

Shipping Infectious Substances - Category A

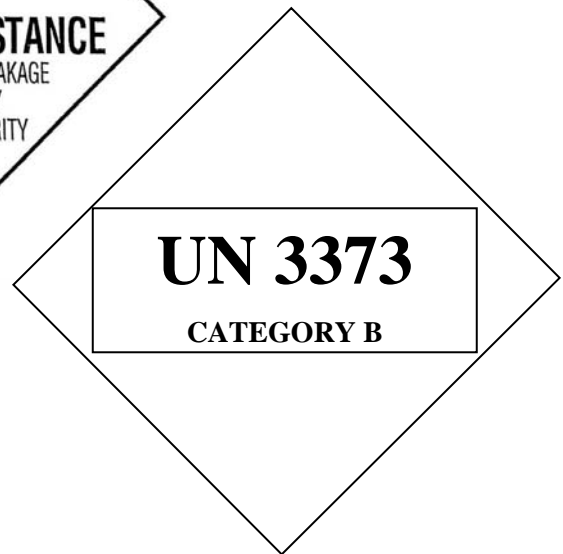


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Introduction and General Awareness

Anyone packaging, handling, shipping or transporting hazardous materials must receive training in the general requirements of handling hazardous materials as well as function specific training for the specific task(s) performed. Training is required before performing any tasks associated with shipping hazardous materials and periodically thereafter. In the U.S., this training must be documented for new employees who package, ship or transport hazardous materials within the first 90 days of hire. The level of training varies for the material being shipped and the complexity of the shipment. For example, individuals shipping known human pathogens require more training than individuals who only ship standard clinical specimens that are not known to contain a human pathogen. This manual reviews applicable regulations, classification of biological materials for shipping purposes, packaging requirements, markings and labels, emergency procedures, and documentation and record keeping required for the range of biological agents and associated materials that may be utilized by the shipper. The United States Department of Transportation (DOT) requires retraining every three years, and the International Air Transportation Association (IATA) requires retraining every two years. Yale University is requiring retraining every two years for anyone shipping biological agents since air transport is routinely involved.

Hazardous materials training must include information on general awareness to familiarize hazardous materials employees (those who package, handle, ship or transport hazardous materials) with the regulations. It must also include function-specific training, safety, security awareness, and driver training for those who will operate a motor vehicle for the transport of hazardous materials. Yale University's training class for the safe transport of hazardous biological materials and this guide will provide information on the following topics:

- Section 1: Classification of biological materials
- Section 2: Packaging requirements for regulated biological materials
- Section 3: Markings and labels
- Section 4: Shipping papers
- Section 5: Permits for restricted shipments and transfers
- Section 6: Security awareness
- Section 7: Emergency response information
- Section 8: Refrigerants

Live training classes are offered each month at the Yale University Office of Environmental Health & Safety (OEHS) located at 135 College Street. Please call 203-785-3550 for the next scheduled class. The training schedule is also published online at www.yale.edu/oehs. Individuals are also allowed to fulfill the training requirement in a self-study mode by reading the course training materials and completing the latest version of the shipping training quiz. Call 203-785-3550 to obtain the course handouts and a copy of the quiz. Once the quiz has been completed, return the quiz to OEHS by fax (203-785-7588) or mail to OEHS, 135 College Street, 1st Floor.

Applicable Shipping, Transport & Transfer Regulations

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

Many of the applicable shipping regulations associated with infectious substances and related biological substances have been changed in 2006 to harmonize U.S. Standards with the World Health Organization Guidance on Regulations for the Transport of Infectious Substances and the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air. This global harmonization effort has been designed to reduce the amount of variation among the organizations. Some of the major organizations that regulate the shipment and transport of infectious agents and related biological substances are listed below.

The United States Department of Transportation (U.S. DOT) is the national authority that regulates the shipment and transport of hazardous material. U.S. DOT regulations governing hazardous materials transport are detailed in the Federal Code of Regulations, 49 CFR Parts 171-178. The Hazardous Materials Regulations are law and must be followed. This manual has been prepared to ensure compliance with the U.S. DOT regulations pertinent to hazardous biological materials, encompassing infectious agents (human and animal) and biological substances (clinical and diagnostic specimens). The complete set of U.S. DOT regulations can be accessed at <http://hazmat.dot.gov>. Questions regarding the U.S. DOT regulations can be answered by OEHS at 785-3550 or the U.S. DOT directly at (800) 467-4922. Please note the use of this guide for the transport of human or animal pathogens or diagnostic/clinical specimens by a trained person will ensure that the shipment is in compliance with U.S. DOT regulations.

International Air Transport Association (IATA): Dangerous Goods Regulations (DGR). “The international regulations for the transport of infectious substances by any mode of transport are based upon the Recommendations made by the Committee of Experts on the Transport of Dangerous Goods (UNCETDG). The United Nations Model Regulations are reflected in international law through international modal agreements. The *Technical Instructions for the Safe Transport of Dangerous Goods by Air* published by the International Civil Aviation Organization (ICAO) are the legally binding international regulations. The International Air Transport Association (IATA) publishes Dangerous Goods Regulations (DGR) that incorporate the ICAO provisions and may add further restrictions. The ICAO rules apply on all international flights. For national flights, i.e. flights within one country, national civil aviation authorities apply national legislation. This is normally based on the ICAO provisions, but may incorporate variations. State and operator variations are published in the ICAO Technical Instructions and in the IATA Dangerous Goods Regulations.” Instructions for shipping infectious substances and related biological substances are also included in the following document from the World Health Organization:

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22/en/

The United States Postal Service (U.S.P.S.) has developed its own set of regulations for the shipment of hazardous materials via the U.S.P.S. These regulations are contained in the Federal Register in 39 CFR Part 111 (New Mailing Standards of Division 6.2 Infectious Substances). Instructions for shipping hazardous materials with the U.S.P.S. are also described in its Domestic Mail Manual. The U.S.P.S shipping regulations for Class 6.2 Infectious Substances were changed in 2006, with the **most notable change that Category A Infectious Substances are now prohibited from the U.S. Mail.**

Occupational Safety and Health Administration (OSHA). The OSHA Bloodborne Pathogens Standard (29 CFR Part 1910.1030, “Occupational Exposure to Bloodborne Pathogens”), provides minimal packaging and labeling requirements for the transport of blood and body fluids within the laboratory and outside of it. The primary requirement is that the packages containing human blood or other potentially infectious materials be labeled with the universal biohazard symbol. OSHA does indicate that other shipping regulations take precedent and their rules must be followed. OSHA does also allow the use of national and international shipping labels on the exterior of the packages to indicate the presence of infectious material or potentially infectious human material in place of the orange universal biohazard symbol in most cases. All OSHA regulations can be accessed at www.osha.gov.

The U.S. Public Health Service also regulates the national shipment and transport of infectious substances in its “**Interstate Transportation of Etiologic Agents**” regulation outlined in the Code of Federal Regulations **42 CFR Part 72**. This regulation is in revision to harmonize it with the other U.S. and international regulations. This regulation places restrictions on the transport of certain agents. Fortunately, the recent national Select Agent regulations (42 CFR Part 73) place restrictions on the same agents and require federal

approval prior to shipping, with additional requirements for tracking and notification of receipt immediately upon delivery.

Forbidden Shipments

- **Don't ship live infected animals by air.** Written authorization is required from all competent authorities, which will include the cargo airline requested to transport the infected animals.
- **Don't ship Category A Infectious Substances through the U.S. Mail or with UPS.** Updated regulations from the US Postal Service, 39 CFR Part 111, now prohibit these materials from US Mail. UPS also prohibits the transport of Category A Infectious Substances by its company.
- **Don't hand carry Category A or Category B Infectious Substances on aircraft or place them within checked baggage.** Category A Infectious Substances must be declared when offered for shipment and Category B Infectious Substances are known to contain human or animal pathogens. Either use a trained courier for these shipments or contact the airline in advance and work with their designated Cargo company to make arrangements for the shipment.
- **Don't ship or order Risk Group 4 or Select Agent pathogens or toxins without prior approval.** These agents require advanced registration with the federal government and OEHS prior to possession.
- **Don't ship (export) infectious substances to restricted countries.** Currently: Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria.
- **Don't combine Category A Infectious Substances and Category B Biological Substances in the same package.**
- Please also note that some transporters/couriers do not accept Risk Group 4 Category A Infectious Substances.

The shipper has the ultimate responsibility for properly identifying, packaging, labeling, and documenting the shipment, using a qualified transporter with personnel trained to transport hazardous materials as well as ensuring that the package is transported in an appropriate manner. The shipper should also verify that the person receiving the hazardous material has verified receipt of the shipment and has not been damaged in transit. The format of this manual has been designed to guide the trained user through the applicable hazardous materials regulations that are associated with biological materials in a sequential fashion.

Section 1: Classification of Biological Materials

The Shipping Regulations have identified the following classes of hazardous materials:

Class 1: Explosives

Class 2: Toxic Gases (Liquid Nitrogen – Non Flammable Gas)

Class 3: Flammable and Combustible Materials (Alcohol, Formaldehyde)

Class 4: Flammable Solids, Spontaneous Combustibles, and Water Reactive Materials

Class 5: Oxidizers and Organic Peroxides

Class 6: Poisonous Materials and Infectious Substances (Toxins, Human and Animal Pathogens)

Class 7: Radioactive Materials

Class 8: Corrosives

Class 9: Miscellaneous Hazardous Materials (Dry Ice, Genetically Modified Microorganisms)

Other Regulated Materials (ORM)

The focus of the guide is on Class 6.2 Infectious Substances and related materials and those other hazardous materials that may be associated with shipments from this hazardous material class. The following classification scheme utilizes current applicable definitions from the US DOT in 49 CFR Part 173.134.

Definitions/Examples of Infectious Substances and Biological Materials

Infectious Substances are materials that are known to or reasonably expected to contain a pathogen. Current regulations apply a ranking scheme to infectious substances based on the probability of causing harm to a person or animal. The ranking scheme is as follows:

Category & UN #	Potential for Harm	Examples
A UN 2814 (human pathogens) UN 2900 (animal pathogens)	High	Human or animal pathogens that are cultured or amplified, such as cultures, stocks, or slants of infectious materials. Yale University also includes any material, including diagnostic or clinical specimens, which contain a Risk Group 4 agent or a Select Agent in this category. See Appendix 2 for a complete list of these high risk agents.
B UN 3373	Moderate	Biological substances, such as diagnostic or clinical specimens from humans or animals that are known to harbor a pathogen or have a high probability of containing a pathogen. At Yale University, biological substances containing or having a high probability of containing a Risk Group 4/BSL-4 agent or a Select Agent cannot be shipped as a Category B infectious substance.
Exempt No UN#	Low	Biological substances that are not known to harbor a pathogen or that have lower probability of containing a pathogen. Most of the general human and animal specimens in research and diagnostic facilities will fall in this category

Category A Infectious Substance – an infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Category A Infectious Substances are assigned the identification number UN 2814 (human pathogens, zoonoses, and prions) or UN 2900 (animal pathogens).

Example: *You wish to ship a vial of HIV culture from a Yale research lab to a collaborating lab in Maryland.*

Ship as: Category A Infectious Substance, Class 6.2 Infectious Agent

Technical Shipping name: UN 2814, Infectious Substance, Affecting Humans (Human Immunodeficiency Virus)

Rationale: This material is amplified and is a known infectious material.

Category B Infectious Substance – an infectious substance that is not in a form generally capable of causing permanent disability of life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Category B Infectious Substances are assigned the identification number UN 3373.

Example: *You have been asked to ship serum specimens from a research protocol that is involved in determining the prevalence of HIV and other bloodborne pathogens among IV drug users. To date, preliminary data show that roughly 45% of those sampled are positive for one of the 3 major bloodborne pathogens (HIV, HBV, or HCV).*

Ship as: Category B Infectious Substance

Technical shipping name: UN 3373, Biological Substance, Category B

Rationale: You either know that these items are infected or have a very high probability of containing a human pathogen. However, as the samples are of clinical/diagnostic origin, they are not cultured or amplified. Therefore you may ship as a biological substance.

Exempt Human or Animal Specimen – human or animal sample (including, but not limited to, secretions, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is low probability the sample is infectious.

Example: *You are conducting a research project investigating the role of elevated cholesterol in heart disease. You are required to ship samples collected in the field here in CT to a testing lab in Indiana for analysis. You will be collecting 10 ml of blood from each test subject.*

Ship as: Exempt Human Specimen

Technical shipping name: Exempt Human Specimen

Rationale: You are not shipping known infectious materials and although the material is of human origin, you also don't have any reason to regard these as having a higher than normal probability of containing an infectious agent. The only way this classification would change is if your study had background pathogen test results on the patient. If you knew that a particular patient had HIV, HBV or some other pathogen, you would be required to ship this as an infectious substance, either Category B or Category A as appropriate.

Other examples or excepted materials that are exempt from the Dangerous Goods Regulations include as specified by the U.S. DOT:

- A material that does not contain an infectious substance or that is 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 non-infectious genetic elements.
- A material containing microorganisms that are non-pathogenic to humans or animals.
- A material containing pathogens that have been neutralized or inactivated.
- A biological product subject to Federal approval, permit, review or licensing requirements, such as those required by the USDA, FDA, and DHHS.
- Blood collected for the purpose of transfusions or preparation of blood products; blood products; plasma; plasma derivatives; blood components; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular and tissue-based products regulated under the FDA or other national authority.
- Dried blood spots or specimens for fecal occult blood detection placed on absorbent filter paper or other material.

Materials of Trade Exceptions

Employees transporting hazardous materials in motor vehicles are not subject to the requirements of the U.S. DOT Hazardous Materials Regulations (HMR) when transporting exempt human or animal specimens and Category B Infectious Substances in a motor vehicle as part of their job duties at Yale. Under this exception, employees do not have to prepare shipping papers, don't have to supply emergency response information, and training records are not required.

Category A Infectious Substances and Select Agents **are not** excluded from the DOT's HMR and additional training and authorizations are required prior to driving either of these materials. Please call OEHS at 785-3550 to arrange for additional training prior to driving Category A Infectious Substances or Select Agents.

According to the DOT HMR (49 CFR Part 173.6), these excepted materials are excluded from the HMR if they "are contained in human or animal samples, including but not limited to secreta, excreta, blood and its components, tissue and tissue fluids, and body parts, when transported for investigational activities or disease treatment or prevention, or its biological product or regulated medical waste."

The DOT's packaging requirements for these excepted materials require containment in combination packaging as follows:

- leak tight packaging for liquids (sift proof for solids)
- sufficient absorbent material to absorb entire contents of inner packaging
- securely closed within a strong outer packaging
- secured against shifting within the vehicle
- protected against damage within the vehicle
- marked with the proper shipping name and label

The amounts allowed are 0.5 kg or 0.5 L per inner package, with a maximum quantity of 4 kg or 4 L per outer packaging. Alternatively, up to 16 kg or 16 L are allowed in a single inner packaging contained in a single outer packaging. The operator of the motor vehicle must be informed of the materials of trade exception information.

Biological Materials Shipping Regulations – Quick Comparison Chart			
	Category A Infectious Substance	Category B Infectious Biological Substance	Exempt Human or Animal Specimen
UN #	2814 – Humans 2900 – Animals	3373	None
Class	6.2	None	None
UN Approved Packaging	YES	NO	NO
Packaging Performance	UN Approved triple packaging. Must be tested and certified packaging.	Triple packaging. Must pass a 1.8 meter or 4 foot drop test. Packages shipped by air must meet a 95 kPa or 14 psi pressure test of primary or secondary container.	None Triple packaging (leak proof primary, leak proof secondary, and sturdy outer container)
Shipper's Declaration Form Needed	YES	NO	NO
Name or Responsible Person on the Package	YES	YES	NO

Classifying Genetically Modified Microorganisms

Under IATA 3.6.2.1.2 category:

(a), genetically modified microorganisms that meet the definition of an infectious substance, must be classified as Class 6.2 Dangerous Goods and assigned UN number 2814 or 2900.

Example: *A recombinant Vesicular Stomatitis Virus vector (lab strain) that will be used to express the envelope protein gene from HIV. Although this is a recombinant virus, it is still in a form that can be infectious to humans or animals. This vector must be shipped as a Category A Infectious Substance, UN 2814.*

(b) covers animals which contain or are contaminated with genetically modified microorganisms that meet the definition of infectious substance and must not be transported by air unless exempted under IATA 2.6.1 by the States concerned.

(c) covers genetically modified microorganisms that are known or suspected to be dangerous to humans, animals or the environment. These are also forbidden in the air unless exempted by the States concerned.

(d) are genetically modified microorganisms which do not meet the definition of infectious substance but which are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction must be classified in Class 9 and assigned to UN 3245.

Example: A replication defective Adenoviral vector that expresses the gene for green fluorescent protein. The packaging sequence has been removed from this vector so it cannot assemble additional virions following the initial infection. However, in this form it can still infect a human or animal cell and transfer the recombinant protein. This vector must be shipped as a Class 9, UN 3245 material (a genetically modified microorganism).

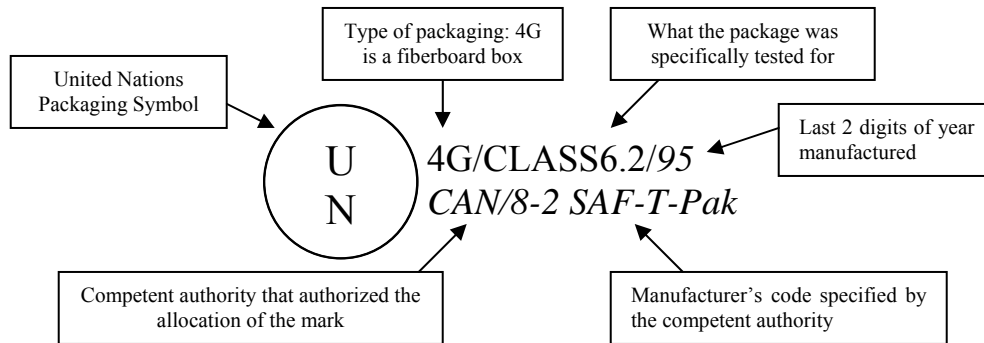
(e) suggests that those samples which do not meet the definition of infectious substance and are not capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction are not subject to the provisions of the regulations.

Example: A recombinant vector used to express various viral envelope genes in *E. coli*. This vector is not capable of infecting and altering a human or animal cell. These materials are exempt from regulation.

Section 2: Packaging Requirements for Regulated Biological Materials

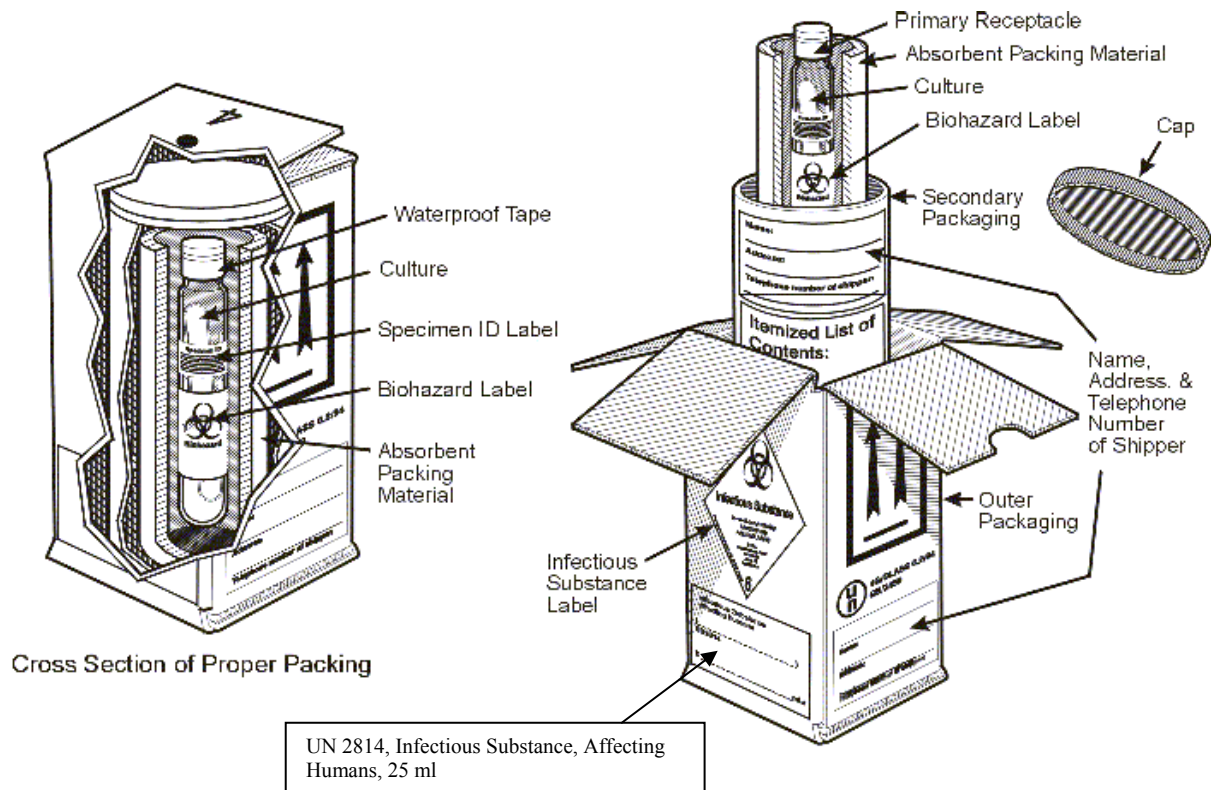
The figure below shows the generalized "triple" (primary receptacle, watertight secondary packaging, and durable outer packaging) packaging required for shipping Category A Infectious Substances. This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must also be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.

Certified packaging will bear a United Nations (UN) mark similar to the following:



Packaging for Category A Infectious Substances

Packaging and Labeling of Category A Infectious Substances, UN 2814 or UN 2900, at ambient temperature.



Packaging Descriptions:

The following packaging criteria are a merger of U.S. DOT, IATA and U.S. Postal Service requirements to ensure compliance with each major requirement.

Specifications of Category A Infectious Substance packaging:

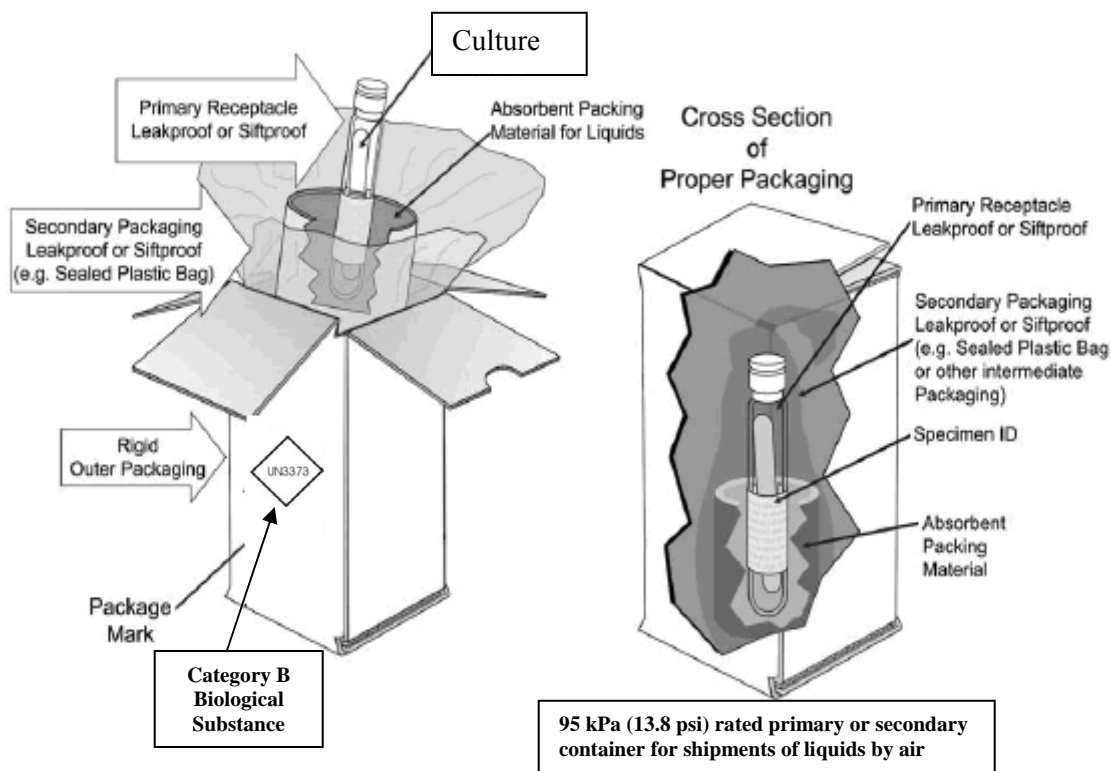
- A watertight primary receptacle.
- A watertight secondary packaging. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either wrapped individually or separated to prevent contact between them.
- A rigid outer packaging (minimum size of 4") of adequate strength for its capacity, mass and intended use.
- For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.
- An itemized list of contents enclosed between the secondary packaging and the outer packaging.
- The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).
- The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding without leakage temperatures in the range of $-40\text{ }^{\circ}\text{C}$ to $+55\text{ }^{\circ}\text{C}$ ($-40\text{ }^{\circ}\text{F}$ to $+131\text{ }^{\circ}\text{F}$).
- The name and phone number of a Responsible Person on the exterior of the package (not the 24 hour emergency number on the Shippers Declaration form, but the name of a person who can be reached during normal business hours, 8:30 AM – 5:00 PM, to respond to questions regarding the package). The names and addresses of the shipper and the consignee (recipient) are also on the exterior of the container.
- The Class 6.2 Infectious Substance Label.
- The technical shipping name and UN number (UN 2814, Infectious Substance, Affecting Humans, 25 ml) with the total net volume of infectious material following the technical name.
- Orientation arrows are included on opposite sides of the package if the net volume of **liquid** infectious materials is $> 50\text{ ml}$.
- **Please note, if the total net quantity of infectious materials exceeds 50 ml or 50 gm, the orange Cargo Only shipping label must be affixed to the package.** Please see Section 3 (Markings and Labels) for additional information on the Cargo Only shipping label.
- If refrigerants such as Dry Ice are used, please use the labels described in Section 3 (Markings and Labels) and Section 8 (Refrigerants).

Very rigorous tests are utilized to verify the performance of Class 6.2 Category A Infectious Substances. Packages that meet these criteria are labeled with the UN mark as indicated above. Only use UN certified packaging for the shipment of these materials. If you have any questions regarding your Class 6.2 Category A Infectious Substance packaging, please call OEHS at 785-3550 for an evaluation.

Please also consult the Section 6 (Security) and Section 7 (Emergency Response) to ensure that the appropriate precautions are taken with the package before, during and upon receipt of the hazardous materials package. Both the 24 hour emergency contact phone number and the phone number for the Responsible Person may be contacted in the event of an incident.

Packaging for Category B Biological Substances

Packaging and Labeling of a Category B Biological Substance, at ambient temperature.



Specifications of Category B Biological Substances include:

- Leak proof primary container
- Absorbent material placed between the primary receptacle and secondary packaging (enough absorbent to absorb the entire contents of the primary receptacles)
- Cushioning in between primary receptacles.
- For air shipments: primary receptacles may not exceed 1 L and each package may not exceed 4 L.
- For shipments of liquid by air, the primary or secondary container must be capable of withstanding a pressure of 95 kPa (13.8 psi) and temperatures between (-40 F to 130 F). **Please note that plastic bags can be used as secondary containers for liquids, but they must be of sufficient strength to pass the 95 kPa pressure test. Please contact OEHS at 785-3550 to have your packaging evaluated if you have any questions or to see an example of a 95 kPa rated secondary plastic bag or solid walled container.**
- Secondary packaging secured in rigid outer packaging (at least 4 inches in width).
- A list of contents in between the secondary and outer rigid shipping container.
- The packaging must be capable of passing the drop tests specified by the DOT from a height of 4 feet, without leaking its contents.
- Outer packaging must include the Category B Biological Substance UN 3373 label.
- The name and phone number of a “Responsible Person” must be placed on the outer container. This is not the 24 hour Emergency phone number on the Shippers Declaration form, but the phone number

of a person who can be reached during normal business hours (8:30 AM – 5:00 PM) to answer questions about the package.

- The UN 3373 Category B Biological Substance Label (which labels the package and includes the technical name for the shipment). Refer to Section 3 (Markings and Labels) for a description of the UN 3373 label.
- Orientation arrows on either side of the package must be utilized if the net quantity of **liquid** Category B Biological Substances is > 50 ml.
- If refrigerants such as Dry Ice are utilized, please refer to Section 3 (Markings and Labels) and Section 8 (Refrigerants).

The entire package must be capable of passing a series of 4' drop tests as specified by U.S. DOT and IATA, but the tests are much less stringent than Class 6.2 UN Approved infectious substance packaging.

Specifications of Exempt Human (and Animal) Specimen Packaging:

The following criteria are a combination of U.S. DOT, IATA, and the U.S. Postal Service requirements for the shipment and transport of Exempt Human Specimens.

- A leak proof primary container, with sufficient cushioning and absorbent material to surround each primary container that contains liquid. The cushioning will prevent individual containers from damaging each other.
- A leak proof secondary container to house the primary containers with enough absorbent inside this container to absorb the entire liquid contents of the package if all were released. Sealed 50 ml conical plastic tubes, sealed plastic bags and other sealed plastic containers are examples of suitable plastic containers that are probably present within your research or diagnostic clinical laboratory for use with Exempt shipments. **The secondary container cannot serve as the outer shipping container for these specimens.**
- The universal biohazard symbol must be placed on the outside of the secondary container. An orange biohazard sticker can be affixed to the secondary container, or a bag that is pre-labeled with the universal biohazard symbol.
- The secondary container must fit snugly inside the outer rigid shipping container to prevent to prevent excessive movement during shipment, which could damage the primary containers.
- The outer rigid shipping container can be a fiberboard or plastic box. The outside of the container must be labeled with an "EXEMPT HUMAN SPECIMEN" or an "EXEMPT ANIMAL SPECIMEN" label. Please refer to Section 3 (Markings and Labels) for additional information on Exempt Specimens. The Exempt Specimen Labels are required by IATA. DOT does not require the exterior label, but the Exempt Specimen label can be used. The U.S. Postal Service will accept either the Exempt Specimen label or the universal biohazard label. The OSHA Bloodborne Pathogens Standard does require the universal biohazard label on all containers of human blood or other potentially infectious materials, but this label is not required if one of the three shipping labels are affixed (Class 6.2 Infectious Substances label, UN 3373 Category B Biological Substances Label, or the EXEMPT HUMAN SPECIMEN label).

There are not test specifications for the EXEMPT HUMAN (OR ANIMAL) SPECIMEN packaging. This indicates that the shipper can assemble their own materials for shipment rather than purchase a complete shipper (as required for Category A Infectious Substance shipments), or purchase specific components (such as the 95 kPa rated primary or secondary container required for liquid Category B Biological Substance shipments when sent by air). However, OEHS recommends that the complete packaging created for Exempt shipments be able to pass a basic 4 foot drop test by the Shipper. For example, if the sealed Exempt Human Specimen package were to be dropped from shoulder height to a solid floor, the primary container would be break or leak.

Shipping Genetically Modified Microorganisms

Genetically modified microorganisms are regulated by IATA but are not discussed by the DOT. Technically, IATA regulations must be followed on any international flight and recommended for flights within the U.S. Yale University recommends that the IATA regulations be followed for all shipments of genetically modified microorganisms regardless of destination. This conservative measure will help to ensure compliance with the myriad of regulations.

Category (a) shipments must be classified as infectious and are subject to all the Class 6.2 regulations involved. Follow all the standard steps for packaging, marking, labeling, and documenting the shipment as an infectious substance. Use the name of the organism as the technical name.

Categories (b) and (c) are forbidden unless exempted. For exempted shipments, "every effort is to be made to achieve an overall level of safety in transport which is equivalent to the Regulations." Call the Biosafety Office prior to shipping any category (b) or (c) materials.

Category (e) is not restricted. We suggest following packaging instructions for exempt human or animal specimens.

Category (d) may cause shippers some confusion as air transport regulations for genetically modified organisms (GMO's) and genetically modified microorganisms (GMMO's) indicate that these packages be shipped similar to infectious substances. However, the infectious substance label and shipping declaration forms ARE NOT required. To avoid confusion and reduce the possibilities of using inappropriate packaging, follow the requirements for infectious substance packaging (but a UN approved shipping container is not required).

To ship category (d) materials in compliance with the air transport regulations, the following steps are necessary:








- Documentation must include
 - Proper Shipping Name (Genetically modified micro-organisms)
 - Class (Class 9), the UN number (UN 3245)
 - Quantity and type of packaging
 - Packing Instruction (PI 913)
 - Statement "Prepared according to ICAO/IATA" in the Additional Handling Information box.
- All package markings are to be completed as per IATA 7.1 and a Class 9 Miscellaneous Hazard label attached instead of the infectious substance label. When shipping genetically modified microorganisms in category (d), primaries must not exceed 100mL or 100g however there is no limit to the overall quantity in a single package shipped on either passenger or cargo aircraft.

Briefly then, category (a) must be shipped with full compliance to Class 6.2, infectious substance. Categories (b) and (c) can be shipped only when exempted under IATA 2.6.1. Category (e) is not restricted and category (d) must follow Packing Instruction 913 with proper packaging, documentation, marking, and labeling.

Section 3: Markings and Labels

All packages of hazardous materials share basic markings, such as the name, address and contact information of the shipper (consignor), recipient (consignee) and the responsible person. In addition to these mailing markings, hazardous materials packages will be marked with the specific UN number, the proper shipping name for the hazard, and the net quantity of the enclosed hazard. Orientation arrows are required on two opposite vertical sides of packages of all Category A and B Infectious Substances that contain liquids in excess of 50ml. Arrows must point in the correct upright direction. The orientation arrows are black or red on white background or other suitable contrasting color. Hazardous materials packages will also contain the United Nations packaging symbol with codes and abbreviations signifying the type of package, what it may be used for, and the year of manufacturer.

Labels provide a description of the type of hazard contained within the package. Labels relevant to the shipment of biological materials are shown and described below.

Shipping Label	Color(s)	Description
	Black on white	Class 6.2 Infectious Substance label for Category A Infectious Substances. UN 2814 (Infectious Substance, Affecting Humans) or UN 2900 (Infectious Substance, Affecting Animals) as appropriate. Note: the Technical name should NOT be marked on the outside of Class 6.2 containers.
	Black letters on white	Category B Infectious Substance label, UN 3373, Category B Biological Substance. For diagnostic and clinical specimens known to contain or that have a high probability of containing a human or animal pathogen.
	Black on white	Class 9 label. Use for shipments containing Dry Ice (Carbon Dioxide, Solid), UN 1845, with Net Quantity in kg. Also use for Genetically Modified Microorganisms, UN 3245.
	Green & White or Green & Black	UN 1977, Non-Flammable Gas, Liquid Nitrogen, with Net Quantity in liters.
	Green & White	Cryogenic liquid label, used for shipments containing Liquid Nitrogen.
	Red or black on white or contrasting color	Orientation arrows for packages of Category A and B Infectious Substances containing liquids in excess of 50 ml. Placed on 2 opposite sides of the package.
	Orange on black	Cargo Aircraft Only shipping label. For quantities of hazardous materials that exceed the Passenger/Cargo Aircraft quantity limits per outer package. (> 50 ml for > 50 g of a Category A infectious substance).

Maximum Quantities for Passenger and Cargo Aircraft

UN or ID Number	Type of Material	Cargo Section of Passenger Aircraft Maximum Quantity per Package	Cargo Aircraft Maximum Quantity per Package
2814	Infectious substance, affecting humans Liquid material	50 ml	4 L
2814	Infectious substance, affecting humans Solid material	50 gm	4 Kg
2900	Infectious substance, affecting animals Liquid material	50 ml	4 L
2900	Infectious substance, affecting animals Solid material	50 gm	4 Kg
2810	Toxic liquid, organic, n.o.s.	1 L	30 L
2811	Toxic solid, organic, n.o.s.	5 Kg	50 Kg
3172	Toxins, liquid, extracted from living sources, n.o.s	1 L	30 L
3172	Toxins, solid, extracted from living sources, n.o.s	5 Kg	50 Kg
3245	Genetically modified micro-organisms	No Limit	No Limit
1845	Carbon dioxide, solid	200 Kg	200 Kg

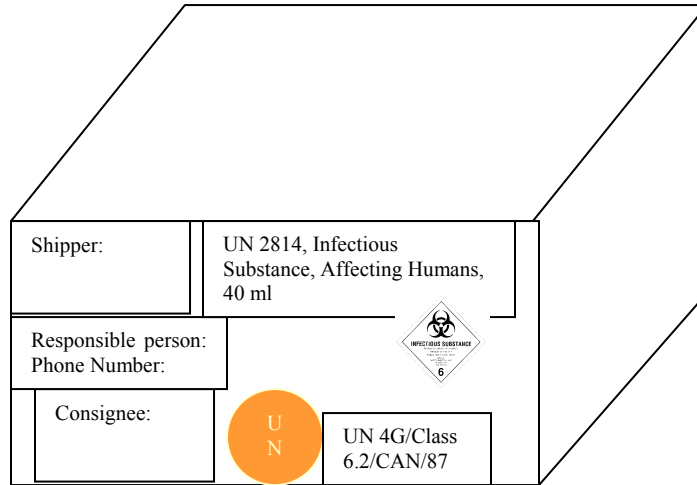
All packages exceeding the quantity limitations for passenger aircraft, but acceptable on cargo aircraft, must also be labeled with the “Cargo Aircraft Only” label (as shown below).



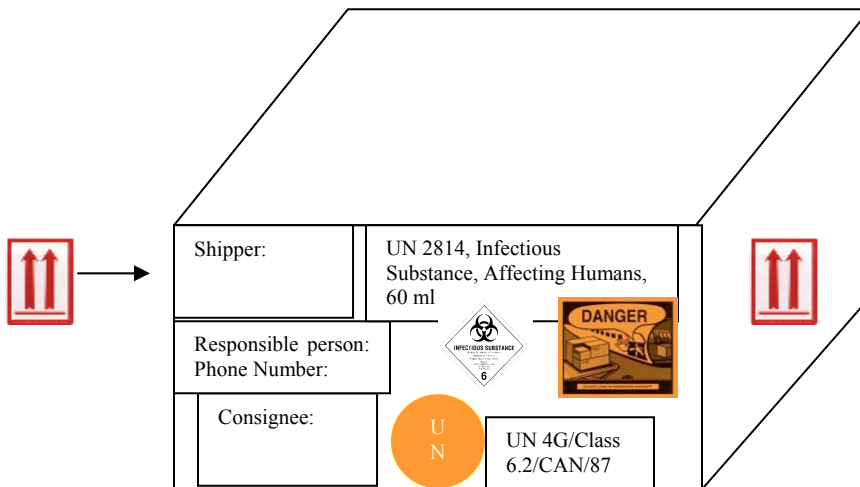
The above label is orange on a black background.

Labels are affixed to any of the surfaces of the package other than the bottom. Labels must be near the proper shipping name and subsidiary labels must be placed next to each other. Example markings and labels for various hazardous materials packages containing biohazards are provided below.

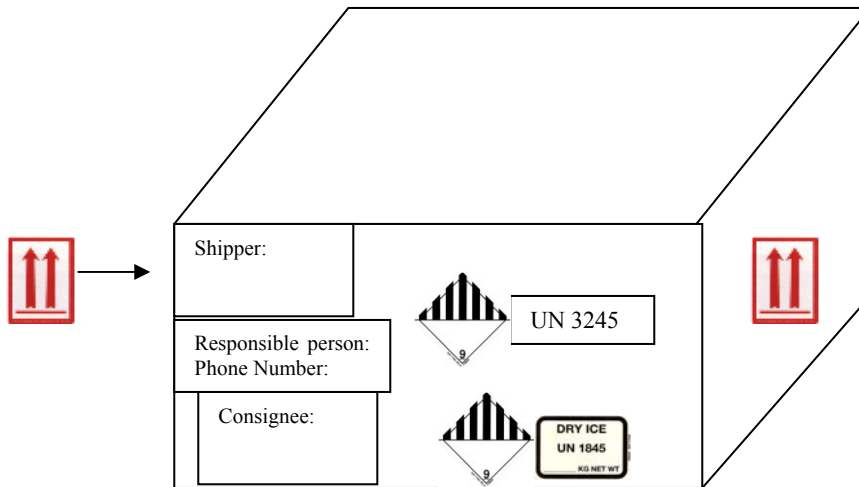
Human Pathogen Shipment (≤ 50 ml)



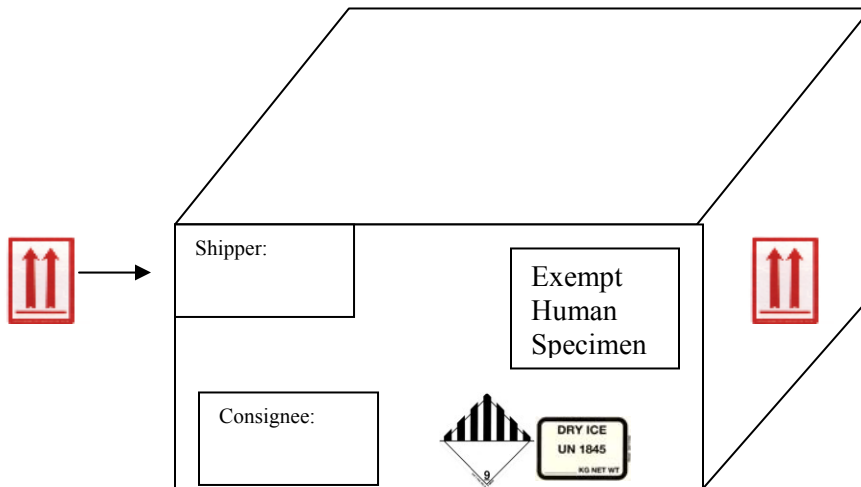
Human Pathogen Shipment (> 50 ml)



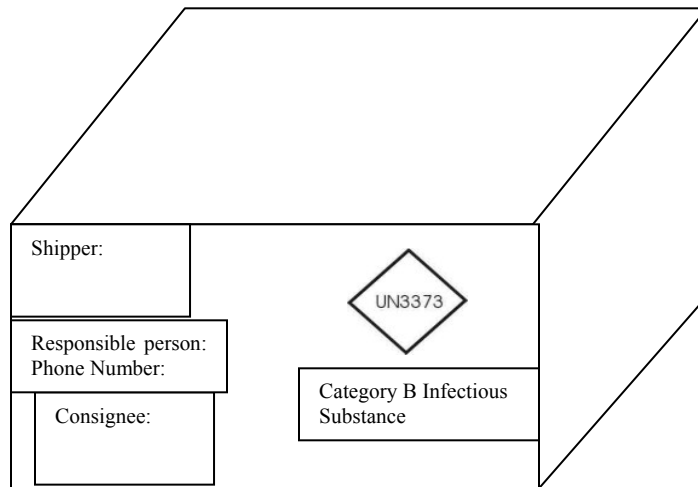
Shipping a Genetically Modified Microorganism (i.e. a replication defective viral vector capable of altering a cell in its current form) on Dry Ice (net quantity of specimen > 50 ml)



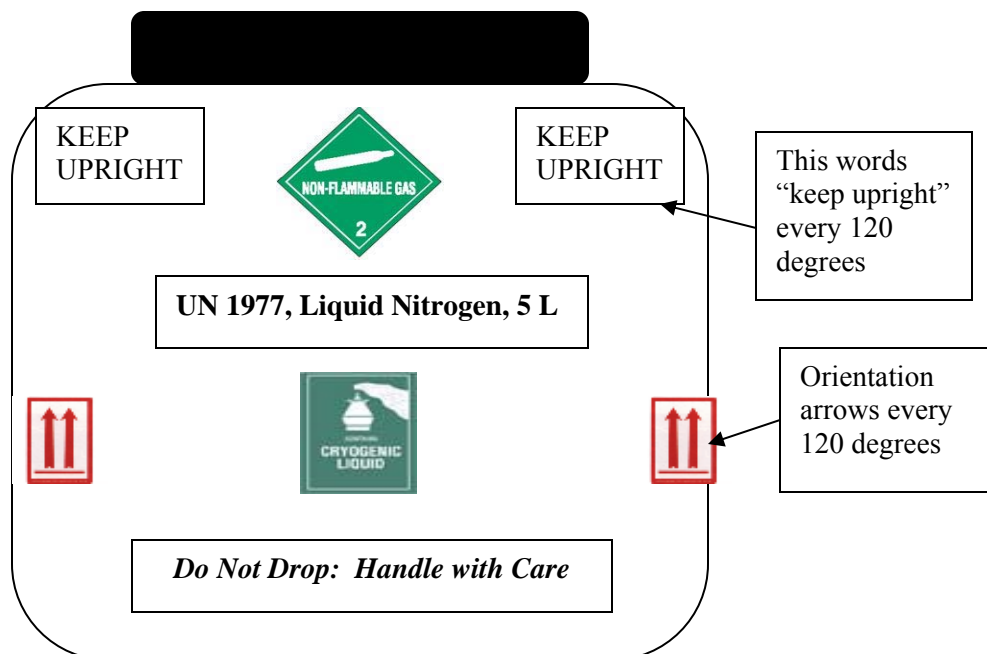
Shipment of an Exempt Human Specimen (or Exempt Animal Specimen) > 50 ml on Dry Ice



Shipment of Category B Biological Substance (diagnostic/clinical specimen known to harbor an infectious agent) < 50 ml



Shipment of Liquid Nitrogen:



Section 4: Shipping Papers

When shipping infectious substances, toxic substances, or genetically modified microorganisms that meet the definition of an infectious substance, a Shipper's Declaration of Dangerous Goods (Shipper's Declaration) is required. The Shipper's Declaration is a legal document completed and signed by the shipper. There must be no spelling errors and the Shipper's Declaration must be completed in one person's hand writing using the same pen, or typed. There are three items on the Shipper's Declaration that may be completed or modified by the carrier: the Airway Bill Number, Airport of Departure and Airport of Destination.

Completing the Shipper's Declaration

1. Shipper:

Enter the full name and address of the shipper as well as a phone number.

2. Consignee:

Enter the full name and phone number of the consignee (recipient) as well as the **name and phone number of a responsible person**. The responsible person has knowledge of the materials shipped and has provided their phone number on the Shipper's Declaration form for acceptance of questions during normal business hours (8:30 AM to 5:00 PM). This is not a replacement of the required 24-hour emergency response number required in the lower half of the form.

3. Airway Bill Number:

Enter the appropriate airway bill number. This information may be entered or amended by the accepting operator.

4. Page_of_Pages

Enter the appropriate page number and the total number of pages of the Shipper's Declaration

5. Type of Aircraft (Quantity Limit):

Delete the box that does not apply by striking it out (> 50 ml or > 50 g of a Category A Infectious Substance will require shipment on Cargo Aircraft Only. Quantities below this limit are allowed on the cargo sections of Passenger Aircraft.

6. Airport of Departure:

Enter the full name of the airport or city of departure. This information may be entered or amended by the carrier.

7. Airport of Destination:

Enter the full name of the airport or city of destination. This information may be entered or amended by the carrier.

8. Shipment Type:

Delete the box that does not apply by striking it out. Invariably, the word Radioactive will be deleted (marked out) as this guide deals with the regulatory transport of infectious substances.

9. Nature and Quantity of Dangerous Goods:

The correct completion of this section is the most important part of the Shipper's Declaration

a. Dangerous Goods Identification:

i. Class or Division, UN or ID Number and Packing Group
(see the table below for the appropriate UN#)

ii. Proper Shipping Name:

Enter the proper shipping name followed by the technical name in brackets. For example:
Infectious Substance, affecting humans (Hepatitis B virus)

Shipping Name	Class	UN Number	Packing Group
Infectious Substance, affecting humans (<i>technical name</i>)	6.2	UN2814	None, leave blank
Infectious Substance, affecting animals	6.2	UN2900	None, leave blank

<i>(technical name)</i>			
Liquid Nitrogen	2.2	UN1977	None, leave blank
Toxic liquid, organic, n.o.s.	6.1	UN2810	I, II or III
Toxic solid, organic, n.o.s	6.1	UN2811	I, II or III
Toxins, liquid, extracted from living sources, n.o.s	6.1	UN3172	I, II or III
Toxins, solid, extracted from living sources, n.o.s	6.1	UN3172	I, II or III
Genetically modified micro-organisms	9	UN3245	None, leave blank
Dry ice	9	UN1845	III

- iii. **Subsidiary Risk:**
There are no subsidiary risks for any of the above.

b. Quantity and Type of Packing:

Enter the total quantity of each dangerous good and the type of material the outer box is made from. For example, 20 ml total (Four 5 ml tubes) and 10 kg of Dry Ice, all packed in one fiberboard box).

c. Packing Instruction:

Enter the packing instruction from the list below:

Shipping Name	Packing Instruction for Passenger Aircraft Quantities	Packing Instruction for Cargo Aircraft Quantity
Infectious Substance, affecting humans (<i>technical name</i>)	602	602
Infectious Substance, affecting animals (<i>technical name</i>)	602	602
Toxic liquid, organic, n.o.s. (<i>technical name</i>)	603	604
Toxic solid, organic, n.o.s (<i>technical name</i>)	606	607
Toxins, liquid, extracted from living sources, n.o.s (<i>technical name</i>)	603	604
Toxins, Solid, extracted from living sources, n.o.s (<i>technical name</i>)	606	607
Genetically modified micro-organisms	913	913
Dry ice	904	904
Liquid Nitrogen	202	202

d. Authorization:

Leave Blank

10. Additional Information:

Enter the following:

- a. An emergency phone number that is manned 24 hours a day by a person knowledgeable about the emergency response requirements for the material being shipped. Yale University has contracted CHEMTREC to serve as an initial contact to provide emergency response information for shipments of hazardous materials from Yale University.
- b. CHEMTREC:
1300 Wilson Blvd.
Arlington, VA 22209
FAX: 703-741-6089

24-hour emergency numbers for use on Shipper's Declaration:

Shipments within USA - 800-424-9300

International shipments - 703-527-3887

c. Certification

The Shipper's Declaration Form must contain the following certification statement in the lower section of the form:

"I hereby declare that the contents of this consignment are fully accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable transport regulations have been met." Most Shipping Declaration forms will contain this statement pre-printed on the form.

d. Name/Title of Signatory

The name and job title of the individual who completed the Shipper's Declaration form.

e. Place and Date:

Enter the place and date of signing

f. Signature:

Only the trained person who actually packaged the container being offered for shipment can sign the Shipper's Declaration. The name of the official "Shipper" in the top left hand corner of the Shipper's Declaration Form may be a different person than the "packager," (i.e. the Shipper can be the Laboratory Director or the Principal Investigator). The person completing the Shipper's Declaration form must have also packaged the hazardous materials.

The Shipping Declaration Form must be **maintained for 2 years** by the shipper and the hazardous materials employer will also maintain a copy for institutional record keeping purposes. A sample completed Shipper's Declaration Form is provided below.

A Shipper's Declaration form **is not required for Category B Biological Substances.**

Shipper's Declaration Forms must be legible (printed very neatly or typed). Please note, that certain carriers, such as FedEx will only accept Shipper's Declaration forms if they are typed.

When hazardous materials that require Shipper's Declaration forms and materials that don't require forms are shipped together, list the hazardous materials first on the Shipper's Declaration form.

Note that individual carriers may have requirements that are more conservative than the existing regulations. For example, **FedEx requires 3 copies of the Shipper's Declaration Form and they will not accept the forms if they are not typed.**

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least two copies to the airline)

Responsible person: _____ phone _____

Air Waybill No. _____
 Page 1 Of _____ Pages
 Shipper's Reference Number _____
 (optional)

Consignee

FedEx
 Federal Express

Two completed and signed copies of this Declaration must be handed to the carrier.

TRANSPORT

XXXX

This shipment is within the limitations prescribed for: (delete non-applicable)

Airport of Departure

PASSENGER AND CARGO AIRCRAFT

CARGO AIRCRAFT ONLY

Airport of Destination:

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any case, be completed and/or signed by a person who is not a forwarder, or an IATA cargo agent.

XXXXXXXXXX

Shipment type: (delete non-applicable)

NON-RADIOACTIVE

RADIOACTIVE

Dangerous Goods Identification

UN or I No.	Proper Shipping Name	Class or Division (Subsidiary risk)	Packing Group	Quantity and type of packaging	Packing Inst.	Authorization
2814	Infectious substance, affecting humans (Human Immunodeficiency virus)	6.2	---	40 ml in twenty 2 ml tubes	602	---
1845	Dry Ice	9	III	20 kg All packed in one fiberboard box	904	---

Additional Handling Information:

Emergency Telephone Number: CHEMTREC (800) 424-9300

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 labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national Governmental Regulations.

Name/Title of Signatory

John Smith, Lab Manager

Place and Date

New Haven, CT

Signature **John Smith**

(see warning above)

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH MEDICAL DIAGNOSIS OR TREATMENT

Shipping Declaration Form Quick Guide

Shipping Declaration Form Quick Guide		
Material	Class and/or UN#	Declaration Form Needed?
Category A Infectious Substances	UN 2814, UN 2900	YES
Category B Infectious Substances	UN 3373	NO
Exempt Human or Animal Specimens	None	NO
Dry Ice (Carbon Dioxide, Solid)	UN 1845	NO (but add to shipping declaration form as a subsidiary risk if being shipped with a hazardous material that requires a shipping declaration form).
Liquid Nitrogen	UN 1977	YES

Section 5: Permits for Restricted Shipments and Transfers

Certain hazardous materials are restricted from transfer into or out of the United States. Importation permits or an export permit must be obtained prior to the shipment of these restricted items. Multiple U.S. regulatory agencies hold authority for granting these permits. The importation or export permit, together with the appropriate package and labeling will expedite the clearance of the package through the U.S. Public Health Service Division of Quarantine and release by U.S. Customs. Agencies that regulate the import and export of infectious substances and related biological substances and/or materials that may contain infectious substances are reviewed below.

Infectious Substance (human pathogens) Import Permit Program

The U.S. Department of Health and Human Services, Centers for Disease Control and Prevention regulate the importation of hazardous biological materials into the United States. Federal Regulation USPHS 42 CFR Part 71 (Foreign Quarantine) govern the importation of human pathogens, hosts, and vectors. Etiologic agents of human disease and materials containing these agents imported in the country must be accompanied by a U.S. Public Health Service importation permit. These materials will not be allowed into the country without a permit issued by the Director. Permits are issued to the importer within the U.S., who will take responsibility for all aspects of the hazardous materials shipment (packaging, labeling, transport, training, and obtaining all applicable permits). The person requesting the permit must also be knowledgeable and skilled in the handling of the infectious agent or biological material. The permittee is also responsible for awareness of the permit's restrictions as provided on the permit itself. Many permits do not allow the transfer of the material to another person, location or entity without prior federal approval.

Items that require a USPHS Importation permit:

- Etiologic Agents. Any infectious agent known or suspected to cause disease in humans.
- Biological Materials. Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing a human infectious or etiologic agent.
- Hosts and Vectors.
 - Animals. Any animal known or suspected of being infected with an organism capable of causing disease in humans may require a permit issued by the CDC.
 - Turtles. Live turtles less than 4 inches in shell length require an import permit from the CDC Division of Global Migration and Quarantine (phone: 404-498-1600) and web: <http://www.cdc.gov/ncidod/dq>.
 - Non-Human Primates. Importation of live non-human primates also require an import permit from the CDC Division of Global Migration and Quarantine (phone: 404-498-1600) and web: <http://www.cdc.gov/ncidod/dq>.
 - Arthropods. Any living insect or other arthropod that is known or suspected of containing an etiologic agent (human pathogen) requires a CDC import permit.
 - Snails. Snail species capable of transmitting a human pathogen.
 - Bats. All live bats require an import permit from the CDC **AND** the U.S. Department of the Interior, Fish and Wildlife Services.

CDC Import Permits for Human Pathogens are available on the web at <http://www.cdc.gov/od/eaipp>. Call OEHS (785-3550) or the CDC Etiologic Agent Import Permit Program (404-718-2077) if you have any questions regarding an import permit for human pathogens (etiologic agents) or biological materials that may harbor a human pathogen.

Animal Pathogens and Related Biological Materials Import Permit Program

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) permits are required for infectious agents of livestock and biological materials containing animal material. Tissue culture materials and suspensions of cell culture grown pathogens containing growth stimulants of bovine or other livestock agents are controlled by the USDA due to the potential risk of introduction of exotic animal diseases into the U.S. The National Center for Import and Export (NCIE) plays an integral role in USDA APHIS' mission of protecting American agriculture. NCIE is responsible for monitoring the health of animals' presented at the border and for also regulating the import and export of animals, animal products, and biologics.

Material derived from any animal is potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Customs and Border Protection (DHS, CBP) Agricultural Specialists at the U.S. port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing exotic animal diseases into the United States.

USDA APHIS permit applications may be obtained several ways: On-line at: <http://www.aphis.usda.gov/vs/ncie/>, or by writing to:

USDA, APHIS, VS,
National Center for Import and Export
4700 River Road, Unit 40
Riverdale, MD 20737
(301) 734-3277 telephone
(301) 734-8226 fax

Current USDA APHIS Forms include:

- VS 16-3. Import Controlled Material or Transport Organisms or Vectors.
- VS 16-7. Additional Information for Cell Cultures and Their Products – Supplement to VS 16-3.
- VS 17-129. Application for Import or in Transit Permit (for Live Animals, Semen or Embryos)

Certain materials do not need a USDA import permit, but will be reviewed at the port of entry by USDA inspectors. To facilitate import, the USDA has prepared fact sheets for the following materials that will not require a USDA import permit if they are free from animal pathogens or suspect pathogenic materials. Consult the specific fact sheet for each item at the USDA website to ensure that all of the criteria needed to exclude the requirement for an import permit are met AND to identify if a permit may be required by another agency. For the complete fact sheet on each of these materials, refer to the following website: http://www.aphis.usda.gov/vs/ncie/fac_imp.html

- Human Pharmaceuticals and Human Vaccines Containing Animal Components
- Human and Non-Human Primate Material (excluding cell cultures)
- Feline and Canine Material
- Live Laboratory Mammals and Their Material (for research purposes)
- Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom)
- Chemically Synthesized Materials
- Microbially Produced Materials
- Recombinant Microbes and Their Products

- Non-pathogenic Microorganisms
- Pet Chews
- Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)
- Test Kits
- Animal Feeds, Feed Supplements, and Pre-Mixes

In addition, material from humans and non-human primates that: (a) are not produced in tissue culture, (b) are not actual zoonotic (affects humans and animals) pathogens, and (c) are not potential zoonotic pathogens may enter the country without USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) restrictions. However, the Centers for Disease Control (CDC) has jurisdiction over human and non-human primate material. The CDC can be contacted by telephoning: (404) 639-3534, (404) 639-3311, (404) 311-3435 or (404) 639-4537.

The exclusion criteria to waive the USDA import permit requirement for the materials indicated above and material from humans non-human primates require that the materials: (a) are not produced in tissue culture, (b) are not actual zoonotic (affects humans and animals) pathogens, and (c) are not potential zoonotic pathogens.

In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, AHPIS, VS recommends that the following documentation accompany each shipment:

1. A detailed and accurate description of the material, with species identification.
2. A written statement confirming that the material was not obtained from humans or non-human primates that have been inoculated with or exposed to any livestock* or poultry disease agent exotic to the United States.
3. A written statement confirming that the material is not of tissue culture origin.
4. A written statement confirming that the material is not zoonotic.

USDA, APHIS, VS recommends that this document be supplied on foreign producer/shipper letterhead, with the letterhead containing the physical address of the foreign producer/shipper. USDA, APHIS, VS further recommends that the document, written in a clear and concise manner, accompany each shipment, and be presented as a separate document for review by the DHS, CBP Agricultural Specialists at the U.S. port of arrival. Do not place this document inside the shipping container.

Countries may change their import requirements without notice. **In all cases, the exporter has the responsibility of having their importer confirm with the Ministry of Animal Health in the importing country the import requirements prior to shipping.**

Call OEHS (785-3550) or the USDA APHIS (301-734-7834) for any questions regarding USDA APHIS Import permits.

Importing a Plant Pathogen or Plant Product

USDA/APHIS Plant Protection and Quarantine (PPQ):

The USDA/APHIS Plant Protection and Quarantine (PPQ) Department regulates the importation (and exportation) of organisms and products that directly or indirectly cause disease or damage in plants. Organism permits are required for the importation and interstate movement of plant pathogens under the federal regulation 7 CFR Part 330. Plant pathogens include nematodes, bacteria, fungi, viruses, viroids, phytoplasmas, or any organisms similar to or associated with these infectious substances.

- **PPQ Permit 526** must be completed to request permission to import these plant pathogens into the U.S. Permit 526 is for movement, possession and environmental release of plant pests, plant pathogens, biological control agents, bees, parasitic plants, and noxious weeds.
- **PPQ Permit 587**: Application for a permit to import plants or plant products.
- **PPQ Permit 588**: Application for a permit to import prohibited plants or plant products for experimental purposes.

Permits 526, 587, 588 and related plant product permits are accessible on the web at:

http://www.aphis.usda.gov/plant_health/permits

Questions can be forwarded to USDA APHIS PPQ Permit Services at (301) 734-0841 or (877) 770-5990, or by email to Permits@aphis.usda.gov.

Plant Pathogen applications that meet the following qualifications will be processed expeditiously:

- Application must contain ONLY organisms stated on the widely prevalent pathogen lists for the destination State;
- Application must be for interstate movement, not from foreign sources imported into the United States;
- Organisms must be of domestic origin, not foreign isolates of organisms on the lists;
- Organisms must not be for environmental release.

<http://www.aphis.usda.gov/ppq/permits/plantpest/>

U. S. Fish and Wildlife and CITES Endangered Species Permits

U.S. Fish and Wildlife Service (USFWS) provides international import/export permits for endangered species, wildlife, reptiles, Convention on International Trade in Endangered Species (CITES), plants, pet birds, circus animals, sport-hunted trophies, museum specimens, and exhibits for scientific exchange. A permit is required for individuals or businesses that import or export wildlife. Permits are valid for one year and must be obtained prior to importing or exporting. Please check the US Fish and Wildlife website: <http://www.fws.gov/> and <http://www.fws.gov/permits>.

U.S. Fish and Wildlife Service, Division of Management Authority
4401 N. Fairfax Drive, Room 700
ARLINGTON, VA 22203-3247
358 2093 or (703) 358 2095

Phone: (703)

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is an international agreement between governments. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival. Around 25,000 plant species and 5,000 animal species are covered by the provisions of the Convention. To examine if a species of animal or plant is covered under CITES and will require an import or export permit, please check: <http://www.aphis.usda.gov/ppq> and <http://www.fws.gov/endangered/wildlife.html>.

Exports of Infectious Materials and Biological Substances

The export of a wide variety of infectious substances for humans, animal, and plants may require a license from the U.S. Department of Commerce (DoC). The DoC Bureau of Export Administration is responsible for issuing the export licenses (<http://www.bis.doc.gov/Licensing/>). The first step in determining if an export license is needed is to classify the items that will be exported. If an Export Control Classification Number (ECCN) has been assigned to the item, then an export license will be required. The ECCN's are used to categorize the items that are covered under the DoC's Export Administration Regulations (EAR). **The most current version of the EAR is available online at <http://www.bis.doc.gov>, under "Key Resources" click on Export Administration Regulations.**

The type of material, the destination and the proposed recipient are all subject to approval by the Bureau of Industry and Security (BIS). If either of these elements (material, destination, recipient) are under the control of the EAR, then an export license will be required. "The Bureau of Industry and Security (BIS) is responsible for implementing and enforcing the Export Administration Regulations (EAR), which regulate the export and reexport of most commercial items. We often refer to the items that BIS regulates as "dual-use" - items that have both commercial and military or proliferation applications - but purely commercial items without an obvious military use are also subject to the EAR. The EAR do not control all goods, services, and technologies. Other U.S. government agencies regulate more specialized exports. For example, the U.S. Department of State has authority over defense articles and defense services."

There are three ways to determine the ECCN for your item. First, contact the manufacturer of the item to attempt to gain this information. Consult the EAR, Federal Code of Regulations, 15 CFR Parts 730-774 to find the ECCN from the Commerce Control List (CCL), in part 774 of the EAR. Also check the CCL use instructions in 15 CFR Part 738. Finally, you can request an official classification of the item on a Bureau of Export Administration (BXA) multipurpose application form (BXA-748P). **Forms can be obtained at <http://www.bis.doc.gov/Licensing/> or by calling the DoC Bureau of Export Administration at (202) 482-4811.**

The following related materials and their ECCN's from 15 CFR 774:

- ECCN 1C351 – Microorganisms (biological agents that could be used in the production of biological weapons).
- ECCN 1C350 – Chemicals (15 CFR 742 lists chemical weapons)
- ECCN 1C991 - Toxins

Toxins, genetically modified microorganisms and pathogens (human, animal and plant pathogens) on the current CCL that require a DoC Permit are listed in Appendix 3 of this manual.

Countries that are not currently eligible to receive materials regulated by the DoC include:

- Cuba
- Iran
- Iraq
- Libya
- North Korea
- Sudan
- Syria

The country list (and also restricted personnel) are subject to change daily by the BIS and verification can be obtained by contacting OEHS at 785-3550 for assistance or by calling the DoC Bureau of Export Administration at (202) 482-4811.

Additional items that require a DoC export license as listed in 15 CFR Parts 742 and 774 include equipment capable of use in handling biological materials classified as CCL 2B352. This includes but is not limited to the following materials:

- Isolators, anaerobic chambers, and glove boxes
- Fermentation vessels \geq 100 liters
- Centrifugal separators, decanters (\geq 100 L per hour)
- Cross flow filtration equipment
- Steam sterilizable freeze drying equipment
- P3/P4 (BSL-3/BSL-4) containment equipment or housing
- Full or $\frac{1}{2}$ protective ventilated suits
- Class III Biological Safety Cabinets or similar devices

Please note that many countries require import permits or licenses similar to the United States. Canada, Germany, Australia, New Zealand and other countries also place restrictions on what may cross their borders. If you do receive an export permit or are sending biological materials that do not require an export permit to a colleague, please have them check if their country requires an import permit. The other countries import permit must be mailed to the shipper who will affix it to the package in order for it to clear customs heading into that country.

An Export License must be obtained for each export shipment. Failure to comply with the regulations can result in adverse publicity, loss of export privileges, fines, and imprisonment. The EAR website: <http://www.gpo.gov/bis>

Federal Register website for the EAR: http://w3.access.gpo.gov/bis/fedreg/ear_fedreg.html

Apply for a license as soon as you have a proposed regulated export. Don't wait until the last minute. Use proper, up-to-date forms available from the Outreach and Educational Services Division in Washington, D.C. by calling (202) 482-4811, or BIS's Outreach and Educational Services Division at (202) 482-4811.

Section 6: Security Awareness

All employees handling hazardous materials in the transport chain must be provided with general security awareness training. Those employees handling and transporting Select Agents or bulk amounts that require a placard or exceed 3,500 gallons must receive enhanced security training. Individuals in this category cannot participate in a shipment until they have satisfied all applicable Yale safety and security trainings and have been cleared for this work.

Disgruntled or nefarious individuals have used hazardous materials from research and clinical laboratories with harmful and lethal results over the past 25 years on U.S. soil. A cult in Oregon poisoned over 700 citizens with *Salmonella typhimurium* in an attempt to influence a local election. The strain of *Salmonella typhimurium* was obtained from the American Type Culture Collection and was grown in a lab at the cult compound for poisoning through local buffet style restaurants. An employee from a clinical lab in Texas was arrested for infecting 13 people who ate donuts that were inoculated with *Salmonella typhi*. The researcher had secretly grown their own cultures for this purpose from a small aliquot obtained from the laboratories stocks. Evidence of an attempted murder was found at a New England college after a man used saxitoxin taken from his research laboratory and placed it in leftover food in his ex-girlfriend's apartment. The poisoning was discovered only after the I-125 radiolabeled saxitoxin resulted in elevated radioiodine levels discovered during thyroid monitoring. Five Americans were killed and 17 others hospitalized after letters containing anthrax spores were placed in the U.S. Mail. This terrorist act remains unsolved. Local, state and federal law enforcement officials continue to uncover plots to use hazardous materials with explosive devices to create dirty bombs. Many in law enforcement believe that academic institutions are a potential source of these hazardous materials as security at these locations may not be as hardened as federal research locations.

Yale University has active police and security forces that patrol campus locations and buildings on a daily basis. In addition to this security presence, each employee involved in the transport of hazardous materials can play a key role in preventing unauthorized access to these packages. Protective measures include:

- Restrict access to your laboratory to authorized personnel only.
- Avoid discussing the nature of your research with those you are not familiar with.
- Report suspicious activities, events, and people to Yale Police (432-4400) and Yale Security (785-5555). This would include lost or damaged packages.
- Keep packages of hazardous materials in a secure location or under direct guidance of laboratory staff at all times.
- Select a courier that will keep the package secure during transport and can track the package at all points from collection through delivery.
- Verify the chain of custody and security by having the package recipient notify your laboratory once it has been received in good condition.

Periodically remind your staff and fellow employees of these basic security measures and follow them whenever shipping or transporting a package of hazardous materials.

If driving a package of Class 6.2 Infectious Substances following approval by OEHS:

- Secure the package of hazardous materials in the trunk or rear of the motor vehicle to keep it from shifting during the trip.
- Keep one copy of the Shipper's Declaration Form with the package and one with the driver.
- Do not leave the motor vehicle or the package of hazardous materials during transport. Maintain constant eyesight with the vehicle. Consider two drivers for longer trips.
- Provide your itinerary to the lab director or fellow employees and check in periodically throughout the trip at once the package of hazardous materials has reached its destination. Bring a cell phone to assist with communication and for use in emergencies.

Do not transport packages containing Select Agents without documented approval from OEHS AND the federal government.

- Couriers transporting Select Agents must have a written security plan and conduct background checks of personnel with access to these packages of hazardous materials.
- Packages of Select Agents may require tamper proof seals and must be secured at each stage of transport.
- The federal government must be informed of the confirmation of delivery of Select Agents within 24 hours of receipt and immediately notified of any incidents involving the package during transport.

Section 7: Emergency Response Information

All employees involved in the hazardous materials transport chain must be aware of the initial emergency response procedures and whom to notify in the event an incident. The Shipper and the Consignee (recipient) must be capable of providing specific information regarding the shipment if asked. For shipments of Category A Infectious Substances, the Shipping Declaration Form must include an emergency phone number that is manned 24 hours a day by a person knowledgeable about the emergency response requirements for the material being shipped. Yale University has contracted CHEMTREC to serve as an initial contact to provide emergency response information for shipments of hazardous materials from Yale University. The 24 Hour Emergency Response Information to provide on the Shipper's Declaration Form for shipments made within the U.S. is: **CHEMTREC: (800) 424-9300**. For international shipments, use the CHEMTREC (703) 527-3887.

CHEMTREC has an online library of Material Safety Data Sheets for Infectious Agents published by the Canadian Laboratory Centres for Disease Control. This library is accessible from the OEHS website (www.yale.edu/ehs) and the American Biological Safety Association (ABSA) website (www.absa.org under their Biosafety Resources and Tools section). If the agent that you are shipping does not have an MSDS in this library, please notify OEHS for assistance. In these situations, OEHS can assist you with the provision of emergency response information to CHEMTREC in advance of the shipment. This will be faxed or mailed to CHEMTREC at:

1300 Wilson Blvd, Arlington, VA 22209. Phone: 800-262-8200. FAX: 703-741-6089

The following emergency response information will be needed in an incident involving a hazardous materials package:

- A description of the hazardous material shipped.
- The immediate precautions to take in the event of an accident.
- The initial steps in the handling spills or leaks in the absence of a fire.
- Preliminary first aid measures for the material.
- The immediate health hazards of the material.
- Any risks of fire or explosion and methods for handling fires if applicable.

If you are contacted for emergency response information for an incident involving a Category A Infectious Substance shipment, you may alert the caller of the 24 hour phone number listed on the Shipper's Declaration Form (CHEMTREC – see above). Provide any detailed risk assessment information that you can on the material, such as the routes of exposure and basic exposure response procedures (i.e. wash affected area for 15 minutes with soap and water or an eyewash, notify supervisors and seek immediate medical assistance). Remind the caller to isolate the spill with caution tape or other means and keep others upwind of the spilled material or out of the spill area until qualified emergency responders arrive for mitigation.

Report of Hazardous Materials Incidents

Certain types of hazardous materials incidents must be reported to the Pipeline and Hazardous Materials Safety Administration (PHMSA). The person in possession of the hazardous material at the time of the incident during shipment is responsible for reporting the incident and completing a DOT Form F 5800.1. Incidents involving “fire, breakage, spillage or suspected contamination involving an infectious substance other than a diagnostic specimen or regulated medical waste” must be reported:

- By telephone within 12 hours to (800)-424-8802 or (202)-267-2675.
- Within 30 days following the telephone report to US DOT, PHMSA, Office of Hazardous Materials Safety, PHH-63, Washington, DC 20590-0001. A blank copy of the DOT Report Form F 5800.1 can be obtained from the DOT website at <http://hazmat.dot.gov/spills>.

Copies of the report must be maintained for at least two years following the date of submission to PHMSA.

Spill of an Infectious Substance

- ◆ Avoid inhaling airborne material, while quickly leaving the room and removing gloves. Notify others to leave. Close door, and post with a warning sign.
- ◆ Remove remainder of contaminated clothing, turning exposed areas inward, and place in a biohazard bag.
- ◆ Wash all exposed skin with soap and water.
- ◆ Inform Supervisor, and, if assistance is needed, consult the Biosafety Office (785-3550).

Clean-up of Infectious Substance Spill

- ◆ Allow aerosols to disperse for at least 30 minutes before reentering the laboratory. Assemble clean-up materials (disinfectant, paper towels, biohazard bags, and forceps).
- ◆ Put on protective clothing (lab coat, face protection, utility gloves, and booties if necessary). Depending on the nature of the spill, it may be advisable to wear a HEPA filtered respirator instead of a surgical mask.
- ◆ Cover the area with disinfectant-soaked towels, and then carefully pour disinfectant around the spill. Avoid enlarging the contaminated area. Use more concentrated disinfectant as it is diluted by the spill. Allow at least a 20 minute contact time.
- ◆ Handle any sharp objects with forceps and discard in a sharps container. Wipe surrounding areas (where the spill may have splashed) with disinfectant.
- ◆ Soak up the disinfectant and spill, and place the materials into a biohazard bag.
- ◆ Spray the area with 10% household bleach solution and allow to air-dry (or wipe down with disinfectant-soaked towels after a 15-minute contact time). Place all contaminated paper towels and any contaminated protective clothing into a biohazard bag and autoclave.
- ◆ Wash hands and exposed skin areas with soap and water.

Blood Spills

For blood or other material with a high organic content and low concentration of infectious microorganisms:

- ◆ Wear gloves, eye protection, and a lab coat.
- ◆ Absorb blood with paper towels and place in a biohazard bag. Collect any sharp objects with forceps or other mechanical device and place in a sharps container.
- ◆ Using a detergent solution, clean the spill site of all visible blood.
- ◆ Spray the spill site with 10% household bleach and allow to air-dry for 15 minutes.
- ◆ After the 15 minute contact time, wipe the area down with disinfectant-soaked paper towels.
- ◆ Discard all disposable materials used to decontaminate the spill and any contaminated personal protective equipment into a biohazard bag.
- ◆ Wash your hands with soap and water.

Section 8 Refrigerants (Dry Ice and Liquid Nitrogen)

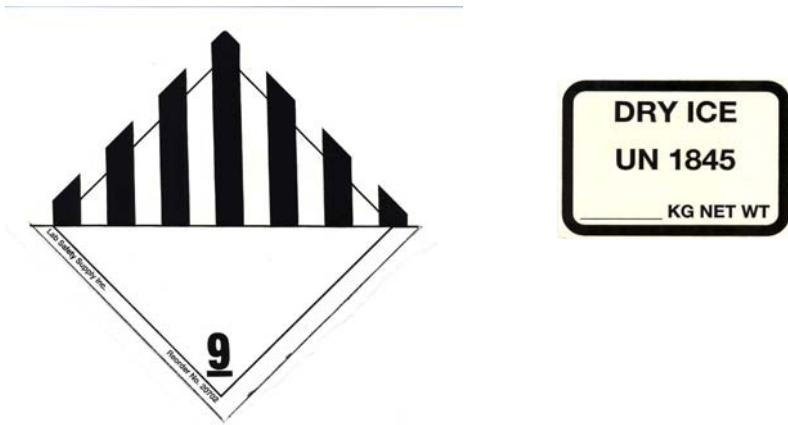
DRY ICE

Dry Ice is a hazardous material regulated by both the US Department of Transportation (DOT) and the International Air Transport Association (IATA). Dry Ice is classified as a Class 9, miscellaneous hazard, and is assigned UN 1845.

Three important safety factors to keep in mind when dealing with dry ice are: 1) it is a cryogen and its cold temperatures can cause frostbite and burns upon contact with unprotected skin; 2) it is a simple asphyxiant and can create a suffocation hazard by the displacement of oxygen; and 3) as it sublimates from a solid directly to a gas, the expansion of molecules can create a very pressurized state if placed within a sealed container. To mitigate these risks, please follow the following simple safety guidelines when working with or using dry ice.

- Wear insulated gloves whenever handling dry ice; never handle dry ice with ungloved hands.
- Store dry ice in a well ventilated area (large quantities of dry ice in an unventilated room can create an oxygen deficiency, i.e. hundreds of kg of dry ice in a large ice chest or a large dry ice chest in a small unventilated closet). Please contact OEHS at 785-3550 to have the oxygen levels evaluated if you are storing very large quantities of dry ice.
- Never place dry ice inside a sealed transport container (i.e. leak proof secondary container). Dry ice must be placed within an outer shipping container or storage container that will allow venting or release of CO₂ gas to avoid pressurization. Sealing dry ice within a leak proof container can result in a bursting or exploding container, which can release its contents and/or create a serious physical hazard.

When shipping dry ice, use a vented container of sufficient strength to hold the amount of dry ice needed to preserve your shipment. The outside of the packages must contain the following labels:



The net quantity of dry ice within the shipment must also be included on the UN 1845 dry ice label in kg. The maximum allowable net quantity of dry ice allowed per package is 200 kg. (This is also the maximum quantity of dry ice allowed in the cargo hold of the aircraft).

A Shippers Declaration form is not required for the shipment of dry ice. However, if dry ice is shipped with a hazard requiring a shippers declaration form, it shall be included on the form as a subsidiary hazard following the major hazards.

If transporting Dry Ice by air, include the following information on the air waybill under the “Nature and Quantity of Dangerous Goods” section:

- Proper shipping name (Dry Ice or Carbon Dioxide, solid)
- UN 1845
- The number of packages; and

- The net quantity of dry ice in each package (with the net weight of dry ice marked on the exterior of the package).

As dry ice sublimates, use containers that have stabilization slots for secondary containers to prevent them from moving during the shipment. You may also secure your samples within the outer box by making stabilizers out of cardboard or Styrofoam to help keep your samples from moving after the dry ice sublimates.

The IATA Packaging Instruction for Dry Ice is number 904.

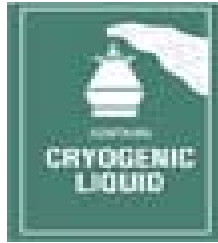
LIQUID NITROGEN

Liquid nitrogen is also a cryogen that presents significant risk of frost bite and burns. Extensive tissue damage can result from exposure to liquid nitrogen. It is also a simple asphyxiant, which could create a suffocation risk if enough material were spilled or released in a poorly ventilated or confined area by displacing oxygen. At low oxygen concentrations, unconsciousness and death may occur in seconds without warning.

- Always wear a face shield over safety glasses, lab coat, and insulated gloves designed for handling liquid nitrogen.
- Wear long sleeved shirts, trousers without cuffs, and sensible solid cover shoes when handling liquid nitrogen.
- Never store or pour liquid nitrogen in a poorly ventilated or confined space.
- Never allow any unprotected part of the body to come in contact with un-insulated equipment or pipes that contain liquid nitrogen or other cryogenic liquids.
- It is normal for liquid nitrogen containers to periodically vent product to release pressure. Never plug, remove, or tamper with any pressure relief devices.
- If unprotected skin is ever in contact with liquid nitrogen, immediately soak the affected area in warm water (but not greater than 105 degrees F) and immediately summon emergency assistance.

The U.S. DOT and IATA both regulate liquid nitrogen as a hazardous material. Shipment and transport of liquid nitrogen require the use of a Shipper's Declaration form. The IATA Packaging Instruction for liquid nitrogen is number 202. The general requirements for liquid nitrogen packaging are:

- Packages are designed for holding low temperature liquefied gases;
- Packages must be capable of withstanding the stresses associated with air transport and handling;
- Packages must have vent openings or safety relief valves;
- Packages must contain instructions on what to do in the event of an emergency;
- Packaging labels include:
 - The words "Keep Upright" at 120 degree intervals on container;
 - Packaging orientation arrows;
 - The phrase "DO NOT DROP – HANDLE WITH CARE";
 - The "Cryogenic Handling Label" (see below)



The proper shipping name is UN 19977, Liquid Nitrogen, 10 liters (the volume contained within the container is the value that follows the proper shipping name). Both DOT and IATA have additional specifications for non-pressurized, low pressure and pressurized packagings that are not detailed in this manual.

Dry Nitrogen Shippers:

Please note that “dry” nitrogen shippers, which maintain the temperature of liquid nitrogen after being charged with liquid nitrogen then emptied before shipment, do not qualify as hazardous materials and are not subject to the shipping regulations if they don’t contain hazardous materials. Researchers are encouraged to pursue the use of dry shippers to reduce their regulatory burden where possible. The liquid nitrogen must be fully absorbed within the container in a porous material, the container must not allow the build-up of pressure, and won’t allow the release of liquid nitrogen in any orientation. If a dry-nitrogen shipper is purchased, follow the manufacturer’s written instructions for its use and double check that there is no free liquid nitrogen inside the container prior to shipment.

Appendix 1: Indicative List of Category A Infectious Substances

UN2814-Infectious substances affecting humans and animals	UN2900-Infectious substances affecting animals only
Bacillus anthracis (cultures only)	African swine fever virus (cultures only)
Brucella abortus (cultures only)	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
Brucella melitensis (cultures only)	Classical swine fever virus (cultures only)
Brucella suis (cultures only)	Foot and mouth disease virus (cultures only)
Burkholderia mallei – Pseudomonas mallei – Glanders (cultures only)	Lumpy skin disease virus (cultures only)
Chlamydia psittaci – avian strains (cultures only)	Mycoplasma mycoides – Contagious bovine pleuropneumonia (cultures only)
Clostridium botulinum (cultures only)	Peste des petits ruminants virus (cultures only)
Coccidioides immitis (cultures only)	Rinderpest virus (cultures only)
Coxiella burnetii (cultures only)	Sheep-pox virus (cultures only)
Crimean-Congo hemorrhagic fever virus	Goatpox virus (cultures only)
Dengue virus (cultures only)	Swine vesicular disease virus (cultures only)
Eastern equine encephalitis virus (cultures only)	
Escherichia coli, verotoxigenic (cultures only)	
Ebola virus	
Flexal virus	
Francisella tularensis (cultures only)	
Guanarito virus	
Hantaan virus	
Hantaviruses causing hemorrhagic fever with renal syndrome	
Hendra virus	
Herpes B virus (cultures only)	
Human immunodeficiency virus (cultures only)	
Highly pathogenic avian influenza virus (cultures only)	
Japanese Encephalitis virus (cultures only)	
Junin virus	
Kyasanur forest disease virus	
Lassa virus	
UN2814-Infectious substances affecting humans and animals	UN2900-Infectious substances affecting animals only
Machupo virus	
Marburg virus	
Monkeypox virus	
Mycobacterium tuberculosis (cultures only)	

UN2814-Infectious substances affecting humans and animals	UN2900-Infectious substances affecting animals only
Nipah virus	
Omsk hemorrhagic fever virus	
Poliovirus (cultures only)	
Rabies and other lyssaviruses (cultures only)	
Rickettsia prowazekii (cultures only)	
Rickettsia rickettsii (cultures only)	
Rift Valley fever virus (cultures only)	
Russian spring-summer encephalitis virus (cultures only)	
Sabia virus	
Shigella dysenteriae type 1 (cultures only)	
Tick-borne encephalitis virus (cultures only)	
Variola virus	
Venezuelen equine encephalitis virus (cultures only)	
Vesicular Stomatitis virus (cultures only)	
West Nile virus (cultures only)	
Yellow Fever virus (cultures only)	
Yersinia pestis (cultures only)	

Appendix 2: Select Agents List

HHS Non-Overlap Select Agents and Toxins	High Consequence Livestock Pathogens and Toxins/Select Agents (Overlap Agents)
Crimean-Congo haemorrhagic fever virus	Bacillus anthracis
Coccidioides posadasii	Brucella abortus
Ebola viruses	Brucella suis
Cercopithecine herpesvirus 1 (Herpes B virus)	Burkholderia mallei (formerly Pseudomonas mallei)
Lassa fever virus	Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)
Marburg virus	Botulinum neurotoxin producing species of Clostridium
Monkeypox virus	Coccidioides immitis
Rickettsia prowazekii	Coxiella burnetii
Rickettsia rickettsii	Eastern equine encephalitis virus
South American haemorrhagic fever viruses: Junin, Machupo, Sabia, Flexal, Guanarito	Francisella tularensis
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	Hendra virus
Variola major virus (Smallpox virus)	Nipah virus
Variola minor virus (Alastrim)	Rift Valley fever virus
Yersinia pestis	Venezuelen equine encephalitis virus
Abrin (> 100 mg regulated)	Botulinum neurotoxin (> 0.5 mg regulated)
Conotoxins (> 100 mg regulated)	Clostridium perfringens epsilon toxin (>100 mg regulated)
Diacetoxyscirpenol (> 1000 mg regulated)	Shigatoxin (> 100 mg regulated)
Ricin (> 100 mg regulated)	Staphylococcal enterotoxin (> 5 mg regulated)
Saxitoxin (> 100 mg regulated)	T-2 toxin (>1000 mg regulated)
Shiga-like ribosome inactivating proteins (> 100 mg regulated)	
Tetrodotoxin (> 100 mg regulated)	

Appendix 2: List of Select Agents (Continued)

USDA High Consequence Livestock Pathogens and Toxins (Non-Overlap Agents and Toxins)	Listed Plant Pathogens
Akabane virus	Liberobacter africanus
African swine fever virus	Liberobacter asiaticus
African horse sickness virus	Peronosclerospora philippinensis
Avian influenza virus (highly pathogenic)	Phakopsora pachyrhizi
Blue tongue virus (Exotic)	Plum Pox Potyvirus
Bovine spongiform encephalopathy agent	Ralstonia solanacearum race 3, biovar 2
Camel pox virus	Schlerophthora rayssiae var zeae
Classical swine fever virus	Synchytrium endobioticum
Cowdria ruminantium (Heartwater)	Xanthomonas oryzae
Foot and mouth disease virus	Xylella fastidiosa (citrus variegated chlorosis strain)
Goat pox virus	
Lumpy skin disease virus	
Japanese encephalitis virus	
Malignant catarrhal fever virus (Exotic)	
Menangle virus	
Mycoplasma capricoluml M.F38/M.mycooides Capri	
Mycoplasma mycooides mycooides	
Newcastle disease virus (VVND)	
Peste Des Petits Ruminants virus	
Rinderpest virus	
Sheep pox virus	
Swine vesicular disease virus	
Vesicular Stomatitis virus (Exotic)	

Appendix 3: Export License List

(From the United States Department of Commerce “Commerce Control List”)

<p>Please Note: In addition to the agents listed below, federally regulated Select Agent pathogens and toxins (Appendix 1) are also restricted from export for shipment outside the United States.</p> <p>Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms and toxins listed below also require an export permit. <i>Genetic elements” include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.</i></p>
Plant Pathogens (Viruses)
Potato Andean latent tymovirus
Potato spindle tuber viroid
Plant Pathogens (Fungi)
Colletotrichum coffeanum var. virulans (Colletotrichum kahawae)
Cochliobolus miya beanus (Helminthosporium oryzae)
Microcyclus ulei (syn. Dothidella ulei)
Puccinia graminis (syn. Puccinia graminis f. sp. tritici)
Puccinia striiformis (syn. Puccinia glumarum)
Magnaporthe grisea (pyricularia grisea/pyricularia oryzae)
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
Xanthomonas oryzae pv. oryzae (syn. Pseudomonas campestris pv. oryzae)
Clavibacter michiganensis subspecies sepedonicus (syn. Corynebacterium michiganensis subspecies sepedonicum or Corynebacterium sepedonicum)
Ralstonia solanacearum Races 2 and 3 (syn. Pseudomonas solanacearum Races 2 and 3 or Burkholderia solanacearum Races 2 and 3)
Animal Pathogens (fungi)
Mycoplasma mycoides
United States Department of Commerce (DOC)

Commerce Control List (CCL)
Animal Pathogens (Viruses)
African horse sickness virus
Lumpy skin disease virus
Teschen disease virus
Vesicular stomatitis virus
African swine fever virus
Avian influenza virus that are: a.2.a. Defined in EC Directive 92/40/EC (O.J. L.16 23.1.92 p.19) as having high pathogenicity, as follows: a.2.a.1. Type A viruses with an IVPI (intravenous pathogenicity index) in 6 week old chickens of greater than 1.2; <i>or</i> a.2.a.2. Type A viruses H5 or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin
Bluetongue virus
Foot and mouth disease virus
Goat pox virus
Porcine herpes virus (Aujeszky's disease)
Swine fever virus (Hog cholera virus)
Lyssa virus
Newcastle disease virus
Peste des petits ruminants virus
Porcine enterovirus type 9 (swine vesicular disease virus)
Rinderpest virus
Sheep pox virus
Teschen disease virus
Vesicular stomatitis virus
Lumpy skin disease virus
United States Department of Commerce (DOC) Commerce Control List (CCL)
Animal Pathogens (Bacteria)

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (Pseudomonas mallei)
Burkholderia pseudomallei (Pseudomonas pseudomallei)
Chlamydia psittaci
Clostridium botulinum
Francisella tularensis
Salmonella typhi
Shigella dysenteriae
Vibrio cholerae
Yersinia pestis
Clostridium perfringens, epsilon toxin producing types
Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes
Rickettsiae
Bartonella quintana (Rochalimea quintana, Rickettsia quintana)
Coxiella burnetii
Rickettsia prowazekii
Rickettsia rickettsii
Viruses
Chikungunya virus
Congo-Crimean haemorrhagic fever virus (a.k.a. Crimean-Congo haemorrhagic fever virus)
Dengue fever virus
United States Department of Commerce (DOC) Commerce Control List (CCL)
Eastern equine encephalitis virus
Ebola virus
Hantaan virus

Japanese encephalitis virus
Junin virus
Lassa fever virus
Lymphocytic choriomeningitis virus
Machupo virus
Marburg virus
Monkey pox virus
Rift Valley fever 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
Kyasanur Forest virus
Louping ill virus
Murray Valley encephalitis virus
Omsk haemorrhagic fever virus
Oropouche virus
Powassan virus
Rocio virus
St. Louis encephalitis virus
Hendra virus (Equine morbillivirus)
United States Department of Commerce (DOC) Commerce Control List (CCL)
South American haemorrhagic fever (Sabia, Flexal, Guanarito)
Nipah virus
Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
Toxins
Botulinum toxins

Clostridium perfringens toxins
Conotoxin
Microcystin (Cyanginosin)
Ricin
Saxitoxin
Shiga toxin
Staphylococcus aureus toxins
Tetrodotoxin
Verotoxin (<i>are Shiga-like ribosome inactivating proteins</i>)
Aflatoxins
Abrin
Cholera toxin
Diacetoxyscirpenol toxin
T-2 toxin
HT-2 toxin
Modeccin toxin
Volkensin toxin
Viscum Album Lectin 1 (Viscumin)

Appendix 4: On Campus Transport of Clinical or Diagnostic Materials

This section is only applicable to the on-campus transport of clinical or diagnostic specimens (Category B Biological Substances or Exempt Human or Animal Specimens), but **NOT Category A Infectious Substances - Human, Animal or Plant Pathogens, or other Regulated Hazardous Materials**. Please contact OEHS at 785-3550 for additional information regarding training and other requirements for shipping Hazardous Materials.

Regardless of which of the three means of transportation below will be used, **decontaminate the exteriors of the primary and secondary containers with an appropriate disinfectant**. Remove personal protective equipment and wash hands before leaving the lab. Since the exterior packaging has been decontaminated, **do not wear personal protective equipment to transport the package within or between buildings**.

1) On campus transport (hand carried within buildings - not outdoors).

When transporting biological materials on campus within a building or series of buildings the following requirements must be met:

Two leak proof containers are required for on campus transport within a building or series of buildings. Sealed primary containers of biohazardous materials transported outside of the laboratory must be placed into a sealed secondary container bearing a biohazard label on which the name of the material has been written. **If the primary container is glass, use a rigid, unbreakable secondary container as broken glass may penetrate a sealed plastic sample bag** (for compliance with the OSHA Bloodborne Pathogens Standard). Also, use paper towels or other absorbent material to separate primary glass containers from each other and from the secondary container to minimize the potential for breakage. The amount of absorbent must be sufficient to absorb the contents of the primary container.

Suitable Examples as packaged above include:

- Commercial plastic transport containers
- Plastic vacutainer or specimen container inside a labeled and sealed plastic bag.
- Glass vacutainer inside a sealed plastic bag, placed within a rigid unbreakable labeled secondary container (such as a plastic tool box, sewing box, fish & tackle box).
- Plastic 2 ml cryovial inside sealed and labeled conical tube.

2) On campus transport (hand carried outdoors)

Triple packaging is required for on campus transport between buildings when hand carried outdoors. Sealed primary containers of biohazardous materials transported outside of the laboratory must be placed into a sealed secondary container bearing a biohazard label on which the name of the material has been written. If the primary container is glass, use a rigid, unbreakable secondary container as broken glass may penetrate a sealed plastic sample bag. Also, use paper towels or other absorbent material to separate primary glass containers from each other and from the secondary container to minimize the potential for breakage. The amount of absorbent must be sufficient to absorb the contents of the primary container. The secondary container is then placed into a sturdy outer packaging. An itemized list of contents must be placed between the secondary and outer packaging. The outer packaging should bear a biohazard label on which the name of the material has been written.

Suitable Examples of outer packaging include:

- Labeled fiberboard box in good condition
- Labeled sturdy plastic container (Sealed cooler or sealable plastic tool box)

3) Transporting Clinical or Diagnostic specimens on public roadways.

Triple packaging meeting U.S. Department of Transportation (DOT) Regulations (as described in Section 2 of this manual) is for transport of clinical or diagnostic specimens (Category B Biological Substances or Exempt Human or Animal Specimens) on public roadways. Sealed primary containers of biohazardous materials

must be placed into a sealed secondary container. If the primary container is glass, use a rigid, unbreakable secondary container as broken glass may penetrate a sealed plastic sample bag. Also, use paper towels or other absorbent material to separate primary glass containers from each other and from the secondary container to minimize the potential for breakage. The amount of absorbent must be sufficient to absorb the contents of the primary container. The secondary container is then placed into a sturdy outer packaging. An itemized list of contents must be placed between the secondary and outer packaging. The outer packaging should bear a biohazard label on which the name of the material has been written.

If you wish to transport diagnostic or clinical specimens by car within Connecticut, you must also read and sign a transport awareness packet for drivers. The package must be placed in the vehicle's trunk or in the rear of the vehicle.

4) Transporting Clinical or Diagnostic specimens through commercial carriers such as FedEx (shipments that are destined for transport via air)

Please refer to Sections 2, 3 and 4 of this manual for instructions on packaging and labeling biological materials. Please also note that secondary containers used for liquid Category B Biological Specimens that will be transported by air must have a primary or secondary container that can withstand, without leakage, an internal pressure of 95 kPa (13.8 psi) in the range of -40C to +55C.

Please don't hesitate to contact a representative of the Office of Environmental Health & Safety's Biosafety Office at 785-3550 if you have any questions or need clarification of the on and off-campus requirements for the transport of clinical or diagnostic specimens.

Appendix 5: Vendors for Shipping Packaging and Labels

This list is not all-inclusive; there are other vendors for UN approved and diagnostic packaging. Shipping labels and declaration forms can also be purchased through any of these vendors. Please be sure to order the appropriate packaging if shipping on dry ice.

Below is a partial listing of shipping container suppliers whose shipping products comply with current DOT, IATA, ICAO and PHS shipping requirements for infectious substances and/or diagnostic specimens. The resources contained in this guidance document are intended for reference purposes only and do not constitute a complete listing of all shipping container suppliers. In addition, the use of manufacturer or supplier names does not constitute an endorsement by CDC or any department or agency of the U.S. Government.

<p>Air Sea Atlanta 1234 Logan Circle Atlanta, GA 30318 Ph: 404-351-8600 Fax: 404-364-4005 Website: http://www.airseatlanta.com</p>	<p>Air Sea Containers, Inc. 2749 NW 82nd Avenue Miami, FL 33122 Ph: 888-272-9883 Fax: 305-599-1668 Website: http://www.airseacontainers.com</p>
<p>All-Pak, Inc. Corporate One West 1195 Washington Pike Bridgeville, PA 15017-2854 Ph: 1-800-245-2283 Fax: 412-257-3001 Website: http://www.all-pak.com</p>	<p>CARGOpak Corporation 3215-A Wellington Court Raleigh, NC 27587 Ph: 919-878-9933 / 1-800-266-0652 Fax: 919-554-9055 Website: http://www.cargopak.com</p>
<p>Inmark, Inc. 675 Hartman Road - Suite 100 Austell, GA 30168 Ph: 770-373-3300 / 1-800-646-6275 (outside Georgia) Fax: 770-373-3301 Website: http://www.inmarkinc.com</p>	<p>O'Berk International, Inc. (Elemental Container, Inc.) 860 Springfield Road South Union, NJ 07083 Ph: 908-687-7720 / 1-800-577-7624 Fax: 908-687-5157 Website: http://aluminumbottles.com</p>
<p>SCA ThermoSafe (formerly Polyfoam Packers Corp.) 2320 Foster Ave Wheeling, IL 60090-6572 Ph: 847-398-0110 / 1-800-323-7442 Fax: 847-398-0653 Website: http://www.thermosafe.com</p>	<p>Saf-T-Pak, Inc. 101 17972 – 106 Avenue Edmonton, Alberta, Canada T5S 1V4 Ph: 1-800-841-7484 Fax: 403-486-0235 Website: http://www.saftpak.com</p>

Note: Some of the suppliers listed above also provide shipping labels and primary receptacle containers as separate products Contact the specific vendor to see if they offer the desired products.

Some Suppliers of Dangerous Goods Forms, Documents and Labels

Label Master

5724 North Pulaski
Chicago, IL 60646
Ph: 1-800-621-5808
Fax: 1-800-723-4357
Website: <http://www.labelmaster.com>

Saf-T-Pak, Inc.

101 17972 – 106 Avenue
Edmonton, Alberta, Canada T5S 1V4
Ph: 1-800-814-7484
Fax: 403-486-0235
Website: <http://www.saftpak.com>

SCA ThermoSafe

2320 Foster Ave
Wheeling, IL 60090-6572
Ph: 847-398-0110 / 1-800-323-7442
Fax: 847-398-0653
Website: <http://www.thermosafe.com>

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Quiz information for the ‘Transportation and Transfer of Biological Agents’

The training requirement for “Shipping and Transportation of Hazardous Biological Materials will be fulfilled after reading the ‘**Transportation and Transfer of Biological Agents**’ manual and completing the quiz located at: <http://learn.yale.edu/oehs/shipping/>.

Once you are notified that you have passed the quiz you may ship the materials covered in the manual (EX: exempt human and animal specimens, category B infectious substances, genetically modified microorganisms and genetically modified organisms, category A infectious substances and dry ice).

PLEASE REMEMBER: Prior to shipping any material, a **Research Materials Shipment Request** must be completed and faxed or mailed to EHS at 785-7588 or campus mail to: EHS, 135 College Street, 1st Floor.