



# Shipping of Biological Materials Training



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## Objectives

After the successful completion of this course, BU/BMC employees will obtain a certification to ship the following:

- Category A Infectious Substances
- Category B Biological Substances
- GMO's & GMMO's
- Exempt Animal/Patient Specimens
- Dry Ice

This training will provide you, as the responsible shipper, knowledge on how to determine the material classification, identification, packaging, marking/labeling and documentation requirements.

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# Dangerous Goods Regulations

## DOT = U.S. Department of Transportation

- Authority over all domestic shipments, ground or air

## ICAO = International Civil Aviation Organization

- Authority over all air shipments, domestically or internationally
- “The UN of Airplane Logistics and Safety”
- Developed the “Technical Instructions” for shipping dangerous goods

## IATA = International Air Transport Association

- Authority rests with the airlines IATA represents
- Took ICAO “Technical Instructions” and turned them into a comprehensive set of “Dangerous Goods Regulations”



## United States Postal Service (USPS or U.S. Mail)

- Independent federal agency that provides mail service in the U.S.
- Developed “Domestic Mail Manual”

Today's training is based mainly on the IATA “Dangerous Goods Regulations”.  
Essentially, if you comply with IATA, you're complying with all.

# What is a Dangerous Good (DG)?

“Articles or substances which are capable of posing a risk to health, safety, property or to the environment and which are shown in the list of dangerous goods in these Regulations or which are classified according to these regulations.”

- IATA, 61<sup>st</sup> Edition, page 1, Section 1.0

## Training Requirements

DOT – Retraining every 3 years

IATA – Retraining every 2 years

Accrediting Agencies – College of American Pathologists – retraining every 2 years

**BU/BMC – Retraining every 2 years  
in order to comply with all regulations**

## Applicability

The rules and requirements laid out in this training material apply to:

- Substances, in any amount, which are known or reasonably expected to contain pathogens
- Biological products (manufactured vaccines, etc.) which are not approved/packaged for use in health care by medical professionals or individuals, and which are known or reasonably believed to contain pathogens
- Patient/Human/Animal Specimens
- Genetically Modified Organisms/Micro-Organisms
- Dry Ice

## Applicability

The rules and requirements described in this training material should **NOT** be used for shipping:

### Live, infected animals

- Contact the Animal Science Center

### Medical or Clinical Wastes

- Have separate RCRA disposal requirements

### Chemicals

- Contact EH&S for assistance

### Radioisotopes

- Contact Radiation Safety for assistance



## 9 Classes of Dangerous Goods

1. Explosives
2. Gases
3. Flammable Liquids
4. Flammable Solids, Combustible
5. Oxidizing Substance
6. Toxic and Infectious Substance
  - **6.2 = Category A, Infectious Substance and Biological Substance, Category B**
7. Radioactive Material
8. Corrosive
9. Miscellaneous **Dry Ice, Genetically Modified Micro Organisms (GMMOs), Genetically Modified Organisms (GMO's)**

## The Shipper...

Is solely responsible for the Package!

- Be sure to package your box correctly every time
- Save all Shippers Declaration Forms, Commercial Invoices, Airway bills and Lists of Contents in your binder for at least 2 years
- Save closure instructions for purchased boxes

## Proper Planning

- If you are expecting to ship something in the future be prepared. Contact EHS several days in advance if needing support.
- Check Holidays especially if shipping internationally.
- Order applicable supplies far in advance! This includes Dry Ice if needed for shipment.



## Questions and Contacts

- To ensure package(s) arrive at the final destination;
- To avoid losing the integrity of your sample with delayed deliveries and costs associated;
- For any questions or concerns;

Contact Environmental Health and Safety

Telephone: 617-358-7840 (BUMC), 617-353-4094 (CRC)

## For Each Dangerous Goods Package it is the Shipper's Responsibility to:

1. Classify
2. Identify
3. Package
4. Labeling and Marking
5. Documentation
6. Contact Receivers

- IATA, 61<sup>st</sup> Edition Section 1.3 & ICAO 5.1.1

## Step 1: Classification

You must identify which of the following categories your substance falls under:

- **Category A Infectious Substance**
- **Category B Biological Substance**
- **Genetically Modified Organism/Microorganism**
- **Exempt Patient/Animal Specimen**
- **Dry Ice**

## What is an Infectious Substance?

“Substances which are known or 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.”

- IATA, 61<sup>st</sup> edition, pg. 185, Section 3.6.2.1.1

# Category A Infectious Substance

- Defined as: “An infectious substance which is transported in a form that, when exposure occurs is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.”
  - IATA 61<sup>st</sup> edition, pg. 185, Section 3.6.2.2.2.1
- Assignment must be based on known medical history and symptoms of the source human or animal, endemic local conditions or professional judgment concerning individual circumstances of the source human or animal
- Next Slide: Indicative example table 3.6.D in regulation; not exhaustive

**Dangerous Goods Regulations**

**TABLE 3.6.D**  
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.6.2.2.1)

UN Number and Proper Shipping Name	Micro-organism
UN 2814	Bacillus anthracis (cultures only)
Infectious substance affecting humans	Bacillus abortus (cultures only)
	Bacillus melitensis (cultures only)
	Bacillus suis (cultures only)
	Burkholderia mallei-Pseudomonas mallei-Glanders (cultures only)
	Burkholderia pseudomallei-Pseudomonas pseudomallei (cultures only)
	Chlamydia psittaci-avian strains (cultures only)
	Clostridium botulinum (cultures only)
	Coccidioides immitis (cultures only)
	Coxsackie burnetii (cultures only)
	Crimson-Congo haemorrhagic fever virus
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	Ectoparasitic ood, vectorogenic (cultures only)
	Ebola virus
	Filoviral virus
	Francisella tularensis (cultures only)
	Guanarito virus
	Hantaan virus
	Hantaan virus causing hemorrhagic fever with renal syndrome
	Hendra virus
	Hepatitis B virus (cultures only)
	Herpes B virus (cultures only)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Javan virus
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus
	Misburg virus
	Monkeypox virus
	Mycobacterium tuberculosis (cultures only)
	Nipah virus
	Oriskany haemorrhagic fever virus
	Poliiovirus (cultures only)
	Rabies virus (cultures only)
	Rickettsia prowazekii (cultures only)
	Rickettsia rickettsii (cultures only)
	Rift Valley fever virus (cultures only)
	Russian spring-summer encephalitis virus (cultures only)

**TABLE 3.6.D**  
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.6.2.2.1) (continued)

UN Number and Proper Shipping Name	Micro-organism
	Sabia virus
	Shigella dysenteriae Type 1 (cultures only)
	Tick-borne encephalitis virus (cultures only)
	Vaccinia virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus (cultures only)
	Yellow fever virus (cultures only)
	Yersinia pestis (cultures only)
UN 2800	African swine fever virus (cultures only)
Infectious substances affecting animals	Avian paramyxovirus Type 1-Velogenic Newcastle disease virus (cultures only)
	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Goatpox virus (cultures only)
	Lumpy skin disease virus (cultures only)
	Mycoplasma mycoides-Contagious bovine pleuropneumonia (cultures only)
	Prion protein-containing agent (cultures only)
	Rinderpest virus (cultures only)
	Sheep pox virus (cultures only)
	Swine vesicular disease virus (cultures only)
	Vesicular stomatitis virus (cultures only)

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## What is a Culture?

- “Cultures are the result of a process by which pathogens are intentionally propagated.”
- Examples include:
  1. Lab stock culture of HIV
  2. Presumptive positive diagnostic cultures being shipped for diagnostic/clinical purposes

Due to the increased risks to health, safety, and environment often cultures are classified as Category A Infectious Substance

## When the sample Affects Both Humans and Animals

Always classify materials according to the greatest potential risk

UN 2814 Infectious Substance Affecting Humans, Category A

UN 2900 Infectious Substance Affecting Animals, Category A

## Category B Biological Substance

- Still a dangerous good, but deemed somewhat less dangerous than Category A.
- Defined as *“infectious substance which does not meet the criteria for inclusion in Category A.”*

## Genetically Modified Organisms and Micro-Organisms (GMO/GMMO's)

- Defined as – “GMMOs and GMOs are micro-organisms or organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally”
- If these meet previous definitions of Category A or Category B Infectious Substance than classify according to the highest applicable risk.
  - (Example: recombinant adenovirus or genetically modified strain of *S. aureus* would both be Category B Infectious Substances)

## Exempt Patient/Human/Animal Specimen Falls under a more relaxed regulation

- IATA/DOT/USPS does not wish to overburden medical professionals shipping relatively benign samples.
- Defined as: “those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissues and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment, and prevention.”

**Note: Triple Packaging is Still Required!**

## Examples of Exempt Patient/Human/Animal Specimen

1. Routine testing of blood or urine tests ordered for a medical examination
  - Cholesterol, Blood Glucose
2. Insurance or employment tests
3. DNA tests
4. Pregnancy tests
5. Tests done for other than testing for the presence of pathogens

**If unable to make a professional judgment on presence of pathogens-  
You CANNOT consider this as an option when shipping**

## More Exempt Materials:

- Patient specimens for which there is minimal likelihood that pathogens are present
- Substances which do not contain infectious substances or substance which are unlikely to cause disease in humans or animals
- Substances containing micro-organism which are non-pathogenic to humans or animals
- Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk (unless the chemical itself is regulated)
- Environmental samples (including food and water) which are not considered to pose a significant risk of infection
- Dried blood spots, collected by applying a drop of blood onto absorbent material
- Faecal occult blood screening samples
- Blood or blood components collected for transfusion or prep to be used for transfusion or transplantation; organs and tissues to be used in transplantation

## When Shipping Exempt Human & Animal Specimens in the Same Package

Always classify materials according to the greatest potential risk



Exempt Human Specimen

Exempt Animal Specimen

## Step 2: Identification

You've determined which classification best describes your material, now you've got to give it an official name and number. All dangerous goods are assigned both:

1. Proper Shipping Name = PSN
2. United Nations Number = UN #

## UN #'s and Proper Shipping Name's

### Category A:

- UN 2814 Infectious Substance Affecting Humans
- UN 2900 Infectious Substance Affecting Animals

### Category B:

- UN 3373 Biological Substance Category B

## UN #'s and Proper Shipping Name's

### GMO's and GMMO's:

- UN 3245 Genetically modified micro-organisms
- UN 3245 Genetically modified organisms

### Dry Ice:

- UN 1845 Dry Ice

### Exempt Human or Animal Specimen:

- Exempt Human Specimen
- Exempt Animal Specimen
- No UN #

## Identification Example

You want to ship 5X5 mL of Mouse blood for routine blood chemistry panel.

- Classify:  
**Animal Specimen**
- PSN:  
**Exempt Animal Specimen**
- UN #:  
**N/A**

## Identification Example

You want to ship 1mL of an *E. Coli* strain (K12) which has been genetically modified to produce a common human enzyme that is not hazardous.

- Classify:  
**GMMO**
- PSN:  
**Genetically Modified Micro-organism**
- UN #:  
**3245**

## Identification Example

You want to ship 1mL of human serum from a patient suffering from a genetic disease to see if an enzyme is present.

- Classify:  
**Patient Specimen**
- PSN:  
**Exempt Patient Specimen**
- UN #:  
**N/A**

## Identification Example

You want to ship 1mL of human serum from a patient suffering from a genetic disease to see if an enzyme is present.

*However, this person is in a high risk group for Hepatitis/HIV infection  
(ex IV drug user)*

- Classify:

**Category B Infectious Substance**

- PSN:

**Biological Substance, Category B**

- UN #:

**3373**

## Identification Example

You want to ship 1mL of a *S. pneumoniae* strain which has been genetically modified.

- Classify:

**Category B Infectious Substance**

- PSN:

**Biological Substance Category B**

- UN #:

**3373**

## Identification Example

You want to ship 1mL of a research stock culture with Rabies

- Classify:  
**Category A Infectious Substance**
- PSN:  
**Infectious Substance, Affecting Humans Category A**
- UN #:  
**2814**

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## As a Refresher...



UN 2814 Infectious Substance Affecting Humans, Category A  
UN 2900 Infectious Substance Affecting Animals, Category A  
UN 3373 Biological Substance Category B  
UN 3245 Genetically Modified Micro-Organisms(GMMO) or  
Genetically Modified Organism (GMO)  
Exempt Animal/Patient Specimens

**Always classify materials according to the greatest potential risk and identify the package with the appropriate UN # and proper shipping name**

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## Step 3: Packaging

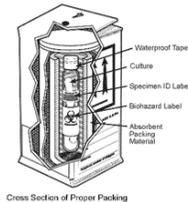
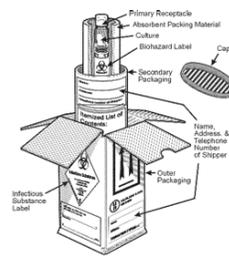
The type of packaging (the actual containers and boxes you will use) required for your shipment is dependent on how your material is classified.

The requirements are slightly different for each material

## Packaging Requirements

Common to all classifications of biological shipments is the requirement for **“Triple Packaging”**

- Leak-proof Primary Receptacle = Sample
- Leak-proof Secondary Packaging = inner container
- Cushioning and Absorbent Material
- Rigid Outer Packaging = outer shipping box



(Note this does not include Styrofoam layer if using wet/dry ice)

## Triple Packaging Examples



Leak-proof primary receptacle (sample)



Cushioning material (ex. bubble wrap)



Absorbent material (ex. paper towel)



Leak-proof secondary container



Rigid outer packaging

- Leak-proof primary container
- Cushioning material
- Absorbent material
- Leak-proof secondary packaging (biological shipper bag)



Rigid outer packaging

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## Packing Instruction (PI)

- PI 620 = Category A
- PI 650 = Category B
- PI 959 = GMMO's
- PI 954 = Miscellaneous, Dry Ice
- Exempt Patient Specimens: the requirements are listed in section 3.6.2.2.3.8 in the IATA Dangerous Goods Regulations.

**Packing Instructions must be followed for all Dangerous Goods**

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## PI 620 - Category A: General Packaging Requirements

Leakproof primary receptacle [leakproof seal, tape or parafilm screw cap]

Leakproof secondary receptacle

- Primary or secondary receptacle must withstand:
  - Pressure not less than 95kPa
  - Temperature (-40° C to 55 ° C)

In between Primary and Secondary Receptacles:

- Absorbent material (if liquid substance) in sufficient quantity
- Cushioning Material (needs to be distinct from absorbent material)

Rigid outer packaging.

- The smallest external dimension must be at least 100X100mm.
- Must meet drop test of 6.0m
- Must have UN packaging symbol
- Must have Responsible Person (as a marking) with 24hr. telephone number

Commercial Invoice (5 copies) & Shipper's Declaration (5 copies)

Itemized list of contents between secondary and outer packaging

## Example: UN Packing Symbol

- All Category A Infectious Substances require a specific type of packaging that must be sourced through a Dangerous Good's supplier.
- To ensure you have the correct rigid outer packaging, look for "UN 4G Class 6.2" stamped on the box by the manufacturer
- They are responsible for testing the box's integrity and stamp it to certify it has passed the testing criteria.

**Look for the UN Marking**



## Category A: Maximum Permissible Quantities

### Passenger & cargo air

Liquid	Solid
Up to 50 mL	Up to 50 g

### Cargo air only

Liquid	Solid
Up to 4 L	Up to 4 KG

Quantity limits do not apply to body parts, organs or whole bodies. If shipping these items as Category A material then "Special Provision A81" must be noted on the Shipper's Declaration

## PI 650 - Category B: General Packaging Requirements

Leakproof primary receptacle [leakproof seal, tape or parafilm screw cap]

Leakproof secondary receptacle

- Primary or secondary receptacle must withstand
  - Pressure not less than 95kPa
  - Temperature (- 40° C to 55 ° C)

In between Primary and Secondary Receptacles:

- Absorbent material (if liquid substance) in sufficient quantity
- Cushioning Material (needs to be distinct from absorbent material)

Rigid outer packaging

- Must meet drop test of 1.2m.
- The smallest external dimension must be at least 100X100mm (Manufacturer can supply this data)

Commercial Invoice for International Shipments (5 copies); NO Shipper's Declaration

Itemized list of contents between secondary and outer packaging

## Category B: Maximum Permissible Quantities

Land – No restrictions



Air, Rail and U.S. Mail

	Liquid	Solid
Primary Receptacle (Sample)	1 L	4 KG
Outer Packaging	4 L or 4 x 1 L bottles	4 KG

- Excludes dry ice, ice or Liquid Nitrogen when used to keep materials cold

## General requirements for Category A and Category B

- Other Dangerous Goods must not be packed in the same packaging as Class 6, Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing of hazards.

Contact EHS if packing anything other than Dry Ice with your sample

- Example: Formalin

## PI 959 – GMO/GMMO: General Packaging Requirements

- Leakproof primary receptacle [leakproof seal, tape or parafilm screw cap]
- Leakproof Secondary packaging
- Absorbent material (if liquid substance) in sufficient quantity
- Cushioning Material (needs to be distinct from absorbent material)
- Itemized list of contents between secondary and outer packaging
- Rigid outer packaging must be strong enough for its capacity, weight and intended use and with at least one surface having minimum dimensions of 100mm x 100mm"
- Commercial Invoice for International Shipments (5 copies); NO Shipper's Declaration

## Genetically Modified Micro-organism: Maximum Permissible Quantities

No Limit on any quantities whether cargo or passenger aircraft

## Exempt Human (Animal) Specimen: General Packaging Requirements

- Leakproof primary receptacle [leakproof seal, tape or parafilm screw cap]
- Leakproof secondary receptacle
- Absorbent material (if liquid substance) in sufficient quantity
- Cushioning Material (needs to be distinct from absorbent material)
- When wrapping multiple fragile primary receptacles in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.
- Rigid outer packaging must be strong enough for its capacity, weight and intended use and with at least one surface having minimum dimensions of 100mm x 100mm”.
- NO Shipper's Declaration needed

## Additional Packaging Requirements

- OSHA requirement: Biohazard symbol required on any sample that contains human blood and other potentially infectious materials (OPIM).
- This label must be affixed to the primary receptacle or secondary packaging.
- For ground shipment transported by U.S. Mail it must be affixed to the secondary packaging.
- Biohazard symbol not required for GMMO's in UN 3245



## PI 954 – Dry Ice: General Packing Requirements

- Dry Ice = Miscellaneous (Class 9) Dangerous Good
- Never seal Styrofoam container – Needs to allow off-gassing



The Styrofoam insert must be appropriately sized and fitted for the outside fiberboard box



Use one piece of clear packing tape to secure the outside fiberboard box and extend it a bit over the edge on both sides

## Dry Ice: Maximum Permissible Quantities

Passenger and Cargo Aircraft	200 KG
Cargo Aircraft only	200 KG

On average, the recommended net weight of Dry Ice per package ranges between 5 - 10 KG

~10 KG is preferred for international shipments

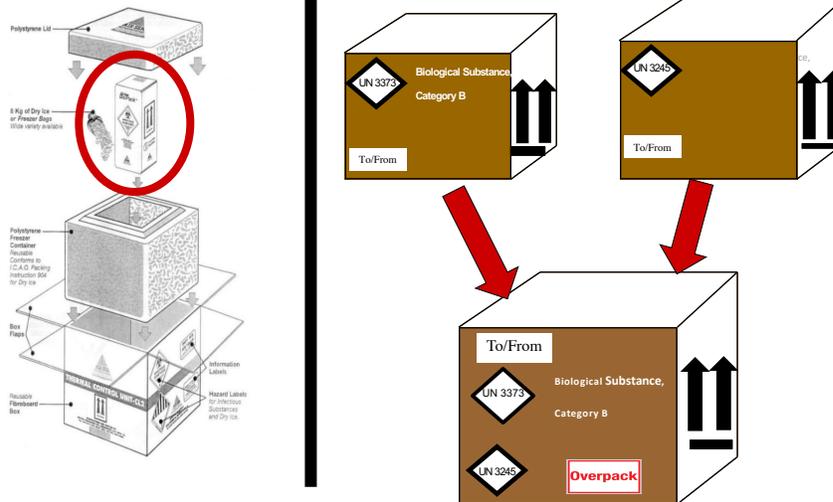
## Disposing of or Repurposing Rigid Outer Packaging

Before an empty packaging is returned to the consignor, or sent elsewhere, it must be disinfected or sterilized to nullify any hazard and any label or mark indicating that it contained an infectious substance must be removed or obliterated.

## Overpack

- An overpack is an extra outside packaging used when shipping multiple boxes to the same address or used to refrigerate materials being shipped in a smaller box.
- All markings and labels must be on the outside of the box along with the word “**OVERPACK**”
- Since your inside package is the “triple package” you need all markings and labels on that package as well.
- For Category A Infectious Substances, UN-specified packaging is not required for the overpack, only for the inner box.

## Overpack Examples



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## Step 4: Labeling

- Labeling on a package is in the form of standardized pictures that must be affixed to the outside.
- When the package dimensions are adequate, labels must be located on the same surface of the package near the Proper Shipping Name mark. IATA DG Reg 7.2.6.2.1

**Except for the orientation arrows, mount all labels and markings on the front side of the box – one surface area**

Labels are required for the following:

- Infectious Substance, Category A
- Dry Ice: Class 9 Diamond
- Cargo Aircraft Only (when applicable)
- Orientation Arrows (liquids)
- Overpack (when applicable)

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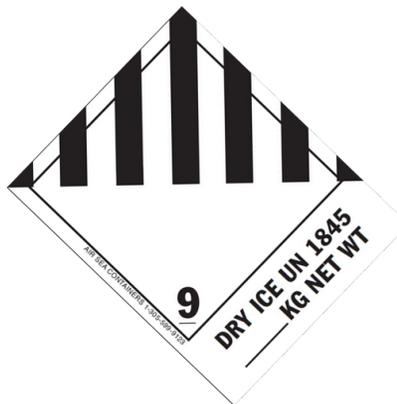
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## Category A Infectious Substance Label @ least 100mm x 100 mm



Label can be halved for smaller packages

## Class 9 Label for Dry Ice



## Cargo Aircraft Only (CAO) Label

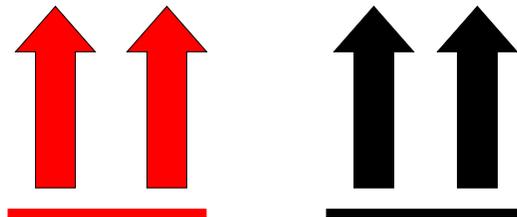
(there is an older version that says DANGER instead of CARGO AIRCRAFT ONLY– DO NOT use that one)

- @ least 120mm(width) x 110mm(height)
- For small packages of 6.2 materials, dimensions can be halved
- Must be near the hazard label
- Must be colored as shown



## Orientation Arrows Label

- Only required for shipping liquids
- Label must be affixed on 2 opposite sides and perpendicular to the front of the package
- Red or black on a contrasting background



## Overpack Label



**OVERPACK**

Height Requirement of 12mm (~0.5 inch) mandatory  
Either of these selections is acceptable

## Step 5: Marking

The markings on a package are the words and numbers that must be present.

Generally, markings include:

- Proper Shipping Name
- UN #
- Net Quantity (Category A Infectious Substance and Dry Ice)
- Contact Information
- Responsible Person (Category A Infectious Substance)
- Under IATA regulations, Category B, Biological Substance and GMMO Diamonds are each considered markings as well.

## Marking Examples: Category A

Ex 1. UN 2814 Infectious substance, affecting humans

Ex 2. UN 2900 Infectious substance, affecting animals

*Note: Do not list specific contents on fiberboard box and/or overpack!*

\*Ex You want to ship a culture of 2 mL of Lumpy Skin Disease Virus:

What would be the required marking for the outer package:

**“UN 2900 Infectious substance, affecting animals Net Quantity: 2 mL”**

## Responsible Person Contact Info.

- **Responsible Person listed on the package must have completed this training requirement prior to shipping materials:**

### Category A:

- Name and # must be listed on outside of package!

### Category B:

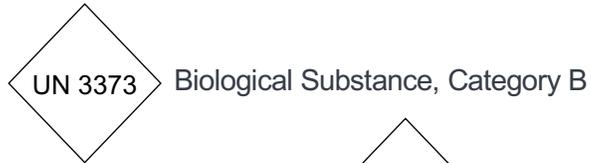
- Name and # must be listed on outside of package!

Best Practice to do this for Exempt and GMMO's as well

### Emergency Contact Number:

- 24 hour, uninterrupted, phone # where someone can be reached about the package while it is in transport

## Biological Substance Category B and GMO/GMMO



GMMO's: **Only the diamond**

- Diamond must be 2" x 2" or 50mm X 50mm
- All letters and numbers must be 6mm tall
- Outside border must be 2mm thick
- Examples on following slide



**BIOLOGICAL SUBSTANCE  
CATEGORY B**



## General Marking Requirements

- Always remember – Contact Information with To/From Address and Telephone Numbers  
(Verify all markings on the box match the information on the airway bill exactly)
- DO NOT abbreviate  
Only abbreviations permitted are: mL, L, G, KG

## Step 6: Documentation Requirements

All Shipments:

- Bill of Lading (if ground transport), or
- Airway Bill (if air transport)
  - Appearance of form will vary between carriers
  - For Us Transport use – US Airway Bill
  - For International Transport – International Expanded Airway Bill Required (**order as a supply**)
- Shipper's Declaration Form (**only** if Category A Infectious Substance)
  - In addition to Bill of Lading or Airway Bill
  - standardized format
  - Columns, border color, etc. all prescribed
- Additional International Shipment Requirements
  - Will be required to provide a Commercial Invoice
  - Contact Research Compliance Office



# Airway Bill: "Nature and Quantity of Goods"

Category B Biological Substance:

- "UN 3373 Category B Biological Substance x 1 pkg"

GMO/GMMO:

- "UN 3245 GMO/GMMO x 1 pkg"

Dry Ice:

- "UN 1845 Dry Ice 1 x 5 KG"
- Note: Requires net quantity per package

Exempt Human/Patient/Animal Specimens

- No description required on airway bill

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**FedEx** NEW Package  
Express **US Airbill**

FedEx Tracking Number: 8768 3465 4985

Form ID No. 0200

**Sender's Copy**

1 From *Please print and press hard.*  
Date: 1/3/13  
Sender's FedEx Account Number: [blank]  
Sender's Name: Colin Brown  
Phone: (617) 638-8830  
Company: Boston University EHS  
Address: 85 East Newton St, M-470  
City: Boston State: MA ZIP: 02118

2 Your Internal Billing Reference  
First 24 characters will appear on invoice. OPTIONAL

3 To  
Recipient's Name: [blank]  
Phone: (800) 442-1103  
Company: Safety Inc  
Address: 119 Foster St Bldg #6  
City: Peabody State: MA ZIP: 01960

HOLD Weekday  
FedEx location address  
RESPONSE NOT possible for  
FedEx First Overnight.

HOLD Saturday  
FedEx location address  
RESPONSE NOT possible for  
FedEx Priority Overnight and  
FedEx Standard Overnight.

4 Express Package Service \*To meet location. Packages up to 150 lbs. For packages over 150 lbs, use the new FedEx Express Freight US Airbill.  
**NOTE: Service order has changed. Please select carefully.**

**Next Business Day**

FedEx First Overnight  
Earliest next business morning delivery to select locations. Friday shipments to the addressee on Monday unless SATURDAY Delivery is selected.

FedEx Priority Overnight  
Next business morning. Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx Standard Overnight  
Next business afternoon. Saturday Delivery NOT available.

**2 or 3 Business Days**

NEW FedEx 2Day A.M.  
Second business morning. Saturday Delivery NOT available.

FedEx 2Day  
Second business afternoon. Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

FedEx Express Saver  
Third business day. Saturday Delivery NOT available.

5 Packaging \*Declared value less \$50.

FedEx Envelope\*  FedEx Pak\*  FedEx Box  FedEx Tube  Other

6 Special Handling and Signature Options

SATURDAY Delivery  
NOT available for FedEx Standard Overnight, FedEx 2Day A.M., or FedEx 2Day.

No Signature Required  
Package may be held without obtaining a signature for delivery.

Direct Signature  
Signature of shipper or recipient may sign for delivery.

Indirect Signature  
If you are unable to sign for the package, someone at your shipping address may sign for delivery for you. Signature required only for FedEx.

UN 3245 GMMO x 1 pkg

Does this shipment contain dangerous goods?  
 No  Yes per shipper  Yes per Declaration  
 Dangerous goods (including dry ice) cannot be shipped in FedEx packaging or outside an FedEx Express Shipping Box.

Dry Ice per FedEx UN 1845 1, 10 kg  
 Cargo Aircraft Only

7 Payment Bill As:  
 Shipper  
 Recipient  Third Party  Credit Card  Cash/Check

Total Packages: 1 Total Weight: 12 lbs. Total Declared Value: \$ 10

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Rev. Date 11/10 - Post #32338 - ©1994-2010 FedEx - PRINTED IN U.S.A. SBY

**The FedEx US Airbill has changed. See Section 4.**  
For shipments over 150 lbs., order the new FedEx Express Freight US Airbill.

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**FedEx US Airbill Express** FedEx Tracking Number **8715 7657 8081** Form ID No. **0200** Sender's Copy

**1 From** Please print and press hard. Sender's FedEx Account Number **SENDER'S FEDEX ACCOUNT NUMBER ONLY**

**2 Your Internal Billing Reference** OPTIONAL

**3 To** Recipient's Name, Address, City, State, ZIP

**4a Express Package Service** Packages up to 150 lbs. FedEx Priority Overnight, FedEx Standard Overnight, FedEx First Overnight, FedEx 2Day, FedEx Express Saver, FedEx 2Day Freight, FedEx 3Day Freight

**4b Express Freight Service** Packages over 150 lbs. FedEx 1Day Freight, FedEx 2Day Freight, FedEx 3Day Freight

**5 Packaging** FedEx Envelopes, FedEx Pak, FedEx Box, FedEx Tube, Other

**6 Special Handling and Delivery Signature Options** SATURDAY Delivery, No Signature Required, Direct Signature, Indirect Signature

**7 Payment - Bill to** Sender, Recipient, Third Party, Credit Card, Cash/Check

**Total Packages** 1 **Total Weight** 8 lbs **Total Declared Value\*** 10

Store your addresses at fedex.com. Simplify your shipping. Manage your account. Access all the tools you need.

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**FedEx Expanded Service International Air Waybill**

Use FedEx Expanded Service International Air Waybill for shipping Express Freight services, dangerous Goods, Broker Select and Letter of Credit shipments. When completing a FedEx Expanded Service International Air Waybill please type or print clearly, pressing hard with a ball-point pen and complete in English.

**1. Sender Information** Add your address details, phone and FedEx account number.

**2. Recipient** For reliable delivery, full and clear details are imperative.

**3. Shipment Information** Commodity Description. Be specific and detailed. List each commodity separately. Use the Commercial Invoice for any description details that don't fit on the air waybill.

Total Value for Customs: Enter the selling price or fair market value (even if not sold or for resale) of your shipment contents. It must agree with the number on your Commercial Invoice.

Total declared value for Carriage: Must not exceed the "Total Value for Customs" amount.

**4. Express Package Services** Indicate your choice of service. If no service is marked, we will send your shipment via FedEx International Priority.

**4b. Express Freight Service** Indicate your choice of service here if your package is over 150lbs/kg. Freight shipments must be booked in advance; write booking number in space provided.

**5. Packaging** Indicate your choice of packaging.

**6. Special Handling** Tick the appropriate box to choose the special service needed. Indicate whether your shipment contains dangerous goods or dry ice by ticking the appropriate box.

**6b. Broker Selection** Fill in the details if you select a broker other than FedEx.

**7a. Payment - Bill Transportation Charges** Select a method of payment and provide the appropriate FedEx Express account number or credit card number. If recipient or third party fails to pay transportation charges, the sender is responsible for payment.

**7b. Payment - Bill Duties and Taxes** Any international shipment can be subject to duties and taxes at destination. If the shipper fails to indicate on the Air Waybill the payer of duties and taxes, the consignee will automatically be billed for such charges.

If the consignee or any third party indicated by the shipper on the Air Waybill to pay the duties and taxes fails to do so, the shipper is responsible for payment.

**8. Your Internal Billing Reference** To help with your records, use this optional area for your internal shipping numbers or codes. We'll print the first 24 characters on your invoice.

**9. Required Signature** Finally sign the Air Waybill, remove the sender's copy and place the remaining copies with your shipment.

Please use if shipping Dangerous Goods with FedEx internationally

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# Commercial Invoice Example

**Commercial Invoice**

<b>Sender:</b> Boston University Diego Catalella 85 E. Newton ST Boston MA 02118 United States Of America Email Address: <a href="mailto:imevdy@bu.edu">imevdy@bu.edu</a> Phone Number: 6173587844	<b>Recipient:</b> collaborator researcher 123 way victoria 1000 Columbia V0B 0B5 Canada
<b>Invoice Date:</b> 21/03/2019	<b>Invoice Number:</b> 110221
<b>DHL Waybill Number:</b>	<b>Sender's Reference:</b>
<b>Carrier:</b> DHL	<b>Recipient's Reference:</b>

Quantity	Country of Origin	Description of Contents	Harmonized Code	Unit Weight	Unit Value	SubTotal
1	United States Of America	protein sample			1.00	1.00
<b>Total Net Weight: ( )</b>		0.000 kgs	<b>Total Declared Value: (USD)</b>	1.00		
<b>Total Gross Weight: ( )</b>		10 kgs	<b>Freight &amp; Insurance Charges: (USD)</b>	0.00		
<b>Total Shipment Pieces:</b>		1	<b>Other Charges: (USD)</b>	0.00		
<b>Currency Code:</b>		USD	<b>Total Invoice Amount: (USD)</b>	1.00		

**Type of Export:** Permanent      **Terms of Trade:** DDP - Delivered At Place

**Reason for Export:** research

**General Notes:**

The exporter of the products covered by this document declares that, except where otherwise clearly indicated, these products are of United States Of America preferential origin.

We hereby certify that the information on this invoice is true and correct and that the contents of this shipment are as stated above.

**Name:** Tanya Catalella  
**Position in Company:** researcher      **Company Stamp:**

**Signature:** \_\_\_\_\_



# Category A Infectious Substances

Airway bill: "Nature and Quantity of Goods"

- "Dangerous Goods as per attached shipper's declaration"

**Shipper's Declaration Required!**

- IATA/DOT standard format required
- Columns, border color, etc. all prescribed
- Specific agent(s) listed in parentheses following proper shipping name **(This is Not Applicable for outside fiberboard box)**
- If agent unknown then state "Suspected Category A Infectious Substance" in parentheses after PSN and on the itemized list of contents
- All contents of package/overpack must be included
- If Dry Ice is present then this must be on the declaration



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Name of SHIPPER 85 Elm Street, 3rd Boston, MA 01801		Air Weight No. 8762 3465 4985 Page 1 of 1 Pages Shipper's Reference Number optional																			
Consignee Michael Bonnet 50 rue de la Paix Paris 75 002 France																					
Person Responsible for Shipper: Tanya Cafarella 617-552-7844 First completed and signed copies of this Declaration must be handed to the operator.																					
<b>TRANSPORT DETAILS</b> This shipment is within the limitations prescribed for: (when one applies)		WADING Failure to comply in all respects with the applicable International Council Regulations may be in breach of the applicable law, subject to legal penalties.																			
PROVISIONS: AHA1 CARC1 HIR3A/ST1	Support of Dispatch Logan International Airport																				
Point of Destination Charle De Gaulle, Paris, France		Shipment Type (when applicable) HIGH-RADIOACTIVITY XXXXXX																			
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b>																					
<table border="1"> <thead> <tr> <th>UN ID No.</th> <th>Proper Shipping Name</th> <th>Net or Gross Weight (kg) or Quantity (L)</th> <th>Quantity and Type of Packing</th> <th>Testing (where applicable)</th> <th>Authorization</th> </tr> </thead> <tbody> <tr> <td>UN 2814</td> <td>Infectious Substance Affecting Humans (Dry cultures)</td> <td>6.2</td> <td>10 ml</td> <td>620</td> <td></td> </tr> <tr> <td>UN 1845</td> <td>Dry Ice</td> <td>9</td> <td>10 KG Above packed in One Fibreboard box</td> <td>954</td> <td></td> </tr> </tbody> </table>				UN ID No.	Proper Shipping Name	Net or Gross Weight (kg) or Quantity (L)	Quantity and Type of Packing	Testing (where applicable)	Authorization	UN 2814	Infectious Substance Affecting Humans (Dry cultures)	6.2	10 ml	620		UN 1845	Dry Ice	9	10 KG Above packed in One Fibreboard box	954	
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UN 1845	Dry Ice	9	10 KG Above packed in One Fibreboard box	954																	
Additional Handling Information UN 2814 ICAO/IATA ERG Code 11Y, DOT ERG 158 UN 1845 ICAO/IATA ERG Code 9L, DOT ERG 120																					
Shipper's Telephone Number: _____ Responsible person's phone #: _____		Name/Title of Shipper: Tanya Cafarella Place and Date: 18-March-2020 Signature: <i>Tanya Cafarella</i> <small>(or stamp, when)</small>																			

**Shipper's Declaration form**

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## Category A Infectious Substance - BU Registered Vendors

- USA Courier (DOT# 1217435)
- DHL Express (DOT# 315026)
- World Courier (DOT# 259596)



### FedEx has restrictions & UPS Does NOT ship Category A!!!

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## Using IATA free online form for Shipper's Declaration

- <https://www.iata.org/en/programs/cargo/dgr/shippers-declaration/>
- Choose the column format (fillable) (PDF.)
- The shipper's declaration must be typed and computer generated – **never handwritten**
- <https://www.iata.org/contentassets/a9f496cd8c87466b98142fa6d4cdb209/shippers-declaration-column-format-fillable.pdf>

## Transporter Responsibilities IATA 1.4, ICAO 7.1.1

- Inspect Document
- Inspect Package
- Store
- Load
- Transport
- Deliver Package
- Deliver 1 Copy of Shippers Declaration

## Other FedEx Requirements

- Absolutely No drop box locations!
- Schedule with FedEx a direct pickup from your BU/BMC site – **to arrange call 1-800-GO-FEDEX or 1-800-463-3339**
- Use a FedEx pouch and insert the airway bill so that it is laying flat-not folded. **Be sure to remove the sender's copy and save this documentation for 2 years.** Affix the adhesive pouch to the top of the fiberboard box.
- If there is a commercial invoice (5 copies is good practice) to include for international shipments, you may fold these together in half once and place behind the airway bill inside the pouch.
- Likewise, if your Dangerous Goods Package contains Category A, Infectious Substance, please include 5 copies of the Shipper's Declaration (keeping format/sourced colors on all pages). You may fold these together in half once and place behind the airway bill inside the pouch.

## DOT Materials of Trade Exception: 49 CFR 173.6

For Division 6.2 material one can transport human and animal samples for research diagnosis, investigational activities, disease treatment and prevention

- **Category A Infectious Substances cannot be transported in this manner**
- **The material must be transported by a motor vehicle that is not public transportation or used for a transportation based business (BU Bus, MBTA, Uber, Lyft, taxi, etc.)**
- **Must abide by the triple package system**
- When transporting multiple primary containers, the primary containers must not exceed .5L or .5kg and the outer package must not exceed 4kg or 4L
- The aggregate gross weight of all materials of trade on the motor vehicle may not exceed 200kg (440 lbs)



## DOT Materials of Trade Exception: 49 CFR 173.6 - Continued

- The package must be secured within the vehicle to prevent shifting
- Package must be properly marked and labeled
- OSHA requires a spill-kit be present including PPE and proper disinfectant
- The universal biohazard symbol must be affixed to the primary or secondary container of blood products and potentially infectious material
- The operator of the vehicle must be informed of the package, its contents and associated hazards
- If Dry Ice is utilized, then the requirements of Packing Instruction 954 must be met
- Dry ice transported in the trunk of the vehicle when possible and there should be adequate fresh air ventilation in the vehicle



## State and Operator Restrictions

- Some States (countries) impose their own restrictions regarding what can/can't be sent across their borders. Some countries may have importing requirements as well.
- Operators (carriers) (FedEx, DHL, etc.) can also impose restrictions on what they will/will not transport and it may depend on the destination as well.  
<http://www.fedex.com/us/dangerousgoods/>  
(Lists countries served and not served)
- Section 2.9 in the IATA Dangerous Goods Regulations lists these State and Operator "variations".
- **Check with EHS before sending internationally**

## U.S. Export Controls

Before you ship any material abroad, you should answer the following questions:

- What are you shipping/is an export license required?
- [Commerce Control List](#)
- [U.S. Munitions List](#)
- Who will receive it ([Restricted Parties List](#))?
- Where is it going ([Embargo Destinations](#))?
- What are they going to do with it (military application/biological weapons)?
- Is the shipment over \$2,500 or subject to a license? If so, you need to file a report with U.S. Census.
- International shipments require commercial invoice
  - Contact Export Control Office for assistance

## International Shipping

**The Office of Research Compliance Can Provide Assistance with:**

- Export Licensing Determination
- Shipment Reporting Requirements
- Temporary Export Shipments
- Export Documentation and Tariff Classification
  
- [Export Control Training](#)
- [Export Controls and Biological Research](#)

**Contact:** Research Compliance Office

**Tel:** 617-358-7882(MED)

**Web:** [www.bu.edu/researchsupport/compliance/export-control/](http://www.bu.edu/researchsupport/compliance/export-control/)

## Material Transfer Agreement (MTA)

- Material Transfer Agreements (MTAs) protect the University's intellectual property rights in materials you've created and indicate what the recipient can and can't do with them. They should routinely be used whenever you're sending out something unique that you have created (e.g. genes, proteins, hybridomas, crystallographic data, compounds, semiconductors, software etc.), whether to a company or another academic researcher.
- Contact the Office of Technology Development for a MTA form.
  - 617-353-4569
  - <https://www.bu.edu/researchsupport/forms-policies/material-transfer-agreement-mta-request/>

## Overview:

- **All Packages:**
  - To/From on Airway Bill and Package
  - Include 24hr. phone numbers
  - Triple packaging
  - The package must be secured to prevent shifting
  - Itemized list of contents between secondary and outer packaging

## Overview continued:

UN2814 Infectious Substance Affecting Humans, Category A

UN2900 Infectious Substance Affecting Animals, Category A

- PI 620
- Drop test of 6m
- UN packaging
- Category A label
- Net weight
- Responsible person (marking on package)
- Shipper's declaration required

UN3373 Biological Substance Category B

- PI 650
- Drop test of 1.2m
- Category B label

## Overview continued:

UN 3245 Genetically Modified Micro-Organisms(GMMO)

Genetically Modified Organism (GMO)

- PI 959
- UN 3245 label

UN 1845 Dry Ice

- PI 954
- Dry Ice Label
- Net weight

No UN # Exempt Human specimen

No UN # Exempt Animal specimen

- Proper Shipping Name

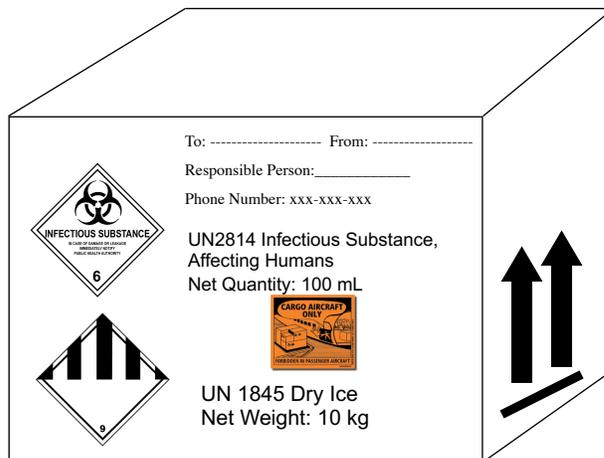
## Putting it all together: Example 1

- You want to ship 2 x 50mL vials of *HIV* cultures to a collaborator on 10 kg of dry ice.
- Classify:
  - **Category A Infectious Substance** for virus
  - **Dry Ice** for Dry Ice
- Identify:
  - **UN 2814 Infectious Substance affecting humans**
  - **UN1845 Dry Ice**
- Packaging:
  - **Triple Packaging** that meets Packing Instruction 620
  - Container Dry Ice is in must be able to ventilate

## Example 1

- You want to ship 2x50mL vials of *HIV* cultures to a collaborator on 10 kg of dry ice

### LABELING & MARKINGS:



## Example 1

- You want to ship 2 x 50mL vials of *HIV cultures* to a collaborator on 10 kg of dry ice.

- Documentation:
  - **Shipper's Declaration is REQUIRED**
  - **Note in parenthesis on description of goods the identity of the Category A substance**
  - **Dry Ice must also be included in shipper's declaration**
  - **Airway bill:** "Dangerous Goods as per attached shipper's declaration"
- Contact:
  - **Receiver before shipping**

## Example 2

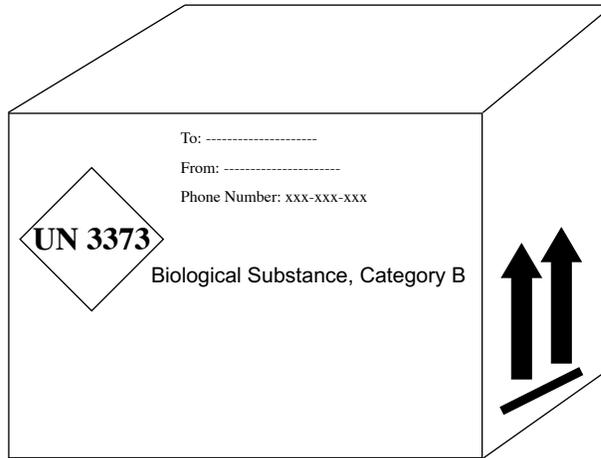
- You want to ship 2mL of a recombinant adenovirus to a collaborator on ice packs.

- Classify:
  - **Category B Infectious Substance** for virus
  - **Exempt for Ice Packs**
- Identify:
  - **UN 3373 Biological Substance, Category B**
  - **N/A for Ice Packs**
- Packaging:
  - **Triple Packaging** that meets Packing Instruction 650

## Example 2

- You want to ship 2mL of a recombinant adenovirus to a collaborator on ice packs.

### LABELING & MARKINGS:



## Example 2

- You want to ship 2mL of a recombinant adenovirus to a collaborator on 10 kg of dry ice.

- Documentation:
  - Shipper's Declaration is **NOT REQUIRED**
  - "UN 3373 Biological Substance, Category B x 1 pkg." must be written on airway bill
- Contact:
  - Receiver before shipping

### Example 3

- You want to ship 5 mL of a recombinant non-pathogenic *E.coli* strain to a collaborator.
- You are sending it in one box plus another box with plasmids.
- You will need a third insulated outer packaging for both boxes to keep everything cold with 10 kg of dry ice

- Classify:
  - **GMMO** for bacteria
  - Exempt for plasmids
  - **Dry Ice** for Dry Ice
- Identify:
  - **UN 3245 Genetically Modified Microorganism**
  - **NA for plasmids**
  - **UN1845 Dry Ice**
- Packaging:
  - **Triple Packaging** that meets Packing Instruction 959 for the E.Coli
  - Container Dry Ice is in must be able to ventilate

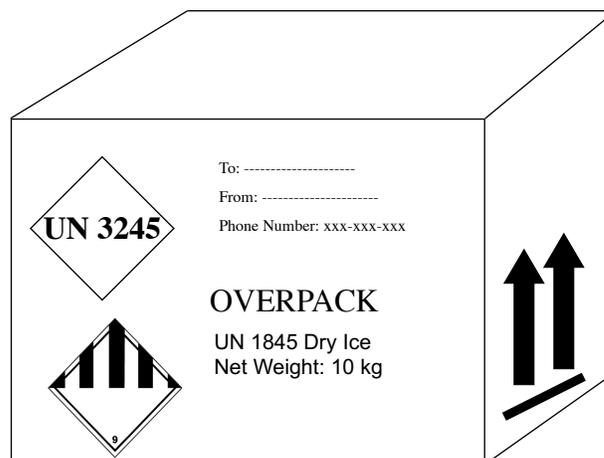
### Example 3

- You want to ship 5 mL of a recombinant non-pathogenic *E.coli* strain to a collaborator on 10 kg of dry ice.

#### LABELING & MARKINGS:

Would you need the same labeling and marking on the inner box?

**YES**



### Example 3

- You want to ship 5 mL of a recombinant non-pathogenic *E.coli* strain to a collaborator on 10 kg of dry ice.
  - Documentation:
    - Shipper’s Declaration is **NOT REQUIRED**
    - “UN3245 GMMO X 1 package” must be written on the airway bill
    - UN1845 Dry Ice and net weight also must be written. Fedex has check box for this
  - Contact:
    - Receiver before shipping



### Penalties and Fines-Examples

Violation	Baseline Assessment
No UN #	\$1000-2000
No Shipping Name	\$1000
No Emergency #	\$2600
Select Agents 42 CFR 73	\$ 250,000/individual
	\$500,000/facility



## Regulatory Resources

- IATA

Regulation citation: DGR 56th Edition.

Website: [www.iata.org](http://www.iata.org)

Telephone: 1-514-390-6770

- DOT

Regulation citation: 49 CFR 173

Website: <http://transportation.gov>

Telephone: 1-800-467-4922

- United States Postal Service

Regulation citation: 601 Mailability Section. Publication 52 Chapter 3

## Vendors for Shipping Supplies

- Air Sea Containers  
[www.Airsecontainers.com](http://www.Airsecontainers.com)

- Therapak [www.therapak.com](http://www.therapak.com)

- Thermosafe [www.thermosafe.com](http://www.thermosafe.com)

- Inmark Worldwide [www.inmarkinc.com](http://www.inmarkinc.com)

- Fisher Scientific [www.fishersci.com](http://www.fishersci.com)



Source:  
[www.inmarkinc.com](http://www.inmarkinc.com)

In an effort to maintain shipping compliance, a supplementary handout in conjunction with this training is being made available to you. Historically, this is something that was disseminated during the instructor led training course. We are encouraging you to access the materials via the EHS Website @ the following link:

<http://www.bu.edu/ehs/ehs-topics/biological/shipping-of-biological-materials/>

All labeling and markings are already at the required sizes, dimensions and colors so the difficult part has been done for you! Use them as direct templates and secure them as needed to your package with clear packing tape.



**THE END**

