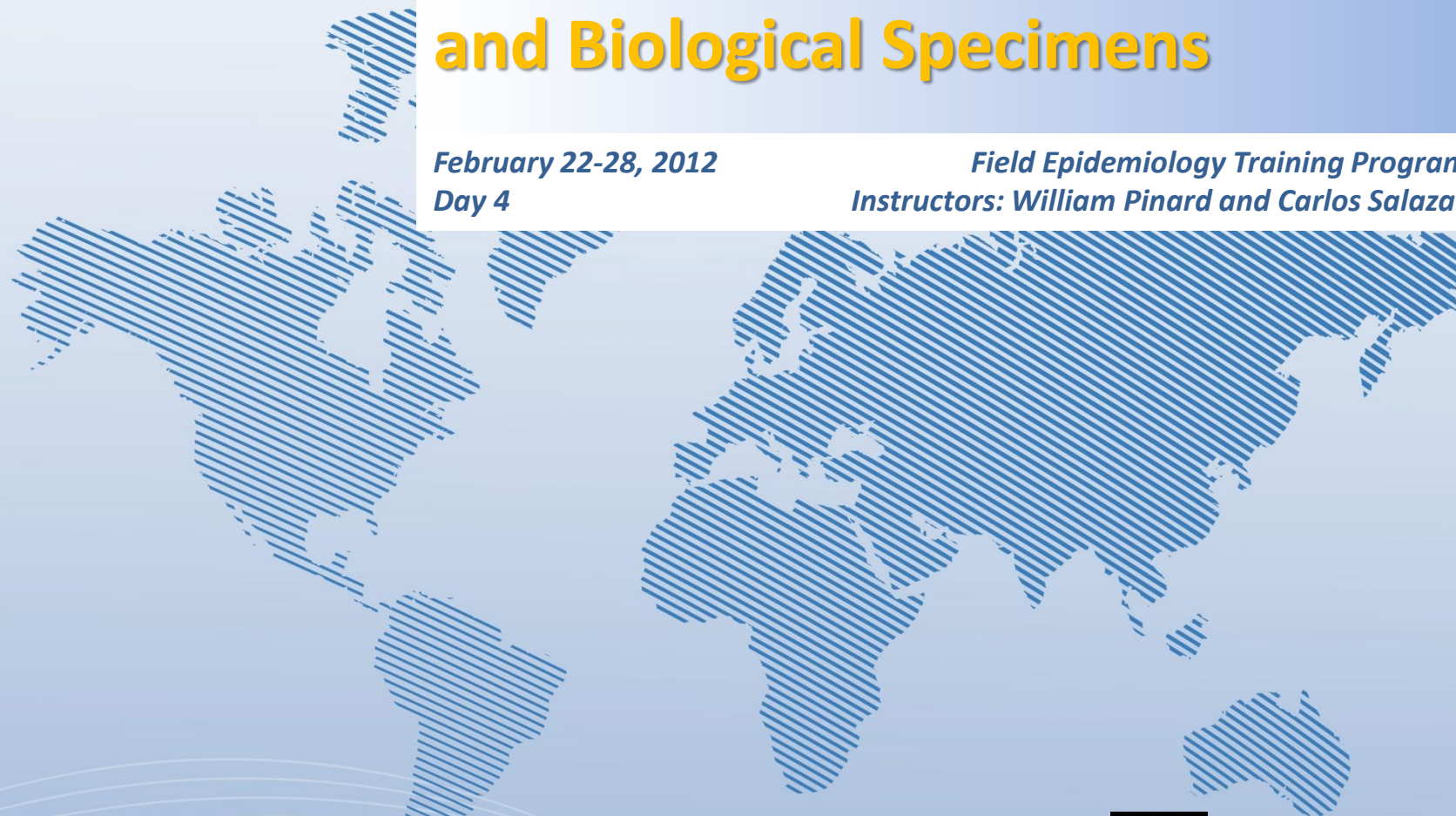


Shipping Infectious Substances and Biological Specimens

*February 22-28, 2012
Day 4*

*Field Epidemiology Training Program
Instructors: William Pinard and Carlos Salazar*



Preview Exercise

- Work with your group
- You have 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



Failure to train employees in the four required areas

Failure to execute a Shipper's Declaration for a shipment of dangerous goods

goods

Failure to label package



PACKING LIST ENCLOSED

REFRIGERATE ON ARRIVAL BLOOD BANK REAGENT

REFRIGERATE ON ARRIVAL BLOOD BANK REAGENT

transportation in an unauthorized non-UN specification pack

Failure to mark the proper shipping name identification number on the package

SHIPPER'S DECLARATION FOR TRANSPORT OF DANGEROUS GOODS

Shipper: Acme Medical Clinic, 1234 Center Street, Fumhandle TX 10101

Consignee: Quality Laboratories Ltd., 456 Downtown Avenue, Atlanta GA 01010

Air Waybill No. Page 1 of 1 Pages

Shipper's Reference Number (optional) 0002

Name and Number of Person Responsible for class 6.2 shipment: Dr. John Smith 1-555-111-9999

SAF-PAK INC.

Two completed and signed copies of this Declaration must be handed to the carrier.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: (delete non-applicable)

Passenger and Cargo Aircraft:

Airport of Departure: _____

Airport of Destination: _____

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 consolidator, a forwarder or an IATA cargo agent.

Shipment type: (delete non-applicable)

NON-RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary risk)	Packing Group	Quantity and type of Packing	Packing Inst.	Authorization
UN2814	Infectious substance, affecting humans (Hepatitis B Virus)	6.2		30mL	602	
UN1845	Dry ice	9	III	3 kg	904	
				All packed in one fibreboard box		

Additional Handling Information

24-hour Emergency contact 800-555-6789

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 Signatory: Henry James, Lab Supervisor

Place and Date: Fumhandle TX, Jan. 1, 2006

Signature: _____ (see warning above)

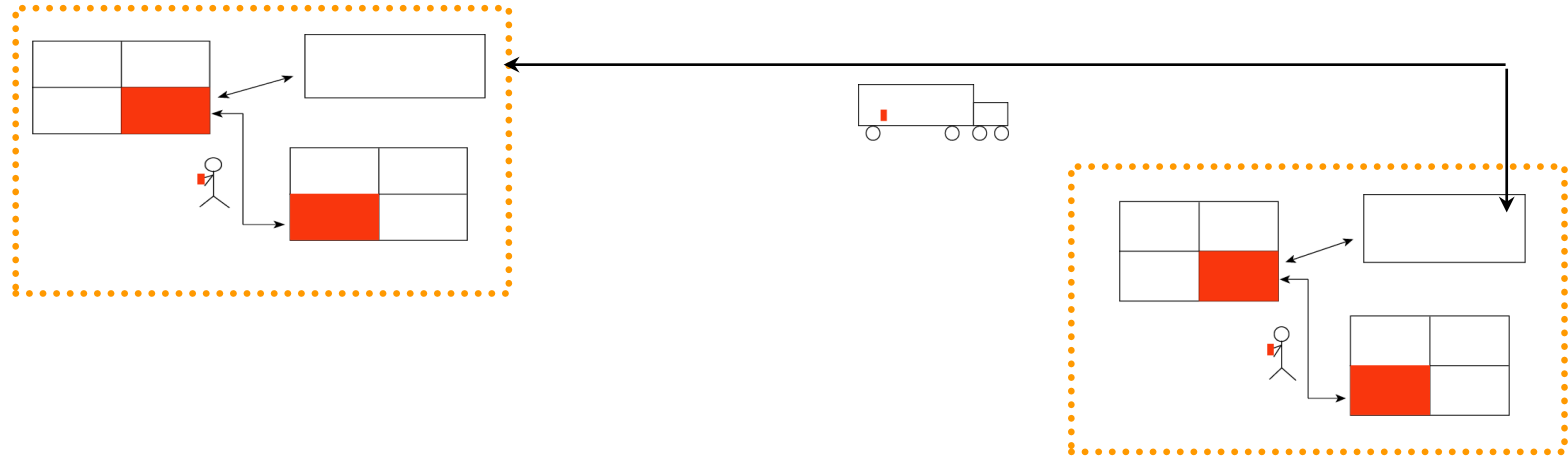
Small Group Exercise

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

Infectious Substance Transport



Transport – movement of biological material outside of a restricted area

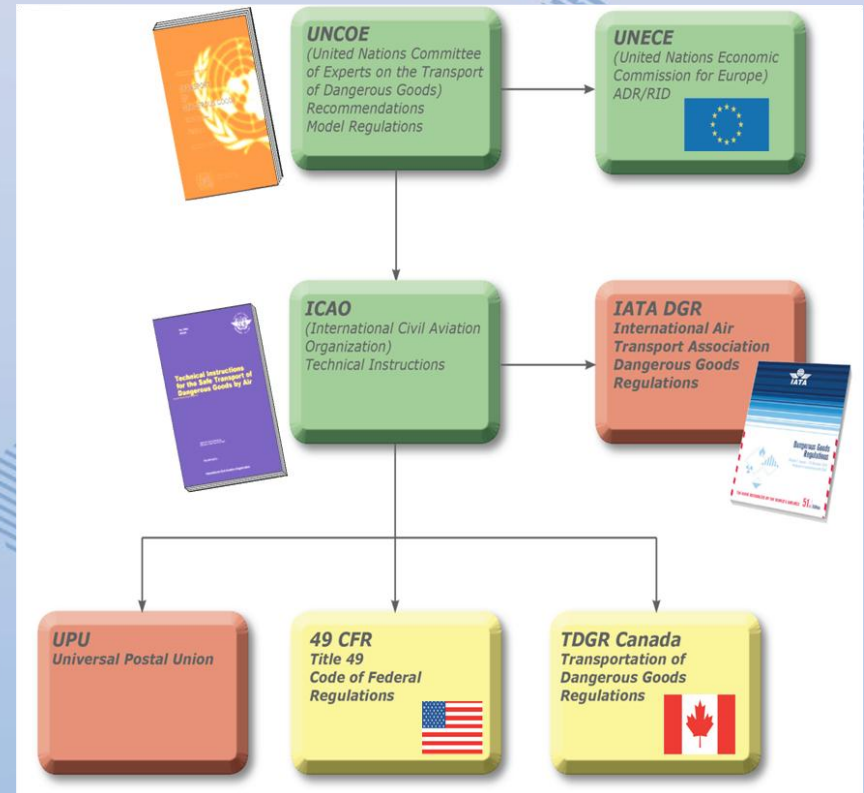
- Research labs
 - Sample transfers are necessary for study and to further research
- Public health labs and diagnostic labs
 - Sample transfers are necessary for diagnosis and analysis

Transport can occur

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

Regulations??

- International
- Regional
- National
- Industry
- Postal regulations
- Mode requirements (Air, Road, Rail, Sea)
- Carrier requirements
- Import/Export



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



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 met the criteria of one or more of the nine UN hazard classes

Dangerous Goods

By Road... **By Sea...**

By Air...

It's YOUR responsibility!

Have you declared it?

Compressed Gas! Corrosive Liquid! Flammable Gas! Flammable Liquid!

Cargo containing dangerous goods is subject to national and international regulation.



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

Shipping Risks

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

In your group, discuss the following,

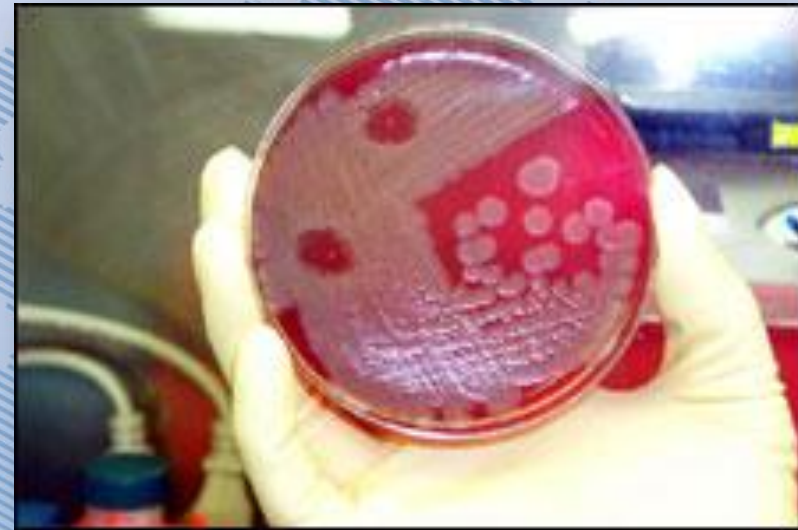
- Do all biological material shipments have the same level of risk?
- What are some of the key differences in biological material shipment that might increase or decrease those risks?

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

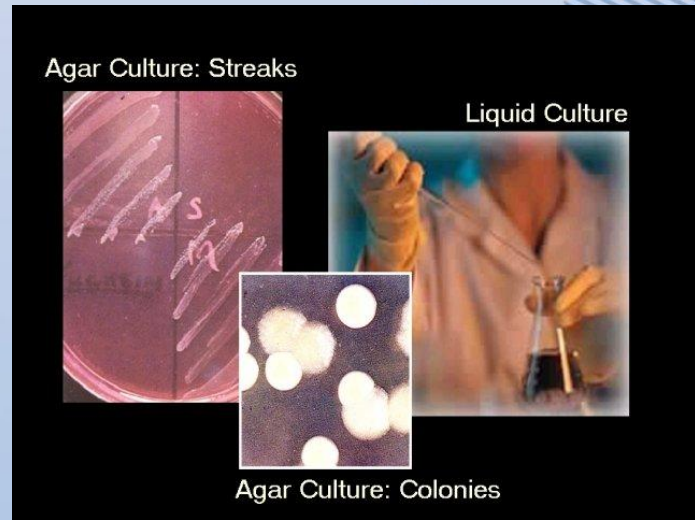
- Can you use these differences to create shipping classifications?

Definitions: Infectious Substance

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



Definitions: Cultures



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

Definitions: Patient Specimens

- ***Patient Specimens*** are those collected directly from humans or animals.
- Examples include: blood, sputum, urine, tissue biopsy, swabs, and body parts.



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



Definitions: Category B



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

Examples: Category A Infectious Substances

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
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus
	Omsk hemorrhagic fever virus
	Poliovirus (cultures only)
	Tick-borne encephalitis virus (cultures only)
	Variola virus
	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Goatpox virus (cultures only)
	Lumpy skin disease virus (cultures only)
	<i>Mycoplasma mycoides</i> – Contagious bovine pleuropneumonia (cultures only)
	Peste des petits ruminants virus (cultures only)
	Rinderpest virus (cultures only)
	Sheep-pox virus (cultures only)
	Swine vesicular disease virus (cultures only)
	Vesicular stomatitis virus (cultures only)

✓ Table lists examples and is not exhaustive

✓ New or emerging pathogens meeting the same criteria shall be classified as Category A

✓ Cultures may be Category A or B depending on the microorganism

UN Number and Proper Shipping Name	Micro-organism
UN 2814	<i>Bacillus anthracis</i> (cultures only)
Infectious affecting humans	<i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> – Glanders (cultures only)
	<i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i>
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	Hantavirus 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)
	Junin virus



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

Anthrax Bioterrorism Scenario

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



Anthrax Bioterrorism Scenario



Nasopharyngeal swabs
are collected from
potentially exposed
office workers

Anthrax Bioterrorism Scenario

- The swabs will be transported to local clinical laboratory for analysis
- Are they infectious substances?
- Would you classify these as Category A or B?



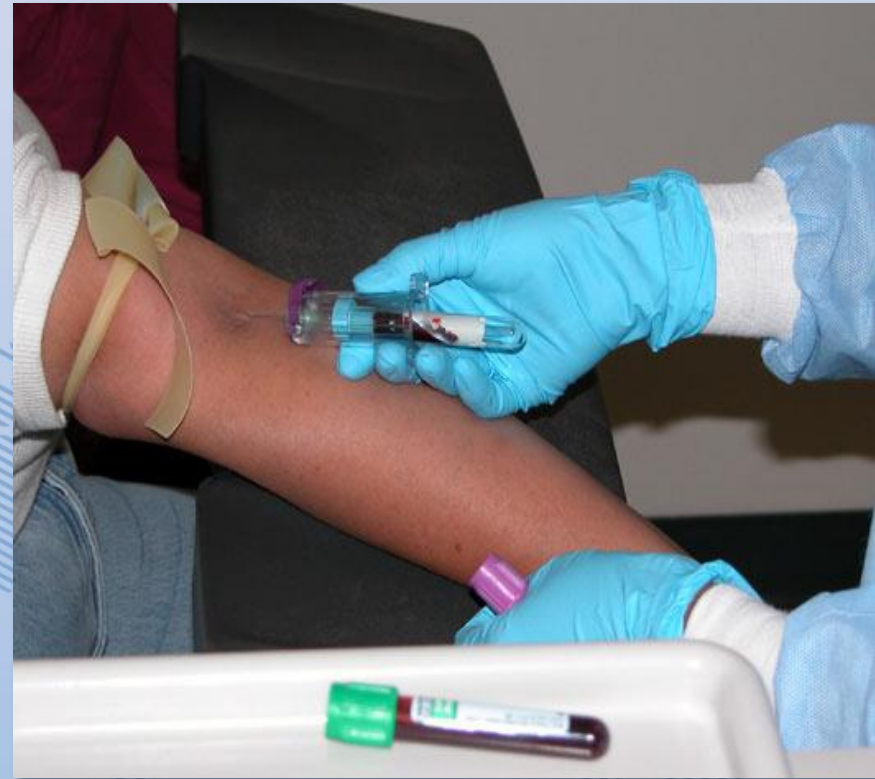
Anthrax Bioterrorism Scenario



- 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)?

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)?



Gonorrhea Scenario



- Patient presents with symptoms of gonorrhea
- 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)?

Classification 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)



Classification Exercise

1. Chicken blood
2. Human, oropharyngeal swab
3. Human sputum sample
4. Culture of Acid Fast Bacilli (AFB)
5. Dead bat
6. Human breast tissue biopsy
7. Culture of *Staphylococcus aureus*
8. Human, pustule/skin scraping
9. Culture of *Salmonella typhi*
10. Bovine sera
11. Human urine and human blood
12. McDonald's French Fries
13. Culture of *Bacillus anthracis*

Proper Shipping Names & UN ID Numbers

- 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



UN/ID No. A	Proper Shipping Name B	Class or Div. C	Hazard Label(s) E	PG F	Passenger and Cargo Aircraft		Cargo Aircraft Only		Special provisions M	ERG Code N
					Pkg Inst I	Max Net Qty/Pkg J	Pkg Inst K	Max Net Qty/Pkg L		
3291	Clinical waste, unspecified n.o.s.	6.2	Infectious substance		622	No Limit	622	No Limit		6L
3373	Diagnostic specimens	6.2			See 650	See 650	See 650	See 650		6L
3373	Biological substance, Category B	6.2			See 650	See 650	See 650	See 650		6L
1845	Dry ice	9	Misc.	III	904	200 kg	904	200 kg	A48	9L
2814	Infectious substance, affecting humans	6.2	Infectious substance		602	50mL or 50 g	602	4L or 4kg	A81 A140	11Y
2900	Infectious substance, affecting animals only	6.2	Infectious substance		602	50mL or 50 g	602	4L or 4kg	A81 A140	6L



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

Proper Shipping Name exercise

Page
48

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



Classification Exercise

1. Chicken blood
2. Human, oropharyngeal swab
3. Human sputum sample
4. Culture of Acid Fast Bacilli (AFB)
5. Dead bat
6. Human breast tissue biopsy
7. Culture of *Staphylococcus aureus*
8. Human, pustule/skin scraping
9. Culture of *Salmonella typhi*
10. Bovine sera
11. Human urine and human blood
12. McDonald's French Fries
13. Culture of *Bacillus anthracis*

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*

Group Activity

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*

Example Shipping Control Measures

Engineering Controls

- *Packaging, marking/labeling, and documentation*
- *Package security*

Administrative Controls

- *Authorizing shipments*
- *Material Transfer Agreements*
- *Import and Export licenses*
- *Carrier selection and requirements*

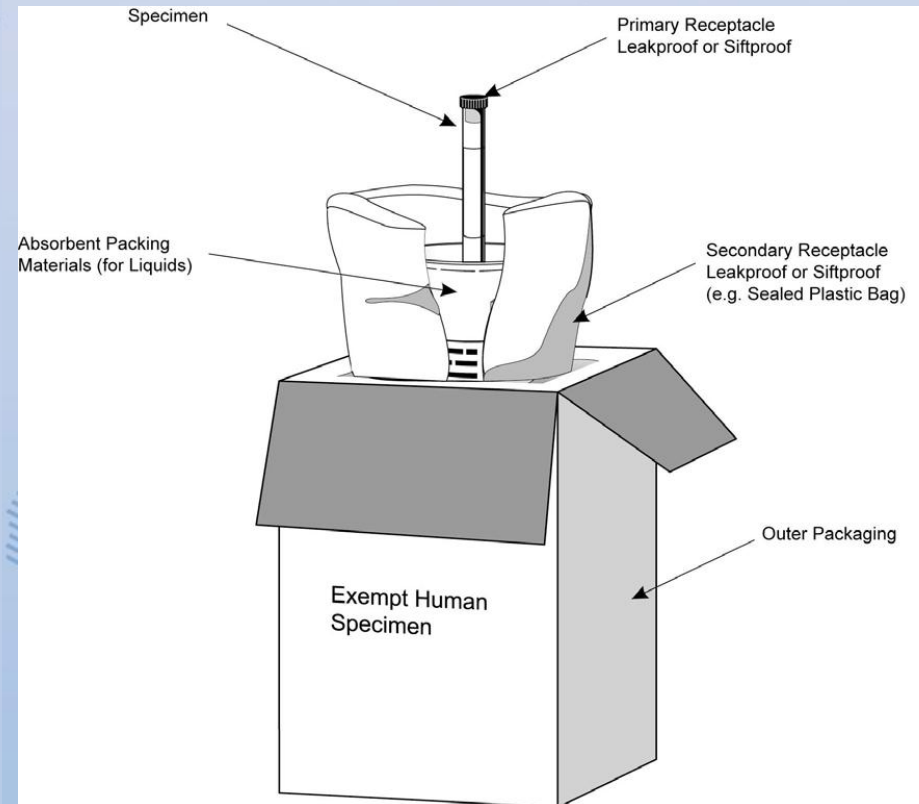
Practices and Procedures

- *Training*
- *Tracking of materials*

Principles of Packaging

Engineering Controls

- ✓ 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



Overview of Packaging

Triple packaging required for Category A, B, and Exempt

Primary receptacle

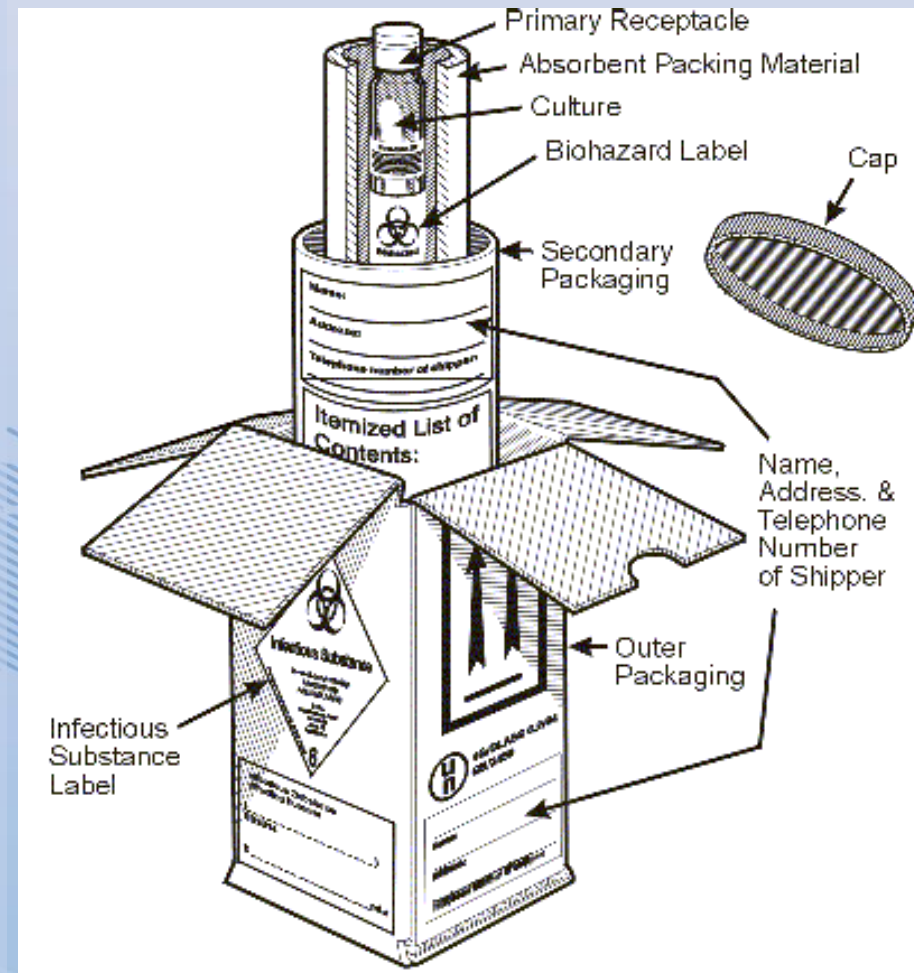
- A primary watertight, leakproof receptacle containing the specimen

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**



Category A Packaging: IATA PI 620

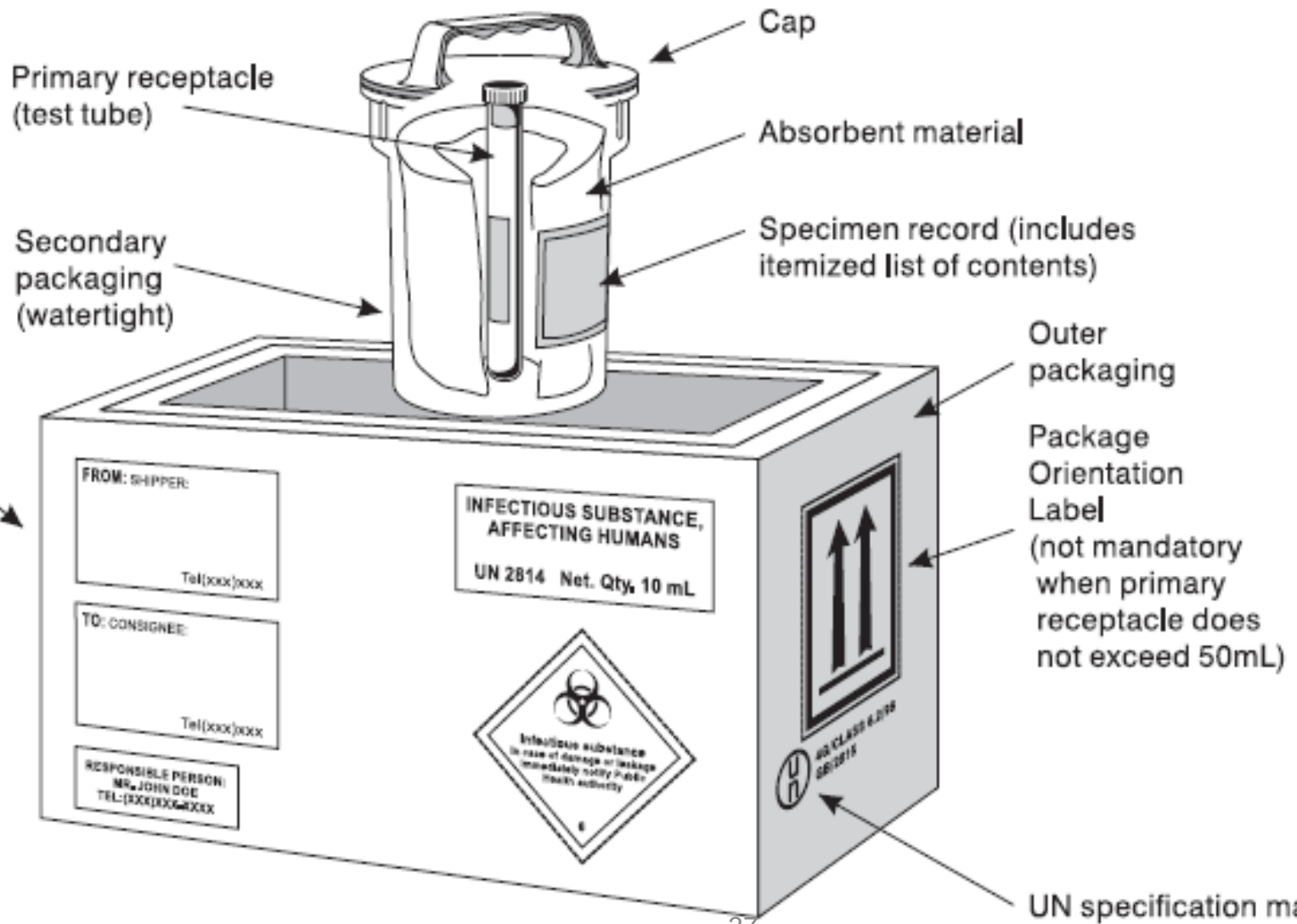
- Good condition
- Leakproof primary
- Leakproof secondary
- Pressure capable primary or secondary
- Absorbent (for liquids)
- Multiple fragile primaries wrapped individually
- Itemized list
- Rigid outer packaging
- 4 in. minimum
- Qty Limit 50 mL or 50 g for passenger aircraft. 4 L or 4 kg for cargo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

U
N

4G/Class 6.2/2010
USA/+AA16324



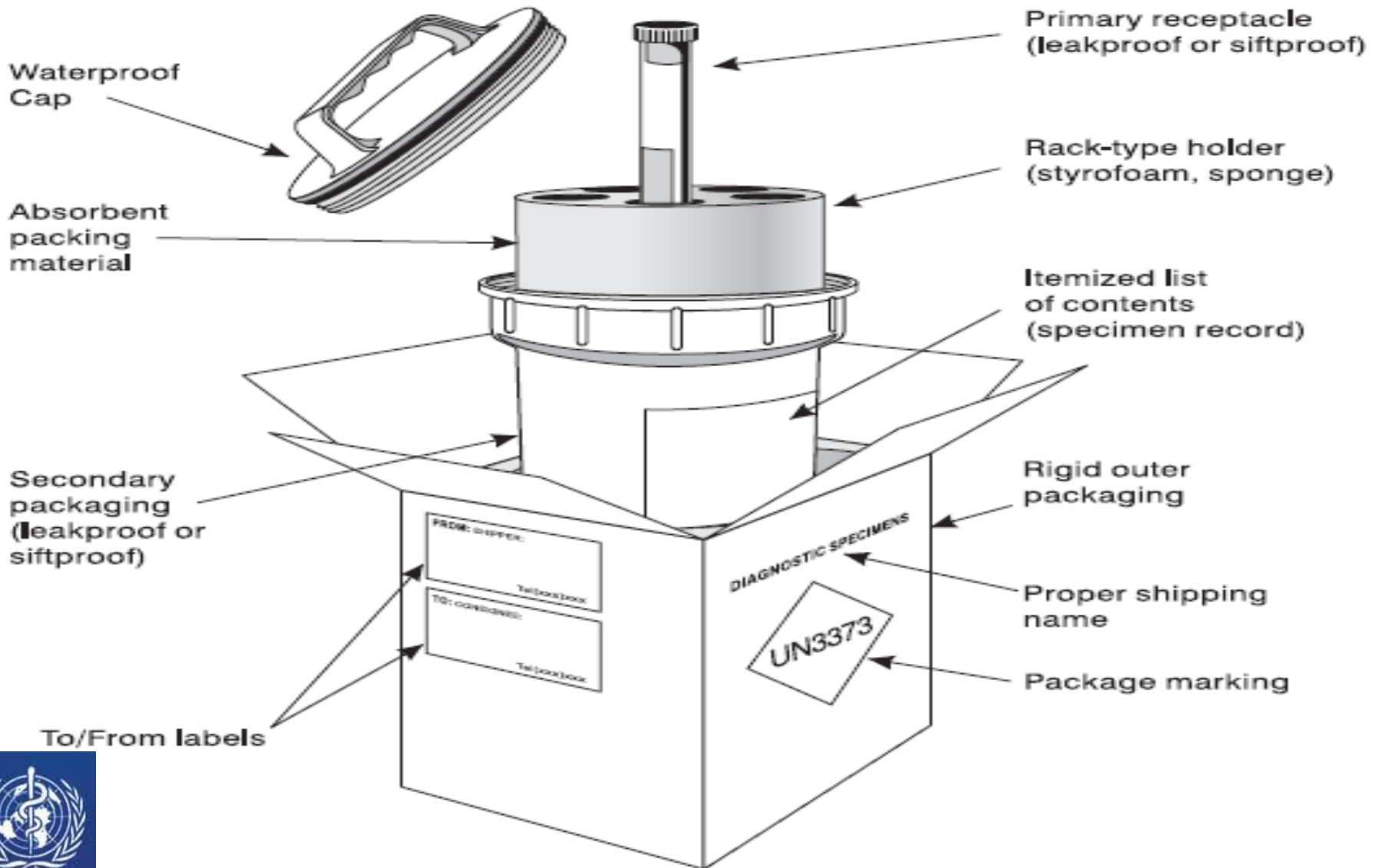
Category A Packaging



Category B Packaging: IATA PI 650

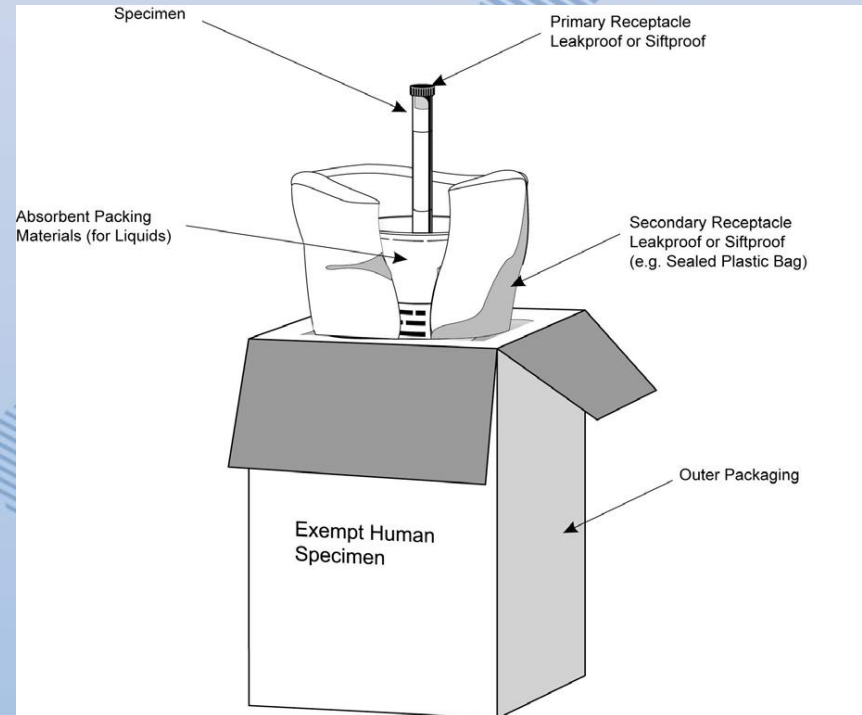
- ✓ Good quality
- ✓ Leakproof/siftproof primary (1 L max)
- ✓ Leakproof/siftproof secondary
- ✓ Absorbent
- ✓ Multiple fragile primaries wrapped individually
- ✓ Pressure capable primary or secondary
- ✓ Itemized list
- ✓ Rigid outer packaging
- ✓ Two sides at least 4 in.
- ✓ Qty. less than 4L or 4kg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

Category B Packaging



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”



Can packaging be re-used?

1. Work in your groups to discuss at least three factors, considerations, risks, or concerns with re-use
2. Do any of these factors change if the shipment is Category A vs. Category B or exempt?
3. What are ways to mitigate these risks?

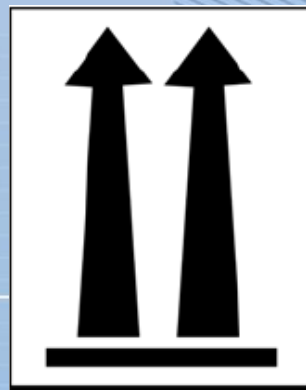
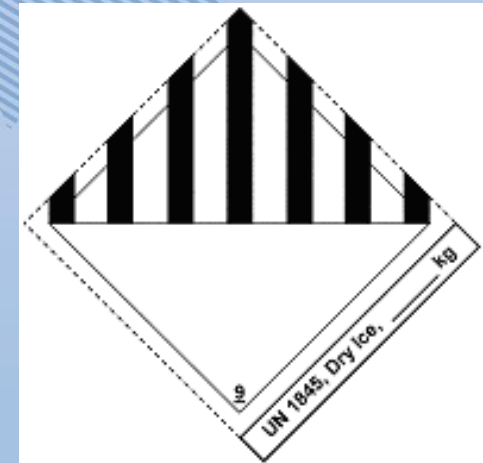
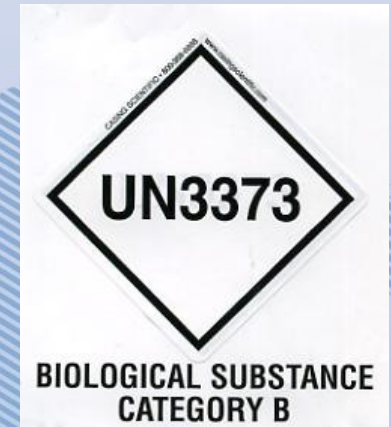
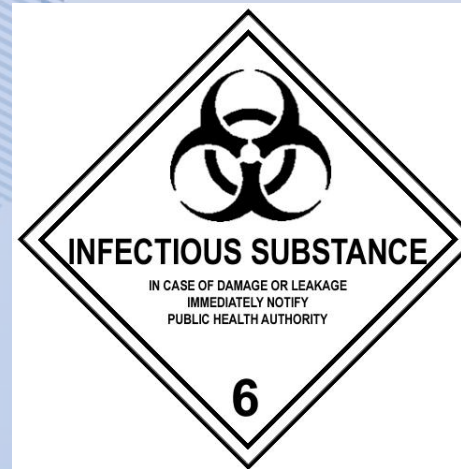
Overview of Marking and Labeling

Markings provide information on

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

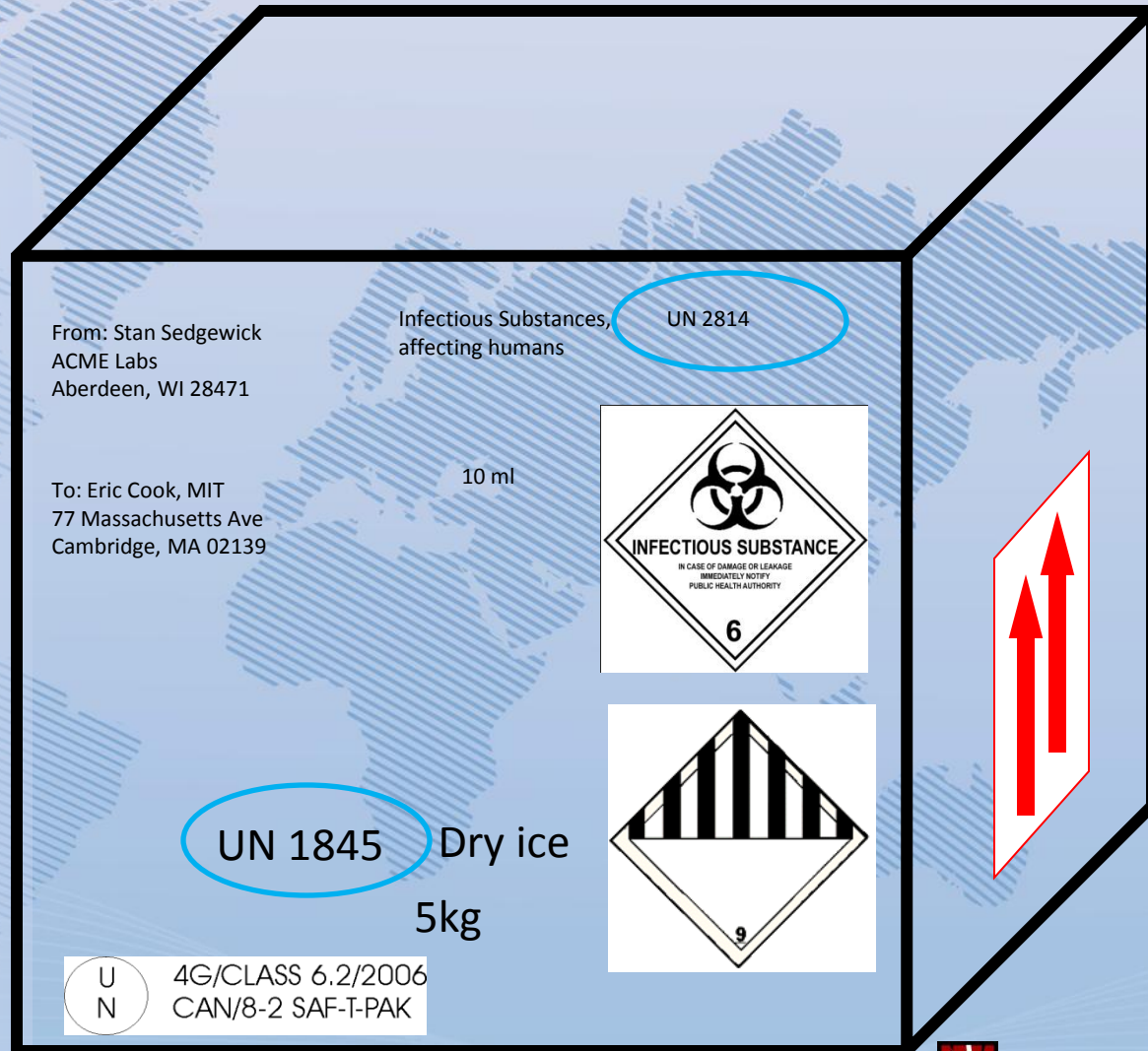
Labels – two types

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



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

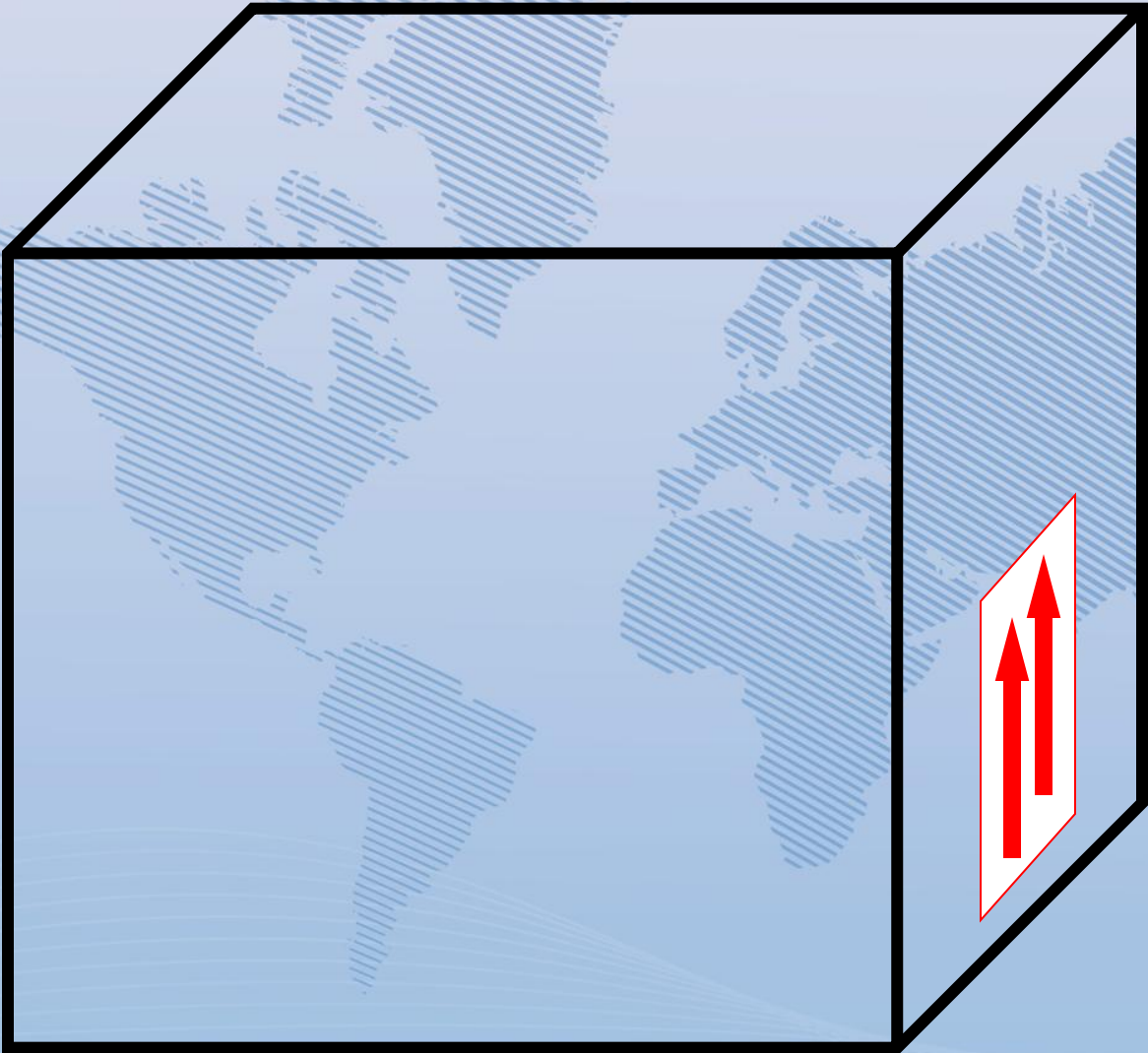


Class Exercise:

What marks and labels?

- Using the picture, mark and label 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.

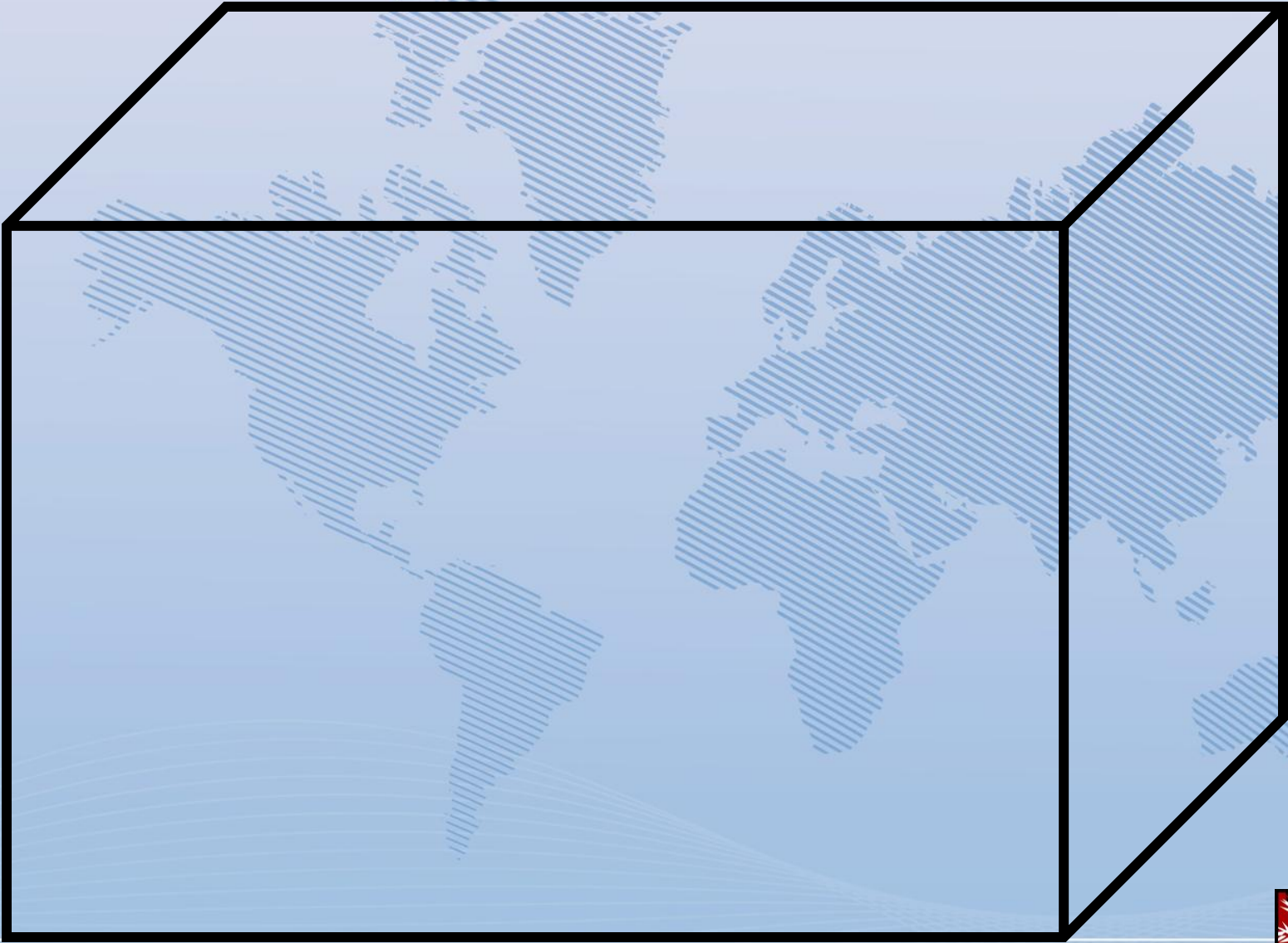
Class Exercise: What marks and labels?



Class Exercise: What marks and labels?

- Using the picture, mark and label the following:
- 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.

Class Exercise: What marks and labels?

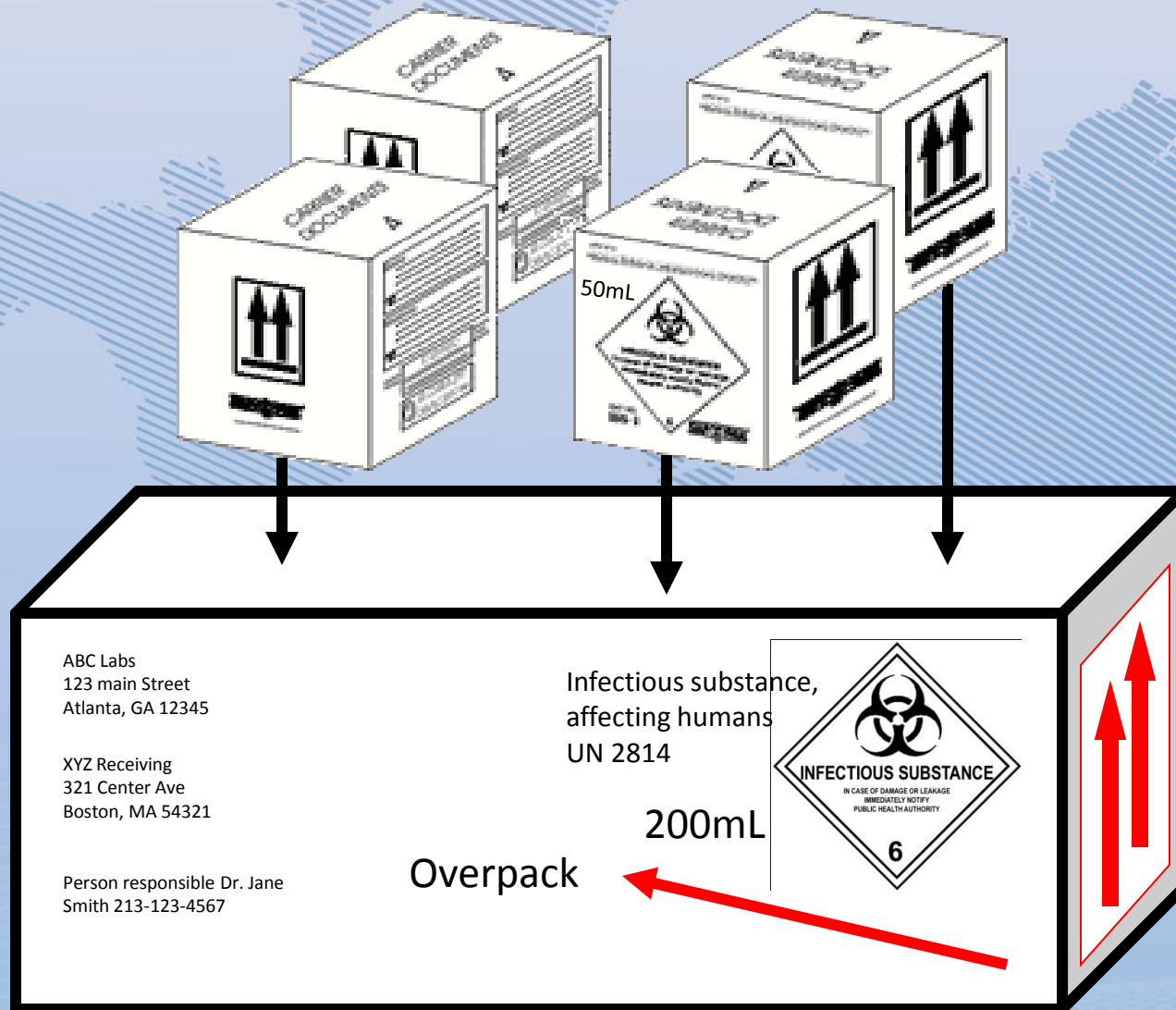


Shipping with Overpacks

- Overpacks may contain one or more inner packages - 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



Multiple small packages in an Overpack



Class Activity: Packaging, Marking, and Labeling Samples

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.



Required Documentation

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)

Shipping waybill

An itemized list of contents (e.g. packing list) which is enclosed between the secondary and outer packaging



Category A packages also require

- Shipper's Declaration for Dangerous Goods

Shipper's Declaration

- 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

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Acme Medical Clinic 1234 Center Street Pumphandle TX 10101		Air Waybill No. Page <u>1</u> of <u>1</u> Pages Shipper's Reference Number (optional) 0002				
Consignee Quality Laboratories Ltd. 456 Downtown Avenue Atlanta GA 01010						
Name and Number of Person Responsible for class 6.2 shipment: Dr. John Smith 1-555-111-9999 Two completed and signed copies of this Declaration must be handed to the operator.		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 consolidator, a forwarder or an IATA cargo agent.				
TRANSPORT DETAILS This shipment is within the limitations prescribed for: Airport of Departure (delete non-applicable)		Shipment type: (delete non-applicable) NON-RADIOACTIVE DANGEROUS				
Airport of Destination						
NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and type of Packing	Packing Inst.	Authorization
UN2814	Infectious substance, affecting humans (Hepatitis B Virus)	6.2		30mL	602	
UN1845	Dry ice	9	III	3 kg All packed in one fibreboard box	904	
Additional Handling Information 24-hour Emergency contact 800-555-6789						
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 Signatory Henry James, Lab Supervisor Place and Date Pumphandle TX Jan. 1, 2006 Signature  (see warning above)		

Completing the Shipper's Declaration

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least two copies to the airline)

Shipper
Eric Cook 617-258-5648
N52-496 Mass Inst. of Technology
265 Massachusetts Ave
Cambridge, MA 02139 - 4307

Air Waybill No.
Page 1 Of 1 Pages
Shipper's Reference Number
(optional)

Consignee
John Doe
Somewhere University
Anywhere Street
Los Angeles, CA 90210

FedEx
Federal Express

Two completed and signed copies of this Declaration must be handed to the operator.

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 consolidator, a forwarder, or an IATA cargo agent.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for:
(delete non-applicable)

Airport of Departure

PASSENGER AND CARGO AIRCRAFT
 ~~PASSENGER AND CARGO AIRCRAFT ONLY~~

Airport of Destination:

Shipment type: (delete non-applicable)

NON-RADIOACTIVE

~~RADIOACTIVE~~

Can be left blank

Completing the Shipper's Declaration

NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification					Quantity and type of packaging	Packing Instr.	Authorization
UN or ID No.	Proper Shipping Name	Class Division	Packing Group	Subsidiary Risk			
UN 2814	Infectious substances affecting humans (Hepatitis B Virus)	6.2			1 fiberboard box X 25 ml	620	
UN 1845	Dry Ice	9	III		2 kg OVERPACK USED	954	
Additional Handling Information							
Emergency Telephone Number CHEMTREC 1-800-424-9300							
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 Signatory Eric Cook Biosafety Officer		
					Place and Date Albuquerque, NM June 30, 2011		
					Signature (see warning above) <i>Eric Cook</i>		



Must be trained and certified



Documentation for Category B (Air waybill)

FedEx USA Airbill Express FedEx Tracking Number: 841593854830 Form No. 0200 Sender's Copy

1 From Please print and press hard. Sender's Name: Nancy LaPoint, Phone: 603-650-8630, Company: Dartmouth-Hitchcock Med Centre, Address: 1 Medical Ctr Dr, Lebanon, NH, ZIP: 03756

2 Your Internal Billing Reference DIAGNOSTIC SPECIMENS UN3373

3 To Recipient's Name: Ngoc-Anh Le, Ph.D., Phone: 1-404-321-6211 ext., Company: Lab Lipoprotein Phys, rm 4a197, Address: Atlanta VAMC, 1670 Clairmont, Decatur, GA, ZIP: 30033

4a Express Package Service Packages up to 150 lbs. FedEx Priority Overnight, FedEx Standard Overnight, FedEx First Overnight

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

5 Packaging FedEx Envelope, FedEx Pak, Other

6 Special Handling SATURDAY Delivery, HOLD Weekday, HOLD Saturday

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

8 Release Signature 446

Try online shipping at fedex.com

By using this Airbill you agree to the service conditions on the back of this Airbill and in our current Service Guide, including terms that limit our liability.

Questions? Visit our Web site at fedex.com or call 1.800.Go.FedEx® 800.463.3333

- 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”



Activity: 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

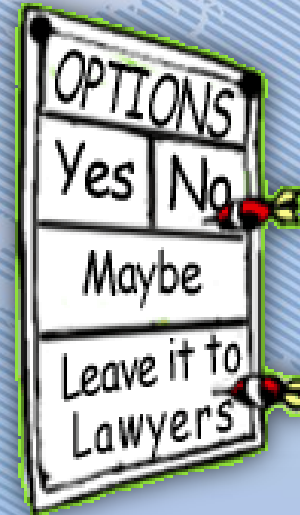
Type of outer packaging: One fibreboard box



Authorizing Shipments

Administrative/
Procedural
Controls

- Discuss in your group,
 - 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?



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



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



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**



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?

State and Operator Variations

PACKING INSTRUCTION XXX

State Variations: AUG-03, AEG-01, BGH-02, GBG-05, CAG-05/06/10/11, ING-01, JPG-22, MYG-06, NLG-02, PKG-01, SAG-03, ~~USG-12/13~~, ~~VUG-02~~, VCC-01, VCC-04, VCC-07

△ Operator Variations: 5X-02, 9C-01, AC-01, AF-01/04, AS-08, BA-03, CA-05, CI-01/07, XS-07, EK-01, FX-08/09/11/12, GF-06, HA-03, HP-02, IC-11, IR-03, IY-01, JD-01, JD-05, JJ-03, JL-01, JP-01, JU-05, KA-06, KE-02/03, KJ-03, LA-07, LH-03/06, ME-06, MN-01, NW-01, OS-01, PZ-03, QF-03, QY-01, RG-06, SQ-08, SV-05, TK-01/02/05, TR-06/07/08, US-07/08, UU-04/05, VN-01, ZW-01

2.9.1 Variations Filed by States

2.9.1 State variations which have been notified to ICAO of the time of printing are

2.9.3 Operator Variations

2.9.3 Operator variations which have been filled with IATA as the time of printing in 2.9.4 and apply

FedEx Operator variation:

FX-12 Shipper's Declarations must be typewritten 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.

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

Training Requirements

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



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



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



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



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



Class Activity: Prepare a Shipping Checklist

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



Shipping Infectious Substances & Biological Specimens

Student Guide





Shipping Infectious Substances & Biological Specimens

Welcome & Introductions

Welcome to Shipping Infectious Substances and Biological Specimens!

Possible prevention options:

- 1.
- 2.
- 3.
- 4.
- 5.

Grouping of answers:

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?

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Shipping Infectious Substances & Biological Specimens

Infectious Substance Transport & Regulations

Reasons for transportation of biological materials:

Shipping Infectious Substances & Biological Specimens

Infectious Substance Transport & Regulations

There are many and varied agencies and interests that regulate the shipment of dangerous goods.

Shipping Infectious Substances & Biological Specimens

Infectious Substance Transport & Regulations

Why IATA?

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

Shipping Infectious Substances & Biological Specimens

Infectious Substance Transport & Regulations

General definition for dangerous goods:

Shipping Infectious Substances & Biological Specimens

Infectious Substance Transport & Regulations

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:

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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?

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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.

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Shipping Infectious Substances & Biological Specimens

Definitions

IATA definition of infectious substance:

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

Define culture:

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Define patient specimens:

List some examples of patient specimens:

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Shipping Infectious Substances & Biological Specimens

Definitions

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:

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Shipping Infectious Substances & Biological Specimens

Definitions

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:

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What if you know or expect a pathogen to be present in the sample but you have little idea which pathogen?

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Requirements for “Exempt human specimen” or “Exempt animal specimen”:

- 1.
- 2.
- 3.

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Record significant observations:

Record significant observations:

Should the swabs being transported be considered infectious substances?

How would you classify these as A or B?

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How do you classify these cultures?

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

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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?

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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?

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Shipping Infectious Substances & Biological Specimens

Classification

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

Shipping Names

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

Shipping Names

Note key shipping names:

Category A

UN 2814-

UN 2900-

Category B

UN 3373-

UN 1845-

Shipping Infectious Substances & Biological Specimens

Shipping Names

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

Working in groups, assign and write down the proper shipping name for each example below. You may refer to the answers you recorded from previous classification exercise.

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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.	
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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

Mitigation of Shipping Risks

Record review notes if necessary.

Shipping Infectious Substances & Biological Specimens

Mitigation of Shipping Risks

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.

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Shipping Infectious Substances & Biological Specimens

Mitigation of Shipping Risks

Notes:

Shipping Infectious Substances & Biological Specimens

Packaging

Note some observations of engineering controls:

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Shipping Infectious Substances & Biological Specimens

Packaging

Packaging Requirements:

Primary receptacle:

-

Secondary packaging:

-

-

Outer packaging:

-

-

-

Category A key components:

Shipping Infectious Substances & Biological Specimens

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.

Category B key requirements:

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Packaging

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

“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 tripled packaged as shown
3. The package is marked “exempt human specimens”

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?

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Marking provide information on

-
-
-
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Labels

-Diamond-shaped

-Various shapes

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

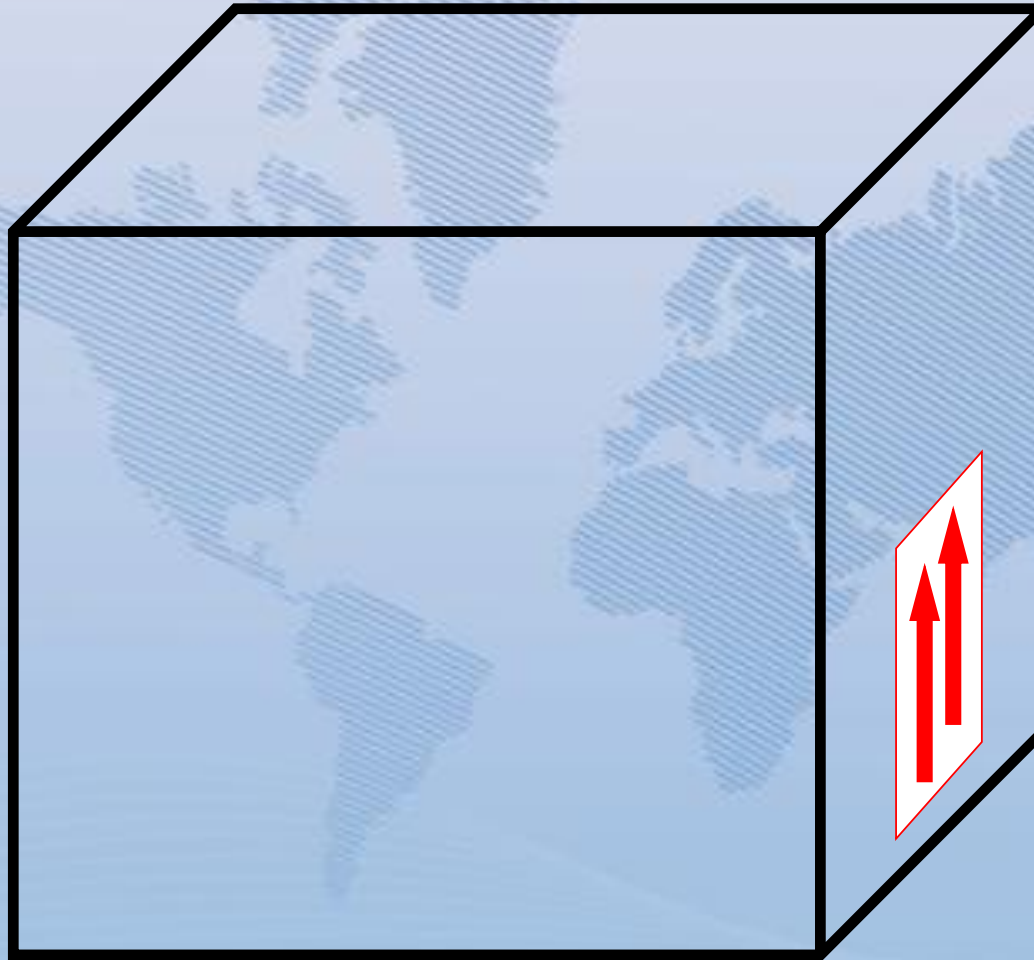
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PSNs with their associated UN Id. numbers appear next to the hazard label they are associated with.

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

Class Exercise: What marks and labels?

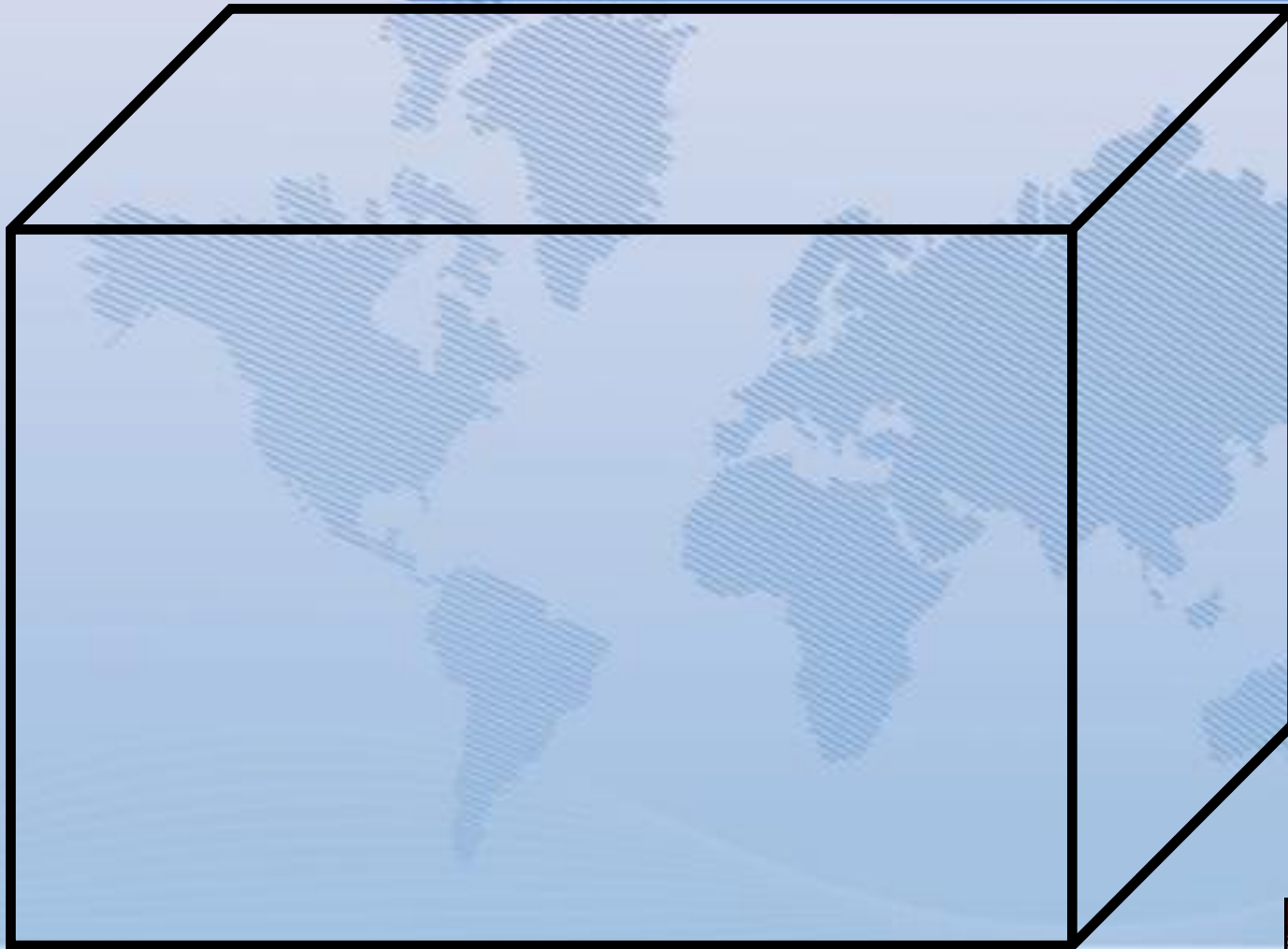


Shipping Infectious Substances & Biological Specimens

Marking & Labeling

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

Class Exercise: What marks and labels?



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Shipping Infectious Substances & Biological Specimens

Marking & Labeling

Definition of an overpack:

When are overpacks used?

Should the UN specification mark be included on the overpack?

Record observations gathered from actual packaging experience.

Shipping Infectious Substances & Biological Specimens

Documentation

Required Documentation

-Packing list

-Shipping waybill

-An itemized list of contents

-Category A packages also require

Note requirements for Category A shipments:

- 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.

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.

List mistakes found:

Shipping Infectious Substances & Biological Specimens

Documentation

Use this information to complete the shipping form.

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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Definition of a Material Transfer Agreement (MTA):

List some key considerations for Import and Export requirements:

Shipping Infectious Substances & Biological Specimens

Authorization & Permits

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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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?

Shipping Infectious Substances & Biological Specimens

Authorization & Permits

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

Training Requirements

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

List some security requirements:

-
-
-
-
-
-

Record key elements of program management:

Key considerations when selecting a carrier:

Shipping Infectious Substances & Biological Specimens

Review & Wrap-Up

Record any overview notes and key ideas that you need:

Shipping Infectious Substances & Biological Specimens

Review & Wrap-Up

Create a shipping checklist:
