

# Management

## BULLETIN

### Packing and Shipping of Infectious Substances

Specific packaging and shipping of clinical laboratory specimens to prevent spills during transport is a requirement and is regulated by the US Department of Transportation (DOT), the International Civil Aviation Organization (ICAO), and the US Postal Service (USPS) as a class 6 hazardous material. The US DOT has regulatory authority for hazardous materials transported, in, from, and through the country by any mode except for the US mail. This includes establishing training requirements and ensuring compliance through on-site inspections. In addition, the International Air Transport Association (IATA) provides guidelines as to the shipping of infectious substances.

**Infectious substances** are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals. Infectious substances are defined as either Category A, Category B, or Exempt Patient Specimens. Category A infectious substances are in a form that can cause permanent disability or life-threatening or fatal disease in otherwise healthy people or animals if exposure occurs. Examples of Category A substances are Bacillus anthracis cultures, Ebola virus, or West Nile Virus cultures. Category A infectious substances pose a higher degree of risk. Category B infectious substances are not generally in a form that can cause permanent disability or

life-threatening or fatal disease in otherwise healthy people or animals if exposure occurs. Examples of Category B infectious substances are blood and body fluids, tissue biopsies, typical microbiology solid media culture plates, and swab specimens. Exempt patient specimens include human samples transported for routine testing not related to the diagnosis of an infectious disease. Examples of exempt human specimens include blood alcohol levels, pregnancy tests, and liver function tests.



## Packaging and Shipping Guidelines

Each laboratory responsible for the packaging and shipping of infectious substances has the responsibility to comply with all U.S. transportation regulations.

**Step 1: Classify** the type of specimen you will be transporting:

- Infectious Substance, Category A
- Biological Substance, Category B
- Patient Specimens (can be classified as Category A, Category B, or Exempt)

**Step 2: Assign** the appropriate UN identification number with its proper shipping name:

- Infectious Substance, Category A: **UN 2814, Infectious Substance Affecting Humans**
- Biological Substance, Category B: **UN 3373, Biological Substance Category B**
- Dry Ice (if used): **UN 1845 Dry Ice or Carbon Dioxide, solid**
- UN numbers or UN IDs are four-digit numbers that identify dangerous goods, hazardous substances and articles (such as explosives, flammable liquids, toxic substances, etc.) for the purpose of international transport. They are assigned by the **United Nations** Committee of Experts on the Transport of Dangerous Goods.

**Step 3: Package, mark and label** according to the appropriate packing instructions.

**Step 4:** Fill out the required shipping documents.

## Packaging and Shipping Instructions, Category A

The UN identification number and proper shipping name for Infectious Substances, **Category A is UN 2814, Infectious Substance Affecting Humans**, and must be used to identify these substances on outer packaging and shipping documents.

IATA Packaging Instruction 620 must be followed for Infectious Substances, Category A. These samples must be triple-packaged.

- Primary receptacle** must be leak-proof and sealed, and labeled with the biohazard label.
- Secondary receptacle** must be leak-proof and contain sufficient absorbent material to absorb entire contents of primary receptacle. Multiple primary containers must be individually wrapped. For surface transport, no quantity limits per package. For air transport, < 50 mL or < 50 g for passenger aircraft AND < 4 L or 4 kg for cargo aircraft.
- Outer packaging** must be UN Certified packaging, rigid and measuring not less than 100 mm. You **MUST** use one manufacturer's complete packaging; do not mix Category A shipping material from different manufacturers. An itemized list of contents must be enclosed between the secondary and outer packaging. When the infectious substance is unknown but suspected of meeting the criteria for Category A, the words "Suspected Category A Infectious Substance" must be included in parentheses on the itemized list of contents inside the outer packaging, as well as the Shippers Declaration.
- Outer packaging must be labeled** with the Infectious Substance diamond hazard label and the UN ID # with its proper shipping name adjacent, UN 2814 "Infectious Substance, Affecting Humans", To/From addresses with phone numbers, and responsible person name with a 24/7 phone number.
- You must complete a DHHS 5010 BTEP Submission form**, a Shipper's Declaration for Dangerous Goods form (accept the Terms and Conditions of usage, then log in or register by creating a username and password to access the Saf-T-Pak Shipper's Declaration) for all Category A substances and if shipping by air, a carrier-specific air waybill.

## Packaging and Shipping Instructions, Category B

The UN identification number and proper shipping name for Biological Substance, **Category B is UN 3373, “Biological Substance, Category B”** and must be used to identify these substances on outer packaging and shipping documents.

IATA Packaging Instruction 650 must be followed for Biological Substance, Category B. These samples must be triple-packaged.

- Primary Receptacle** must be leak-proof, maximum quantity 1 L, with biohazard label. The biohazard label may be placed on the primary or secondary receptacle.
- Secondary receptacle** must be leak-proof, contain cushioning material, and contain sufficient absorbent material to absorb entire contents of primary receptacle. Maximum quantity per outer package is 4 L, excluding ice or dry ice used to keep specimens cold. Multiple primary containers must be individually wrapped.
- Outer packaging** must be rigid and measuring not less than 100 mm. An itemized list of contents must be enclosed between the secondary and outer packaging. If used, wet ice or dry ice must be placed between the secondary and outer packaging; wet ice must be placed into a leak proof container and dry ice must be allowed to vent during transport.
- Outer packaging must be labeled** with the diamond UN 3373 label and its proper shipping name adjacent “Biological Substance, Category B”, To/From addresses with phone numbers, and responsible person name with an 8am-5pm phone number placed on the package, if not on the air-specific waybill. If dry ice is used, the outer packaging must also be labeled with the Miscellaneous diamond hazard label adjacent to the proper shipping name “Dry Ice” and total weight in kg.
- Submitter must complete a DHHS 5010 BTEP Submission form, and if shipping by air, a carrier-specific air waybill, noting on the waybill the substance is UN 3373, Biological Substance, Category B.



## Packaging and Shipping Instructions, Patient Specimens

Patient specimens are material collected directly from humans, including but not limited to excreta, secretions, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as diagnosis, research, investigational activities, disease treatment and prevention. Patient specimens can be considered **Exempt, Category A or Category B**.

- After careful consideration, using professional judgment based on known medical history, symptoms and individual circumstances of the source, and endemic local conditions, if the patient specimen is NOT EXPECTED to be infectious, it can be considered Exempt. However, Exempt specimens are still required to be triple-packaged, and the outer package must be labeled “Exempt human specimen”.
- **ALL cultures must be classified as Category B**, unless they are found on the Category A lists and then they must be classified as Category A.
- If the patient specimen is KNOWN to contain or REASONABLY EXPECTED to contain a pathogen listed on either IATA or DOTs Category A list, this patient specimen must be packaged, marked and labeled appropriately as Category A.



## Packaging and Shipping Training

**All employees actively involved in the responsibility for packaging and shipping infectious substances must understand classification and follow all instructions.** This applies to specimens for shipment to the state lab and other reference labs, as well as diagnostic specimens that result from exposure to a chemical threat agent.

- Federal law requires specific training and testing of all individuals “...who affect the transport of hazardous materials in commerce.”.

The North Carolina State Laboratory of Public Health (NCSLPH) sponsors a hands-on, function specific training program to assist employers in certifying their employees to safely collect, package and ship Category A, Category B and Exempt Human specimens. Classes are held numerous times throughout the year at various locations across the state. Attendance will assist in maintaining compliance with the College of American pathologists (CAP), JACHO, and DOT regulations in effect as of March 2011. See <https://slph.ncpublichealth.com/labimprovement/labtraining.asp> for more information about registration. Initial training must be function specific in order to demonstrate competency, by attending an in-person workshop.

Subsequent renewal training must be performed every two years per IATA regulations or three years per DOT and can be accomplished by successfully completing an accredited online course or attending another hands-on workshop.

## References

NCSLPH website [https://slph.ncpublichealth.com/bioterrorism/shipping\\_guidelines.asp](https://slph.ncpublichealth.com/bioterrorism/shipping_guidelines.asp)

NCSLPH Scope Guide to Laboratory Services.  
March 2018.

UN3373 website  
<https://www.un3373.com/category-biological-substances/category-a/>

International Air Transport Association website  
<https://www.iata.org/Pages/default.aspx>

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