Infectious Specimen Shipping Guidelines

Most medical specimens sent to an esoteric laboratory such as Mayo Medical Laboratories are flown on passenger aircraft or are carried by common air carrier such as FedEx. The International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA) have stringent rules to protect passengers and package handlers from exposure to these potentially infectious substances. These regulations are enforced by the Federal Aviation Administration (FAA) or other similar agencies around the world who can levy significant fines against shippers and carriers who violate the regulations.

Shipper Responsibilities
Your test send-out area is considered the “shipper” when you send specimens to a reference laboratory. Therefore, your send-out area must understand and follow regulations for shipping infectious substances affecting humans.

It is the responsibility of the “shipper” to ensure correct identification, classification, packaging, labeling, marking, and documentation for all shipments of infectious substances. In addition, the “shipper” is responsible for ensuring that all persons involved in the transport of infectious substances receive the required initial and recurrent training. Information on these requirements can be found at:

- hazmat.dot.gov/regs/rules.htm
- iata.org/dangerousgoods

Ground vs. Air
We will focus on the regulations for shipping infectious substances by air. If you use a ground service, you must follow US Department of Transportation (DOT) regulations found in “49 Code of Federal Regulations (CFR),” parts 100-185. If you use the US Postal Service, you must follow Post Office regulations. In either case, contact the Dangerous Goods Departments of the carrier you plan to use for details.

Two Categories of Specimens
IATA and ICAO have established two categories of specimens, Category A and Category B.1,2 Both specimen types require specific packaging and handling procedures designed to protect anyone who comes in contact with the package. The shipper (your send-out staff) must decide in which category specimens belong.

Under Universal Precautions, all blood and body fluids are considered potentially infectious. To clarify the situation for air transport, the regulators redefined “Infectious Substances.” Infectious substances are substances known to contain, or reasonably expected to contain, pathogens.3 These specimens must be packaged as infectious substances, following IATA Packing Instruction 620.4

On the other hand, specimens sent for diagnostic or investigational purposes are classified as “Biological Substance, Category B.” Similarly, most clinical laboratory tests (eg, sodium, thyroid-stimulating hormone) are performed on what are considered to be Category B specimens. These specimens must be packaged following IATA Packing Instruction 650.5
IATA Infectious Substances Classification
For a list of Category A infectious substances, see Infectious Substances Classification at https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf

If the name of the test you are sending to Mayo Medical Laboratories includes one of the pathogens listed in IATA Infectious Substances Classification, it should presumptively be considered Category A infectious. Of course, medical knowledge can override generalities. Some specimens may not be capable of transmitting disease. The judgment of your medical director should prevail.

Shipper's Declaration for Dangerous Goods
Regulators require that the technical name of a Category A infectious substance (eg, pathogen’s name) be on the Shipper’s Declaration for Dangerous Goods form (see example form p. 4). This poses a problem when a specimen is being sent for identification, as its name is unknown. In this situation, we suggest entering the technical name as “Suspected Category A Infectious Substance.”

If the culture being sent is not listed by IATA as a Category A infectious substance, then it can legally be sent as a “Biological Substance, Category B,” eliminating the need to prepare a Shipper’s Declaration for Dangerous Goods or to use a UN-certified container with the Class 6 hazard label.

Prepackaging Cultures
Prepack culture specimens using the Mayo Medical Laboratories’ infectious container (Supply T146). You may also use commercial packaging; follow instructions carefully.

Affixing the C Label
Mayo Medical Laboratories’ policy is to treat all actively growing cultures with extra care. To alert the send-out laboratory, the courier, and the receiving laboratory that the box contains a culture, these containers must each have affixed to them a blue “C” label (Supply T549):
- Specimen bag
- Styrofoam lid
- Shipping box

Affix a blue “C” label to each specimen bag containing any culture, whether that culture is classified as Category A or as Category B. If you do not have a Mayo Medical Laboratories’ courier who picks up and ships your specimens for you, affix blue “C” labels to the Styrofoam lid and to the outside of the box as well.

Shipping Category A Infectious Specimens
Once specimens are prepackaged, they must be boxed for shipment. If you are using a commercially available infectious mailer, follow their instructions carefully. If you are using a Mayo Medical Laboratories’ certified shipping container (Supply T146), place the prepackaged specimens into the shipping box (Supply T570) for shipment.

Mayo Medical Laboratories’ couriers have been trained to follow our standard procedures for shipping infectious substances. If your send-out area must ship the specimens themselves, be warned that the process requires the shipper to follow the “letter of the law.”
Mayo Medical Laboratories’ T570 box and T146 large infectious container.

Once the box is sealed and documentation is complete, tender the box with an air carrier such as FedEx. If any part of the labeling or documentation is incorrect, the box will be returned on the next working day. **Be sure** to complete every label and document correctly.

**References**

1. Dangerous Goods Regulations, International Air Transport Association, Montreal, Quebec, Canada, Section 3.6.2
2. Technical Instructions for the Safe Transport of Dangerous Goods Regulations, Montreal, Quebec, Canada, Section 6.3
3. Dangerous Goods Regulations, International Air Transport Association, Montreal, Quebec, Canada, Section 3.6.2
4. Dangerous Goods Regulations, International Air Transport Association, Montreal, Quebec, Canada, Packing Instruction 620
5. Dangerous Goods Regulations, International Air Transport Association, Montreal, Quebec, Canada, Packing Instruction 650

**Contact Us**

Mayo Medical Laboratories Transportation Department
800-533-1710
507-266-5700
Fax: 507-284-1790
mmltrans@mayo.edu
**Shipper’s Declaration for Dangerous Goods – Example**

The shipper (either you or the courier) must fill out a Shipper’s Declaration for Dangerous Goods for any Category A infectious substance.

<table>
<thead>
<tr>
<th><strong>SHIPPER’S DECLARATION FOR DANGEROUS GOODS</strong></th>
<th><strong>(Provide at least three copies to the airline.)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipper</td>
<td>Air Waybill No.</td>
</tr>
<tr>
<td></td>
<td>Page of Pages</td>
</tr>
<tr>
<td></td>
<td>Shipper’s Reference Number</td>
</tr>
<tr>
<td>Consignee</td>
<td></td>
</tr>
</tbody>
</table>

**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.

**NATURE AND QUANTITY OF DANGEROUS GOODS**

<table>
<thead>
<tr>
<th>UN or ID No.</th>
<th>Proper Shipping Name</th>
<th>Class or Division (Subdivision)</th>
<th>Packing Group</th>
<th>Quantity and type of packaging</th>
<th>Packing Inst.</th>
<th>Authorization</th>
</tr>
</thead>
</table>

**Additional Handling Information**

**Emergency Telephone Number**

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 labelled/labeled, 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 air transport requirements have been met.

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

Name/Title of Signatory

Place and Date

Signature (see warning above)