



GBRMC

Shipping Infectious Substances & Biological Specimens

Student Guide

2012




GLOBAL BIORISK MANAGEMENT CURRICULUM

Shipping Infectious Substances & Biological Specimens

Welcome & Introductions




Welcome to Shipping Infectious Substances and Biological Specimens!



Introductions

- Instructors
- Students
 - What is your name?
 - Where are you from?



Slide 2

Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
<i>Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.</i>					
What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?		

Use space on back, if needed



Key Messages

- There can be many regulatory requirements that affect the shipment/transport of infectious substances. Observance of IATA regulations is the best way to ensure regulatory compliance.
- Regulations have specific definitions and criteria for dangerous goods.
- Every dangerous good is assigned a "Proper Shipping Name" (PSN) and corresponding UN identification number.
- Packing instructions inform shippers specifically how to properly package dangerous goods. All biological agents must be triple packaged.
- There are six key components that must be marked/labeled on the outside of an infectious substance package.

Slide 4



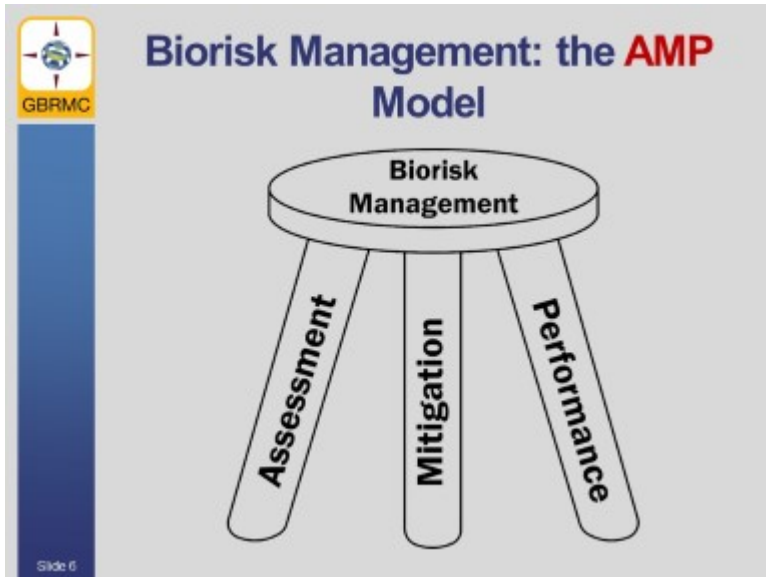
Key Messages, continued

- Overpacks are enclosures over packages, they must be marked and labeled exactly as the inner packages.
- There will be a variety of paperwork that may be required for shipping depending on the nature of the shipment. Shipper's Declarations are legal documents, three copies are required for most dangerous goods shipments.
- Before shipping high consequence agents, there are many additional considerations.
- Different countries have different requirements for importing and exporting biological materials. Consideration must be given to import and export requirements for the countries of origin and destination.

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Shipping Infectious Substances & Biological Specimens

Biorisk Management



Record refresher notes on the AMP model and **Biorisk Management**.



Key Components of Biorisk Management

- **Biorisk Assessment**
 - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable



Slide 7

Define Biorisk Assessment:



Key Components of Biorisk Management

- **Biorisk Mitigation**
 - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins



Slide 8

Define Biorisk Mitigation:



Key Components of Biorisk Management


- **Biorisk Performance**
 - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.




Define Performance:

Shipping Infectious Substances & Biological Specimens

Introduction to Safe & Secure Shipping

 **Preview Exercise**

Group Exercise:
What went wrong?
In your groups, take **10 minutes** to discuss the possible reasons why this happened and –
List at least five things that should have been done to prevent this.
Put your answers on your **flip chart**



Slide 10

Reasons why this happened?

List 5 things that could prevent this?



Preview Exercise

Expected Answers:

Failure to:

- Package correctly – using glass tubes, no leak-proof container, no absorbent.
- Label package correctly - no standard warning labels or proper shipping name.
- Execute a Shipper's Declaration for a shipment of dangerous goods – no documentation of package contents.
- To train employees in the dangers of handling packages.



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Additional answers:

Shipping Infectious Substances & Biological Specimens

Introduction to Safe & Secure Shipping



Small Group Exercise

Group Exercise:

In your group, discuss how **biological materials are moved in and out** of your laboratory and facility?

- Where are materials coming from and how?
- Where are materials going to and how?
- To whom are materials coming from or going to?

Be prepared to share one or two examples with the class

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Where are materials in your lab coming from and how?


Where are materials going to and how?

To whom are materials coming from or going to?

Shipping Infectious Substances & Biological Specimens

Introduction to Safe & Secure Shipping

 **Infectious Substance Transport**



Transport – movement of biological material outside of a restricted area

- Research labs
 - Sample transfers are necessary for study and to further research
- Public health labs and diagnostic labs
 - Sample transfers are necessary for diagnosis and analysis

Transport can occur

- Across international borders
- Within a country
- Within a facility

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Reasons for transportation of biological materials:

Shipping Infectious Substances & Biological Specimens

Introduction to Safe & Secure Shipping

 **IATA Dangerous Goods Regulations**

- IATA – Represents, leads and serves the air industry
- 230 member airlines and air carriers (93% of intl. air traffic)
- International standard – most air shipments will be inspected based on IATA requirements
- **Generally most restrictive**
- Incorporates all ICAO/UN requirements and most national regulations



http://www.iata.org/whatwedo/cargo/dangerous_goods

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Why IATA?

- Most restrictive => most universal
- “Gold” standard
- Majority of air transport services are members
- Compatible with UN/ICAO



Definitions from IATA

Dangerous Goods


- Articles or substances which are capable of posing a risk to health, safety, property or the environment
- Those goods which meet the criteria of one or more of the nine UN hazard classes

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General definition for dangerous goods:

Shipping Infectious Substances & Biological Specimens

Introduction to Safe & Secure Shipping



9 Classes of Dangerous Goods

- Class 1 Explosives
- Class 2 Gases
- Class 3 Flammable Liquids
- Class 4 Flammable Solids
- Class 5 Oxidizing substances and Organic Peroxide
- Class 6 Substances affecting health**
- Class 7 Radioactive Material
- Class 8 Corrosives
- Class 9 Miscellaneous Dangerous Goods

6.1 Toxic Substances and
6.2 Infectious Substances

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Other substances that are occasionally shipped together with biological agents are also considered dangerous goods and require special considerations.

List some examples of other substances:



Key Components of Biorisk Management

- **Biorisk Assessment**
 - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable



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Define Biorisk Assessment for Shipping:

Shipping Infectious Substances & Biological Specimens

Shipping Risk Assessment



Shipping Risk Assessment

Group Exercise:

In your group, take **15 minutes** to:

- Identify several risks associated with shipping.
- Think about some of the worst-case consequences for each of these risks. What determines the degree of consequences?
- What determines the likelihood of occurrence for each of these risks?

Put the identified risks on your flip chart and be prepared to define the likelihood and consequences for each risk

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What are risks associated with shipping?

What determines the degree of consequences?

What determines the likelihood of occurrence for each of these risks?



Shipping Risk Assessment

Group Exercise:

In your group, discuss the following:

- Do all biological material shipments have the same level of risk?
- What are some of the key differences in biological material shipment that might increase or decrease those risks?

Identify **2 or 3 key differences in biological material** that would alter the associated risks; put these on your **flip chart**.

- Can you use these differences to create shipping classifications?

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Do all biological material shipments have the same level of risk?


What are some of the key differences in biological material shipment that might increase or decrease those risks?

Key differences in biological material that would alter the associated risks:


- 1.
- 2.
- 3.

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories

 **Definitions: Infectious Substance**

Infectious substances are substances which are known or are reasonably expected to contain human or animal pathogens.




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IATA definition of infectious substance:
Infectious substances are substances which are known or are reasonably expected to contain human or animal pathogens.


Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories



Definitions: Cultures

Cultures are the result of a process by which pathogens are intentionally grown.



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Define culture:

Examples:

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories



Definitions: Patient Specimens

Patient Specimens are those collected **directly** from humans or animals.

Examples include: blood, sputum, urine, tissue biopsy, swabs, and body parts.



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Define patient specimens:

List some examples of patient specimens:

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories



Definitions: Category A

Category A:

An infectious substance which is transported in a **form** that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in **otherwise healthy** humans or animals



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Category A:

An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.


List some examples of Category A substances:

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories

 **Definitions: Category B**

Category B:
An infectious substance which does not meet the criteria for inclusion in Category A



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Category B:
Consists of all the non-deadly pathogenic agents; the low to medium risk infectious substances.

List some examples of substances that would be considered Category B:

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories



Definitions: Exempt Patient Specimens

- Patient specimens for which there is **minimal likelihood** that pathogens are present are not subject to these Regulations if the specimen is transported in packaging that will prevent any leakage and which is marked with the words "**Exempt human specimen**" or "**Exempt animal specimen**"
- Note: In determining whether a patient specimen has minimal likelihood . . . an element of **professional judgment** is required . . . that judgment should be based on:
 - known medical history
 - symptoms
 - individual circumstances
 - endemic local conditions

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Requirements for "Exempt human specimen" or "Exempt animal specimen":

- 1.
- 2.
- 3.

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories



Anthrax Bioterrorism Scenario

A letter containing a terror threat and a mysterious white powder is opened at the Ministry of Defense office building




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Record significant observations:

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories

 **Anthrax Bioterrorism Scenario**

- Nasopharyngeal swabs are collected from potentially exposed office workers
- The swabs will be transported to local clinical laboratory for analysis
- **Are they infectious substances?**
- **Would you classify these as Category A or B?**

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Record significant observations:

Should the swabs being transported be considered infectious substances?


How would you classify these as A or B?

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories

 **Anthrax Bioterrorism Scenario**

- The clinical lab cultures the swabs and determines that several colonies from three individuals appear to be *Bacillus anthracis*
- These are sub-cultured and agar stabs are prepared for shipment to Central lab for verification
- **How do you classify these cultures (Category A or B)?**




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How do you classify these cultures?


Is the risk different between the clinical specimen and the culture?

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories

 **HIV Scenario**

- Blood is collected from a patient with AIDS in order to determine HIV viral load
- **Is this sample an infectious substance?**
- **Is HIV on the Indicative list? Is this a culture or patient specimen?**
- **How would you classify this test tube of blood (Category A or B)?**



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Is the collected blood sample an infectious substance?

Is HIV on the Indicative list? Is this a culture or patient specimen?


How would you classify this test tube of blood?

Shipping Infectious Substances & Biological Specimens

Shipping Definitions & Categories

 **Gonorrhoea Scenario**

- Patient presents with symptoms of gonorrhoea
- **Urine is collected and sent to lab for culture.**
- **Is this an infectious substance?**
- **Is *Neisseria gonorrhoeae* on the Indicative list?**
- **How would you classify this urine (Category A or B)?**



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Is the urine sample collected an infectious substance?

Is *Neisseria gonorrhoeae* on the Indicative list?

How would you classify this urine sample?

Shipping Infectious Substances & Biological Specimens

Classification & Shipping Names



Classification Exercise

Exercise:

Working in groups, take up to **15 minutes** to **classify the following samples**.

If you have any questions about the nature of the samples, don't hesitate to ask the instructor

The samples will fall into one of four categories:


1. Infectious substance, Category A
2. Infectious substance, Category B
3. Exempt Human/Animal Specimen
4. Not Regulated (excepted from the regulations)

Working in groups, perform a risk assessment. Use your knowledge of the regulatory definitions to complete the table below by indicating the appropriate classification.


Material	What is known or expected	Classification (A, B, Exempt*, Not Regulated)
1. Chicken blood	Suspected H5N1 Highly Pathogenic Avian Influenza.	
2. Human, oropharyngeal swab	Suspect <i>Streptococcus</i> .	
3. Human sputum sample	Testing for <i>Mycobacterium tuberculosis</i> .	
4. Culture of Acid Fast Bacilli (AFB)	Testing antibiotic susceptibility. Probable <i>Mycobacterium</i> spp.	
5. Dead bat	Testing for rabies. Presence of rabies virus is likely.	
6. Human breast tissue biopsy	Cancer screening. Patient health status or medical history is unknown.	
7. Culture of <i>Staphylococcus aureus</i>	Clinical isolate. Testing for antibiotic susceptibility.	
8. Human, pustule/skin scraping	Possible small pox (Variola virus).	
9. Culture of <i>Salmonella typhi</i>	Clinical isolate. Sent to determine serotype.	
10. Bovine sera	Possible case of foot and mouth disease.	
11. Human urine and human blood	Minimal likelihood of disease. Sent for pregnancy testing.	
12. McDonald's French Fries	Tastes good, lots of fats and salt.	
13. Culture of <i>Bacillus anthracis</i>	Isolated from a dead goat.	

Shipping Infectious Substances & Biological Specimens

Classification & Shipping Names



Proper Shipping Names & UN ID Numbers



CLASSIFICATION	PROPER SHIPPING NAME	PSN	UN ID	HAZARDOUS CLASSIFICATION				HAZARDOUS CLASSIFICATION	UN ID		
				Class	Subclass	Division	Subdivision			Class	Subclass
2.3	Infectious substances, Category B	6.2	2811	2.3	Infectious substances	6.2	2811	2.3	Infectious substances	6.2	2811
6.2	Infectious substances, Category B	6.2	2811	6.2	Infectious substances	6.2	2811	6.2	Infectious substances	6.2	2811
6.1	Infectious substances, Category A	6.1	2812	6.1	Infectious substances	6.1	2812	6.1	Infectious substances	6.1	2812
6.0	Infectious substances, Category A and B	6.0	2813	6.0	Infectious substances	6.0	2813	6.0	Infectious substances	6.0	2813

- Every dangerous good must be assigned a **Proper Shipping Name (PSN)**
- The United Nations publishes a list of internationally standardized proper shipping names with corresponding four digit "UN" identification numbers
- **A dangerous good can have only one PSN**

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Every dangerous good has one (and only one) PSN assigned by the shipper.

PSNs come from international agreement out of the UN and are in English.

Dangerous goods can be identified by both the PSN and/or the corresponding UN ID no.

Shipping Infectious Substances & Biological Specimens

Classification & Shipping Names



Examples of Proper Shipping Names

Category A

- UN 2814 – Infectious substance, affecting humans
- UN 2900 – Infectious substance, affecting animals only

Category B

- UN 3373 – Biological substance, Category B

Dry Ice

- UN 1845 – Dry ice
- UN 1845 – Carbon dioxide, solid

Exempt

- Exempt human specimen
- Exempt animal specimen

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Note key shipping names:
Category A

UN 2814-

UN 2900-

Category B

UN 3373-

UN 1845-

Shipping Infectious Substances & Biological Specimens

Classification & Shipping Names



Proper Shipping Name Exercise

- Using the samples that you classified previously, **assign a proper shipping name** to each.
- Record your answers on the sheet provided.



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PSNs must appear exactly as they do on the list. Do not abbreviate or take short cuts.

Assign and write down the proper shipping name for each example below. You may refer to the answers you recorded from previous classification exercise.

Material	What is known or expected	Proper Shipping Name
1. Chicken blood	Suspected H5N1 Highly Pathogenic Avian Influenza.	
2. Human, oropharyngeal swab	Suspect <i>Streptococcus</i> .	
3. Human sputum sample	Testing for <i>Mycobacterium tuberculosis</i> .	
4. Culture of Acid Fast Bacilli (AFB)	Testing antibiotic susceptibility. Probable <i>Mycobacterium</i> spp.	
5. Dead bat	Testing for rabies. Presence of rabies virus is likely.	
6. Human breast tissue biopsy	Cancer screening. Patient health status or medical history is unknown.	
7. Culture of <i>Staphylococcus aureus</i>	Clinical isolate. Testing for antibiotic susceptibility.	
8. Human, pustule/skin scraping	Possible small pox (Variola virus).	
9. Culture of <i>Salmonella typhi</i>	Clinical isolate. Sent to determine serotype.	
10. Bovine sera	Possible case of foot and mouth disease.	
11. Human urine and human blood	Minimal likelihood of disease. Sent for pregnancy testing.	
12. McDonald's French Fries	Tastes good, lots of fats and salt.	
13. Culture of <i>Bacillus anthracis</i>	Isolated from a dead goat.	


Shipping Infectious Substances & Biological Specimens

Shipping & Transport Risk Mitigation



Key Components of Biorisk Management

- **Biorisk Mitigation**
 - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins



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Define Biorisk Mitigation for Shipping:

Shipping Infectious Substances & Biological Specimens

Shipping & Transport Risk Mitigation



How Do Mitigate the Risks Associated with Shipping?

Through Mitigation Control Measures:

- Engineering Controls
- Administrative Controls
- Practices and Procedures
- Elimination



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Notes:

Shipping Infectious Substances & Biological Specimens

Shipping & Transport Risk Mitigation



Mitigation Control Measures

- Engineering Controls**
 - Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards
- Administrative Controls**
 - Policies, standards and guidelines used to control risks
- Practices and Procedures**
 - Processes and activities that have been shown in practice to be effective in reducing risks
- Personal Protective Equipment**
 - Devices worn by the worker to protect against hazards in the laboratory
 - This measure is not applicable in shipping since the materials have left the laboratory**



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Notes:

Shipping Infectious Substances & Biological Specimens

Shipping & Transport Risk Mitigation



Shipping Risk Mitigation

Group Exercise:

- Engineering Controls**
 - Identify one or two engineering control measures that reduce a risk of **shipping** biological material
- Administrative Controls**
 - Identify one or two administrative control measures that reduce a risk of **shipping** biological material
- Practices and Procedures**
 - Identify one or two practices or procedures that reduce a risk of **shipping** biological material



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Identify one or two engineering control measures that reduce a risk of shipping biological material.

Identify one or two administrative control measures that reduce a risk of shipping biological material.

Identify one or two practices or procedures that reduce a risk of shipping biological material.

Shipping Infectious Substances & Biological Specimens

Shipping & Transport Risk Mitigation



Shipping Risk Mitigation

Expected Responses:

- Engineering Controls**
 - Packaging, marking/labeling, and documentation
 - Package security
- Administrative Controls**
 - Authorizing shipments
 - Material Transfer Agreements
 - Import and Export licenses
 - Carrier selection and requirements
- Practices and Procedures**
 - Training
 - Tracking of materials



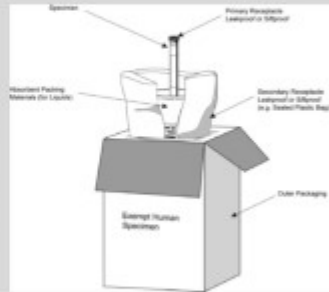
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Notes:



Principles of Packaging

- Must be designed to withstand damage and prevent leakage during transport
- Must be labeled in a manner to alert carriers of hazards
- Must have documentation to alert operators and emergency responders to hazards and allow for appropriate response in event of leakage/damage



Notes:



Overview of Packaging

Triple packaging required for Category A, B, and Exempt

Primary receptacle

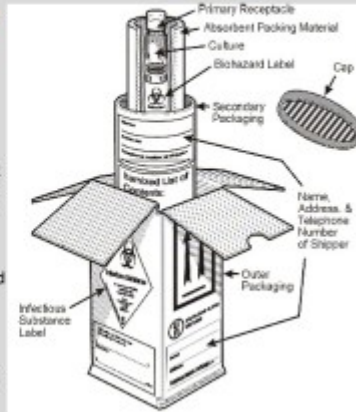
- A primary watertight, leakproof receptacle containing the specimen

Secondary packaging

- A durable, watertight, leakproof packaging to enclose and protect the primary receptacle(s)
- Absorbent material shall be used to absorb all fluid in case of breakage

Outer packaging

- Secondary packagings are placed in outer packagings with cushioning material
- Outer packagings protect their contents from physical damage while in transit
- At least one external surface with a minimum dimension of 10x10 cm



Packaging Requirements:
Primary receptacle:


Secondary **Packaging:**

Outer **Packaging:**

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Shipping Infectious Substances & Biological Specimens

Packaging



Category A Packaging: IATA PI 620

- Good condition
- Leakproof primary
- Leakproof secondary
- Pressure capable primary or secondary
- Absorbent (for liquids)
- Multiple fragile primaries wrapped individually
- Itemized list
- Rigid outer packaging
- 4 in. minimum
- Qty Limit 50 mL or 50 g for passenger aircraft. 4 L or 4 kg for cargo only aircraft
- Name and telephone # marked on package
- **Must be marked with UN specification**

U 4G/Class 6.2/2010
N USA/+AA16324

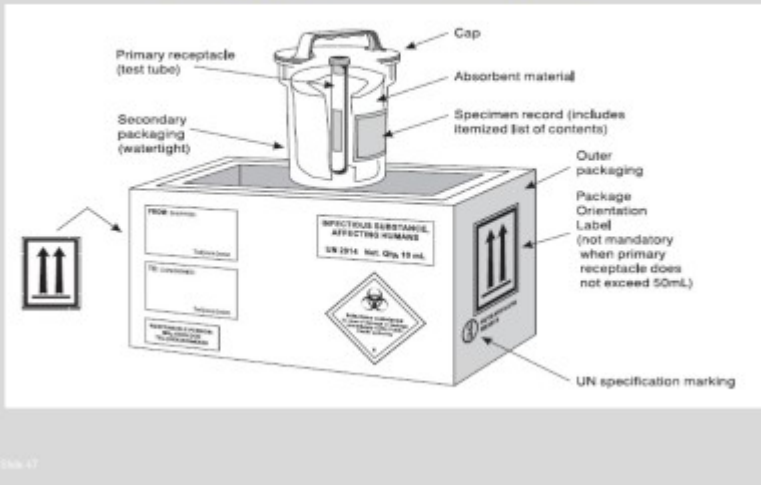
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Category A key components:

Shipping Infectious Substances & Biological Specimens

Packaging

Category A Packaging



The UN specification mark is an indication from the manufacturer of the **Packaging** that the package has been tested and certified to these standards.

Shipping Infectious Substances & Biological Specimens

Packaging



Category B Packaging: IATA PI 650

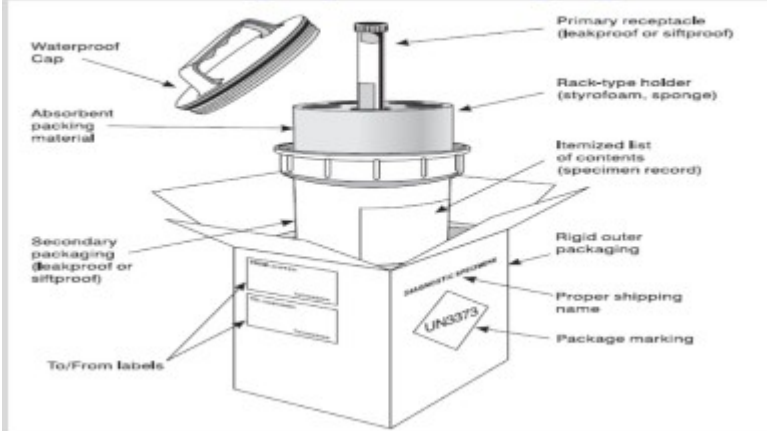
- Good quality
- Leakproof/siftproof primary (1 L max)
- Leakproof/siftproof secondary
- Absorbent
- Multiple fragile primaries wrapped individually
- Pressure capable primary or secondary
- Itemized list
- Rigid outer packaging
- Two sides at least 4 in.
- Qty. less than 4L or 4kg
- Name and telephone # marked on package or airwaybill
- **NO spec marks but 1.2m drop**

Category B key requirements:

Shipping Infectious Substances & Biological Specimens

Packaging

Category B Packaging

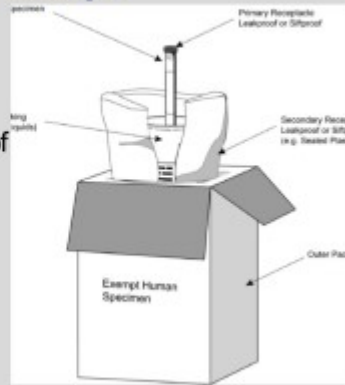


Note: "Diagnostic specimens" is no longer an acceptable proper shipping name and must be replaced with "Biological Substance, Category B".



Before a specimen is considered "Exempt"

- Must be a patient specimen
- Professional determination - minimal likelihood of pathogens
- Must be triple packaged
- Package marked "Exempt Human Specimen" or "Exempt Animal Specimen"



"Exempt human specimens" are considered dangerous goods by IATA until they meet three criteria:

1. A professional determination has been made that the material has a "minimal likelihood" of containing any pathogens
2. They are triple packaged as shown
3. The package is marked "exempt human specimens"



Can Packaging be Re-used?

Group Exercise

Work in your groups to discuss at least three **factors, considerations, risks, or concerns** with re-use.

1. Do any of these factors change if the shipment is Category A vs. Category B or exempt?
2. What are ways to mitigate these risks?

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Can **Packaging** be re-used?

- 1.
- 2.
- 3.

Do any of these factors change if the shipment is Category A vs. Category B or exempt?

What are ways to mitigate these risks?

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

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Marking & Labeling Overview

Markings provide information on

- Contents of package
- Nature of hazard
- Applicable packaging standards
- Must be clearly visible

Labels – two types

- Hazard labels required for most dangerous goods
 - Diamond-shaped
- Handling labels required for some dangerous goods
 - Various shapes
- Affixed to outside of each package



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Markings provide information for:

-
-
-
-

Labels
-Diamond-shaped

-Various shapes

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

 **Marking & Labeling**

- Addresses of shipper and consignee
- Name and Phone number of person responsible
- Applicable Hazard label for each dangerous good
- Proper shipping name
- UN Number
- Quantity of Dry Ice




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There are the six required marks and labels associated with Class 6.2 dangerous good shipments and dry ice:


-
-
-
-
-
-

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

 **Proper Shipping Names and UN ID Numbers**

- The name must appear exactly (no abbreviation, no spelling errors, no extra information) on both the package and the paperwork
- The UN ID number always is listed next to the name



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PSNs with their associated UN Id. numbers appear next to the hazard label they are associated with.



Class Exercise: Marking & Labeling

Exercise:

Using the blank picture of a box - mark and label based on the following:

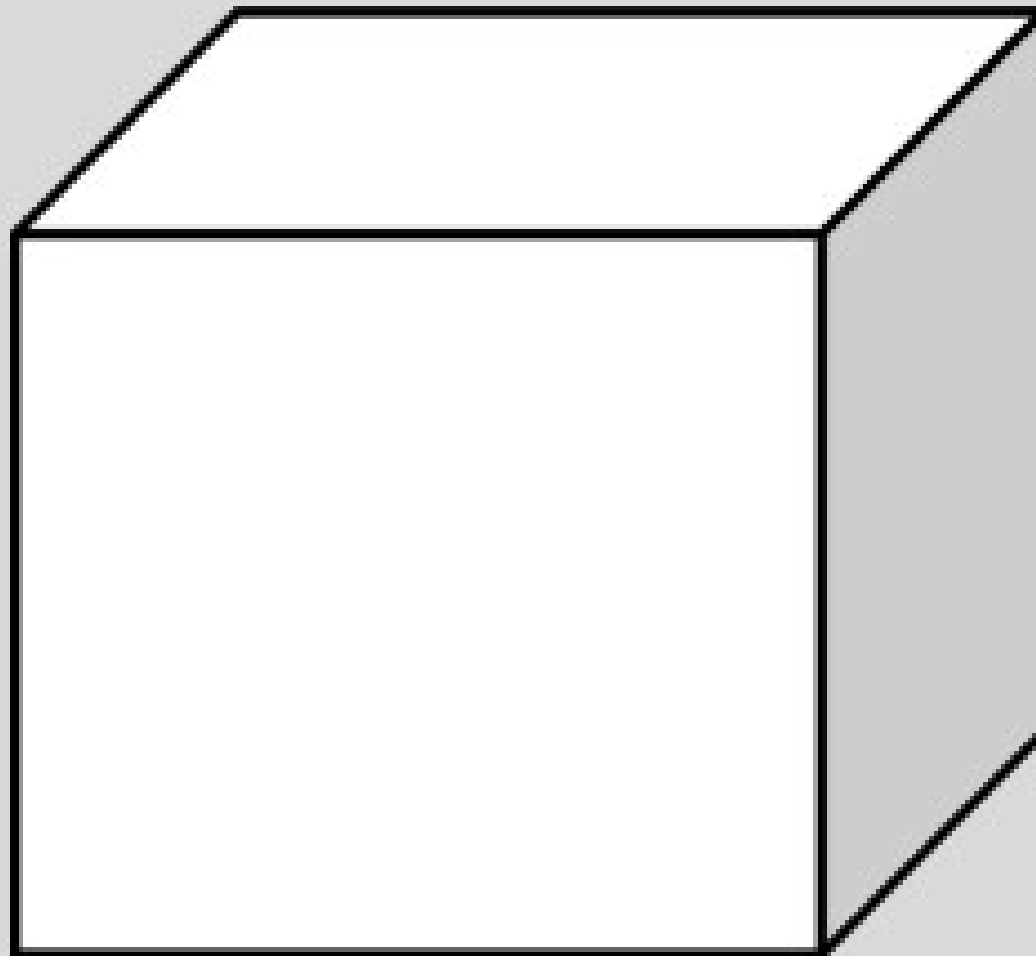
The package contains **frozen HIV positive human plasma**. The plasma must remain frozen, so 5 kg of dry ice is present in the package.

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Perform this exercise on the blank box on the following page.



Class Exercise: Marking & Labeling



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Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

Class Exercise: Marking & Labeling

The diagram shows a 3D perspective of a white shipping box. On the front face, there is a rectangular label with the following text: 'From: Sam Sedgwick, ACMS Lab, Magoroni Rd, Doris Selam, United Republic of Tanzania', 'Biological substance, Category B', 'UN 3373' (with a diamond hazard symbol), 'UN 1845', 'Dry ice', '5kg' (with a diamond hazard symbol), and 'Person Responsible: Dr. Mary Smith, 014-123-4567'. On the right side of the box, there is a vertical rectangular label with two red arrows pointing upwards. The box is set against a light gray background.

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Perform this exercise on the blank box on the following page.



Class Exercise: Marking & Labeling

Using the blank picture of a box - mark and label based on the following:

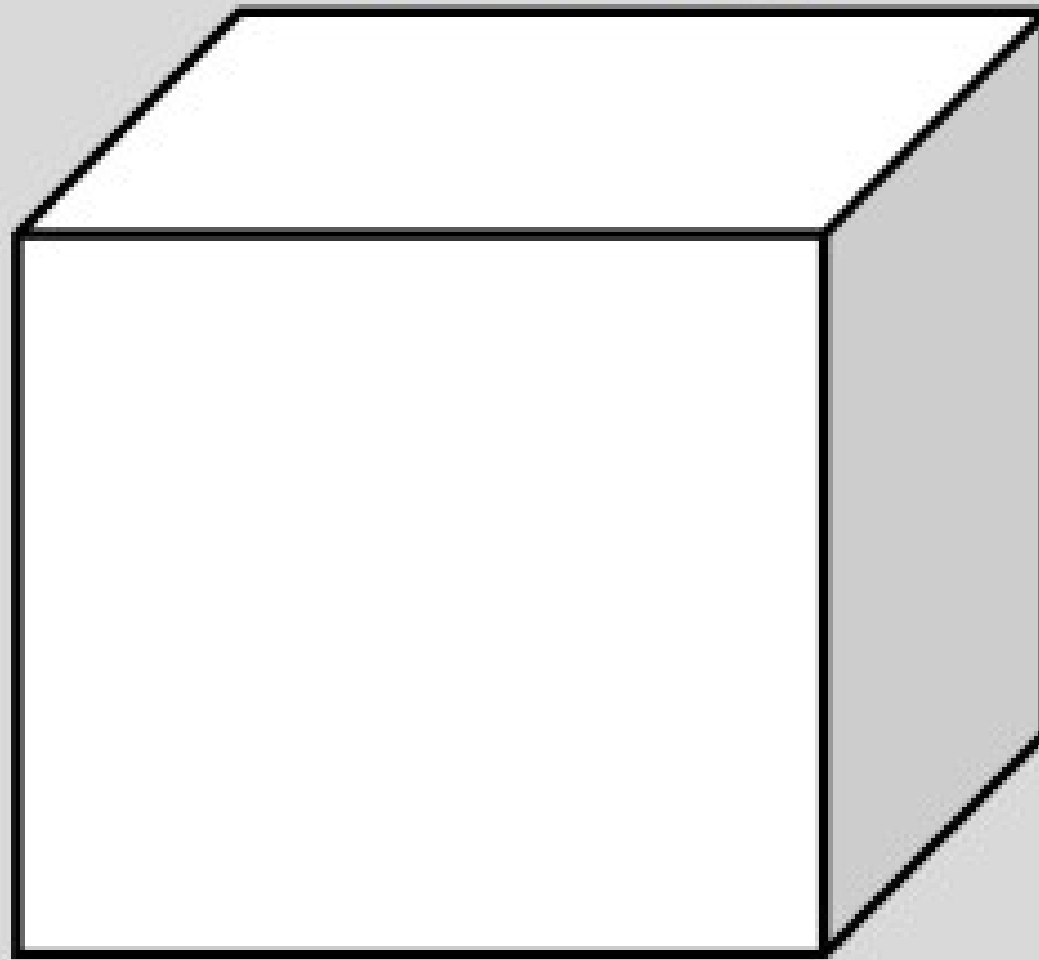
A 10 ml sample of animal blood being sent to test for **Monkeypox**. Gel packs are being used as a refrigerant to keep samples cool but not frozen.

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Perform this exercise on the blank box on the following page.



Class Exercise: Marking & Labeling



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Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

Perform this exercise on the blank box on the following page.



Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation



Shipping with Overpacks

- Overpacks may contain one or more inner packages and may be used with Dry Ice
- Each inner package must contain only the maximum quantity allowed under the List of Dangerous Goods
- Overpacks must be marked & labeled exactly as the inner packages
- The word OVERPACK must appear on the outside



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Definition of an overpack:

When are overpacks used?

Should the UN specification mark be included on the overpack?

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

 **Class Exercise: Packaging, Marking, and Labeling Samples**


Exercise:

In your group, classify the material:

- Determine whether it should be shipped as Category A, B, or exempt.

Use the packaging supplies provided,

- Select packaging that would be appropriate for your assigned material.
- Package the mock infectious agent. (Do not seal the boxes)



Using the reusable, Velcro marks and labels, select those that are appropriate for your assignment

- Mark and label your package.

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Notes:

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation



Required Documentation

1. Packing list / proforma invoice, which includes
 - Receiver's address
 - Number of packages
 - Detail of contents
 - Weight
 - Value (for customs purposes, indicate a minimal value if items supplied free of charge)
2. Shipping waybill
3. An itemized list of contents (e.g. packing list) which is **enclosed between the secondary and outer packaging**
4. **Category A packages also require**
 - **Shipper's Declaration for Dangerous Goods**

Required Documentation

- Packing list

- Shipping waybill


- An itemized list of contents

- Category A packages also require

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

Note requirements for Category A shipments:



Shipper's Declaration

GBRMC

Required for Category A shipments

- Need at least three original copies
- Technical Name must be on declaration
- Must be in English
- Most countries require 24-hour emergency phone number
- Legal document must be accurate
 - Legible
 - Neat
 - No spelling errors; no abbreviations
 - Whiteout must never be used

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Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

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Completing the Shipper's Declaration

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least two copies to the airline)

Shipper: Bio Cook #17 288 8048
 582 288 Mass Ave #17 288 8048
 255 Massachusetts Ave
 Cambridge, MA 02138-4307

Consignee: John Doe
 Science Fair University
 Department Name
 1234 University Dr
 Los Angeles, CA 90012

Page: _____ of _____ Pages
 Shipper Reference Number: _____

FedEx
 Federal Express

This completed and signed original copy of this Declaration must be handed to the operator.

TRANSPORT DETAILS

This shipment is within the _____
 boundaries prescribed in the _____
 (check non-applicable)

Origin: _____ Airport of Departure: _____

Destination: _____ Airport of Destination: _____

Radioactive: ~~Radioactive~~

Shipment type: (delete not applicable)
 Non-Radioactive: ~~Radioactive~~

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. This Declaration must not, in any circumstances, be completed or/and signed by a consignor, a forwarder, or an IATA cargo agent.


Can be left blank

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- The three spaces indicated can be left blank; the carrier can fill them in.
- Make sure to cross out (delete) the non-applicable aircraft type and the word “Radioactive”.
- Address boxes of the shipper and consignee must match the To: and From: address boxes on the package.
- Don't forget to mark 1 of 1 pages.

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation



Completing the Shipper's Declaration

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class Division	Packing Group	Quantity and type of packaging	Packing Instructions	Authorization
UN 2814	Infectious Substances affecting humans (Hepatitis B Virus)	6.2		25 ml	620	
UN 1845	Dry Ice	9		2 kg All packed in one 5 liter cold pack	954	

Additional marking information:

Emergency Telephone Number: CHEMTREC 1-800-431-9800

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 labeled, stowed, 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.

Name/Title of Shipper: Eric Cook
Biocases Officer
48002899999, MA
June 10, 2012
Signature: *Eric Cook*
(see marking sheet)

Must be trained and certified

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The technical name is not necessary on the package, it must be included on the paperwork. (In this case Hepatitis B virus) Include a name, title, place and date.


24 hour emergency number requirements:

- Must be answered at all times the package is in transit (no voice mail or pager)
- The person who answers must have
 - Detailed emergency response and incident mitigation information for the shipment
 - Must be a legal representative (or someone who is capable of and accepts responsibility for) the shipper.

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

 **Documentation for Category B (Air waybill)**



- Air waybill must be marked **“Biological Substance, Category B UN3373”**
- UN1845, Dry Ice, 9
- Must include net wt. of Dry Ice
- Air waybill must include the text **“Dangerous Goods – Shipper’s Declaration not required”**


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List mistakes found:

Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation

Use this information to complete the shipping form.



Exercise: Completing a Shipper's Declaration for Dangerous Goods

Dr. Treponema has asked you to help him with the following shipment because he is not trained. Complete a Shipper's Declaration for Dangerous Goods for the following:

To: Thamer Leprae, PhD +29-522-2896-45
Rickettsia National University
Typhusville City, Republic Prowazekii

From: Hamid Treponema, MD +29-832-4687-42
University Hospital
Capitol City, Republic of Prowazekii

Dr. Leprae is the contact person responsible for the shipment.

The **24 hour emergency** response telephone number is +29-800-4392-89

What: 2 small culture tubes, agar slants (<1 g of total culture). Patient isolates of *Francisella tularensis*.

Temperature considerations: gel packs to keep the package somewhat cool

Type of outer packaging: One fiberboard box

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Shipping Infectious Substances & Biological Specimens

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Exercise: Completing a Shipper's Declaration for Dangerous Goods

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least two copies to the airline)

<p>Shipper: Harold Truesdell, MD +202-462-4867-42 University Hospital Capitol City, Republic of Processia</p>	<p>01/18/2016 Page 1 of 1 Shipper Reference Number: 888888</p>		
<p>Complere: Thomas Lopez, PhD +202-555-2226-65 Molecular Biology Institute Typhoid City, Republic of Processia</p>	 <p>Federal Express</p>		
<p><small>You completed and signed copies of this Declaration must be handed to the operator.</small></p>			
<p>TRANSPORT DETAILS</p> <p>This shipment is within the limitations prescribed for: (check non-applicable)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;"> <input checked="" type="checkbox"/> PERMITTED <input checked="" type="checkbox"/> RESTRICTED <input checked="" type="checkbox"/> EXCEPTED </td> <td style="width: 50%; vertical-align: top;"> <p>Airport of Departure:</p> <p>Airport of Destination:</p> </td> </tr> </table>		<input checked="" type="checkbox"/> PERMITTED <input checked="" type="checkbox"/> RESTRICTED <input checked="" type="checkbox"/> EXCEPTED	<p>Airport of Departure:</p> <p>Airport of Destination:</p>
<input checked="" type="checkbox"/> PERMITTED <input checked="" type="checkbox"/> RESTRICTED <input checked="" type="checkbox"/> EXCEPTED	<p>Airport of Departure:</p> <p>Airport of Destination:</p>		
<p>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. This Declaration must not, in any circumstances, be completed and/or signed by a consignor, a forwarder, or as the cargo agent.</p>			
<p>Shipment type: (state non-applicable)</p> <p><input checked="" type="checkbox"/> NON-RAADIOACTIVE <input checked="" type="checkbox"/> OTHER</p>			

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Shipping Infectious Substances & Biological Specimens

Marking, Labeling & Documentation



Exercise: Completing a Shipper's Declaration for Dangerous Goods

REFUNDABLE QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or IATA	Proper Shipping Name	Class Division	Packing Group	Quantity and Type of Packaging	Packing Instructions	Authorization
UN 2814	Infectious substances affecting humans (Trenchococcus lateralis)	6.2		1 Fibreboard box X 1 g	530	

Additional Handling Information
 Person Responsible: Thamer Leprae, PhD +25-522-2096-45
 Emergency Response Number +25-800-4581-89

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 labeled, placarded, 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.

Name/Title of Signer: Your Name
 Your title
 Place and Date: This place, today's date
 Signature: (Use marking placard) Your signature

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Exercise: Completing a Shipper's Declaration for Dangerous Goods

Group Exercise:

In your group, using the same example used in packaging:

- Determine what is the required and appropriate documentation
- Fill out or create the required documentation and include it with your package



Your packaging and documentation will be checked by another group

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A small, dark logo in the bottom right corner of the slide.

Shipping Infectious Substances & Biological Specimens

Administrative Controls: Authorization, Training, Security & Program Management

 **Authorizing Shipments**

Discussion:

In your group, discuss

- Who at your facility is authorized to approve the shipment of samples?
- What needs to be considered in determining whether to approve a shipment from your facility?



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Who at your facility is authorized to approve the shipment of samples?

What needs to be considered in determining whether to approve a shipment from your facility?

Shipping Infectious Substances & Biological Specimens

Administrative Controls: Authorization, Training, Security & Program Management



Material Transfer Agreement (MTA)

A material transfer agreement is a contract between the sender and recipient organizations

- Defines the rights and responsibilities of each
- Provides a record of the transfer

Issues with sharing materials that may be addressed in a MTA include:

- Ability to publish / academic freedom
- Ownership of materials to be shared
- Ownership of intellectual property
- Further distribution of materials
- Liability

Review of Example NIH MTA's

- Simple Letter Agreement
- Uniform Biological Material Transfer Agreement

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Definition of a Material Transfer Agreement (MTA):

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Administrative Controls: Authorization, Training, Security & Program Management



Import, Export, and Biosecurity Regulations


- **Many countries have import regulations requiring recipients to get a permit prior to importation**
 - Helps expedite clearance of infectious materials through customs
- **Export controls and export licensing help facilitate legitimate trade and ensure compliance with international treaties**
 - Some countries abide by Australia Group recommendations for export controls
 - Biological and Toxin Weapons Convention requires State Parties to:
 - Prevent the transfer of materials which might assist the manufacture, or any means of acquiring biological weapons (Article III)
 - United Nations Security Council Resolution 1540 requires all States to:
 - Establish and maintain appropriate effective national export and trans-shipment controls
- **National biosecurity regulations**
 - Typically require approval of recipient prior to shipment

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List some key considerations for Import and Export requirements:

Shipping Infectious Substances & Biological Specimens

Administrative Controls: Authorization, Training, Security & Program Management



What Requires an Import Permit into the US?



- Etiologic agents (human pathogens)
- Human and animal specimens with a suspected human pathogen
- Host & Vectors of human disease
- Non-Human Primates
- Infectious agents of livestock
- Biological materials containing animal material
- Tissue culture containing growth stimulants of bovine or other livestock origins
- **Any animal source material**

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These are some examples of materials that require import permits **in the US**. Other countries may have similar requirements.

If you are shipping one of these items to the US, who is responsible for obtaining the necessary import permit?

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Administrative Controls: Authorization, Training, Security & Program Management



For All Shipments, Consider:

- Is an import and/or an export permit needed?
- Material transfer agreement or other agreement to share materials prior to shipping?
- Documentation indicating recipient is authorized to have material?

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Questions to consider for all shipments:

- Is an import and/or an export permit needed?
- Material transfer agreement or other agreement to share materials prior to shipping?
- Documentation indicating recipient is authorized to have material?

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State and Operator Variations

PACKING INSTRUCTION XXX

State Variations: AK-01, AK-02, AK-03, AK-04, AK-05, AK-06, AK-07, AK-08, AK-09, AK-10, AK-11, AK-12, AK-13, AK-14, AK-15, AK-16, AK-17, AK-18, AK-19, AK-20, AK-21, AK-22, AK-23, AK-24, AK-25, AK-26, AK-27, AK-28, AK-29, AK-30, AK-31, AK-32, AK-33, AK-34, AK-35, AK-36, AK-37, AK-38, AK-39, AK-40, AK-41, AK-42, AK-43, AK-44, AK-45, AK-46, AK-47, AK-48, AK-49, AK-50, AK-51, AK-52, AK-53, AK-54, AK-55, AK-56, AK-57, AK-58, AK-59, AK-60, AK-61, AK-62, AK-63, AK-64, AK-65, AK-66, AK-67, AK-68, AK-69, AK-70, AK-71, AK-72, AK-73, AK-74, AK-75, AK-76, AK-77, AK-78, AK-79, AK-80, AK-81, AK-82, AK-83, AK-84, AK-85, AK-86, AK-87, AK-88, AK-89, AK-90, AK-91, AK-92, AK-93, AK-94, AK-95, AK-96, AK-97, AK-98, AK-99, AK-100.

Operator Variations: 35-02, 35-03, 35-04, 35-05, 35-06, 35-07, 35-08, 35-09, 35-10, 35-11, 35-12, 35-13, 35-14, 35-15, 35-16, 35-17, 35-18, 35-19, 35-20, 35-21, 35-22, 35-23, 35-24, 35-25, 35-26, 35-27, 35-28, 35-29, 35-30, 35-31, 35-32, 35-33, 35-34, 35-35, 35-36, 35-37, 35-38, 35-39, 35-40, 35-41, 35-42, 35-43, 35-44, 35-45, 35-46, 35-47, 35-48, 35-49, 35-50, 35-51, 35-52, 35-53, 35-54, 35-55, 35-56, 35-57, 35-58, 35-59, 35-60, 35-61, 35-62, 35-63, 35-64, 35-65, 35-66, 35-67, 35-68, 35-69, 35-70, 35-71, 35-72, 35-73, 35-74, 35-75, 35-76, 35-77, 35-78, 35-79, 35-80, 35-81, 35-82, 35-83, 35-84, 35-85, 35-86, 35-87, 35-88, 35-89, 35-90, 35-91, 35-92, 35-93, 35-94, 35-95, 35-96, 35-97, 35-98, 35-99, 35-100.

2.0.1 Variations Filed by States
2.0.1.1 State variations which have been notified to IATA as the state of origin.

2.0.3 Operator Variations
2.0.3.1 Operator variations which have been filed with IATA as the state of origin.

FedEx Operator variation:
EX-12 Shipper's Declaration must be type-written or computer generated. Handwritten forms will not be accepted.

US State variation:
US(G)-12 Shipper's Declaration must have the 24 hour emergency response tel. number.

Note: State and operator variations add further restrictions that are applicable only to country or carrier.

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You may need to research and **Review** with your State and Operator variations that may apply to your county/region.

Shipping Infectious Substances & Biological Specimens

Administrative Controls: Authorization, Training, Security & Program Management



Training Requirements

- General Awareness/Familiarization
- Function Specific
- Safety/Security
- Record Keeping
- Testing
- Employer certification
- Valid for 2 years
- Update when regulations change




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Additional Training Requirements:

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Administrative Controls: Authorization, Training, Security & Program Management




Security Requirements

DANGEROUS GOODS SECURITY IATA 1.6

Handlers of high consequence DGs should have a security plan. Plan must be based on risk assessment. Basic elements of a security plan

- Specific allocation of responsibilities and authorities
- Record keeping
- Review of current operations and risk assessment
- List of mitigation measures (training policies, operating practices, response to higher threat conditions, personnel verification process, access controls, equipment and other resources) to be used to reduce security risks.
- Procedures for reporting and dealing with security threats, breaches and incidents
- Performance measures and periodic review and update plan



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List some security requirements:

-
-
-
-
-
-

Shipping Infectious Substances & Biological Specimens

Administrative Controls: Authorization, Training, Security & Program Management



Elements of Program Management

- Training program
- Records retention
- Written security and safety plans
- Emergency response plan
- Written policies that ensure:
 - appropriate approvals and paperwork in place prior to shipping
 - packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport
- Access control (secure storage)
- Personnel assurance

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Record key elements of program management:

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Administrative Controls: Authorization, Training, Security & Program Management



Who is Going to Transport it?

Select a carrier that can provide appropriate security

- Ensure reliable and trustworthy people handle the package
- Control access to transport facilities, docks, and vehicles
- Track shipping progress
- Provide ongoing security training for employees

Verify that recipient receives package as expected


- Email or fax preferred since receipt is documented

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Key considerations when selecting a carrier:

Shipping Infectious Substances & Biological Specimens

Review



Shipping Infectious Substances & Biological Specimens


To wrap-up, let's discuss what we learned. . .

What did we learn?

What does it mean?


Where do we go from here?

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Shipping Overview

- Before Shipping**
 - Understanding the risks of shipping
 - Determine the appropriate mitigation measures
 - Determine the relevant regulations
- Shipping Process**
 - Classification of samples
 - Packaging, marking, and labeling
 - Documentation
 - Transfer agreements and permits
 - Transferring package to carrier
- Program Management**
 - Verification of receipt
 - Incident response
 - Training
 - Records
 - Access controls




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Notes:


Shipping Infectious Substances & Biological Specimens

Review



Class Exercise: Prepare a Shipping Checklist

Exercise:
Working in groups, create a shipping checklist for your institution covering all of the steps from deciding to ship through successful receipt.



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Create a shipping checklist:

Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
------	--	------	--	---------------	--

Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

Use space on back, if needed