



UNIVERSITY *of* NEW HAMPSHIRE

UNH Shipment of Biological Materials Manual

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The most current version of this document can be found at:
<http://www.unh.edu/ehs/shipping>

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I. Introduction

The Office of Environmental Health and Safety (EHS) has developed this manual to assist in the shipment of biological materials and dry ice. This document includes information about how to properly classify, package, mark and label your shipment. This manual also describes the training requirements necessary to ship biological materials and dry ice.

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

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

Several agencies regulate the shipment of biological materials including:

- International Air Transport Association (IATA).
- US Department of Transportation (DOT).
- US Public Health Service (PHS).
- Occupational Health and Safety Administration (OSHA).
- 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/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. If you are shipping with UPS or otherwise need to make shipments that comply only with DOT regulations, contact EHS at 862-5038.

II. 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 or fill out a [Shipper's Declaration for Dangerous Goods](#) you must follow the training certification requirements outlined below.

1. **Read this manual.** This manual will provide familiarity with the general provisions relating to the regulations and detailed training in the requirements applicable to shipping biological materials and dry ice.
2. **Have a current bloodborne pathogen training certification from EHS.** This training ensures that you are familiar with hazards presented by infectious materials, proper handling and emergency response procedures.
3. **Submit to EHS an [Intent to Ship Hazardous Materials form](#) (Appendix E).** EHS will review this form with you and, upon successful completion, will certify you to ship only those materials that are listed on your Intent form.

Shipping regulations change frequently so it is necessary to repeat training certification every two years. Training sessions reviewing the material in this manual are available from EHS. Call EHS at 862-5038 to schedule training or to ask questions regarding the shipment of biological materials and dry ice.

III. Shipping Overview

Follow these steps when shipping biological materials and dry ice.

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

IV. Shipment Type

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

- Unregulated biological material;
- Infectious substances (Category A infectious substances);
- Diagnostic specimens (Category B infectious substances);
- Biological products; or
- Genetically modified organisms and micro-organisms.

Read each material section carefully to determine how to classify a material. If you are shipping a biological material that *cannot cause disease*, infectious substance regulations do not apply, unless sent by mail (see [Section IX](#)). **Note:** All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (see [Other Packaging Requirements](#)). All samples preserved with flammable or corrosive materials, such as ethanol or formalin, must be shipped appropriately (please see the [UNH Shipment of Hazardous Materials Manual](#) on the EHS website).

The terms “infectious” and “diagnostic” have distinct connotations in research that **do not** necessarily correlate to their use in shipping terminology. Many items will qualify for shipment as diagnostic specimens that, in reality, are not diagnostic specimens according to academic or clinical use of the word. If you are still not sure how to classify a material for shipment after reviewing the following sections, contact EHS at 862-5038.

A. Unregulated Biological Material

The following materials are not subject to IATA or DOT shipping regulations:

- Material that does not contain pathogens;
- Substances for which there is a low probability that infectious substances are present, or where the concentration is at a level naturally encountered (i.e., food, water, soil, or dust samples).

The following materials are not subject to IATA regulations, but primary or secondary containers must be marked with a biohazard symbol. Also, if mailing any of the following items, refer to USPS regulations ([Section XII](#)):

- Dried blood spots or fecal occult screening tests;
- Blood or blood components collected for the purpose of transfusion; and
- Tissue or organs for use in transplantation.

B. 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.

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 (UN 2814), or infectious substances affecting animals (UN 2900). Indicative examples of Category A infectious substances are listed in [Appendix A](#).

a. Packaging

The triple packaging concept (explained in [Section V](#)) applies to Category A infectious substances. Purchase packaging compliant with IATA Packing Instruction 602. See [Appendix B](#) 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.

b. 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 ([Figure 1](#));
- Proper shipping name, UN number and net quantity of infectious substance;
- Name and telephone number of a person responsible for the shipment;
- Class 9 label ([Figure 2](#)), including UN 1845 and net weight, if packaged with dry ice; and
- Cargo Aircraft Label, when shipping over 50 mL or 50 g ([Figure 3](#)).

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 shipped with the proper shipping name “diagnostic specimens” or “clinical specimens” and assigned to UN 3373.

a. Packaging

The basic triple packaging concept applies to Category B infectious substances. Purchase packaging that complies with IATA Packing Instruction 650. See [Appendix B](#) for a list of some packaging suppliers. Be sure to specify if the shipment is a refrigerated sample (ice packs or dry ice).

For Category B infectious substances, the maximum quantity for a primary receptacle is 500 mL or 500 g and outer packaging must not contain more than 4 L or 4 kg.

b. Labeling

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

- The sender and recipient’s full name and address;
- The words “DIAGNOSTIC SPECIMENS,” or “CLINICAL SPECIMENS;”
- UN 3373 label ([Figure 4](#));
- Name and telephone number of a person responsible for the shipment; and
- Class 9 label ([Figure 2](#)), if packaged with dry ice;

Figure 1.



Figure 2.



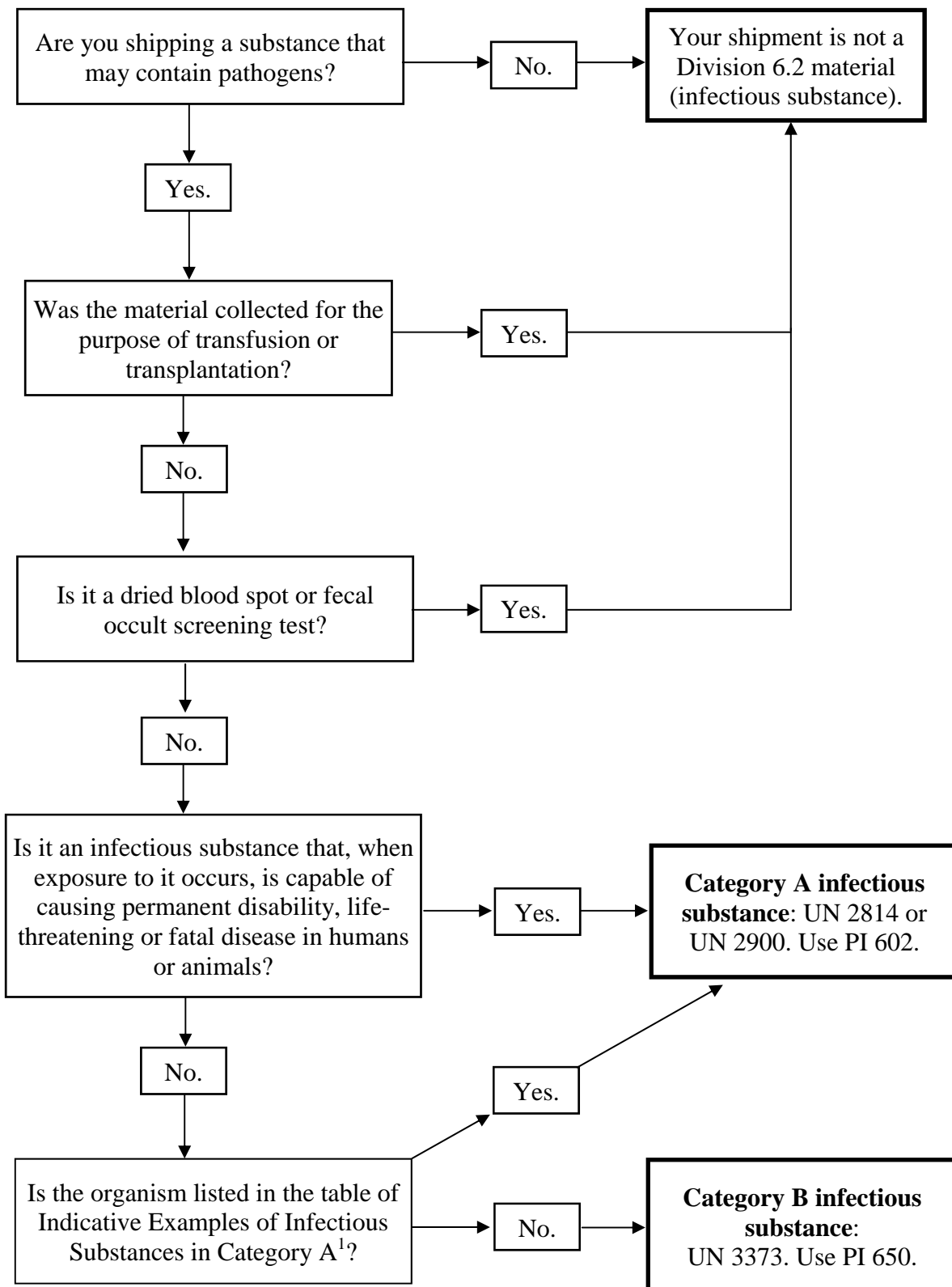
Figure 3.



Figure 4.



Figure 5 - Classification Guide for Infectious Substances and Diagnostic Specimens Shipped According to IATA regulations.



1. See [Appendix A](#) for indicative examples of Category A Infectious Substances.

C. 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.

Biological products transported for final packaging, distribution, or use by medical professionals are not subject to biological shipping regulations. Biological products that do not meet these criteria must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

D. 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 UN 3245. GMOs and GMMOs that are infectious must be assigned to UN2814, UN 2900 or UN 3373.

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. You may not be able to purchase packages designed for Packing Instruction 913. 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.

2. Labeling

The outer container of a GMO or GMMO assigned to UN 3245 must display the following information:

- The sender and recipient's full name and address;
- Class 9 label ([Figure 2](#)); and
- Genetically modified micro-organisms, UN 3245, and net quantity.

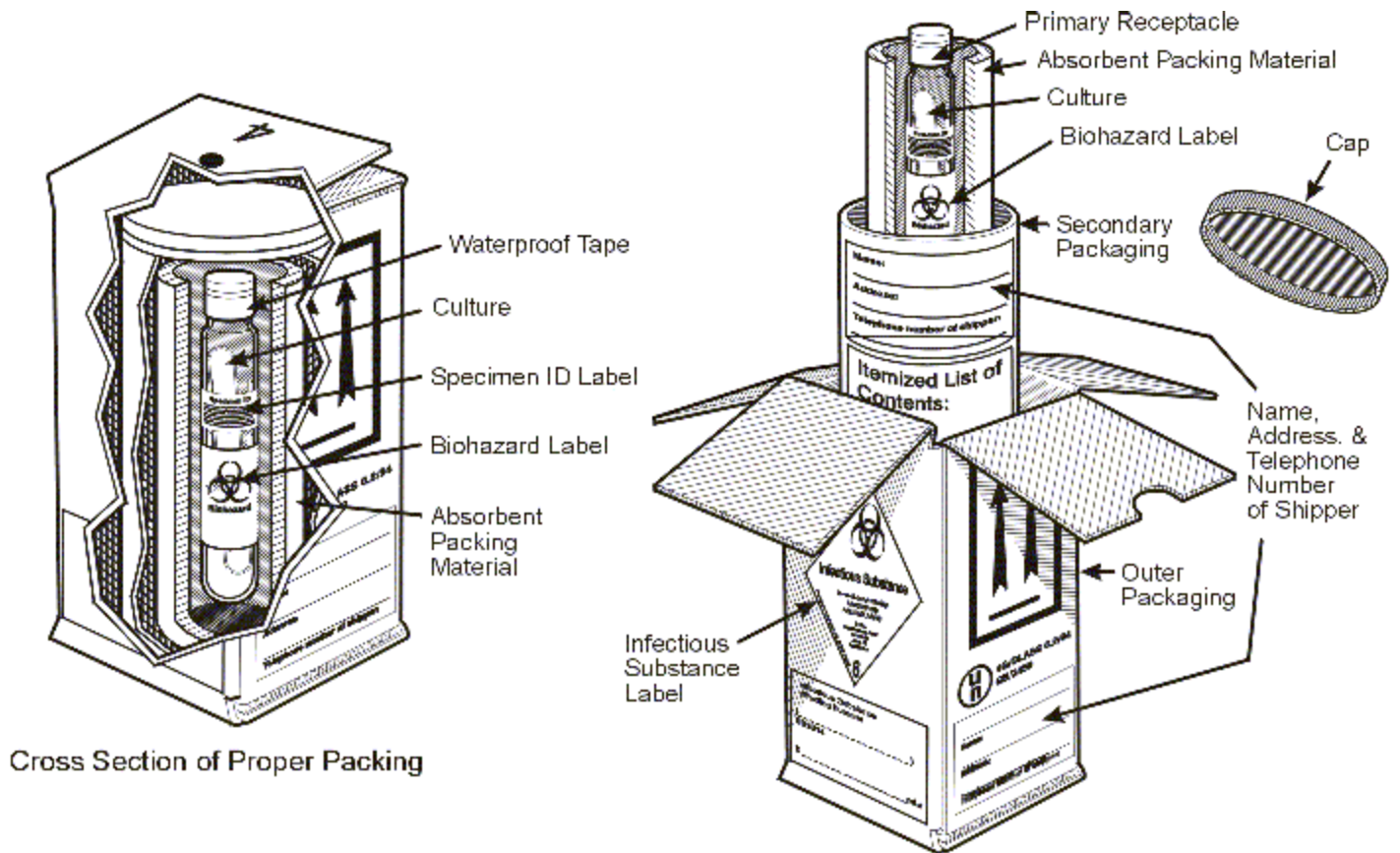
V. Packaging Biological Materials

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

A. Triple Packaging

Biological materials must be packaged according to the triple packaging principle depicted in [Figure 6](#). The three elements of triple packaging include: *primary receptacle*, *leak-proof secondary container*, and *durable outer container*. Infectious substances, diagnostic specimens and genetically modified micro-organisms must be packaged in this way, with slight variations.

Figure 6 - Packaging and labeling of biological materials.



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

The **secondary container** holds one or more primary containers, and must also be leak-proof. This container must meet specific 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 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. It must also be certified with a UN specification mark, when required. An **itemized list** of package contents must be included between the outer and secondary container. The outer package should be marked to identify hazardous contents, including the proper shipping name, UN number and net quantity for each substance.

B. Other Packaging Requirements

Overpacks. An overpack can be used to combine several triple packages into one large package. This may be done to save freight charges when shipping multiple samples. Each triple package inside the overpack must be properly marked and labeled. The outside of the overpack must bear the same markings and labels as the triple packages within including hazard labels, proper shipping names and net quantities. The outer container of the overpack must also be marked with the word, "Overpack."

Dry Ice. If a shipment includes dry ice, special packaging must be purchased. The outer packaging must allow for the release of carbon dioxide gas when the solid sublimates. Dry ice must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary container as the refrigerant sublimates. Dry ice is considered a miscellaneous hazard (Class 9). Packages containing dry ice must bear a Class 9 label and be marked with the proper shipping name, UN number, and net quantity, (e.g., Dry Ice, UN 1845, 3 kg). Packages designed for dry ice most likely will be pre-labeled and marked. A Shipper's Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material. Dry ice is included on declarations for shipments that include other hazardous materials such as infectious substances.

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

VI. Shipper's Declaration for Dangerous Goods

A [Shipper's Declaration for Dangerous Goods](#) must be completed when shipping a Category A infectious substance or a GMO or GMMO assigned to UN 3245. 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 UN 3373. Improperly completed declarations are the most common cause of package refusal.

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

- A. Shipper:** Enter your full name, address and telephone number.
- B. Consignee:** Enter full name and address of recipient. When shipping infectious substances, include the text, "Person responsible for the shipment," followed by your name and phone number.
- C. Transport Details:** Indicate here if your shipment is restricted to cargo aircraft only (if it is more than 50 ml or 50 g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.
- D. Shipment Type:** Cross out "radioactive" to indicate you are shipping a non-radioactive substance.
- E. UN or ID Number:** Enter appropriate UN number as found in [Table 1](#).
- F. Proper Shipping Name:** Enter the proper shipping name exactly as it appears in Table 1.
- G. Class or Division:** Enter appropriate hazard class as found in Table 1.
- 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."). Do not spell like "fiberboard." If using an overpack, indicate here with "Overpack Used."
- J. Packing Instructions:** Enter appropriate packing instruction number. Refer to Table 1.
- K. Authorization:** Leave this column blank.
- L. Additional Handling Instructions:** The statement "Emergency Contact: Chem-Tel 1-800-255-3924." UNH has an annual contract with Chem-Tel to provide 24-hour emergency telephone response service. Chem-Tel must be notified of each shipment; specific details will be provided upon review of your Intent to Ship form.
- 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 in [Appendix F](#) or on our website at <http://www.unh.edu/ehs/shipping>. Please note the following:

- Declarations must be typewritten or computer-generated; handwritten declarations will not be accepted.
- 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 **375 days**.

A completed sample declaration can be found in [Appendix D](#). Contact EHS with any questions regarding the Shipper's Declaration.

Table 1. Summary of Shipping Information.

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

VII. CDC Select Agents

The U.S. Department of Health and Human Services has developed a list of biological agents (see [Appendix G](#) and [Appendix H](#)) that have the potential to pose a severe threat to public health. Special regulations apply to the use and transfer of these materials, including registration with the UNH Institutional Biosafety Committee and the Centers for Disease Control and Prevention. If you are planning to, or currently work with, any of the select agents listed in [Appendix G](#) and [Appendix H](#) and have not registered, contact David Gillum, Laboratory Safety Officer, at 862-0197. Specific shipping restrictions apply to these agents which are not discussed in this document.

VIII. Shipping Company Restrictions

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

DHL/Airborne Express. Airborne Express has merged with 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.

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, see [Section XII](#).

United States Postal Service (USPS). The USPS has highly restrictive regulations concerning the shipment of hazardous materials by mail. Diagnostic specimens may be shipped by the USPS. For more information, refer to [Section XII](#).

UPS. UPS will not accept domestic shipments prepared according IATA regulations. If you would like to make shipments of diagnostic specimens with UPS, contact EHS at 862-5038.

IX. 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.

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. Check the following U.S. governmental agencies for permits and additional information.

APHIS Agricultural Permits
[\[http://aphisweb.aphis.usda.gov/ppq/permits/\]](http://aphisweb.aphis.usda.gov/ppq/permits/)
Telephone: 1-877-770-5990

APHIS permits are required to import or domestically transfer a plant pest, plant biological agent, or other material listed below.

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

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

[\[http://www.cdc.gov/od/ohs/biosfty/imprtper.htm\]](http://www.cdc.gov/od/ohs/biosfty/imprtper.htm)
Telephone: 1-404-498-2260

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.

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.

Commerce Department – Bureau of Industry and Security (BIS)

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

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.

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 (Cyanginisin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- *Staphylococcal aureus* toxins
- T-2 toxin
- Tetrodotoxin
- Verotoxin
- Volkensin toxin
- Viscum Album Lectin 1 (Viscumin)

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)
- Rift Valley fever virus
- 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
- Western equine encephalitis virus
- White pox
- Yellow fever virus

Rickettsiae

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

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
- Newcastle disease virus
- Peste des petits ruminants virus
- Porcine enterovirus type 9 (swine vesicular disease virus)
- Porcine herpes virus (Aujeszky's disease)
- Rinderpest virus
- Sheep pox virus
- Swine fever virus (Hog cholera virus)
- Teschen disease virus
- Vesicular stomatitis virus

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*)

FDA Import Permits

[\[http://www.fda.gov/ora/import/\]](http://www.fda.gov/ora/import/)

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.

Fish and Wildlife Service Permit Station

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

Telephone: 1-800-770-0150

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

EXPORT

- African elephant ivory
- Animals
- Artificially propagated plants
- Asian elephant ivory
- Biological samples
- Captive-born export
- Circuses/traveling animal exhibitions
- Goldenseal
- Ginseng
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Raptors
- Trophies by taxidermist
- Wildlife

IMPORT

- African elephant
- African elephant ivory
- African leopard
- Argali
- Asian elephant ivory
- Biological samples
- Birds
- Bontebok
- Circuses/traveling animal exhibitions
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Polar bears
- Scientific and zoological breeding or display
- Sport hunted trophy
- White rhinoceros
- Wildlife

X. Exporting from the United States

Depending on the nature of the shipment, an 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.

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:

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

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.

Consider including a courtesy letter with the shipment.

XI. 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.

XII. United States Postal Service Mailings

The United States Postal Service (USPS) allows very few hazardous materials to be mailed. USPS regulations are found in the USPS Domestic Mail Manual (DMM) and in Publication 52, both of which are based upon Department of Transportation (DOT) regulations. As a result, the definition of diagnostic specimen and infectious substance are identical to DOT regulations, yet packaging

requirements vary. Diagnostic specimens can be mailed with certain restrictions, which are discussed in this section. EHS does not recommend mailing infectious substances as restrictions apply (*not discussed in this document*).

A. Definitions

Use the following definitions when mailing diagnostic specimens through the US Mail. These definitions reflect DOT regulations and apply only to this section ([Section XII](#)).

Diagnostic specimen: any human or animal material, including excreta, secretions, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals.

Infectious substance: a material known to contain or suspected of containing a pathogen. A pathogen is a virus or micro-organism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals.

Risk Group 1 (no or low individual and community risk): A micro-organism that is unlikely to cause human or animal disease.

Risk Group 2 (moderate individual risk, low community risk): A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.

Risk Group 3 (high individual risk, low community risk): A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.

Risk Group 4 (high individual and community risk): A pathogen 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.

B. Mailing Diagnostic Specimens

Classify the material for shipment by mail by referring to the USPS mailing guide ([Figure 7](#)). Shipments sent by mail *may not* be classified according to [Figure 5](#), which is based on IATA regulations.

According to USPS regulations, specific packing instructions apply when mailing any type of diagnostic specimen. Even specimens that contain only Risk Group 1 pathogens or are fixed, preserved, or are otherwise neutralized or inactivated are subject to packing instructions. The following packing instructions are taken from the USPS Publication 52. Consult these instructions when mailing diagnostic specimens.

For diagnostic specimens containing Risk Group 1 pathogens, or pathogens that are inactivated or neutralized, follow the procedures below.

Liquid, Not Exceeding 50 ml – A diagnostic specimen consisting of 50 ml or less per mailpiece must be packaged in a securely sealed primary receptacle. Two or more primary receptacles whose combined volume does not exceed 50 ml may be enclosed within a single mailpiece. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary

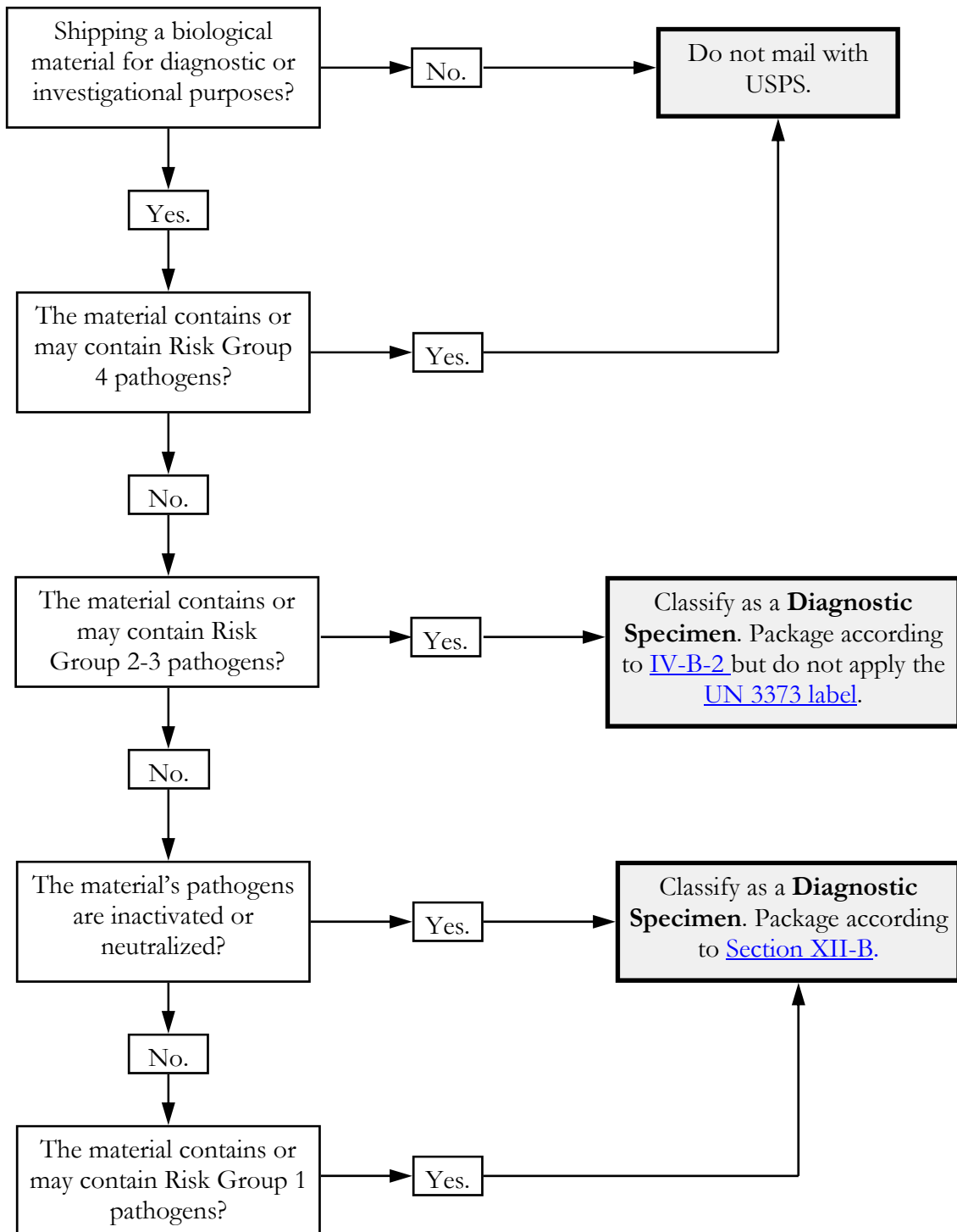
receptacle(s) and the absorbent cushioning must be enclosed in a secondary container having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container must be securely sealed and it may serve as the outer shipping container provided it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international biohazard symbol except when the secondary container also serves as the outer shipping container. In that case, the biohazard symbol must appear either on the inner packaging or on the primary container. A shipper's declaration and a content marking on the outer shipping container are not required.

Liquid, Exceeding 50 ml – A specimen that exceeds 50 ml must be packaged in a securely sealed primary receptacle. A single primary receptacle must not contain more than 500 ml of specimen. Two or more primary receptacles whose combined volume does not exceed 500 ml may be enclosed in a single secondary container. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary receptacle(s) and the absorbent cushioning must be enclosed in a secondary container having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container cannot serve as the outer shipping container. The secondary container must be marked with the international biohazard symbol. The secondary container must be securely and snugly enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping container. The maximum amount of a specimen that may be enclosed in a single mailpiece must not exceed 4,000 ml. A shipper's declaration and a content marking on the outer shipping container are not required.

Solid (or Dried) Specimens – A solid or dry specimen, such as a saliva swab, blood spot, or fecal smear must be completely dried prior to placing it in or on a secure primary receptacle. Cushioning material to withstand shock and pressure changes is required only if the dry specimen is held in a breakable primary receptacle. When required, the cushioning material must surround the primary receptacle to prevent breakage or damage to the primary receptacle. The primary receptacle (and cushioning material, if required) must be enclosed in a secondary container having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle breaks during shipment. The secondary container must be securely sealed and it may serve as the outer shipping container provided it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international biohazard symbol, except when the secondary container also serves as the outer shipping container. In that case, the biohazard symbol must appear either on the inner packaging or on the primary container. A shipper's declaration and a content marking on the outer shipping container are not required.

For diagnostic specimens containing Risk Group 2-3 pathogens, package and label according to [Section IV-B-2](#), but do not apply the [UN 3373 label](#).

Figure 7 - Guide for Mailing Biological Material with the US Postal Service



Appendix A – Indicative Examples of Category A Infectious Substances

UN # and Proper Shipping Name	Microorganism	
<p>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 	<ul style="list-style-type: none"> - 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>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.

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

Air Sea Atlanta
1234 Logan Circle
Atlanta GA 30318
Phone: 404-351-8600

<http://www.airseaatlanta.com>

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>

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper <b style="font-size: 2em; text-align: center;">A	Air Waybill No. Page of Pages Shipper's Reference Number (optional)
---	--

Consignee <b style="font-size: 2em; text-align: center;">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	

PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY
------------------------------	---------------------

C

Airport of Destination	<b style="font-size: 2em; text-align: center;">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 <b style="font-size: 2em; text-align: center;">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

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper	Air Waybill No. Page of Pages Shipper's Reference Number (optional)
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Consignee	
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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%;"> <tr> <td style="width: 50%; text-align: center;">PASSENGER AND CARGO AIRCRAFT</td> <td style="width: 50%; text-align: center;">CARGO AIRCRAFT ONLY</td> </tr> </table>	PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY		
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY			

Airport of Destination	Shipment Type <i>(delete non-applicable)</i> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">NON-RADIOACTIVE</td> <td style="width: 50%; text-align: center;">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 Instruc- tions	Authorization

Additional Handling Information
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>
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Appendix E – Intent to Ship Hazardous Materials

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

1. What regulated material(s) might you ship via mail or courier service? List all hazardous materials that you intend to ship. Also, list the mailing service you intend to use.

2. What packaging will you use to ship your material(s)? Include company name and product number for chosen packaging for each material you intend to ship.

3. Check those that should appear on your package:
 - Class 6.2 label
 - Class 9 label
 - UN 3373 label
 - Cargo Aircraft label
 - Dry ice, UN 1845, net weight _____ kg
 - Infectious substance, affecting humans (*technical name*), UN 2814, net quantity _____
 - Infectious substance, affecting animals (*technical name*), UN 2900, net quantity _____
 - Name, Address and Phone Number of Shipper
 - Name and Address of Consignee
 - Name and Phone Number of Person Responsible for Shipment
 - Overpack
 - Genetically modified micro-organisms, UN 3245, net quantity _____
 - Diagnostic Specimens

4. Fill out attached [Shipper’s Declaration for Dangerous Goods](#) (if your shipments require one). An example of each material you intend to ship must be included in the “Nature and Quantity of Dangerous Goods” section.

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

Print name:	
Signature:	
Date:	
Please return, in campus mail, to EHS – 11 Leavitt Lane.	

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper	Air Waybill No. Page of Pages Shipper's Reference Number (optional)
---------	--

Consignee	
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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	

PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY
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Airport of Destination	Shipment Type <i>(delete non-applicable)</i> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">NON-RADIOACTIVE</td> <td style="width: 50%; text-align: center;">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

Additional Handling Information
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>
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Appendix G – APHIS Plant Pathogens, HHS Select Infectious Agents & USDA High Consequence Livestock Pathogens/Toxins

Viruses

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

Prion

1. Bovine spongiform encephalopathy agent ^δ

Toxins

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

Bacteria

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

Fungi

1. *Coccidioides immitis* ^γ
2. *Coccidioides posadasii* ^β
3. *Peronosclerospora philippinensis* ^α
4. *Sclerophthora rayssiae var zea* ^α
5. *Synchytrium endobioticum* ^α

Exemptions

The following select agents or toxins are exempt:

1. Any select agent or toxin that is in its naturally-occurring environment provided it has not been intentionally introduced, cultivated, collected or otherwise extracted from its natural source.
2. Non-viable select agent organisms or nonfunctional toxins.
3. Toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts:

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

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

1. Nucleic acids that can produce infectious forms of any of the select agent viruses.
2. Recombinant nucleic acids that encode for the functional form(s) of any of the select agent toxins if the nucleic acids: a) can be expressed *in vivo* or *in vitro*; or b) are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.
3. Select agents that have been genetically modified.

Restricted Experiments

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

^α APHIS Plant Pathogen ^β HHS Select Infectious Agent

^δ USDA High Consequence Livestock Pathogen or Toxin

^γ USDA-HHS Overlap Agent

Appendix H – Exclusions for HHS Select Agents/USDA High Consequence Livestock Pathogens & Toxins

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* requires the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) to establish regulations regarding the possession, use, and transfer of select biological agents and toxins. In accordance with the Act, HHS and USDA published new regulations in the Federal Register on December 13, 2002 (67 FR 76886-76905 and 67 FR 76908-76938, respectively). The HHS regulations are set out in 42 CFR Part 73 and the USDA regulations are set out in 7 CFR Part 331 and 9 CFR Part 121.

The regulations in 42 CFR Part 73 and 9 CFR Part 121 establish a procedure by which an attenuated strain of a select biological agent or toxin that does not pose a severe threat to public health and safety, animal health, or animal products may be excluded from the list of select biological agents and toxins.

HHS received requests for exclusions for *Yersinia pestis* strains, *Bacillus anthracis* strains, *Francisella tularensis* subspecies *novicida* and *Francisella tularensis* subspecies *holartica* LVS.

USDA received requests for exclusions for *Bacillus anthracis* Sterne strain and *Francisella tularensis* subspecies *holartica* LVS.

Based upon consultations with subject matter experts and a review of relevant published studies and information provided by the entities requesting the exclusions, HHS and USDA have determined that the following attenuated strains are not subject to the requirements of 42 CFR Part 73 and 9 CFR Part 121 if used in basic or applied research, as positive controls, for diagnostic assay development, or for the development of vaccines and therapeutics.

However, an individual or entity that possesses, uses, or transfers an excluded attenuated strain will be subject to the regulations if there is any reintroduction of factor(s) associated with virulence or other manipulations that modify the attenuation such that virulence is restored or enhanced.

Attenuated strains of HHS select agents and toxins excluded:

- *Coccidioides posadasii* Δ chs5 strain.
- Conotoxins specifically *excluded* are: the class of sodium channel antagonist μ -conotoxins, including GIIIA; the class of calcium channel antagonist ω -conotoxins, including GVIA, GVII, MVIIA, MVIIC, and their analogs or synthetic derivatives; the class of NMDA-antagonist conantokins, including con-G, con-R, con-T and their analogs or synthetic derivatives; and the putative neurotensin agonist, contulakin-G and its synthetic derivatives.
- *Yersinia pestis* strains which are Pgm⁻ due to a deletion of a 102-kb region of the chromosome termed the *pgm* locus (i.e., Δ *pgm*). Examples are *Y. pestis* strain E.V. or various substrains such as EV 76.
- *Yersinia pestis* strains (e.g., Tjiwdej S and CDC A1122) devoid of the 75 kb low-calcium response (Lcr) virulence plasmid.

Attenuated strains of Overlap select agents and toxins excluded:

- *Bacillus anthracis* strains devoid of both plasmids pX01 and pX02.
- *Bacillus anthracis* strains devoid of the plasmid pX02 (e.g., *Bacillus anthracis* Sterne, pX01⁺pX02).
- *Brucella abortus* Strain 19.
- *Brucella abortus* strain RB51 (vaccine strain).

- *Coxiella burnetii* Phase II, Nine Mile Strain, plaque purified clone 4.
- *Francisella tularensis* subspecies *novicida* (also referred to as *Francisella novicida*) strain, Utah 112 (ATCC 15482).
- *Francisella tularensis* subspecies *holartica* LVS (live vaccine strain; includes NDBR 101 lots, TSI-GSD lots, and ATCC 29684).
- *Francisella tularensis* ATCC 6223 (also known as strain B38).
- Venezuelan Equine Encephalitis (VEE) virus vaccine candidate strain V3526.

Attenuated strains of USDA select biological agents and toxins excluded:

- Highly pathogenic avian influenza (HPAI) virus, recombinant vaccine reference strains of the H5N1 and H5N3 subtypes.
- Japanese encephalitis virus, SA14-14-2 strain.