

<p>Guidance and Education for Receipt of and Transport of Biohazardous Materials</p> <p>Version 5/21/2019</p>	<p>DePaul University Office of Research Services Institutional Biosafety Committee 1 East Jackson Blvd Chicago, Illinois 60604-2201 email: orp@depaul.edu Phone: (312) 362-7593 Web: http://offices.depaul.edu/ors/Pages/default.aspx</p>
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Introduction:

The U.S. Department of Transportation (DOT) regulates shipping and receiving of biologics as Dangerous goods. The International Air Transport Association (IATA) regulates shipments if they are transported by air. Anyone who prepares a hazardous material for shipment must be trained to classify, pack (including proper containment procedures), label, and prepare manifests for the materials being shipped. When packages containing dry ice or infectious substances are shipped off campus, they are classified as “Dangerous Goods” and must be shipped according to federal agency regulations. The International Air Transportation Association (IATA) regulates all air transport. FedEx and other carriers require that all shipments comply with these regulations. Critical to this compliance is the requirement that shippers are properly trained prior to shipping these materials off campus. Training pertaining to shipping of biohazardous materials is available through CITI and is required, when anyone at DePaul is shipping materials, including dry ice, that are included in the shipping regulations.

Regulations do not outline training requirements for persons receiving biohazardous shipments or transporting biohazardous materials between laboratories or buildings on the DePaul Lincoln Park Campus or transporting materials locally without the use of shipping. However, given the potential for harm to individuals related to unpacking or transporting hazardous materials, it is important for all personnel conducting these activities to have a basic understanding of biosafety principles related to packaging in order to avoid potential injury or exposure.

Scope:

This guidance/education document applies to DePaul faculty, staff, or students who are responsible for receiving shipments of potentially biohazardous materials or who transport biohazardous materials on campus (between laboratories or buildings) or transport biohazardous materials locally. This guidance/education document is not applicable to persons preparing biohazardous materials for shipping as additional shipping training is required through the CITI program.

Principal Investigator Responsibilities:

The Principal Investigator (PI) is responsible for ensuring that any person assigned the responsibility for receiving and unpacking or transporting biohazardous materials has read and understands this guidance/education document and that documentation of completion of training is provided to the IBC with the specific protocol submission. Additionally, the PI must ensure that personnel are knowledgeable regarding the specific risks related to the biohazardous material they are handling, including the Risk Group (RG) for the material and Biosafety Containment Level (BSL) required for the material. If injury or illness occurs, the PI is responsible for ensuring that personnel report the injury to the Environmental Health and Safety at DePaul (<https://offices.depaul.edu/environmental-health-and-safety/Pages/default.aspx>) and that personnel receive necessary medical care or treatment, if needed.

Personnel assigned the task of receiving or transporting biohazardous materials should be provided with informational materials that describe the potential risks related to the material they will be handling. Personnel should understand the shipment type or category, the required type of packaging or containment standards, and shipment labeling requirements. Any package the personnel receive should be properly labeled to alert them to any risks.

The Department of Transportation (DOT) classifies infectious substances as Class 6, Division 6.2 materials. These are further divided into two categories: Category A, Infectious Substances and Category B, Biological Substances. Regulated medical waste may be classified as category A or B depending on the infectious agent. Patient specimens may be classified as Biological Substances, Category B or exempt depending on the health status of the patient. International shipments of non-infectious genetically modified organisms or micro-organisms (GMOs/GMMOs) are assigned to Class 9, Miscellaneous by the International Air Transport Association (IATA).

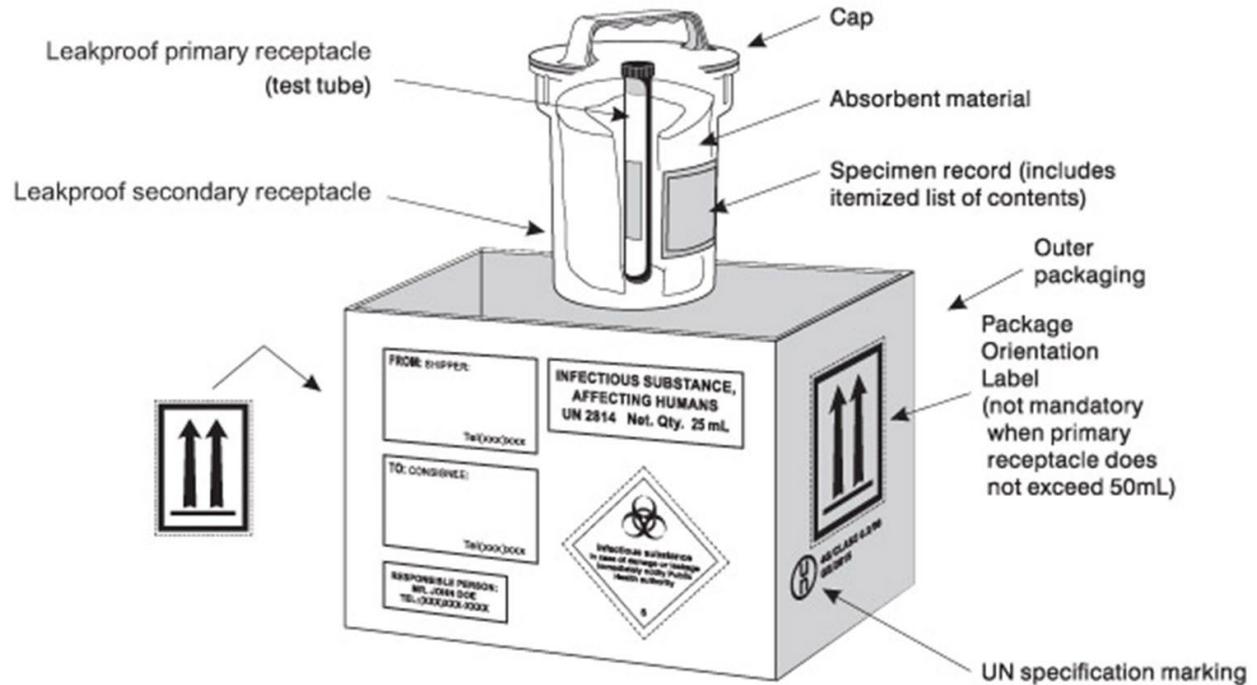
For shipment purposes, all biological materials fall into one of the following categories:

- Infectious Substances (Category A);
- Biological Substances (Category B);
- Regulated medical waste;
- Patient specimens (human or animal); Genetically modified organism or microorganisms (GMOs or GMMOs);
- Unregulated biological materials.

Category A substances are infectious substances which are transported in a form that, when exposure to them occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Human blood may also fall into Category A; this classification requires professional judgment and is based on a patient's known medical history, symptoms, individual circumstances of the source and endemic local conditions. These shipments must follow 49 CFR 173.196 - Category A infectious substances instructions: <https://www.govinfo.gov/app/details/CFR-2011-title49-vol2/CFR-2011-title49-vol2-sec173-196>

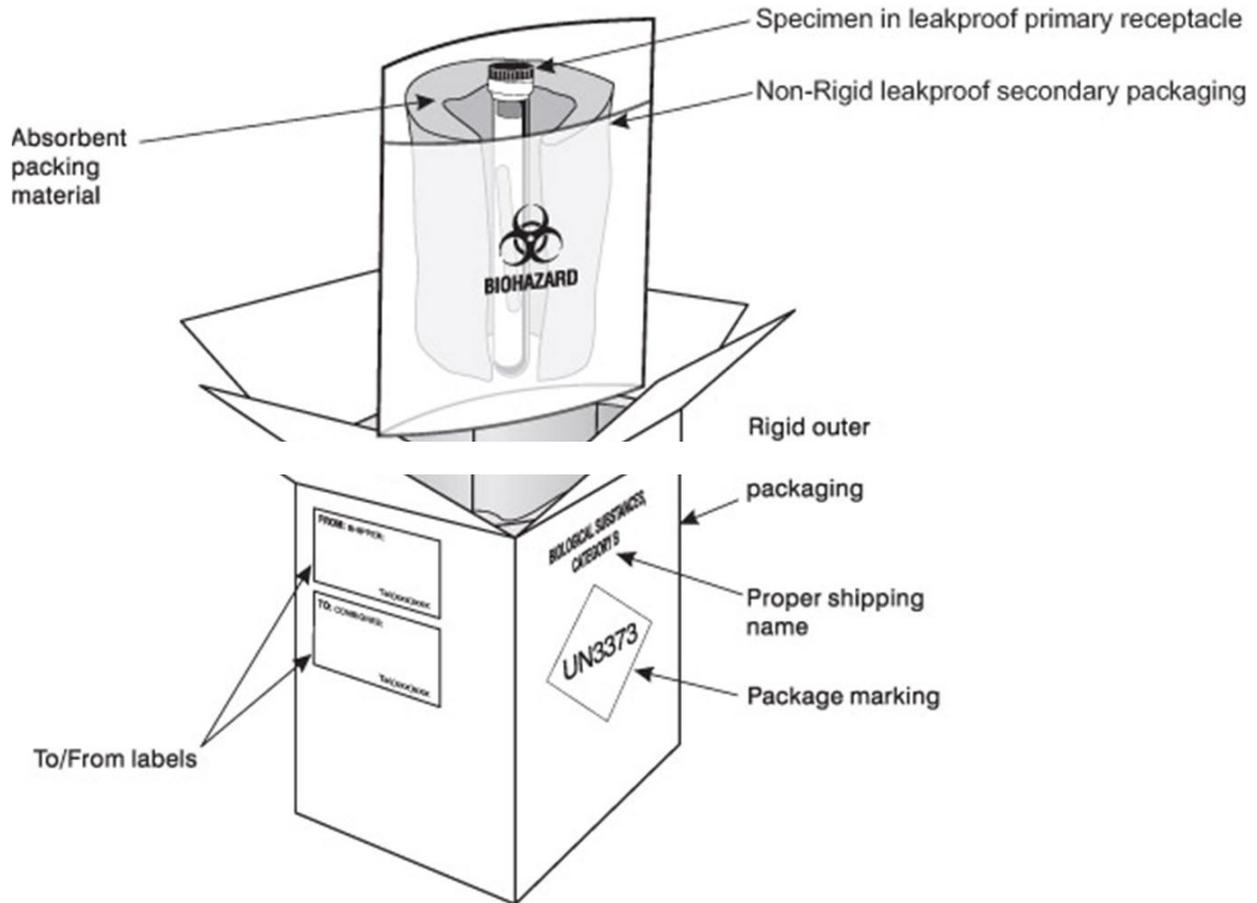
or IATA packaging instructions 620: https://www.uccs.edu/pusafety/sites/pusafety/files/inline-files/IATA_pack_instr_620.pdf

Category A Packaging



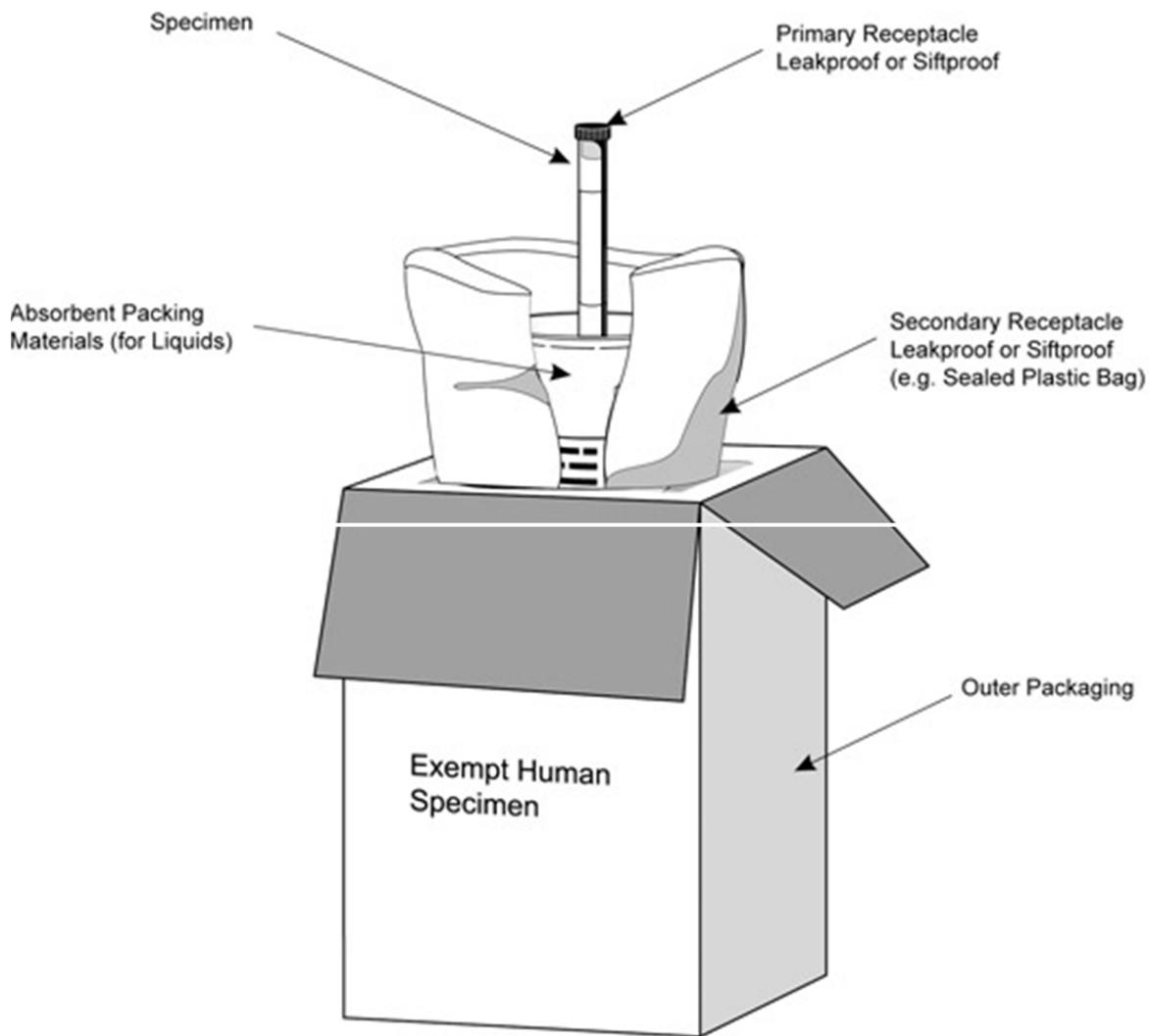
Category B substances are infectious substances which do not meet the criteria for inclusion in Category A. **Human blood** may also fall into Category B; again, this classification requires professional judgment and is based on a patient's known medical history, symptoms, individual circumstances of the source and endemic local conditions. These shipments must follow packaging instructions 650: <https://www.iata.org/whatwedo/cargo/dgr/Documents/packing-instruction-650-DGR56-en.pdf>

Category B Packaging



Exempt human/animal specimens are specimens in which it is **NOT LIKELY** that a pathogen is present (i.e., biopsies, dried blood spots, fecal occult samples, blood urine or tissue specimens, or tissues for transplant). Biological material that is not considered infectious (i.e., K-12 derived *E. coli*, mammalian cells lines infected/transduced by a vector, neutralized or inactivated pathogenic organisms, non-infectious and non-toxic, pure DNA, RNA, or proteins (e.g., plasmids, primers, antibodies)) can also be shipped as exempt.

Exempt Packaging



Proper classification of biological materials is a crucial step in the transportation of biological materials. The category determines the packaging, labeling, and documentation requirements.

Any PI wishing to receive a select agent must contact Katie Abma in the Environmental Health and Safety at (773) 325-8985.

Procedures:

Persons who will be receiving or transporting biohazardous materials must review the information in this document and then sign and date the bottom of the document certifying that they have read the guidance/education.

For Receiving of Biohazardous Materials

Shipments of biohazardous materials must be received (generally) by the person to whom it is addressed. This is usually accomplished by the use of a certified carrier such as Federal Express or UPS. The PI or personnel to whom the package is addressed should be notified when the package arrives. The recipient should be familiar with the sender, having had previous communications with the sender regarding shipment and expected arrival date. The recipient should notify the sender once the materials have been received and examined for damage.

Biologics should be received in a designated and secure area of the laboratory. Personnel should have at-hand and utilize all appropriate personal protective equipment and containment devices (i.e., biological safety cabinets or chemical fume hoods). Before accepting delivery, the package should be carefully examined and inspected for damage or leakage indicated by broken or improperly sealed containers. If the package is rejected (not accepted) due to damage or leakage, the carrier should work with the shipper to resolve the problem.

Before being opened, the package should be examined for the following before being brought into the laboratory:

- **Package Integrity:** The package should not be leaking or appear damaged in any way (i.e., holes or no longer sealed properly). If the package is leaking or damaged, the PI should be notified immediately, if they are not the person inspecting the package. Appropriate disinfecting agents and clean up materials should be available for spills.
- **Proper paperwork and labeling:** The label and accompanying documentation should be examined and this information should be given to the PI or the recipient. The paperwork should be examined for use of proper labeling and marking of the Infectious substance or diagnostic specimen.
 - The recipient should be familiar with the proper labeling requirements for the type of hazard they are receiving.
 - The recipient should be familiar with properly completed shippers Declaration of Dangerous Good paperwork.

The recipient should use proper precautions when opening the package.

- The package should be opened in a room that has the appropriate biosafety level rating for the type of material being received. Laboratories should be inspected and approved for BSL-2 materials by the Office of Environmental Health and Safety before materials are received.
- The recipient should wear gloves, a lab coat, and protective eye protection when opening packages containing infectious substances or diagnostic specimens. Additional personal protective equipment (PPE) may be required depending upon the type of biohazardous agent being received.
- Disinfectant should be readily available to use in the event that a primary container is found to be damaged. If the package contains broken glass, use forceps or other

mechanical means to remove the broken glass and dispose of the broken glass into proper containers.

- The package should be examined to ensure it was properly packaged according to the biohazardous materials category being shipped (i.e., primary receptacle, absorbent material, secondary packaging, and outer packaging).
- The outer package should be opened first and then the secondary container removed. Due to the possibility that the primary container may have leaked, the secondary container should be wiped down with an appropriate disinfectant before it is opened. If the primary container has leaked, all packaging materials should be placed in a biohazard bag and autoclaved or appropriately disinfected before disposal.
- If the package is leaking or damaged, it should be opened in a biological safety level 2 (BSL-2) cabinet by personnel trained in proper procedures for spill clean-up. Depending upon the size of the spill and the type of biohazardous material, the spill may need to be reported to DePaul Public Safety (if after hours, weekends or holidays) and the Environmental Health and Safety at (773) 325-8985 during the normal work day. See the DePaul Emergency Operations Plan for details (<https://resources.depaul.edu/emergency-plan/Documents/Campus%20Emergency%20Operations%20Plan%206%2013%202017.pdf>).
- If the package is leaking, the recipient should follow spill clean-up procedures as outlined in the DePaul University Institutional Biosafety Committee (IBC) Policy and Procedure Manual.

Responsibilities of the Receiver for Importation of Infectious Substances

- Be sure to obtain the necessary authorization(s) from national authorities for the importation of the materials.
- Provide the sender with the required permit(s), letter(s) of authorization, or other document(s) required by the authorities to ship the materials.
- Arrange for timely receipt of the package upon arrival.
- Send an acknowledgment of receipt to the sender as soon as possible after receipt of the package.
- The shipment must not be sent until all advance arrangement between the sender, carrier, and receiver have been made, the receiver has confirmed with the appropriate national authorities that the material may be legally imported, and the receiver has confirmed that there will be no delay in delivery of the package.

For Persons Transporting Biohazardous Materials

Although there are no regulations that cover the transport of biohazardous materials (that do not involve shipping or transport on public roads), the goal of the IBC is to ensure that people on the DePaul campus are kept safe from any potential risks related to the use of biohazardous materials

on the campus. Therefore, the IBC requires that persons who will be transporting biohazardous materials should read this document to obtain a basic understanding of packaging requirements and procedures to follow in the event of a spill.

Almost all life science-related research teams will need to transport biological materials between lab areas in support of their lab analyses. Common examples include cell cultures, viral vectors, body fluid and tissue specimens and infectious agents. Containment procedures are used in the lab to protect personnel from unnecessary contact with these materials. When transporting materials, containment procedures are utilized to prevent exposure to non-authorized personnel (with unknown health status) and potential environmental release and contamination. When they are transported from one lab location to another, it is important to apply the same containment principles in order to minimize the potential for a release of these materials while en route.

General Requirements

Prior to transporting any biological materials the following controls must be in place:

- Emergency procedures (e.g., contact names and information, spill clean up, disinfection protocols, etc.) must be known to the person carrying the materials.
- Container must be appropriate for the material being transported.
- Material must be packed so that it will stay upright during transportation.
- The containers must be properly labeled (i.e., type of materials, correct UN number or universal symbol, BSL level, orientation label).
- Proper protective clothing must be worn during the packaging of the material.
- Hands should be washed after handling materials.
- Open cuts or other wounds should be covered before handling the materials.
- Aerosol generation must be avoided when handling and packing the materials.
- The person packaging the material must ensure that the exterior surfaces of each package is free of any potential contamination by the packed material.

Biohazardous Material Transport through Public Areas within a Building

The goal of safe biohazardous material transport is to prevent spills, accidental exposure, or release into the environment. Procedures for safe transport include:

- Placing the biohazardous material in a primary leak-proof container or vessel (blood tubes, vial, agar plates, flasks, test tubes, or ampoule) that is designed for the type material contained within and which is securely closed with a tight-fitting cap, tape, or parafilm.
- Placing the primary container in an unbreakable, hard-walled, lidded, watertight secondary container (constructed of materials that can be effectively cleaned and disinfected) with absorbent towels to cushion the primary container and absorb liquids in

the event of a leak or spill. When transporting liquids in glass vials/containers, sufficient absorbent materials must be placed around the primary container to absorb the entire contents of the primary container in the event of breakage or leakage. Acceptable secondary containers include plastic or metal devices with a lid or a plastic cap (i.e., plastic or metal cooler or Rubbermaid tote). If a small number of plates or tubes are involved, a ziplock bag containing absorbent material may be used.

- If the materials need to be transported on dry ice, enclose the styrofoam container in a secondary container that is twice the size of the liner to allow sufficient expansion space for the dry ice during transport. (Assure that the lid is loosened when you reach your destination!)
- If the materials need to be transported on wet ice, assure that the container meets the criteria for a secondary container as described above. Otherwise, place the ice container within another container that does meet the criteria.
- Securely close the secondary container in such a way that if it were dropped, the container will not come open.
- If there is a possibility that the outside of the primary container or vessel is contaminated, use 10% fresh bleach solution, an EPA approved disinfectant, or a disinfectant appropriate for the biological materials being utilized to decontaminate it prior to placing it in a secondary container.
- The secondary container must be labeled with the international biohazard symbol on the outside of the container and each primary container should be labeled with its contents. The secondary container should be a dedicated transport vessel.
- The outside of the secondary container must be free of any biohazardous materials so that personnel can carry the package safely between laboratories or buildings utilizing minimal PPE (i.e., gloves and a lab coat).
- At a minimum disposable gloves and a lab coat should be worn during transport.
- If more materials need to be moved than can be effectively carried in one hand, use a cart. **Remember: Do not touch common contact surfaces in public areas with gloved hands!** If you wear gloves for handling the secondary container, you must have one hand ungloved for touching door knobs, elevator buttons and other common contact surfaces while en route.
- When transporting biological materials avoid traveling through areas where food is served or consumed. Also, avoid transport routes through stairwells, carpeted areas, high traffic public areas, and outdoor areas.
- The package must be taken directly to its intended location.
- Upon delivery or arrival at the destination, when applicable, the receiving laboratory personnel should be informed and the material properly stored. The package should be carefully inspected for signs of leakage or other contamination and, if necessary, decontaminated before opening.

- If a spill occurs during transport, do not attempt to clean it up without appropriate spill response materials and personal protective equipment (PPE). Keep other persons clear of the spill.

Biohazardous Material Transport between Buildings on the DePaul Lincoln Park Campus

Biohazardous material being hand-carried and transported on foot by DePaul personnel from one building to another on campus must be packaged as indicated above. If the primary container is not labeled, documentation of the contents should be taped to the outside of the secondary container or placed inside.

Biohazardous Material Transport Off the DePaul Lincoln Park Campus

If you need to transport regulated biological materials on public roads, you must comply with US Department of Transportation (DOT) regulations. Unregulated or exempted biological materials may be transported either on campus, to campus from an off-site location, or to an off-site research location. However, you should transport these materials following the strict packaging instructions noted below. Public transportation, such as trains, taxis, ride share, or buses may not be used to transport these materials.

Transport of Biohazardous Materials by Personal or University Vehicle

Unregulated or exempted biological materials may be transported either on campus, to campus from an off-site location, or to an off-site research location for university business in a personal or university vehicle if they meet all packaging and labeling training requirements and the personnel transporting them are properly trained. Keep in mind that transport of hazardous materials (which may include biological material, dry ice and liquid nitrogen) is against the terms of most private automobile insurance policies. Check with your insurer.

For materials that qualify for transport in a personal or university vehicles, the following precautions should be followed:

- At a minimum, a triple packaging system must be used for all materials. The three components of a triple packaging system are: 1. Primary receptacle, 2. Leak-proof secondary container, 3. Rigid outer container.
- Hazardous materials should be transported in the trunk or as far away from passengers as possible.
- All containers should be clearly labeled as to the type of biohazardous material in the container (i.e., infectious agent, Category B materials) and the biosafety containment level required using the universal symbols and categories.
- A complete inventory of the material shall accompany the package.
- The vehicle shall be driven directly from the point of origin to the intended destination without stopping at other locations on the way.
- Materials needed to contain or clean-up a spill, such as sorbent pads, gloves, and eye protection, should be available in the vehicle.

The **primary receptacle** holds the biological material and must be leak-proof. The closures should be secured with lids, caps, tape or parafilm to prevent them from opening due to vibration during transport. It is packed in the secondary container in such a way that, under normal conditions of transport, it will not break, be punctured, or leak its contents into the secondary container. If there are multiple fragile primary receptacles, they must be individually wrapped or separated to prevent contact.

The **secondary container** is a durable, watertight, leak-proof container that encloses and protects the primary receptacle(s). Several cushioned primary receptacles may be placed in one secondary container. If the primary receptacle contains any liquid, the secondary container must contain enough absorbent material to absorb all of the fluid from the primary receptacle(s) in case of breakage.

The **outer container** is a rigid and durable container with one side that is at least 10 cm by 10 cm (or 4 inches by 4 inches) that houses the secondary container. The outer package should be properly marked and labeled. It should be able to withstand outside influences such as physical damage while in transit. An itemized list of package contents must be included between the outer and secondary container.

Materials meeting the definition of Category B biological substances may only be transported by personal or university vehicle if they are packaged and labeled according to DOT 173.199 and PI 650 and the driver has received proper training (certified to ship/transport category B material).

Transport of Category A infectious material by personal vehicle is prohibited.

Figure 1: Sample of Types of Labels Demonstrating the UN number, labeling for type of substance, and the directional label

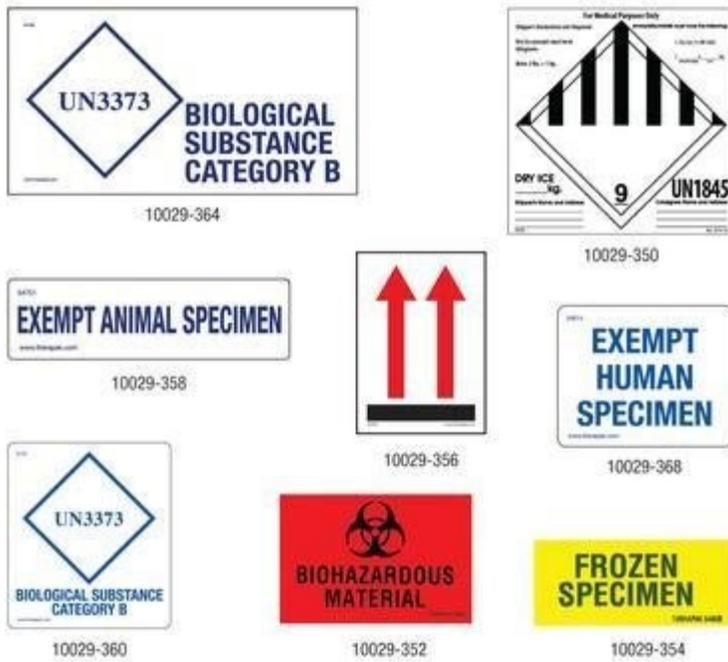


Figure 2: Category A Sample Package Labeling:

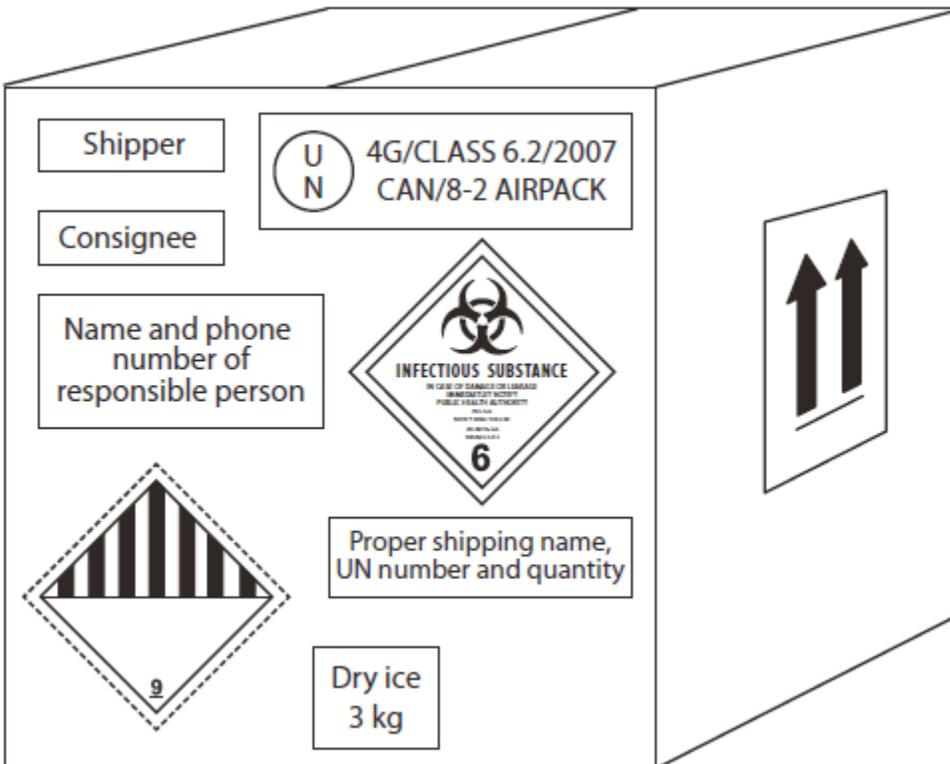
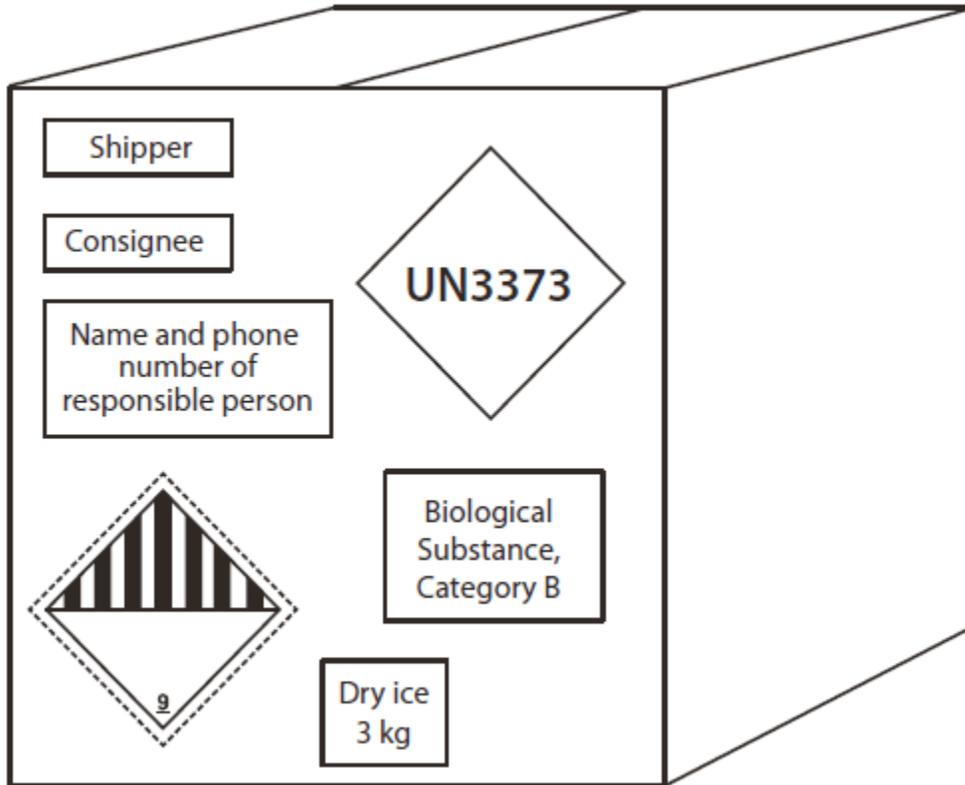


Figure 3: Category B Sample Package Labeling.



Assurance of Guidance/Education Completion:

I have reviewed the information in this training/education document and any additional information necessary to ensure that I understand the risks related to the type of materials I will be receiving or transporting, the required packaging and shipment documentation for the type of materials I will be receiving or transporting, and appropriate safety procedures in the event of a spill. I understand that I should contact the Environmental Health and Safety at (773) 325-8985 during business hours or the DePaul Public Safety Office (773_ 325-7777 (<http://publicsafety.depaul.edu/index.asp>) in non-business hours or during weekends or holidays in the event of a spill or if I have questions regarding receiving shipments of or transport of biohazardous materials.

Printed Name: _____

Signature: _____

Date completed: _____

[Please send a completed copy to the IBC/Office of Research Services with the IBC protocol materials.]