Transportation and Shipping

The US Department of Transportation (DOT) is the federal agency empowered by Congress to regulate the safe transport of hazardous materials in intrastate (within a state), interstate (between states), and foreign commerce. The Pipeline and Hazardous Materials Safety Administration (PHMSA) within DOT, is responsible for coordinating a national safety program for the transportation of hazardous materials by air, rail, highway and water. For more information, please go to http://hazmat.dot.gov.

The DOT hazardous materials regulations are found in Title 49 of the Code of Federal Regulations (49 CFR), parts 100 through 185. http://myregs.com/dotrspa/.

The International Air Transport Association (IATA) publishes the Dangerous Goods Regulations. http://www.iata.org/whatwedo/cargo/dangerous_goods/index.htm These regulations describe the requirements for transporting dangerous goods by air and are based on the International Civil Aviation Organization’s (ICAO) technical instructions. These instructions provide proper procedures for shippers to safely transport hazardous materials by air on member and associate member airlines.

The IATA Dangerous Goods Regulations apply to shipment of infectious substances via international and domestic air transportation. 42 CFR Part 72 and 49 CFR Parts 171 – 180 and the United States Postal Service (USPS) regulations apply to domestic transportation by land, air, sea and rail. The IATA regulations are the most stringent. These organizations periodically review and amend their regulations to maintain alignment with international standards.

Safe shipping of infectious substances involves proper packing, correct marking and labeling, complete documentation and proper classification. Training is required for any individual who prepares hazardous materials for shipping, selects packaging, completes paperwork related to shipping, handles hazardous materials including loading and unloading, and operates a vehicle used to transport hazardous materials.

Some of the other agencies having jurisdiction over the movement of biological materials are:

U.S. Customs www.customs.ustreas.gov
U. S. Postal Service http://www.usps.com/aviationsecurity/
CDC http://www.cdc.gov/od/eaipp/faq.htm

Evaluating Agency Jurisdiction
Because of the sometimes complex interplay between agencies and their respective requirements, you can ask yourself the following questions to assist in choosing the appropriate packaging, labeling and carrier.

1. Does the material I am receiving/sending contain a pathogen? See CDC;APHIS
2. Is the material I am receiving/sending a pathogen? See CDC;APHIS
3. Is the material a Select Agent? See CDC; APHIS
4. Is the material a restricted animal pathogen? See APHIS;CDC
5. Is the material a plant or plant pathogen? See APHIS
6. Is the material a human specimen? See CDC
7. Is the material an animal or animal product? See APHIS;CDC Customs
8. Is the material an animal? See APHIS; U.S. Customs
9. Is the material a genetically engineered organism? See APHIS; CDC

Since many carriers restrict what can be shipped through their service, be sure to confirm ahead of time what the shipper’s requirements are.

If you are receiving a package from a colleague overseas, it is strongly advised that you discuss packaging, labeling and carrier use BEFORE the material is shipped to the U.S. It is also advised that you contact the carrier to find out when and at what port the package will arrive.

Once this information is known, you should contact the U.S. Customs Service Office at that port and inform the agents about your package including its contents. All appropriate permits, registrations, and licenses should be in your possession BEFORE arranging the shipment. Otherwise, your package could sit in quarantine and become damaged while U.S. Customs investigates and clears the shipment for release. Also, be aware that you could incur a fine/penalty if quarantine or shipping regulations are violated.

Packaging
There are specific requirements for the packaging of biohazardous material in order to protect the people and environment that may come in contact with the package. The 5th edition of the BMBL http://www.cdc.gov/od/ohs/biosfly/bmbl5/sections/AppendixC.pdf has a section on the transportation of infectious substances.

The DOT packaging for the transport of infectious substances by aircraft is required by domestic and international aircraft carriers, and is the basis for infectious substance packaging for motor vehicle, railcar, and vessel transport. The following is a summary of each packaging type and related transportation requirements.
Category A Infectious Substance (UN 2814 and UN 2900): Figure 1. Category A material is an infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Category A substances include the select agents.

Category A infectious substances are assigned to identification number “UN 2814” for substances that cause disease in humans or in both humans and animals, or “UN 2900” for substances that cause disease in animals only. Figure 1 shows an example of the UN standard triple packaging system for materials known or suspected of being a Category A infectious substance. The package consists of a watertight primary receptacle or receptacles; a watertight secondary packaging; for liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of all primary receptacles; and a rigid outer packaging of adequate strength for its capacity, mass, and intended use. Each surface of the external dimension of the packaging must be 100 mm (3.9 inches) or more. The completed package must pass specific performance tests, including a drop test and a water-spray test, and 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 completed package must also be capable of withstanding, without leakage, temperatures in the range of -40 ºC to +55 ºC (-40 ºF to 131 ºF). The completed package must be marked “Infectious substances, affecting humans, UN 2814” or “Infectious substances, affecting animals, UN 2900” and labeled with a Division 6.2 (infectious substance) label. In addition, the package must be accompanied by appropriate shipping documentation, including a shipping paper and emergency response information.
Biological specimen, Category B (UN 3373): Figure 2. (previously known as Clinical specimen and Diagnostic Specimen). A Category B infectious substance is one that does not meet the criteria for inclusion in Category A. A Category B infectious substance does not cause permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs. The proper shipping name for a Category B infectious substance, “Biological specimen,
**Category B.**” is assigned to identification number “UN 3373.” The proper shipping names “Diagnostic specimen” and “Clinical specimen” may no longer be used after January 1, 2007.

Figure 2 shows an example of the triple packaging system for materials known or suspected of containing a Category B infectious substance. A Category B infectious substance must be placed in a packaging consisting of a leakproof primary receptacle, leakproof secondary packaging, and rigid outer packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches). The packaging must be of good quality and strong enough to withstand the shocks and loadings normally encountered during transportation.

For liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of all primary receptacles. The primary or secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of 95 kPa. The package must be constructed and closed to prevent any loss of contents that might be caused under normal transportation conditions by vibration or changes in temperature, humidity, or pressure. The completed package must be capable of passing a 1.2 meter (3.9 feet) drop test. The package must be marked with a diamond-shaped marking containing the identification number “UN 3373” and with the proper shipping name “Biological substance, Category B”. In addition, the name, address, and telephone number of a person knowledgeable about the material must be provided on a written document, such as an air waybill, or on the package itself.
Many of the laboratory vendors such as VWR, Fisher Scientific, Lab Safety Supply, and Saf-T-Pak have kits which meet all of the current regulatory requirements for shipment.

**Special Note: Dry Ice**
Many shipments include dry ice as a preservation agent. Carbon dioxide, solid or dry ice is considered a Class 9 hazardous material when transported by air or water. Specific packaging requirements must be followed to allow for the continuous release of the CO₂ gas so that pressure does not build up resulting in an explosion.