Shipping Infectious Agents

This module applies to personnel shipping infectious agents and dry ice.

This module is comprised of 6 parts (42 slides) and should take approximately 45 minutes to review.

A downloadable copy of this presentation is available at www.musc.edu/biosafety/Shipping.
Part I: Dangerous Goods Overview
Why is this training necessary?

The federal government requires training and certification prior to shipping or transporting hazardous materials. This presentation provides the necessary training and certification, which must be renewed every 24 months.

- Agencies providing applicable regulations and guidelines include:
  - IATA – International Air Transport Association
  - ICAO – International Civil Aviation Organization
  - DOT – U.S. Department of Transportation

Penalties for non-compliance with shipping regulations can result in the following fines:

- Up to $250,000 and up to a year jail sentence for individuals
- Up to $500,000 per incident for organizations
What are dangerous goods?

• A **dangerous good** is any article or substance capable of posing a risk to health, safety, property, or the environment. (IATA)

• A material or substance posing an unreasonable risk to health, safety, and property when transported. (DOT)

• An equivalent term is **hazardous material**, or hazmat.
What are the shipping regulations?

• By law, anyone who packs, ships, transports or receives dangerous goods must be trained to properly:
  – Identify and classify dangerous goods
  – Package dangerous goods
  – Label and mark packages
  – Document shipments

The shipper bares ultimate legal responsibility and liability for properly performing these tasks.
Key Steps for Shipping Dangerous Goods

1) **Classification**: The material being shipped must be categorized as a type of hazardous material.

2) **Identification**: The shipper selects the proper shipping information from the IATA Dangerous Goods Regulations.

3) **Packaging**: Properly packing the hazardous material for shipment.

4) **Marking**: Writing the following on the package: addresses, shipping name of hazardous material and UN code.

5) **Labeling**: Identify the package as possessing a hazardous material and give a general indication of the type of material.

6) **Documenting**: Filling in and signing the airway bill and shipper’s declaration. Maintaining records of training and shipments for two years following the shipment.
Part II. Proper Identification and Classification Of Infectious Agents
Hazard Classes

- There are nine hazard classes—two are often used by laboratories:

<table>
<thead>
<tr>
<th>Class 1: Explosives</th>
<th>Class 6: Toxic (poisonous) and Infectious Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 2: Gases</td>
<td>- 6.1 Toxic Substances</td>
</tr>
<tr>
<td>Class 3: Flammable Liquids</td>
<td>- 6.2 Infectious Substances</td>
</tr>
<tr>
<td>Class 4: Flammable Solids</td>
<td>Class 7: Radioactive</td>
</tr>
<tr>
<td>Class 5: Oxidizers and Organic Peroxides</td>
<td>Class 8: Corrosive</td>
</tr>
<tr>
<td></td>
<td>Class 9: Miscellaneous Dangerous Goods (includes dry ice)</td>
</tr>
</tbody>
</table>
2) **Identification:** The shipper selects the proper shipping information from the International Air Transport Association’s Dangerous Goods Regulations (IATA DGR).

The IATA DGR is recognized by the world’s airlines as the accepted guide for shipping hazardous materials.

The IATA DGR provides:

- The proper shipping name
- The UN number specific to each type of dangerous good
- Packing Instructions
- Quantity limits for packages
- Quantity limits for varying types of aircraft
This table provides information from the IATA Dangerous Goods Regulations that are most likely to be required when shipping infectious agents related to biomedical research.

<table>
<thead>
<tr>
<th>Shipment Type</th>
<th>Proper Shipping Name</th>
<th>UN Number</th>
<th>Hazard Class</th>
<th>Packing Group</th>
<th>Packing Instruction (PI)</th>
<th>Max. Qty. per primary package</th>
<th>Max. Net Qty/Pkg. for passenger aircraft</th>
<th>Max. Net Qty/Pkg. for cargo aircraft</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category A: Infectious substance</strong></td>
<td>Infectious Substance, Affecting Humans</td>
<td>UN2814</td>
<td>6.2</td>
<td>--------------</td>
<td>620</td>
<td>Liquids: 4 L</td>
<td>50 mL or 50 g</td>
<td>4 L or 4 Kg</td>
</tr>
<tr>
<td></td>
<td>Affecting Animals</td>
<td>UN2900</td>
<td></td>
<td></td>
<td></td>
<td>Solids: 4 Kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Category B: Infectious Substance</strong></td>
<td>Biological Substance, Category B</td>
<td>UN3373</td>
<td>6.2</td>
<td>--------------</td>
<td>650</td>
<td>Liquids: 1 L</td>
<td>4 L or 4 Kg</td>
<td>4 L or 4 Kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Solids: 4 Kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry Ice</td>
<td>Dry Ice Or Carbon Dioxide, solid</td>
<td>UN1845</td>
<td>9</td>
<td>III</td>
<td>904</td>
<td>No Limit</td>
<td>200 Kg</td>
<td>200 Kg</td>
</tr>
</tbody>
</table>
Infectious Agents are Class 6.2 Dangerous Goods

Two major classifications exist for shipping infectious substances:

• **Category A** infectious agents capable of causing permanent disability, life threatening or fatal disease in humans or animals.

  Require **Packing Instruction 620** and are assigned to either **UN 2814** (affecting humans) or **UN 2900** (affecting animals).

• **Category B** infectious agents that do not pose a risk of causing permanent disability, life threatening or fatal disease to humans or animals.

  Most infectious cultures or clinical specimens are considered Category B and are assigned **UN 3373** and follow **Packaging Instruction 650**.
### Examples of Infectious Agents Categorized as Category A, Infectious Substance Affecting Humans

<table>
<thead>
<tr>
<th>Category A Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus anthracis</em> (cultures only)</td>
</tr>
<tr>
<td><em>Brucella abortus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Brucella melitensis</em> (cultures only)</td>
</tr>
<tr>
<td><em>Brucella suis</em> (cultures only)</td>
</tr>
<tr>
<td><em>Burkholderia mallei - Pseudomonas mallei - Glanders</em></td>
</tr>
<tr>
<td>(cultures only)</td>
</tr>
<tr>
<td><em>Burkholderia pseudomallei - Pseudomonas pseudomallei</em></td>
</tr>
<tr>
<td>(cultures only)</td>
</tr>
<tr>
<td><em>Chlamydia psittaci - avian strains</em> (cultures only)</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em> (cultures only)</td>
</tr>
<tr>
<td><em>Coccidioides immitis</em> (cultures only)</td>
</tr>
<tr>
<td><em>Coxiella burnetii</em> (cultures only)</td>
</tr>
<tr>
<td><em>Crimean-Congo hemorrhagic fever virus</em></td>
</tr>
<tr>
<td><em>Dengue virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Eastern equine encephalitis virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Escherichia coli, verotoxigenic</em> (cultures only)</td>
</tr>
<tr>
<td><em>Ebola virus</em></td>
</tr>
<tr>
<td><em>Flexal virus</em></td>
</tr>
<tr>
<td><em>Francisella tularensis</em> (cultures only)</td>
</tr>
<tr>
<td><em>Guanarito virus</em></td>
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<tr>
<td><em>Hantaan virus</em></td>
</tr>
<tr>
<td><em>Hantavirus causing hantavirus pulmonary syndrome</em></td>
</tr>
<tr>
<td><em>Hendra virus</em></td>
</tr>
<tr>
<td><em>Hepatitis B virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Herpes B virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Human immunodeficiency virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Highly pathogenic avian influenza virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Japanese Encephalitis virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Junin virus</em></td>
</tr>
<tr>
<td><em>Kyasanur Forest disease virus</em></td>
</tr>
<tr>
<td><em>Lassa virus</em></td>
</tr>
<tr>
<td><em>Machupo virus</em></td>
</tr>
<tr>
<td><em>Marburg virus</em></td>
</tr>
<tr>
<td><em>Monkeypox virus</em></td>
</tr>
<tr>
<td><em>Mycobacterium tuberculosis</em> (cultures only)</td>
</tr>
<tr>
<td><em>Nipah virus</em></td>
</tr>
<tr>
<td><em>Omsk hemorrhagic fever virus</em></td>
</tr>
<tr>
<td><em>Poliovirus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Rabies virus</em></td>
</tr>
<tr>
<td><em>Rickettsia prowazekii</em> (cultures only)</td>
</tr>
<tr>
<td><em>Rickettsia rickettsii</em> (cultures only)</td>
</tr>
<tr>
<td><em>Rift Valley fever virus</em></td>
</tr>
<tr>
<td><em>Russian spring-summer encephalitis virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Sabia virus</em></td>
</tr>
<tr>
<td><em>Shigella dysenteriae type 1</em> (cultures only)</td>
</tr>
<tr>
<td><em>Tick-borne encephalitis virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Variola virus</em></td>
</tr>
<tr>
<td><em>Venezuelan equine encephalitis virus</em></td>
</tr>
<tr>
<td><em>West Nile virus</em> (cultures only)</td>
</tr>
<tr>
<td><em>Yellow fever virus</em> (cultures only)</td>
</tr>
</tbody>
</table>

Updated 2/2/09
Infectious agents that are not listed as Category A are most likely Category B agents.

- **Category B** infectious agents do not pose a risk of causing permanent disability, life threatening or fatal disease to humans or animals.

Most infectious cultures or clinical specimens are considered Category B and are assigned UN 3373 and follow Packaging Instruction 650.

Examples include:
- Adenovirus
- Herpes Simplex Virus (HSV-1)
- Epstein Barr Virus
- Streptococcal bacteria

- **Genetically Modified Organisms** (viral vectors, *E. coli* clones) are also considered Class 9 (miscellaneous) dangerous goods and are assigned UN 3245 and follow Packing Instruction 913.
Part III. Proper Packaging for Shipping Infectious Agents
Selecting the Proper Packaging

Federal regulations state that packaging used to ship hazardous materials must be tested and certified as capable of performing up to regulatory standards for ability to withstand:

- Vibrations,
- Drops,
- Pressure,
- Stacking,
- Rainfall,
- Puncture,
- Leaks,
- Etc.

It is highly recommended to purchase packaging specifically designed for shipping the intended hazardous material.

Diligence in selecting the proper packaging will safeguard your shipment, and reduce your liability in case of a shipping accident.
### Commercial Vendors of Packaging for Infectious Agents and Dry Ice

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Address</th>
<th>Phone Number</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Sea Atlanta</td>
<td>1234 Logan Circle</td>
<td>(880) 351-8600</td>
<td><a href="http://www.airseaatlanta.com">http://www.airseaatlanta.com</a></td>
</tr>
<tr>
<td>DG Supplies, Inc.</td>
<td>5 Boxal Drive</td>
<td>(800) 347-7879</td>
<td><a href="http://www.dgsupplies.com">http://www.dgsupplies.com</a></td>
</tr>
<tr>
<td>Polyfoam Packers Corporation</td>
<td>2320 S. Foster Avenue</td>
<td>(888) 765-9362</td>
<td><a href="http://www.polyfoam.com">http://www.polyfoam.com</a></td>
</tr>
<tr>
<td>All-Pak, Inc.</td>
<td>Corporate One West</td>
<td>(800) 245-2283</td>
<td><a href="http://www.all-pak.com">http://www.all-pak.com</a></td>
</tr>
<tr>
<td>CARGOpak Corporation</td>
<td>3215-A Wellington Court</td>
<td>(800) 266-0652</td>
<td><a href="http://www.cargopak.com">http://www.cargopak.com</a></td>
</tr>
<tr>
<td>HAZMATPAC, Inc.</td>
<td>5301 Polk St., Bldg. 18</td>
<td>(800) 923-9123</td>
<td><a href="http://www.hazmatpac.com">http://www.hazmatpac.com</a></td>
</tr>
<tr>
<td>SAF-T-PAK, Inc.</td>
<td>10807-182 Street, Edmonton</td>
<td>(800) 814-7484</td>
<td><a href="http://www.saftpak.com">http://www.saftpak.com</a></td>
</tr>
<tr>
<td>Inmark, Inc.</td>
<td>220 Fisk Drive S.W.</td>
<td>(800) 646-6275</td>
<td><a href="http://www.inmarkinc.com">http://www.inmarkinc.com</a></td>
</tr>
<tr>
<td>Source Packaging of New England, Inc.</td>
<td>405 Kilvert Street</td>
<td>(800) 200-0366</td>
<td><a href="http://www.sourcepak.com">http://www.sourcepak.com</a></td>
</tr>
</tbody>
</table>
Packing for Category A

• Ensure the box has the UN-certified marking, which ensures it is certified for shipping Category A agents:

```
        U
      UN
4G/CLASS6.2/07
USA/+AA4447
```

• Use a package large enough to accommodate all markings and labels without overlapping:

• Do not consolidate infectious agents categorized as Category A, Infectious Substance Affecting Humans with other infectious agents
Packing for Category A

According to packing instruction 620, your package:

- Must arrive in good condition without presenting a hazard to the public
- Must be packed in leak-proof primary and secondary packaging
- Must contain enough absorbent material between primary receptacles and secondary packaging to soak up entire contents of the shipment
- Must include an itemized list of contents between the secondary packaging and outer packaging
- Must withstand 95kPa of pressure and temperatures between 40°F and 130°F. UN certified packaging has been tested to meet these and other standards.
Packing for Category A

According to packing instruction 620, your package:

- Must fit in a box with a smallest external dimension measuring no less than 100 mm² (4 inches²)
- Must not be consolidated with any other types of agents
- Must be marked with the proper shipping name, “Infectious Substance Affecting Humans” and UN Code
- Must display the name and telephone number of a responsible contact person on the exterior
- Must provide a positive means of ensuring a leak-proof seal for ambient temperature samples (e.g. parafilm or tape around the cap).
- If shipping on dry ice, the dry ice should be outside of the secondary container or in an overpack and the outer package should be marked and labeled as a dry ice shipment.
Example of Packing and Marking for Category A Infectious Substances
(See Packing Instruction 602 for additional requirements)

Notes:
1. The smallest external dimension of the outer packaging must not be less than 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.
Packing for Category B

According to packing instruction 650, your package:

- Does not require a UN-certified box
- Must be triple packaged with a primary receptacle, secondary packaging, and rigid outer packaging
- Must include a leak-proof primary receptacle containing less than 1 liter of any liquid, as well as leak-proof secondary packaging
- Must provide a positive means of ensuring a leak-proof seal for ambient temperature samples (e.g. parafilm or tape around the cap).
- Must use packaging to prevent breakage of fragile vials
- Must contain enough absorbent material between primary receptacle and secondary packaging to soak up entire contents of the bag
Packing for Category B

According to packing instruction 650, your package:

- Must withstand 95kPa of pressure and temperatures between 40°F and 130°F
- Must contain no more than 4 liters in the outer packaging, excluding ice
- Must include an itemized list of contents between the secondary packaging and outer packaging
- Must be marked with the proper shipping name, “Biological Substance, Category B”
- Must display the name and telephone number of a responsible contact person on the exterior
- Must be labeled with the UN3373 marking
Example of Packing and Marking for Category B Infectious Substances
(See Packing Instruction 650 for additional requirements, e.g. drop test)

- Waterproof Cap
- Primary receptacle (leakproof or siftproof)
- Pack-type holder (styrofoam, sponge)
- Itemized list of contents (specimen record)
- Secondary packaging (leakproof or siftproof)
- Rigid outer packaging
- Proper shipping name
- Package marking

Notes:
1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.
Part IV: Proper Marking and Labeling of Packages Containing Infectious Agents
Marking Packages Containing Infectious Agents

Requires writing the following on the package:

• Sender’s (shipper’s) address and 24 hour phone number(s)

• Recipient’s (Consignee’s) address and 24 hour phone number(s)

• Proper shipping name of hazardous material
  (e.g. Infectious Substance, Affecting Humans)
  (e.g. Biological Substance, Category B)

• UN code

• Quantity (e.g. 10 mL, Category A only)
Labeling Category A Packages

- Packages containing substances classified as Category A, Infectious Substance Affecting Humans must be labeled with:
  - Proper shipping name, “Infectious Substance Affecting Humans”
  - UN 2814 marking
  - Name and address of shipper and consignee
  - 6.2 infectious substance label
  - Cargo-only aircraft label if box contains more than 50 milliliters or 50 grams of infectious substance
  - Name and telephone number of responsible contact person
Labeling Category A Packages

• Use proper labels:

Class 6 Hazard Label

Cargo Aircraft-Only Label

Dry Ice: Hazard Class 9 diamond

If quantities exceed 50 mL or 50 g.

If using dry ice.
Labeling Category B Packages

- Packages containing Category B, Biological substances must be labeled with:
  - The words, “Biological Substance, Category B”
  - UN3373 marking
  - UN1845 marking and Hazard Class 9 label if the substance needs to be shipped on dry ice
Part V: Proper Documentation for Shipping Infectious Agents
Documentation

• Personnel should maintain records of shipping training for two years.

• Training must be renewed every 24 months.

• Filling in and signing a shipment’s airway bill and shipper’s declaration (if needed) provides documentation of the shipment.

• Records of shipments should be maintained for two years following the shipment.
The Shipper’s Declaration

- Complete the Shipper’s Declaration for Dangerous Goods (as shown) when shipping Category A, Infectious Substances

- A Shipper’s declaration is **NOT** required for Category B Infectious agents.

Shipping name:
Infectious substance, affecting humans

Technical name (species name):
Human Immunodeficiency Virus (HIV)
Another example:
A shipper’s declaration for shipping cultured hepatitis B virus on dry ice.

Reminder:
A shipper’s declaration is only required for Category A infectious agents.
• Complete an Air Waybill for every air shipment:

  – An Air Waybill is the only document requirement for substances categorized as Category B, Biological Substance

  – Each airline has its own Air Waybill
The air waybill must include the statement:

“Dry ice, 9, UN1845, number of packages \* net weight in kilograms.”

FedEx has a check box on their airbill to satisfy this requirement. For example, the highlighted area documents 1 box containing 6 kg of dry ice.

If shipping more than 50 mL or 50 g of a Category A infectious substance, mark:

“Cargo aircraft only”
Import

The importer is legally responsible for assuring that foreign personnel package, label and ship infectious materials in accordance with the U.S. Public Health Service (USPHS) and IATA. Shipments of infectious materials imported from foreign countries require the import permits and shipping labels issued by the USPHS.

The importer must be located within the United States. Shipping labels bearing the universal biohazard symbol, address of the importer, permit number, expiration date and one or more copies of the permit must be sent to the shipper.

In return the shipper must secure the label to the package along with a copy of the permit prior to shipping. The shipper may chose to attach a letter to the package describing its contents and other pertinent information. NOTE: packages may be opened and inspected by customs officials upon entry into the U.S.

Export

Exportation of infectious material may require a license from the Department of Commerce.

Permits

Importation of microbial agents or toxins that cause disease in humans, animals or plants are subject to regulation by the federal government. Permits may be required from the CDC or USDA when importing such agents.
Other agents that may require a CDC permit include:

• Some recombinant viral vectors derived from human pathogens
• Animals and human or animal specimens that may contain a human pathogen
• Live bats
• Any living insect or other arthropod (fleas, flies, lice, mites, mosquitoes, or ticks)
• Snail species capable of transmitting a human pathogen
• Select Agent Toxins in quantities beyond exclusion limits

Animal Pathogens are regulated by the USDA.

Such agents include:

• Infectious agents of livestock
• Biological materials containing animal material.
• Tissue culture materials and suspensions of cell culture grown viruses
• Other etiologic agents containing growth stimulants of livestock origins
Part VI: Documentation of Training Associated with Shipments
Emergency Measures

• Take measures to protect yourself and your employees who ship dangerous goods:
  – Participate and maintain records of training such as:
    • General Lab Safety
    • Blood Borne Pathogen
    • Employee Right to Know
  – Always wear gloves and protective clothing
  – Consider opening packages containing infectious agents in biosafety cabinets
  – Treat all spills as if they are infectious
General Security Guidelines

- General industry guidelines for the security of dangerous goods:
  - Keep storage areas locked
  - Keep updated and accurate inventories
  - Conduct regular inspections of storage areas
  - Conduct security spot checks of personnel and vehicles
  - Lock all equipment
  - Restrict access of non-employees
Obtaining Certification

You will soon be administered a quiz on the material contained in this module.

Personnel must obtain a score of at least 85% or 13 of 15 questions correct to pass.

Individuals who fail should retake the quiz until passing.

CATTS will generate a certificate of training upon passing the quiz.

Please PRINT the Certificate and keep for two years as your record of training.

Please remember to retake the training within 24 months to keep your training current.
CATTS has experienced compatibility issues with newer versions of Internet Explorer leading to trouble printing certificates.

Troubleshooting Certificate Printing Issues

If the printing option is not available

Maximize the window

Right click on the grey background to open a windows dropdown menu

Click on “Print”

If the problem persists, contact:
Daniel Eisenman, PhD
Tel. 792-4304
eisenman@musc.edu
Questions or Emergencies Contact:

Daniel Eisenman, Ph.D.
Biosafety Officer
Phone: (843) 792-4304
Fax: (843) 792-0284
Pager: (843) 792-0590/12883
email: eisenman@musc.edu

A downloadable copy of this presentation is available at www.musc.edu/biosafety/Shipping.

Certain materials included in this presentation were adapted from the following sources with permission:
University of New Hampshire Guides for Shipping Dry Ice, Formaldehyde and Biological Materials, By Andy Globe and David R. Gillum
The MAYO Clinic Laboratories Guide to Transporting Dangerous Goods, By Terry Severson and Michelle E. Buri