and cause severe burns. It is recommended to pour the excess liquid nitrogen back into a large liquid nitrogen dewar.
- d. Hold the dry shipper upside down until the liquid stops flowing.
- e. Stand the dry shipper upright for the period specified by the manufacturer.
- f. Repeat steps a-e, above as many times as necessary to remove remaining liquid nitrogen.
- g. Place your canes of material into the dry shipper and replace the cap.
- h. Place the dry shipper into the case supplied by the manufacturer.

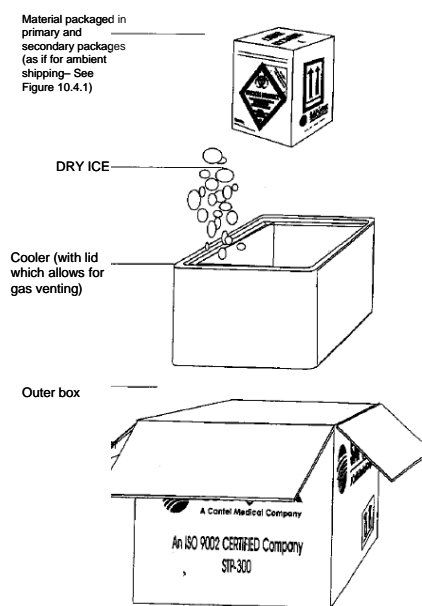


Figure 10.2.2.2D Packaging for Dry Ice

Make sure that the materials you are transporting are not hazardous chemicals such as samples frozen in propane, ethane, halocarbon or other hazardous gas. If you are shipping biological materials, your specimens will still have to comply with the IATA/DOT standards for biologicals, as described above.

Special packing regulations apply to shipments containing liquid nitrogen. Contact the Chemical Safety Office at x1-2663 if you need ship or transport materials with liquid nitrogen.

10.4.2.4 Samples Preserved in Fixative

Special consultation with both the Biosafety and Chemical Safety Offices are required before shipping materials which may be preserved in chemical, such as formalin or ethanol. However, below are reference guidelines for shipping materials preserved in aqueous solutions of formalin or ethanol. Packages prepared according to these guidelines must not contain any materials other than those described (i.e. containers holding formalin- or ethanol-preserved specimens and related absorbent or packaging materials). Laboratory or sampling equipment, unrelated documents, or other goods must be packaged and shipped in separate boxes.

10.4.2.4.1 In Aqueous Formaldehyde Solutions (Formalin) <25%

Aqueous formaldehyde solutions of less than 25% are considered hazardous materials when shipped by air. This is because formalin can cause eye, skin, and respiratory tract irritation. Formaldehyde is regulated by OSHA as a carcinogen. Additionally, exposure to formaldehyde solutions may cause an allergic respiratory reaction. Be sure to review the MSDS before handling or shipping any hazardous material.

Proper packaging shipments of formalin will minimize the chance of leakage during transportation. Properly labeling and documenting these shipments will communicate the hazard to transport workers who may be exposed to the formaldehyde in the event of a leak.

Formaldehyde solutions are assigned to hazard class 9, packing group II. As such, each inner packaging may not contain more than 30 ml. Each outer package may contain not more than 500 ml. At this amount, these are considered "excepted quantities".

Packaging for excepted quantities must have three basic components:

- a. Inner (primary) packaging**, such as a vial, tube, jar, etc. Do not completely fill inner packagings; allow 10% head-space for liquid expansion. Liquids must not completely fill inner packagings at a temperature of 55°C (130°F). Closures of inner packagings must be held securely in place with tape, wire, metal crimps, or other positive means.
- b. Intermediate (secondary) packaging**, such as a ziplock or other plastic bag. Use good quality bags that are well sealed. Intermediate packaging must contain enough absorbent material to absorb all contents and must not react with formaldehyde. Use two plastic bags: put the absorbent and the inner container(s) in the first bag and seal it well with tape. Then seal this bag in another bag for added protection.
- c. Outer packaging**, such as a cardboard box. Formaldehyde solutions may not be shipped in envelopes, Tyvek sleeves, or other non-rigid mailers. The dimensions of the outer box must be at least 100 mm (~4 inches) on two sides.

Labels and Marks on the outer packaging must include the following:

- a. **Dangerous Goods in Excepted Quantities Label**, See Figure 10.4.2.4A. This label must be filled out with the signature, title, name and address of the shipper and the date. It must be affixed to the outer container on a vertical side. For formaldehyde solutions of less than 25%, check the box for Class 9 material and enter “UN 3334” as the applicable UN number. The printable label may be found in Appendix K and must be printed in color. Its overall dimensions must be at least 100 mm x 100 mm (~4 in. x 4 in).
- b. **Name and Address:** The outer container must display the name and address of the shipper and consignee.

Many printer inks run when exposed to small amounts of water, such as rain or snow. Therefore, it may be necessary to fully cover each label you have affixed to the box with clear plastic tape. Also, when re-using shipping boxes, completely obliterate all unnecessary labels and marks.

DANGEROUS GOODS IN EXCEPTED QUANTITIES

This package contains dangerous goods in excepted small quantities and is in all respects in compliance with the applicable international and national government regulations and the IATA Dangerous Goods Regulations

Signature of Shipper

Title

Date

Name and address of Shipper

This package contains substance(s) in Class(es)
(check applicable box(es))

Class: 2 3 4 5 6 8 9

and the applicable UN Numbers are: UN 3334

Figure 10.4.2.4A. Dangerous Goods in Excepted Quantities Label (not to scale)

Package Tests must be performed and documented to ensure package compliance. A representative example of packaging used for excepted quantities of formaldehyde solutions must pass a drop test and compressive load test without any breakage or leakage of any inner packaging and without any significant reduction in package effectiveness. Perform the following tests on representative example of your packaging and keep a record of the results.

Drop Test. Drop a representative package from a height of 1.8 m (5.9 feet) directly on to a solid unyielding surface:

- One drop flat on bottom;
- One drop flat on top
- One drop flat on the long side;
- One drop flat on the short side; and
- One drop on a corner at the junction of three intersecting edges.

Compressive Load Test. Apply a force to the top surface of a representative package for a duration of 24 hours, equivalent to the total weight of identical packages if stacked to a height of 3 meters.

Proper documentation is required for all shipments of hazardous materials. Incorrect documentation is the most common cause of package refusal. If using documentation for couriers other than FedEx and DHL, contact EHS for assistance.

For domestic shipments with FedEx Express, fill out the standard US waybill. Fill out the form completely and be sure to include the following information:

In section 6, Special Handling, check the box “Yes, Shipper’s Declaration not required.”

On the top of the form above the FedEx tracking number, include the statement, “Dangerous Goods in Excepted Quantities”. See example in Figure 10.4.2.4B.

For DHL shipments, under the “Nature and Quantity of Goods” box on the air waybill, include the words “Dangerous Goods in Excepted Quantities”.

Include this statement and check this box.

Figure 10.4.2.4B Example of FedEx waybill for excepted quantity shipment

10.4.2.4.2 In Aqueous Ethanol Solutions of 55-100%

Ethanol solutions of 55-100% are considered hazardous materials when shipped by air. This is because ethanol is a flammable liquid (NFPA rating = 3), and its vapor can travel a considerable distance to an ignition source and “flash back”. Contact of ethanol with strong oxidizers, peroxides, strong alkalis, and strong acids may cause fires and explosions. Be sure to review the manufacturer MSDS before handling or shipping any hazardous material.

Ethanol solutions are assigned to hazard class 3, packing group II. As such, each inner packaging may not contain more than 30 ml. Each outer package may contain no more than 500 ml.

Packaging, labeling requirements, package tests and documentation are similar to those indicated above for formaldehyde solutions (See Section 10.4.2.4.1) *with the exception* that for ethanol solutions of 55-100%, the Dangerous Goods in Excepted Quantities Label (as seen in Figure 10.4.2.4A for formaldehyde solutions) should have the Class 3 material box checked and “UN 1170” as the applicable UN number.

10.5 SHIPPER’S DECLARATION FOR DANGEROUS GOODS

A Shipper’s Declaration for Dangerous Goods must be completed when shipping a Category A infectious substance assigned to UN2814 or UN2900 or a GMO or GMMO assigned to UN3245. A declaration is not required for shipments in which dry ice is the only hazardous material. A declaration is not required for shipments of Category B infectious substances assigned to UN3373. Improperly completed declarations are the most common cause of package refusal.

Refer to the Shipper’s Declaration for Dangerous Goods (Figure 10.5) 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:” *[then you must provide a 24 hr/day, 7 days/week contact for a person who knows what material has been shipped and emergency response information. This should be documented in your shipping/transport SOP]*.
- 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. UN or ID Number:** Enter appropriate UN number as found in Table 10.5.
- F. Proper Shipping Name:** Enter the proper shipping name exactly as it appears in Table 10.5.
- G. Class or Division:** Enter appropriate hazard class as found in Table 10.5.
- H. Packing Group:** For dry ice, enter “III” in this column. Biological materials are not assigned packing groups.
- I. 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.”). If using an overpack, indicate here with “Overpack Used.”
- J. Packing Instructions:** Enter appropriate packing instruction number. Refer to Table 10.5.
- K. Authorization:** Leave this column blank.
- L. Additional Handling Instructions:** You must provide an emergency contact name and phone number which can be reached 24 hours per day, 7 days per week to provide emergency response information should a question develop about your package during transport. The statement “Emergency Contact: [fill in contact name; phone number]” must be provided.
- M.** This section is self-explanatory. Sign and date each copy of your Shipper’s Declaration.

A blank Shipper’s Declaration for Dangerous Goods is available in Adobe PDF format at <http://www.unh.edu/ehs/shipping>. Please note the following:

- Declarations must be typewritten or computer-generated; handwritten declarations will not be accepted.
- Declarations must be printed in color to display the red-striped border.
- Always print at least four copies: provide three to the carrier and keep one for your records.

- Remember to sign and date each copy.
- Regulations require that you must retain your copy for **2 years**.

A completed sample declaration can be found in Figure 10.5B. Contact the Biosafety Office x1-2663 or BIOSAFETY@AU.edu with any questions regarding the Shipper's Declaration.

Table 10.5. Summary of Shipping Information.

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Group (PG)	Packing Instruction (PI)	Max. qty. per primary receptacle	Max. Net qty./pkg. for Passenger Aircraft	Max. Net qty./pkg. for Cargo Aircraft
Category A infectious substance, affecting humans and possibly animals	Infectious substance, affecting humans	UN2814	6.2	-	602	Liquids: 4 L Solids: 4 kg	50 ml or 50 g	4 L or 4 kg
Category A infectious substance, affecting only animals (not humans)	Infectious substance, affecting animals	UN2900	6.2	-	602	Liquids: 4 L Solids: 4 kg	50 ml or 50 g	4 L or 4 kg
Category B infectious substance	Biological substance, Category B	UN3373	6.2	-	650	Liquids: 1 L Solids: 4 kg	4 L or 4 kg	4 L or 4 kg
Dry Ice	Dry Ice or Carbon Dioxide, solid	UN1845	9	III	904	N/A	200 kg	200 kg
Non-infectious, transducing genetically modified organism or microorganism	Genetically modified microorganisms	UN3245	9	-	913	No limit	No limit	No limit
Clinical waste, Biomedical waste, Regulated medical waste	Regulated medical waste, n.o.s.	UN3291	6.2	II	650	No limit	No limit	No limit
Aqueous formaldehyde solutions of less than 25%	Aviation regulated liquid, n.o.s.	UN3334	9	II	Dangerous Goods in Excepted Quantities instructions (IATA 2.7)	30 ml	-	500 ml
Aqueous ethanol solutions (55-100%)	Ethanol solution	UN1170	3	II	Dangerous Goods in Excepted Quantities (IATA 2.7)	30 ml	-	500 ml

Figure 10.5A. Shippers Declaration

SHIPPER'S DECLARATION FOR DANGEROUS GOODS								
A				Air Waybill No. Page of Pages Shipper's Reference Number (optional)				
B								
Two completed and signed copies of this Declaration must be handed to the operator.				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.				
TRANSPORT DETAILS								
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure						
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">PASSENGER AND CARGO AIRCRAFT</td> <td style="padding: 2px;">CARGO AIRCRAFT ONLY</td> </tr> </table>	PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	C					
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY							
Airport of Destination			D Shipment Type <i>(delete non-applicable)</i> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NON-RADIOACTIVE</td> <td style="padding: 2px;">RADIOACTIVE</td> </tr> </table>				NON-RADIOACTIVE	RADIOACTIVE
NON-RADIOACTIVE	RADIOACTIVE							
NATURE AND QUANTITY OF DANGEROUS GOODS								
Dangerous Goods Identification								
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization		
E	F	G	H	I	J	K		
Additional Handling Information								
L								
Emergency Telephone Number								
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory Place and Date Signature <i>(see warning above)</i>				
				M				

Figure 10.5B. Example of Completed Shippers Declaration

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Ben Thompson Georgia Regents University 1120 15 th St., CB-4100 Augusta, GA 30912		Air Waybill No. Page 1 of 1 Pages Shipper's Reference Number (optional)				
Consignee Sam Research 2 Langley Road Boston, MA 11111						
Person Responsible: Ben Thompson (706)555-1212						
Two completed and signed copies of this Declaration must be handed to the operator.		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.				
TRANSPORT DETAILS						
This shipment is within the limitations prescribed for: (delete non-applicable)	Airport of Departure					
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	Airport of Destination	Shipment Type (delete non-applicable) NON-RADIOACTIVE			
NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
UN2814	Infectious substance, affecting humans (Mycobacterium tuberculosis)	6.2		25 mg	602	
UN1845	Dry ice	9	III	5 kg All packed in one fibreboard box	904	
Additional Handling Information						
Emergency Telephone Number Ben Thompson (706)555-1212						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory Ben Thompson/professor Place and Date Augusta, GA, March 30, 2008 Signature <i>Ben Thompson</i> (see warning above)		

10.6 REGULATED AGENTS WHICH MAY REQUIRE SPECIAL PERMITS FOR TRANSFER

10.6.1 CDC/USDA Select Agents and Toxins

The U.S. Department of Health and Human Services has developed a list of biological agents (see Section 2.6.2.2) 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 AU Institutional Biosafety Committee and the Centers for Disease Control and Prevention (CDC) or United States Department of Agriculture (USDA). If you are planning to, or currently possess, use or transfer any of the select agents and have not registered, contact the Biosafety Officer at x1-2663 (BIOSAFETY@mcg.edu). Specific shipping restrictions apply to these agents which are not discussed in this document.

10.6.2 Agricultural Pests, Pathogens and Biological Agents

The USDA/APHIS requires permits to transfer any **plant or agricultural animal pest or pathogens**. In addition, permits may be required to export or import the agents shown below. Further information can be obtained from the URL and phone number shown below:

APHIS Agricultural Permits

<http://aphisweb.aphis.usda.gov/ppq/permits/>

http://www.aphis.usda.gov/import_export/index.shtml

Material which do not require permits instruction: http://www.aphis.usda.gov/vs/ncie/fac_imp.html

Telephone: 1-877-770-5990

EXPORT/IMPORT

- Arthropods (insects and mites)
- Arthropods inhabiting dung or of medical/veterinary significance
- Bees and bee related articles
- Biological materials containing animal material
- Butterflies
- Cell cultures of bovine or other livestock origins
- Cut flowers
- Earthworms
- Endangered species
- Endangered species of wild fauna and flora
- Entomopathogens
- Farm animals
- Foreign cotton and covers
- Fruits and vegetables
- High consequence livestock pathogens and toxins
- Indian corn or maize, broomcorn and related plants
- Infectious agents of livestock
- Khapra beetle products
- Live arthropods for display or educational purpose
- Livestock
- Moths
- Noxious weeds
- Nursery stocks (including seeds)
- Parasitic plants
- Plant pathogens
- Predators and parasitoids of arthropods
- Prohibited material for research purposes
- Rice and rice related articles
- Seeds
- Snails and slugs
- Soil
- Sugarcane products and by-products (including parts of the sugarcane plant)
- Tissue culture materials of bovine or other livestock origins
- Weed biocontrol
- Wildlife
- Wood products

10.6.3 Agents of Vectors of Human Disease

CDC permits are required when shipping any infectious agent known or suspected to cause disease in humans, unsterilized specimens of human or animal tissues (including blood and other fluids), or biological vectors of infectious animals, bats, insects, arthropods and snails. This includes the materials in the table below; further information can be obtained at the URL and phone numbers below.

CDC Permit to Import or Transport Agents or Vectors of Human Disease

[<http://www.cdc.gov/od/ohs/biosfty/imprtper.htm>]

Telephone: 1-404-498-2260

INFECTIOUS SUBSTANCES

- It is impractical to list all of the several hundred species of infectious substances. In general, an import permit is needed for any infectious substance known or suspected to cause disease in man.

BIOLOGICAL MATERIALS

- Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious agent requires a permit in order to be imported.

VECTORS

- **Animals:** Any animal known or suspected of being infected with an organism capable of causing disease transmissible to man may require a CDC permit. Importation of live turtles of less than 4 inches in shell length and all nonhuman primates requires an importation permit issued by the Division of Quarantine.
- **Bats:** All live bats require an import permit from the CDC and the U.S. Department of Interior, Fish and Wildlife Services.
- **Insects or Arthropods:** All live fleas, flies, lice, mites, mosquitoes, or ticks require a CDC import permit, regardless of infection status. Permits are required for adult forms, as well as eggs, larvae, pupae, and nymph stages. Any other living insect or arthropod, known or suspected of being infected with any disease transmissible to man requires a CDC import permit.
- **Snails:** Any snail species capable of transmitting a human pathogen require a permit from the Centers for Disease Control.

10.6.4 Department of Commerce- Bureau of Industry and Security (BIS) Regulated Agents

A permit may be required from the Commerce Department, 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 (Commerce Control List Supplement No. 1 to Part 774 Category 1, pages 54 - 59). In fact, in some instances, permits may be required to domestically ship commerce-controlled materials to certain foreign nationals or U.S. nationals who may fall on U.S. Governmental prohibition lists. In fact, these same individuals may even require a permit in order to access to these materials or their information while at AU (known as “deemed exports”). See the list below for the biological agents which fall on the Commerce Control List. For further information on export compliance, view the URL below and contact the AU Legal Office for further guidance.

Commerce Department – Bureau of Industry and Security (BIS)

[<http://www.bis.doc.gov/index.htm>]

HUMAN PATHOGENS and TOXINS

Bacteria

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* (*Pseudomonas mallei*)
- *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*)
- *Chlamydia psittaci*
- *Clostridium botulinum*
- *Clostridium perfringens*, epsilon toxin producing types
- Enterohaemorrhagic *Escherichia coli*, serotype O157 and other verotoxin producing serotypes
- *Francisella tularensis*
- *Salmonella typhi*
- *Shigella dysenteriae*
- *Vibrio cholerae*
- *Yersinia pestis*

Toxins

- Abrin
- Aflatoxins
- Botulinum toxins
- Cholera toxin
- *Clostridium perfringens* toxins
- Conotoxin
- Diacetoxyscirpenol toxin
- HT-2 toxin
- Microcystin (Cyanginosin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- *Staphylococcal aureus* toxins
- T-2 toxin
- Tetrodotoxin
- Verotoxin
- Volkensin toxin
- Viscum Album Lectin 1 (Viscumin)

ANIMAL PATHOGENS and TOXINS

Bacteria

Mycoplasma mycoides

Viruses

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (certain highly pathogenic strains – see the Export Administration Regulations for more information)
- Bluetongue virus
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Lassa virus

Viruses

- Chikungunya virus
- Congo-Crimean haemorrhagic fever virus
- Dengue fever virus
- Eastern equine encephalitis virus
- Ebola virus
- Hantaan virus
- Hendra virus (Equine morbillivirus)
- Japanese encephalitis virus
- Junin virus
- Kyasanur Forest virus
- Lassa fever virus
- Louping ill virus
- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Monkey pox virus
- Murray Valley encephalitis virus
- Nipah Virus
- Omsk haemorrhagic fever virus
- Oropouche virus
- Powassan virus
- Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
- Rabies virus cultures
- Rift Valley fever virus cultures
- Rocio virus
- South American haemorrhagic fever virus (Sabia, Flexal, Guanarito)
- St. Louis encephalitis virus
- Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
- Variola virus
- Venezuelan equine encephalitis virus cultures
- Western equine encephalitis virus
- White pox
- Yellow fever virus

Rickettsiae

- *Bartonella quintana* (*Rochalimea quintana*, *Rickettsia quintana*)
- *Coxiella burnetii*
- *Rickettsia prowasecki*
- *Rickettsia rickettsii*

Commerce Department – Bureau of Industry and Security (BIS) - CONTINUED

[\[http://www.bis.doc.gov/index.htm\]](http://www.bis.doc.gov/index.htm)

GENETIC ELEMENTS/GENETICALLY MODIFIED ORGANISMS

- Genetic elements that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.
- Genetic elements that contain nucleic acid sequences coding for any controlled “toxins” or “sub-units of toxins.”
- **Technical Note:** Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.
- Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.
- Genetically modified organisms that contain nucleic acid sequences coding for any controlled “toxins” or “sub-units of toxins.”

PLANT PATHOGENS

Bacteria

- *Xanthomonas albilineans*
- *Xanthomonas campestris* pv. citri including strains referred to as *Xanthomonas campestris* pv. citri types A,B,C,D,E or otherwise classified as *Xanthomonas citri*, *Xanthomonas campestris* pv. aurantifolia or *Xanthomonas campestris* pv. Citrumelo.

Fungi

- *Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kahawae*)
- *Cochliobolus miyabeanus* (*Helminthosporium oryzae*)
- *Magnaporthe grisea* (*pyricularia grisea/pyricularia oryzae*)
- *Microcyclus ulei* (*Dothidella ulei*)
- *Puccinia graminis* (*Puccinia graminis* f. sp. *tritici*)
- *Puccinia striiformis* (*Puccinia glumarum*)

10.6.5 FDA Import Permits

All food (except most meat and poultry), drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation require a permit or registration before importation into the United States. See:

<http://www.fda.gov/ora/import/> for more information about FDA import permits.

Export permits requirement information can be found at:

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>

10.6.6 Fish and Wildlife Service Permits

A permit may be required for transporting fish, wildlife, endangered species, or materials found in the list below.

Fish and Wildlife Service Permit Station

[\[http://www.fws.gov/international/permits/antiques.html\]](http://www.fws.gov/international/permits/antiques.html)

Telephone: 1-800-770-0150

EXPORT

- African elephant ivory
- Animals
- Artificially propagated plants
- Asian elephant ivory
- Biological samples
- Captive-born export
- Circuses/traveling animal exhibitions
- Goldenseal

IMPORT

- African elephant
- African elephant ivory
- African leopard
- Argali
- Asian elephant ivory
- Biological samples
- Birds
- Bontebok

- Ginseng
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Raptors
- Trophies by taxidermist
- Wildlife

- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Polar bears
- Scientific and zoological breeding or display
- Sport hunted trophy
- White rhinoceros

10.7 INTERNATIONAL SHIPMENTS

Shipping and receiving animals and animal-derived materials, infectious or biohazardous agents, biological toxins, and genetically modified organisms may require the approval of federal agencies, both domestic and foreign. Regulations that govern the transfer of biological materials help to minimize or eliminate the possible threats to public health and agriculture. In addition, the Departments of Commerce, Treasury and State regulate exportation based on special considerations on the material's economic impact, commercial value, ecological impact and/or military dual-use.

Some countries, couriers and airlines restrict the importation or transportation of some hazardous materials (*e.g.*, dry ice). It is advisable for the shipper to determine these restrictions prior to shipment/transport. Contact the Biosafety Office for assistance x1-2663 or BIOSAFETY@AU.edu.

Packages shipped internationally generally require increased preparation time due to the additional paperwork required for such packages. An import/export permit may be required when shipping biological materials internationally (See Section 10.6). Check the following U.S. governmental agencies for permits and additional information.

10.7.1 Exporting from the United States

Depending on the nature of the shipment, a U.S. export permit may be required when sending your package. Additionally, an import permit may be required in the country where the package is being shipped. If your shipment requires an export permit, it must be completed and approved by the appropriate government agency prior to shipment. Typically, a copy of the import permit of the country of destination is included in the shipping documentation and should be obtained from the consignee prior to shipment. For more information on whether your shipment requires an export permit, please contact the AU Biosafety Office x1-2663 or BIOSAFETY@AU.edu.

Note: Packages may be opened and inspected when leaving the United States or at any time by any inspection service provided by other countries. In order to assure that your package is safely delivered to its intended destination, always consider the following:

1. If necessary, obtain an export permit from the appropriate governmental organization prior to shipment.
2. Package and label the material according to the guidelines listed in this manual.
3. Include a courtesy letter with the shipment describing the contents in detail including information about whether the material is infectious. Copies of importation paperwork from the consignee should be included, if required.

10.7.2 Importing into the United States

All shipments entering the United States are processed by the U.S. Bureau of Customs and Border Protection. An import permit may be required to deliver the package even if a permit is not required by the originating country. Check with the appropriate governmental organization prior to shipment of the material.

Note: Packages may be opened and inspected upon entry into the United States. In order to assure that your package is safely delivered to its intended destination, always consider the following:

If necessary, obtain an import permit from the appropriate governmental organization prior to shipment.

1. Package and label the material according to the guidelines listed in this manual.

2. Consider including a courtesy letter with the shipment.

The **importer** is legally responsible for assuring that foreign personnel package, label, and ship the infectious materials according to USPHS and IATA regulations. Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number, and the expiration date are also issued to the **importer** with the permit. The **importer** must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U.S. Customs and Border Protection and U.S. Division of Quarantine personnel of the package contents.

10.8 SHIPPING COMPANY RESTRICTIONS

Some shipping companies may have requirements that are more restrictive than those discussed in this document. Consider the following information before planning a shipment.

10.8.1 DHL

DHL will accept shipments made according to IATA or DOT regulations. Shipments made according to instructions in this manual will be acceptable to DHL.

10.8.2 FedEx

FedEx Express and FedEx Ground will accept shipments prepared according to instructions in this manual. FedEx will not accept any material considered to be in Risk Group 4. A Risk Group 4 pathogen is one that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.

10.8.3 United Parcel Service (UPS)

UPS will not accept shipments of Category A materials. UPS will accept shipments of UN3373 and exempt patient specimens.

10.8.4 United States Postal Service (USPS)

The USPS has highly restrictive regulations concerning the shipment of hazardous materials by mail. Category A materials may not be mailed with the USPS. USPS will accept shipments of UN3373 and exempt patient specimens. For more information, refer to Section 10.9.

10.9 UNITED STATES POSTAL SERVICE MAILINGS

The United States Postal Service (USPS) does not allow Category A infectious substances to be mailed. Follow the procedures below when mailing Category B substances, exempt patient specimens and non-regulated items.

10.9.1 Mailing Category B Substances

Follow packaging and labeling requirements listed in Section 10.3.2.2 and note the following variations:

- Shipments of both liquid and solid substances must be packaged in a pressure tested primary or secondary container; and
- Category B substances may be mailed as First-Class, Priority, or Express mail.

10.9.2 Mailing Exempt Human and Animal Specimens

Follow packaging and labeling requirements listed in Section 10.3.3 and note the following variations:

- Inner containers and the total volume per package are limited to 500 mL or 500 g;
- Outer packaging must be rigid; and
- Exempt specimens must be mailed as First-Class, Priority, Express, or Package Services mail.

10.9.3 Mailing Non-Regulated Materials

According to USPS regulations, specific packing instructions apply when mailing non-regulated materials. The following are examples of non-regulated biological materials:

- Biological products not containing Category A or Category B substances;
- Blood or blood products collected for transfusion or preparation of blood products;
- Tissues or organs intended for transplantation;
- Dried blood spots; and
- Dried specimens for fecal occult blood detection.

Quantity limits and form of substance (liquid or solid) determine the packaging requirements for non-regulated materials. Refer to the appropriate category below to determine how to package your material.

10.9.3.1 Non-Regulated Liquid Substance, Not Exceeding 50 ml

Primary container and total package contents may not exceed 50 ml. Primary receptacle must be leak-proof and properly sealed. Include cushioning and enough absorbent to absorb entire contents of liquid. Enclose the primary container(s) in a leak-proof secondary container (e.g. plastic bag). Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

10.9.3.2 Non-Regulated Liquid Substance, Exceeding 50 ml

Primary container must not exceed 50 ml; total package may not exceed 500 ml. Package in triple packaging. Include cushioning and enough absorbent to absorb entire contents of liquid. Label primary or secondary container with a biohazard symbol. No other labeling is required.

10.9.3.3 Non-Regulated Dry Substance

Primary container must be sift-proof and must be enclosed in a sift-proof secondary container. Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

10.10 TRANSPORT AS AIRLINE BAGGAGE

Hazardous materials should **never** be carried in the passenger compartment of an airplane. Do not even attempt to carry these aboard an airline. Although occasionally, limited *non-infectious* biological materials and small amounts of dry ice may be transported as checked baggage on some passenger flights, these must not only comply with DOT/IATA and other standards as described above, but must adhere to *each airlines policies* and prerogative to carry such materials. Some airlines may refuse to carry these. Because of this, the practice is highly discouraged and it is recommended that AU personnel make arrangements to ship their materials prior to departure rather than attempt to check their baggage. However, in the exceptional situations where shipment is not possible, those wishing to transport non-infectious biological materials and/or dry ice as checked baggage must contact the

airline(s) well ahead of time to confirm that the airline's policies will permit this and any special limitations/instructions they may have for preparing such packages. All packages must comply with the IATA/DOT packing, marking and labeling standards, and comply with any special permit standards as described in earlier sections. Those who intend on transporting such materials in this manner must have documented shipping training and declare their intentions to carry these materials on a passenger airline on their IBC-approved Biosafety Protocols and SOPs and fully disclose the nature of these materials to airline and TSA personnel.

10.11 TRANSPORT IN GROUND VEHICLES

USDOT regulations do not apply to private or contract motor carriers used exclusively to transport biological materials, diagnostic specimens or biological products; however, other standards (e.g., permits) may still be required. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination. Note, in order for the vehicle to be "dedicated," the vehicle can not be utilized for other purposes at the same time (e.g., patient or passenger transport, food transport). Although no specific packing instructions are required by law, packages should be prepared in accordance with the packaging guidelines outlined in Section 10.4 and the carrier's specifications, if applicable.

All those transporting materials must be licensed drivers and comply with all applicable driving laws and accepted safety standards (e.g., seat belt use).

Intention to transport biological materials or dry ice via vehicles by AU personnel should be fully disclosed in each IBC-approved Biosafety Protocol and SOPs prior to transport. These SOPs should include a description of the steps which should be taken if one is involved in a motor vehicle accident *en route*. These include:

- Call for emergency assistance, if needed
- Let all emergency response teams know that you are transporting potential biohazards
- Notify your supervisor to contact the shipper and recipient of the sample status
- Arrange for alternate transportation if you are not able to get to your destination

10.11.1 Automobiles

Special considerations should be made for the locations and security of the package in a passenger vehicle. During transport, the vehicle must be dedicated to the purpose. Biological materials should not be transported in any area where food/beverages are transported and these areas should be fully decontaminated prior to transport of food/beverages. Packages with dry ice or liquid nitrogen should never be transported in the passenger compartment of the vehicle due to the suffocation hazards (see Section 10.4.2.2). Materials should be secured from theft. Any material transported in an open truck must be secured to prevent loss via jostling of the vehicle during transport.

Transport via privately-owned vehicle is discouraged as many private insurance companies do not cover this activity. Check with your insurance company to verify the terms of your policy prior to transport.

10.11.2 Public Modes of Transportation (e.g., Shuttles busses)

Transport of biological materials or other hazardous materials is not permitted in passenger compartments of vehicles used for public transportation, such as shuttle busses.

10.11.3 Courier Services

Several commercial courier services are available to transport patient (diagnostic) specimens or biological products. Although USDOT regulations do not apply to private or contract motor carriers used exclusively to transport patient (diagnostic) specimens or biological products, and therefore no specific packing instructions are required by law,

those wishing to offer their packages of biological materials to a commercial carrier for transport must prepare shipments in accordance to the courier's standards and must fully declare the nature of the materials which are being offered for transport. Often, these will be similar to that described in Section 10.4.