All regulated materials that are shipped to a lab for testing or analysis, shipped to a research facility, returned to the manufacturer, or sent to a field research site must follow applicable shipping requirements. To comply, regulated materials are classified according to their hazards, properly packaged, labeled, documented and handled by trained employees.

**Hazardous materials** are substances or materials that are capable of posing an unreasonable risk to health, safety and property when transported in commerce. This includes biological agents, diagnostic specimens, laboratory chemicals, compressed gases, refrigerants and equipment or instruments that contain hazardous materials.

**What Are Hazardous Materials?**

The purpose of hazardous materials regulations is to provide protection to the shippers, the carriers, the environment and the recipients of each package. To keep everyone safe from the potential hazards shipped daily, the U.S. Department of Transportation (DOT) has launched a program to aggressively pursue persons and companies who fail to comply with regulations that dictate how biological, chemical and radioactive materials must be mailed or shipped. This has been accomplished by increasing the number of inspectors five-fold and has resulted in the collection of $14 million in fines since 1997. Possible consequences for failure to comply include the following:

- Packages could be refused by the carrier
- Delivery of packages could be delayed
- Specimens or equipment could be damaged or destroyed
- Clean up of leaking packages could result in increased liability for the shipper
- Citations may be issued against the originator
- Shipment originator could be fined from $250 to $500,000
- Shipment originator could face up to 5 years in prison

**What Happens if I Don’t Comply?**

Each mode of transportation has unique regulations that must be adhered to in order to comply. In addition to each mode of transportation’s regulations, each type of sample being sent also has a set of regulations that must be followed. Shipping isolates fall under different rules depending on the mode of transportation and whether the sample has any infectious substances present. See other articles in this publication entitled “Regulatory Agencies Involved in Transportation” and “Important Terms to Know” for more details.
When shipping by mail, the Postal Service regulations require that all clinical specimens sent by U.S. mail be shipped with a minimum of First-Class postage.

A diagnostic (clinical) specimen means any human or animal material including, but not limited to, excreta, secreta, blood, blood components, tissue and tissue fluids, being shipped for purposes of diagnosis and no infectious substance is present.

A hazardous material means any article or substance designated by the U.S. DOT as being capable of posing unreasonable risk to health, safety and property during transportation. Hazardous materials are also known as dangerous goods.

A biological product means a material that is prepared and manufactured in accordance with 9 CFR 102-104 (licenses and permits for biological products), 21 CFR 312 (investigational new drug application), or 21 CFR 600-680 (biologics), such as vaccines.

An infectious substance (etiologic agent) means a viable microorganism, or its toxin, that causes or may cause disease in humans or animals. This includes any agent that causes or may cause severe, disabling, or fatal disease.

Specimens shipped by ground (courier, bus, taxi, postal service, etc.) must follow the U.S. Department of Transportation (DOT) 49 Code of Federal Regulations (CFR). When clinical specimens are being shipped and it is known the sample does not contain pathogens, then it can be sent as a diagnostic specimen. Information on shipping diagnostic specimens is found on page 3. All specimens being transported for the purpose of initial or confirmatory testing for the presence of pathogens or are known to contain a pathogen must be sent as infectious substances. Information on packaging infectious substances is found on page 4.

When shipping by air, the Postal Service regulations require that all clinical specimens sent by U.S. mail be shipped with a minimum of First-Class postage.

Most specimens sent by air are under the jurisdiction of the International Air Transport Association (IATA). The U.S. DOT rules apply to the specimens while traveling on the ground. When clinical specimens are being shipped and it is known the sample does not contain pathogens, then it can be sent as a diagnostic specimen, see the article “Packaging Diagnostic Specimens”. All specimens being transported for the purpose of initial or confirmatory testing for the presence of pathogens or are known to contain a pathogen must be sent as infectious substances.

The packaging material for infectious substances shipped by air must meet the IATA Dangerous Goods Regulations Packaging Instructions 602. This is a combination package that must be purchased and used as a unit. The outer package must display the UN (United Nations) specification marks for shipping Class 6.2 Infectious Substances. A list of package suppliers is listed in the article “Common Carriers and Package Suppliers.”

Be aware that shipping regulations are complex and changes are continually being proposed. At this time regulations are determined by multiple agencies and application of the regulations will vary dependent upon the sample being transported and the mode of transportation chosen.
Packaging Diagnostic Specimens

1. Primary Container/Vial (an organism growing on a slant, a tube of blood or serum, etc.)
   ◊ Must be watertight, includes glass, plastic, metal or screw cap tubes.
   ◊ Labeled with the following information:
     • The patient’s name or unique identifier.
     • For clinical specimens: source of the specimen and the date the specimen was taken.
   ◊ To ensure a leak-proof seal, screw caps must be fastened with tape, shrink seals, or other comparable packaging.
   ◊ Absorbent material must surround each primary container and be sufficient to absorb the total content of the primary container.

2. Secondary Container
   ◊ Must be watertight.
   ◊ Place the primary container(s) into the secondary container. Several primary containers/vials may be placed inside the secondary container if they are carefully packaged with shock-absorbent material between them to prevent breakage. The total volume (including culture medium) must not exceed 500 ml. More than one secondary container may be used. Total quantity must not exceed 4 kilograms or 4 liters.
   ◊ Enclose a letter stating the shipper’s address and phone number, the receiver’s address and phone number, and all materials being sent in the package. Place this between the secondary container and the outer packaging in a fluid-resistant protective covering.
   ◊ The primary or secondary packaging used for liquid diagnostic specimens must be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar, 13.8 lb/in$^2$) in the range of –40° C to 55° C.

3. Outer Packaging
   ◊ The outer package may be any sturdy container such as Styrofoam, fiberboard or cardboard box. The outer packaging must be able to withstand the rigors of shipment.
   ◊ Place the secondary container into the outer package.
   ◊ If the specimen(s) must be kept cold or frozen, the cold packs must be placed between the secondary and outer containers. Be sure to use cold packs, not wet ice!
   ◊ Dry Ice (CO$_2$) has additional requirements. Please call your carrier to determine what additional measures you must take.
   ◊ Shock-absorbent material must be placed so that the inner container(s) do not become loose inside the outer shipment container.

To send via most carriers, mark the package and the “Nature and Quantity of Goods” box of the airwaybill with the text “DIAGNOSTIC SPECIMEN PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650.”

Questions about what to do next? Call your carrier.

Regulatory Agencies Involved in Transportation

Agencies involved in the transportation of regulated materials include:

*Public Health Service/CDC: 42 CFR, Part 72 regulates interstate shipment of etiologic agents. The regulations provide requirements for minimum packaging and labeling for biological products and diagnostic specimens and include a list of infectious agents for which special tracking and permitting are required. For more information, see www.cdc.gov/od/ohs.


*U.S. Department of Transportation (DOT): 49 CFR, Parts 171-180 regulate ground and air transportation of diagnostic specimens, infectious substances, medical waste and chemical and radioactive materials. For more information, see www.hazmat.dot.gov.

*International Air Transportation Association (IATA) and International Civil Aviation Organization (ICAO): IATA’s infectious substances shipping guidelines regulate the shipment of hazardous materials and infectious substances by air.

*The Department of Labor, Occupational Safety and Health Administration (OSHA): 29 CFR 1910.1030, regulates the worker safety aspects of the handling, packaging and transport of human blood and body fluids.

*USDA-APHIS Veterinary Services: Permitting for import and interstate transport for animal and plant pathogens. For more information, see www.aphis.usda.gov/vs/ncie.
It is important to package biological specimens according to the regulations. The packaging is more complex than just putting the sample in an envelope or a box.

During the course of research, materials are often shipped from one location to another. While some materials can be shipped without restriction, many more are classified and regulated by the U.S. Department of Transportation (DOT) and the International Air Transportation Association (IATA) as hazardous materials. U.S. DOT and IATA regulations governing the transport of these materials were formulated to enable their safe transport and to minimize the risk to health and property.

Packaging Infectious Substances

Shippers of infectious substances must comply with the regulations and must ensure that the shipments are prepared in such a manner that they arrive at their destination in good condition and that they present no hazard to persons or animals during the shipment.

The packaging material for infectious substances must meet the regulatory guidelines for shipment of an infectious material. This is a combination package that must be used as a unit and components cannot be substituted. The outer package must display the UN (United Nations) specification marks for shipping Class 6.2 Infectious Substances. Following these regulations will assure the safety of the public and those handling the specimens during shipment. A list of package suppliers is listed in the article “Common Carriers and Package Suppliers.”

Packages must be at least 100 mm (4 in) in the smallest overall external dimension.

Packages containing greater than 50 grams or 50 milliliters must be sent via air transport per the U.S. DOT regulations.

All packages containing infectious substances must be marked durably and legibly on the outside of the package with the NAME and TELEPHONE NUMBER OF A PERSON RESPONSIBLE FOR THE SHIPMENT. An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

Each package must have the following:
- Proper shipping name
- Identification number
- Address label
- Hazard label
- United Nations packaging symbol and packaging code
- Responsible person’s name and phone number.

The regulations briefly outlined here can be found in the 49 CFR, Parts 100-185 under 173.196 Infectious Substances and in IATA under Packaging Instruction 602.

When shipping by U.S. mail, the Postal Service regulations require that all etiologic agents sent by U.S. mail be shipped at a minimum First-Class, with Registered Mail being required for specific etiologic agents as specified in

Common Carriers and Package Suppliers

Common Carriers:

Airborne Express
www.airborne.com
800-AIRBORNE (247-2676)
Airborne Express HazMat Hotline
800-558-2002
FedEx
www.fedex.com
800-GO-FEDEX (463-3339)
UPS
www.ups.com
800-PICK-UPS (742-5877)
UPS HazMat
800-554-9964
U.S. Postal Service
www.usps.com
800-ASK-USPS (275-8777)

Package Suppliers (UN Performance-Oriented):

Fisher Scientific
www.fishersci.com
800-766-7000
Labelmaster
www.labelmaster.com
800-621-5808
Lab Safety Supply
www.labsafety.com
800-356-0783
Saf-T-Pak
www.saftpak.com
800-814-7484