

Shipping Infectious Substances and Biological Specimens Training Course

International Biological Threat Reduction Program

Global Security Programs

Sandia National Laboratories

Albuquerque, NM USA



SAND No. 2010-4482 P

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

What went wrong?





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

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 or non-specification package

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, Pumphandle TX 10101

Air Waybill No. Page 1 of 1 Pages

Shipper's Reference Number (optional) 0002

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

SAF-PAK INC.

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

TRANSPORT DETAILS

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

Passenger and Cargo Aircraft: Passenger Aircraft Cargo Aircraft

Airport of Departure: _____

Airport of Destination: _____

Shipment type: (delete non-applicable) NON-RADIOACTIVE RADIOACTIVE EXTREMELY 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 and/or signed by a consolidator, a forwarder or an IATA cargo agent.

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)



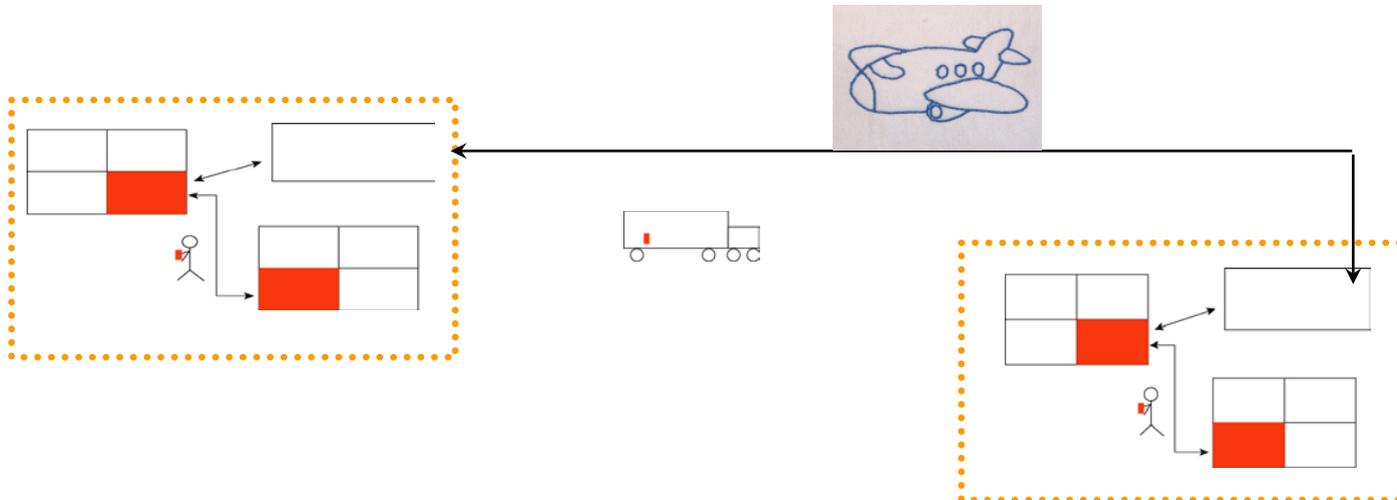
- **In your group, discuss how biological materials are moved in and out of your laboratory and facility?**
 - Where are materials coming from and how?
 - Where are materials going to and how?
 - To whom are materials coming from or going to?
- **Be prepared to share one or two examples with the class**



Infectious Substance Transport

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- **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





Shipping Risks

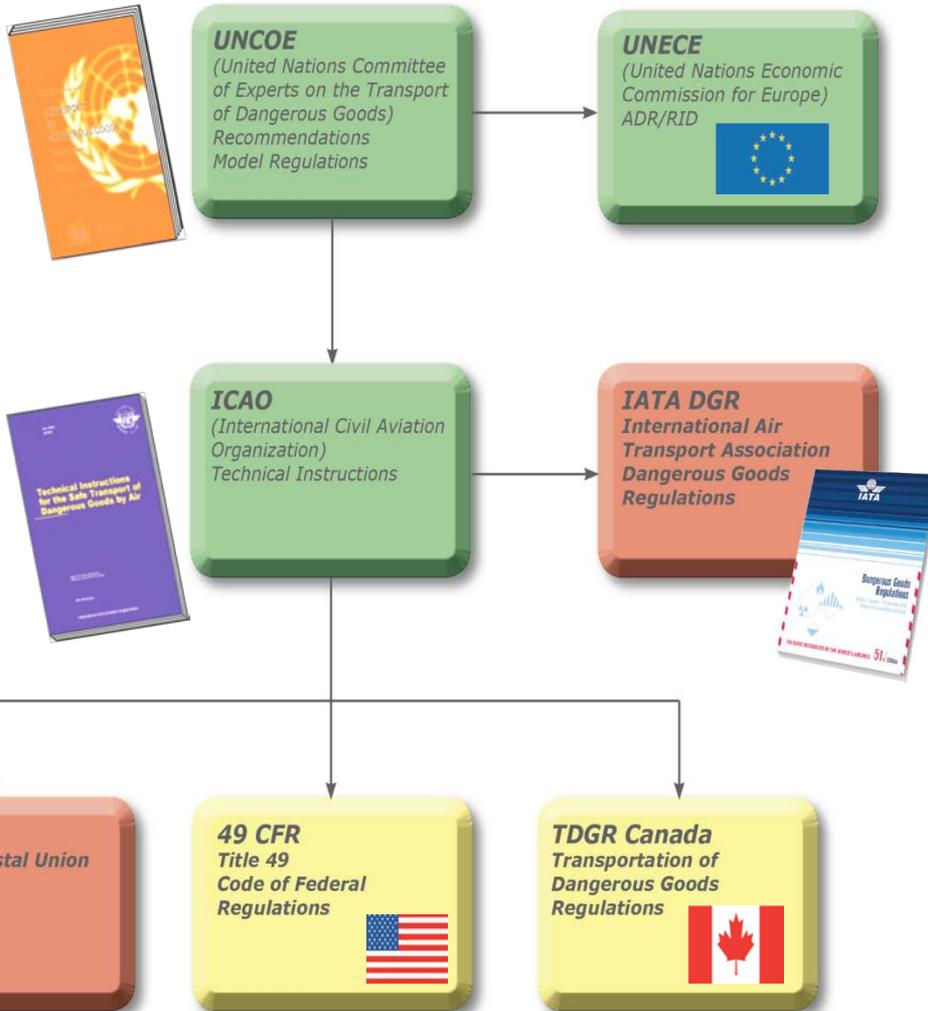
- **In your group, take 15 minutes to:**
 - Identify one or two risks associated with shipping?
 - **Consider safety, security, and intellectual property**
 - What are the worst-case consequences for each of these risks?
 - **What determines the level of consequences?**
 - What determines the likelihood 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?



Regulations?



- ✓ International (UN/ICAO)
- ✓ Regional (NAFTA, ADR/RID)
- ✓ National (US 49CFR, Canada TDGR)
- ✓ Industry (IATA, UPU)
- ✓ Postal regulations
- ✓ Mode requirements (Air, Road, Rail, Sea)
- ✓ Carrier requirements (FedEx variations)
- ✓ Import/Export

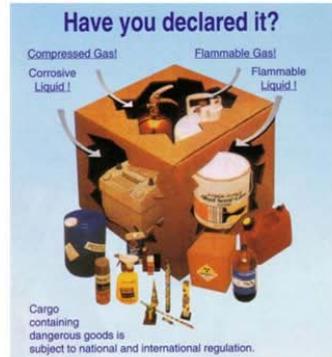


- **IATA – Represents, leads and serves the air industry**
- **230 member airlines and air carriers (93% of intl. air traffic)**
- **International Gold standard – most air shipments will be inspected based on IATA requirements**
- **User-friendly format**
- **Generally most restrictive**
- **Incorporates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



- **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





9 Classes of Dangerous Goods

Class 1 Explosives

Class 2 Gases

Class 3 Flammable liquids

Class 4 Flammable Solids - Substances liable to spontaneous combustion - Substances which in contact with water, emit flammable gases

Class 5 Oxidizing substances and Organic Peroxide

Class 6 Toxic and Infectious Substances

Class 7 Radioactive Material

Class 8 Corrosives

Class 9 Miscellaneous Dangerous Goods





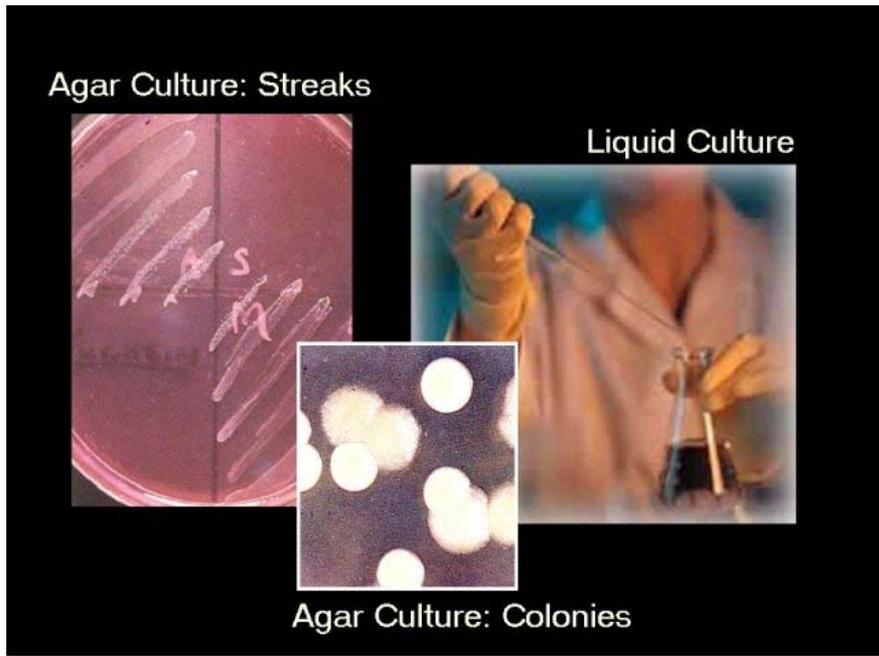
- **Infectious substances** are substances which are known or are reasonably expected to contain pathogens.
- Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which **can cause disease in humans or animals.**





Definitions: Cultures

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



Definitions: Patient Specimens

Patient Specimens are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.





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





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



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 . . .

known medical history

symptoms

individual circumstances

endemic local conditions



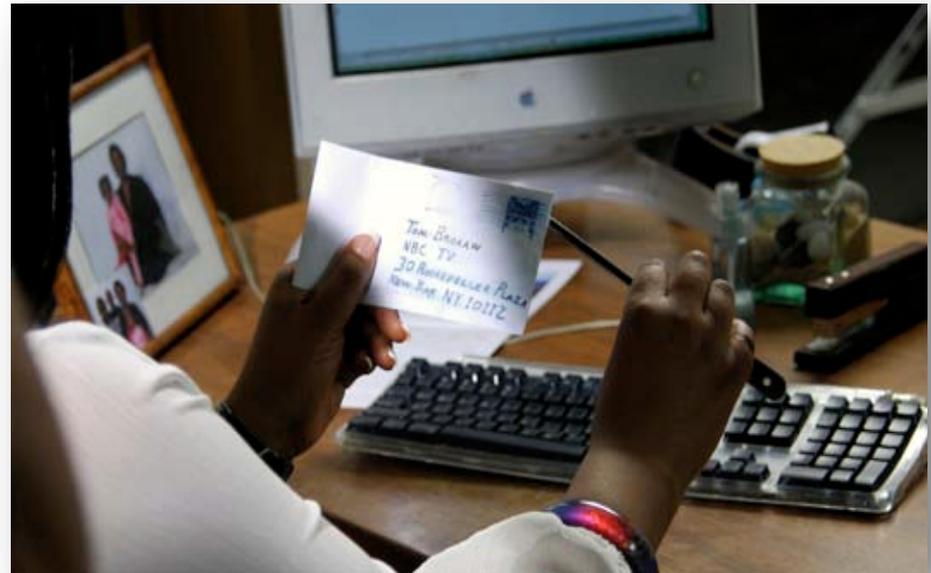
EXAMPLES





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?**
- **How would you classify these as 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)?





Break



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 and 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**



Proper Shipping Name exercise

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*



Examples of Category A Infectious Substances

Table 3.6.D

Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.6.2.2.2.1)

UN Number and Proper Shipping Name	Micro-organism	UN Number and Proper Shipping Name	Micro-organism
			Kyasanur Forest disease virus
			Lassa virus
UN 2814	<i>Bacillus anthracis</i> (cultures only)		Machupo virus
Infectious affecting			
	<i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> – Glanders (cultures only)		Omsk hemorrhagic fever virus
	<i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i>		Poliovirus (cultures only)
	Dengue virus (cultures only)		Tick-borne encephalitis virus (cultures only)
	Eastern equine encephalitis virus (cultures only)		Variola virus
	Hantavirus causing hemorrhagic fever with renal syndrome	affecting animals	Classical swine fever virus (cultures only)
	Hendra virus		Foot and mouth disease virus (cultures only)
	Hepatitis B virus (cultures only)		Goatpox virus (cultures only)
	Herpes B virus (cultures only)		Lumpy skin disease virus (cultures only)
	Human immunodeficiency virus (cultures only)		<i>Mycoplasma mycoides</i> – Contagious bovine pleuropneumonia (cultures only)
	Highly pathogenic avian influenza virus (cultures only)		Peste des petits ruminants virus (cultures only)
	Japanese Encephalitis virus (cultures only)		Rinderpest virus (cultures only)
	Junin virus		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





Break



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*

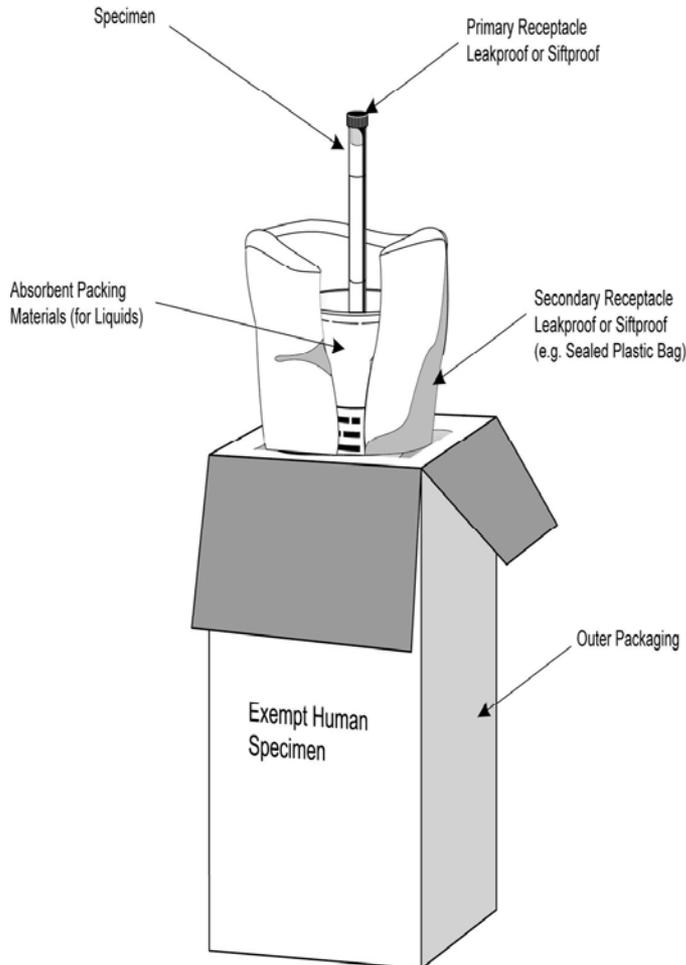
Practices and Procedures

- *Training*
- *Tracking of materials*



Principles of Packaging

Engineering
Controls



- ✓ **Must be designed to prevent damage during transport**
- ✓ **Must be designed to prevent leakage during transport**
- ✓ **Must be labeled in a manner to alert shippers of hazards**
- ✓ **Must have documentation to alert shippers to hazards and allow for appropriate response in event of leakage/damage**



Triple packaging required for Category A, B, and Exempt

Primary receptacle

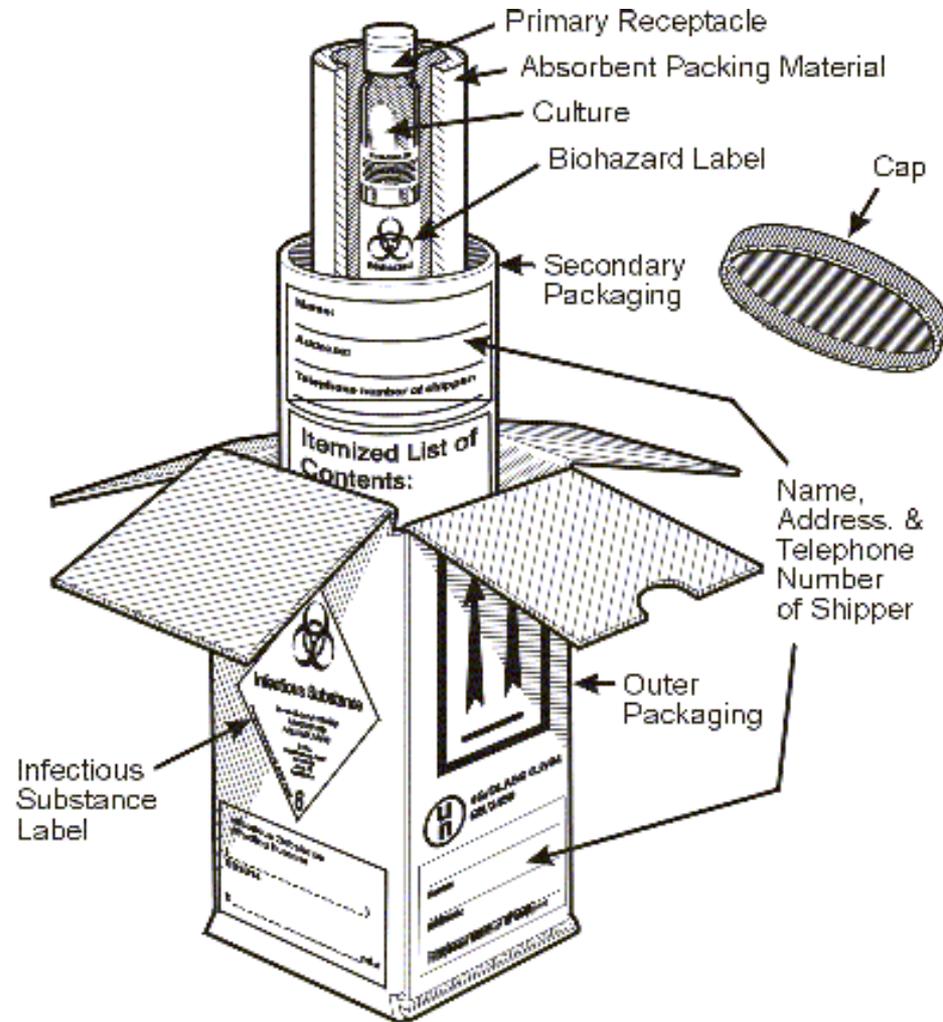
- A primary watertight, leakproof receptacle containing the specimen

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

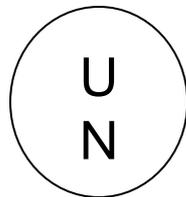




Category A Packaging: IATA PI 602

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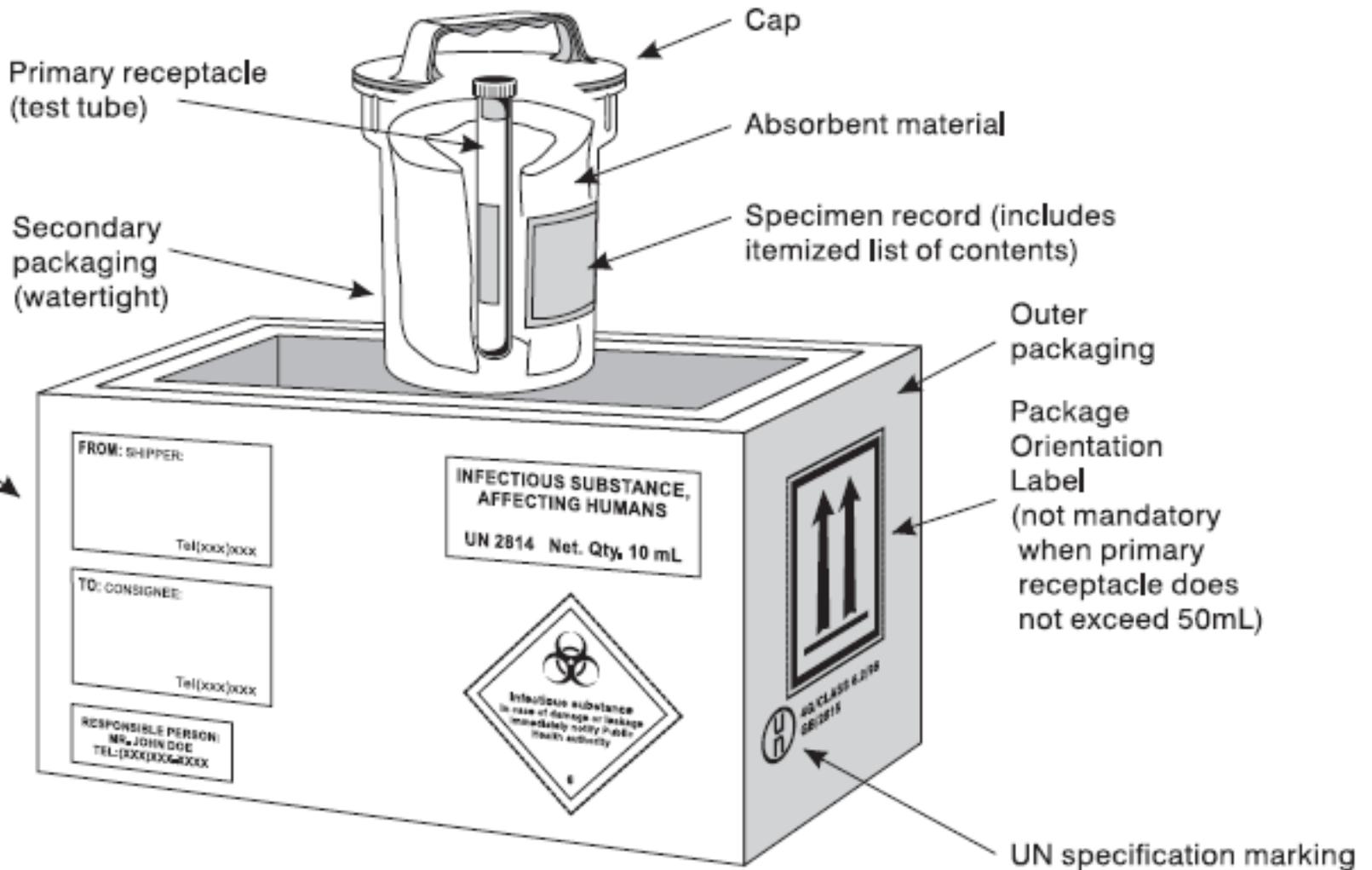
- Good condition
- Leakproof primary
- Leakproof secondary
- Pressure capable primary or secondary
- Absorbent (for liquids)
- Multiple fragile primaries wrapped individually
- Itemized list
- Rigid outer packaging
- 4 in. minimum
- Qty Limit 50 mL or 50 g for passenger aircraft. 4 L or 4 kg for cargo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



4G/Class 6.2/2010
USA/+AA16324



Category A Packaging





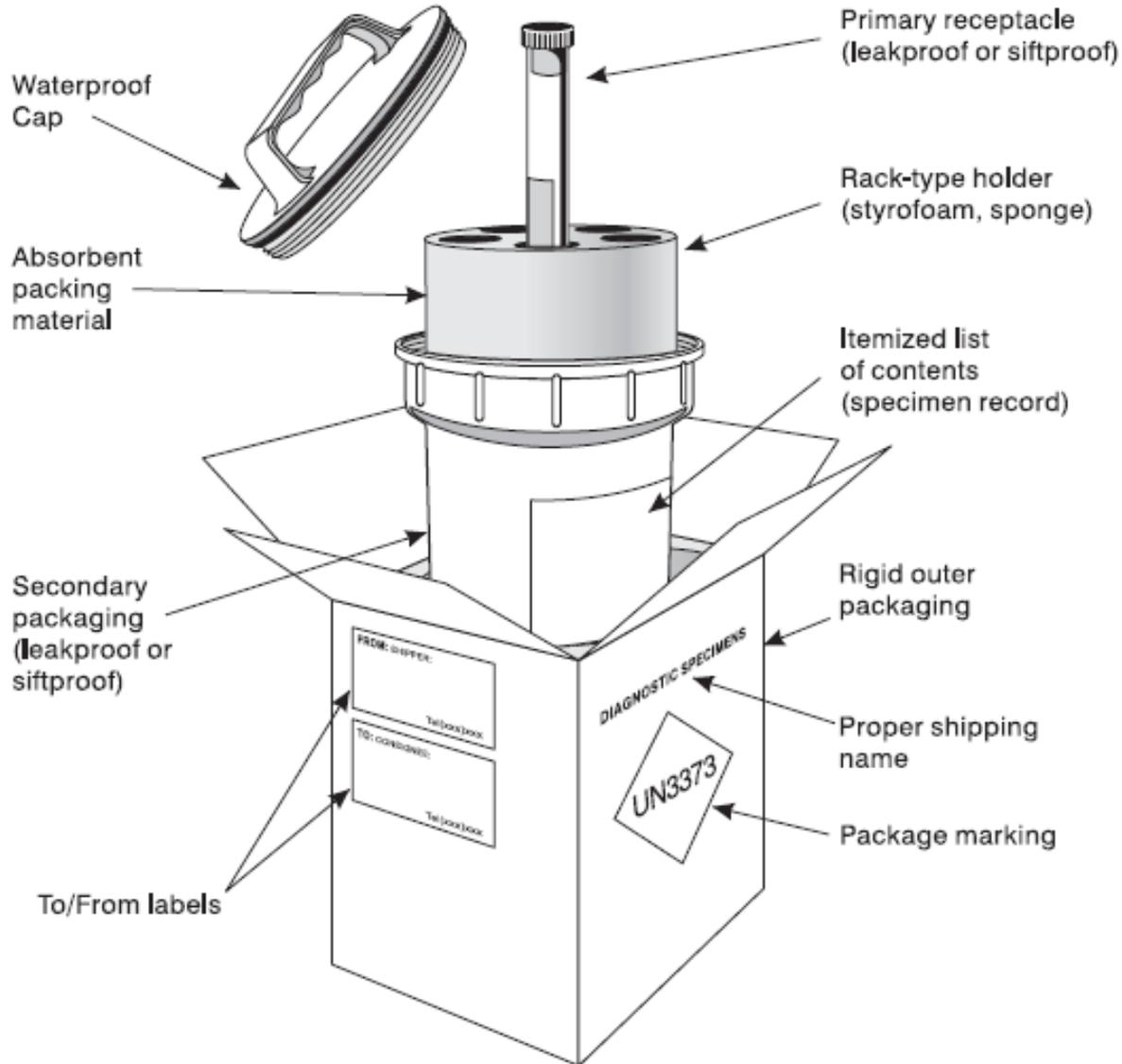
Category B Packaging: IATA PI 650

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- ✓ 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**



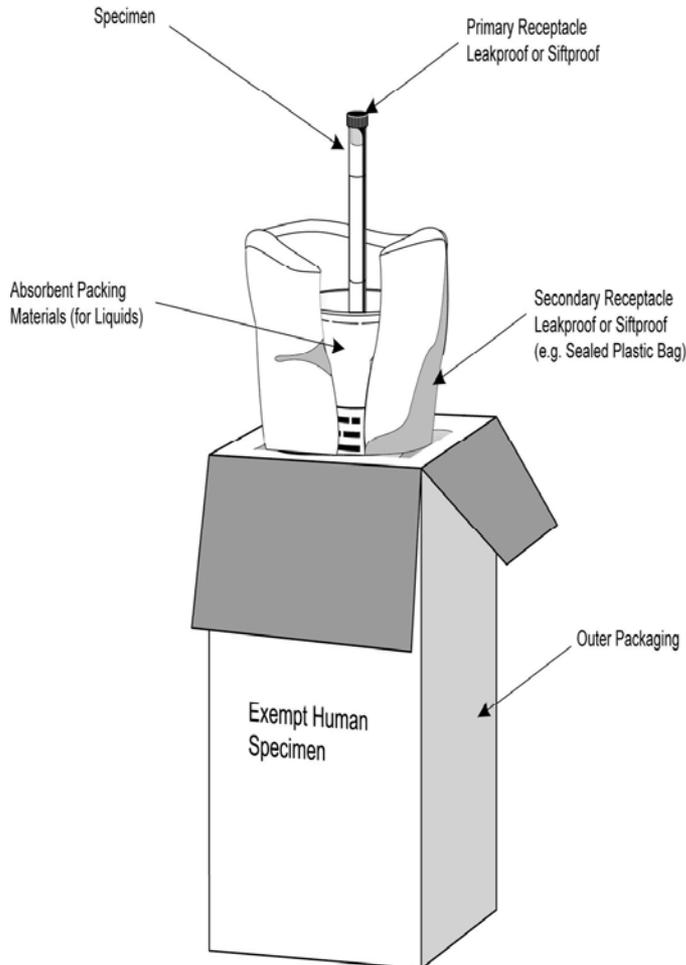
Category B Packaging





Before a specimen is considered “Exempt”

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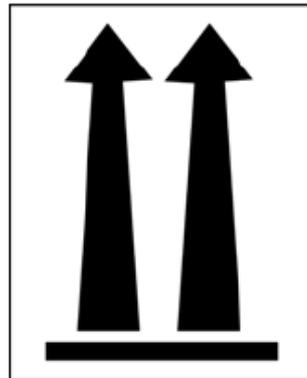
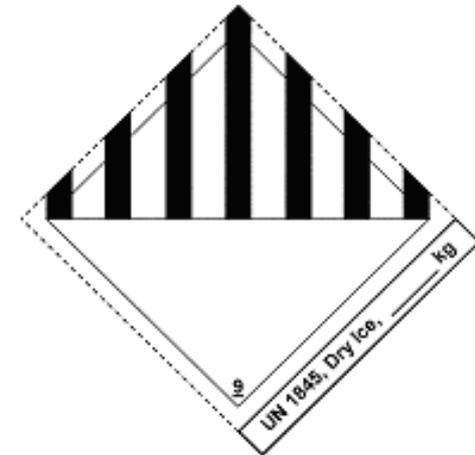
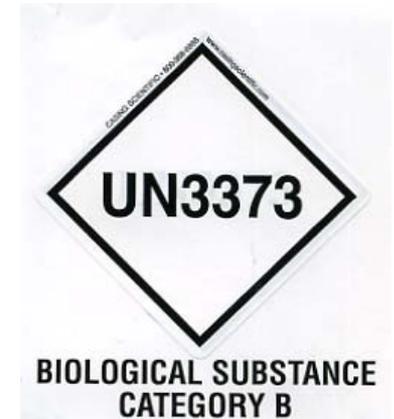


- ✓ **Must be a patient specimen**
- ✓ **Professional determination - minimal likelihood of pathogens**
- ✓ **Must be triple packaged**
- ✓ **Package marked “Exempt Human Specimen” or “Exempt Animal Specimen”**



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





Marking & Labeling

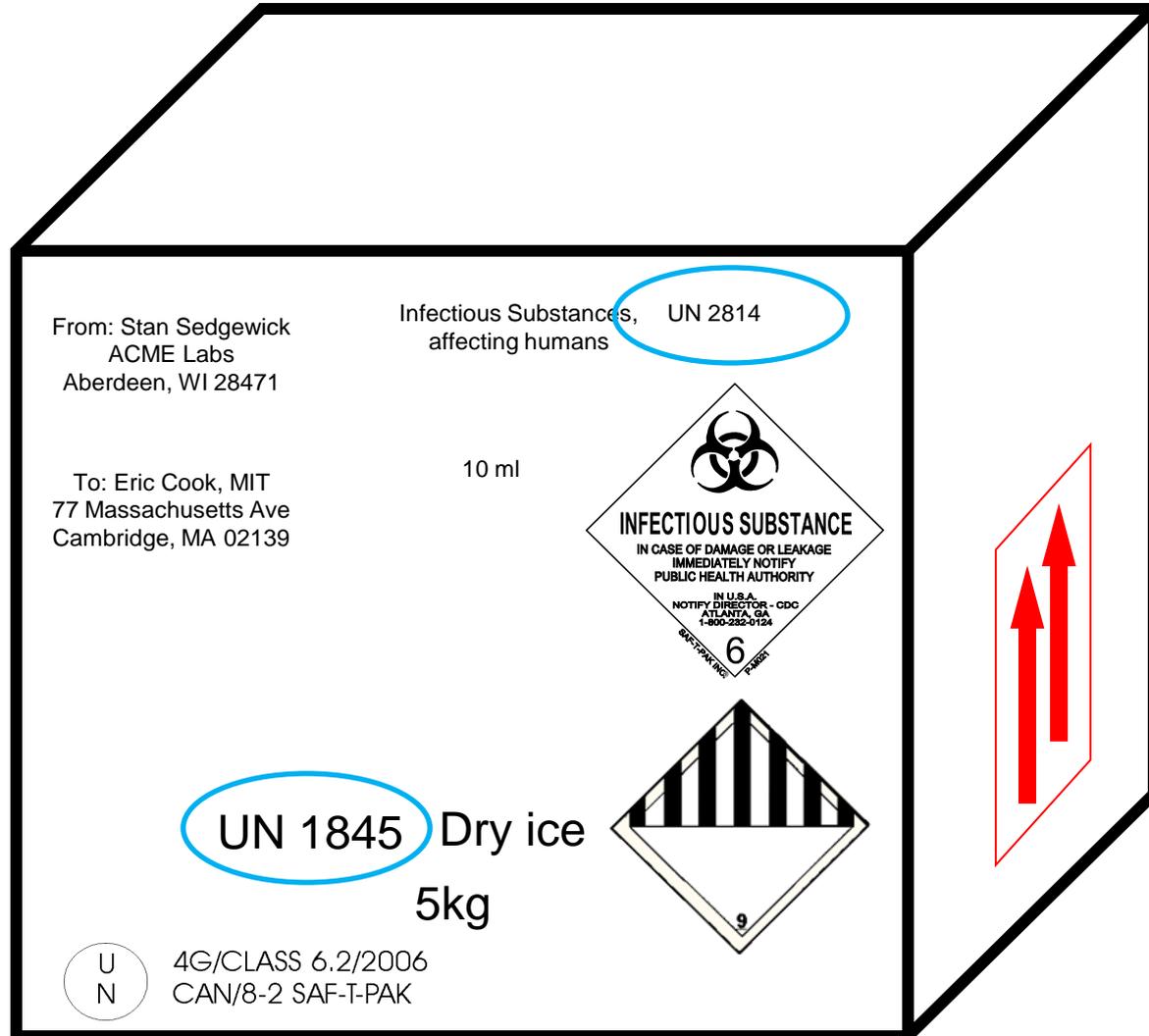
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- Addresses of shipper and consignee
- Name and Phone number of person responsible
- Applicable Hazard label for each dangerous good
- Proper shipping name
- UN Number
- Quantity of (Category A and Dry Ice)





- 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





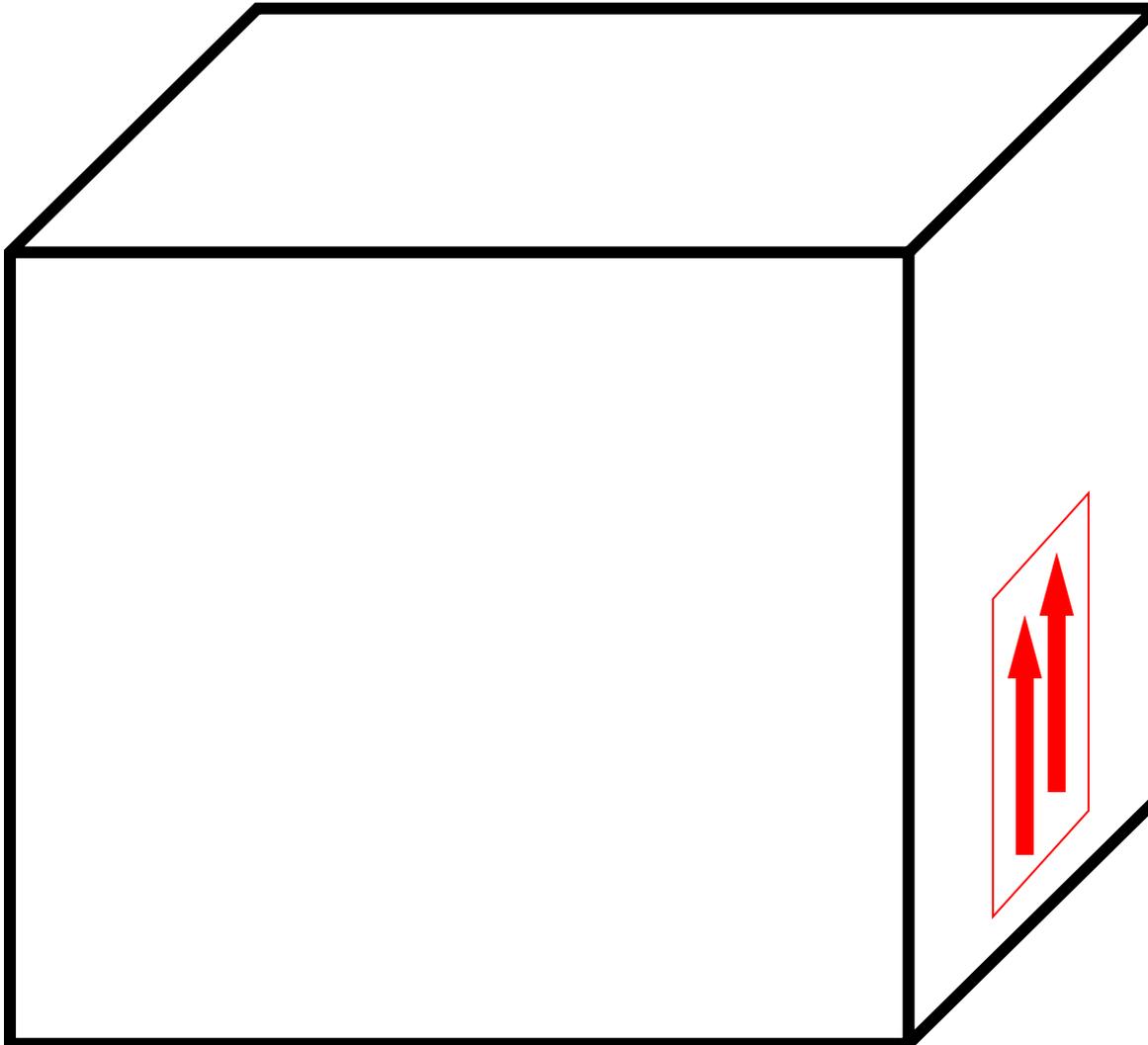
Class Exercise: What marks and labels?

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.

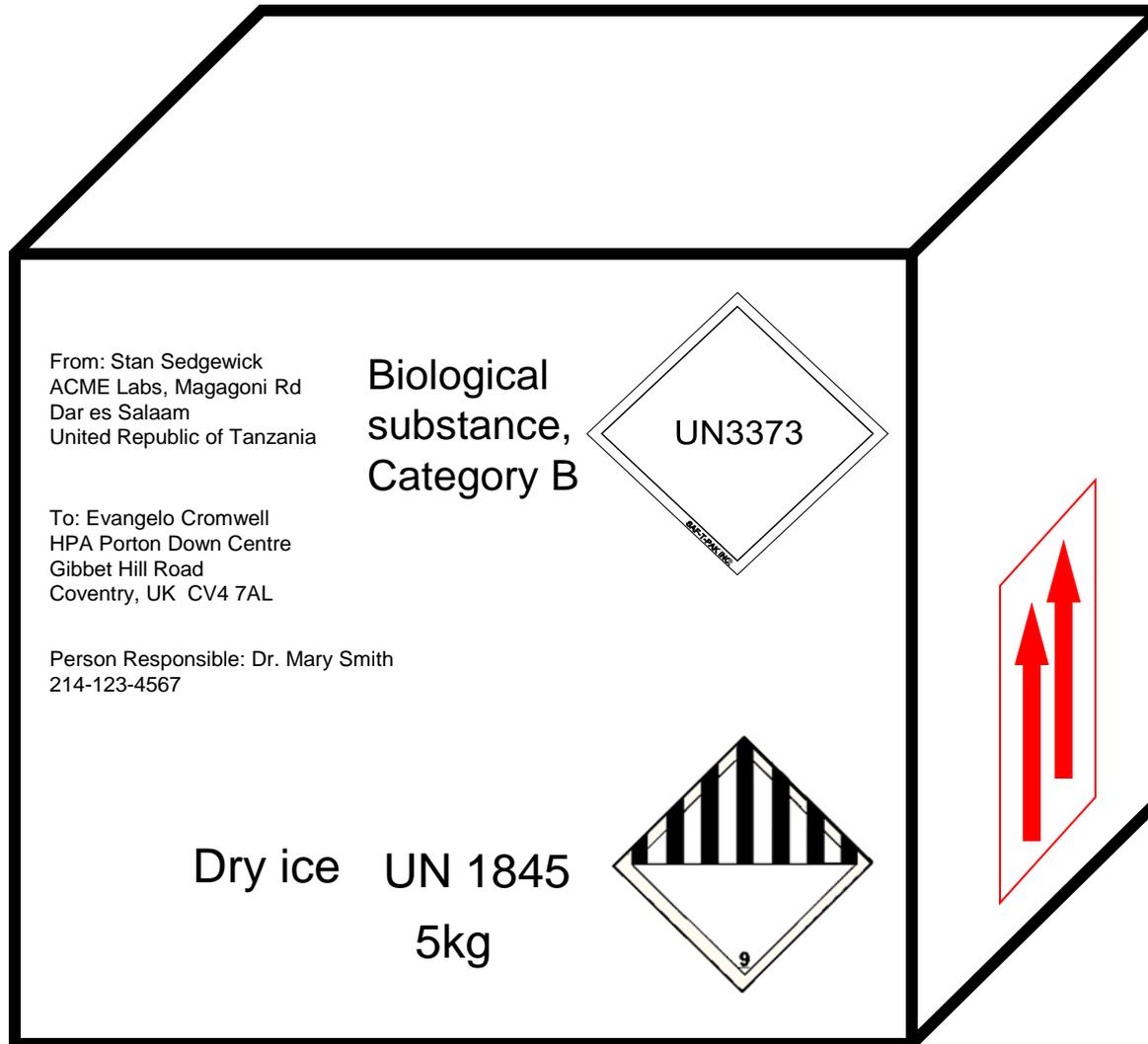


Class Exercise: What marks and labels?





Class Exercise: What marks and labels?





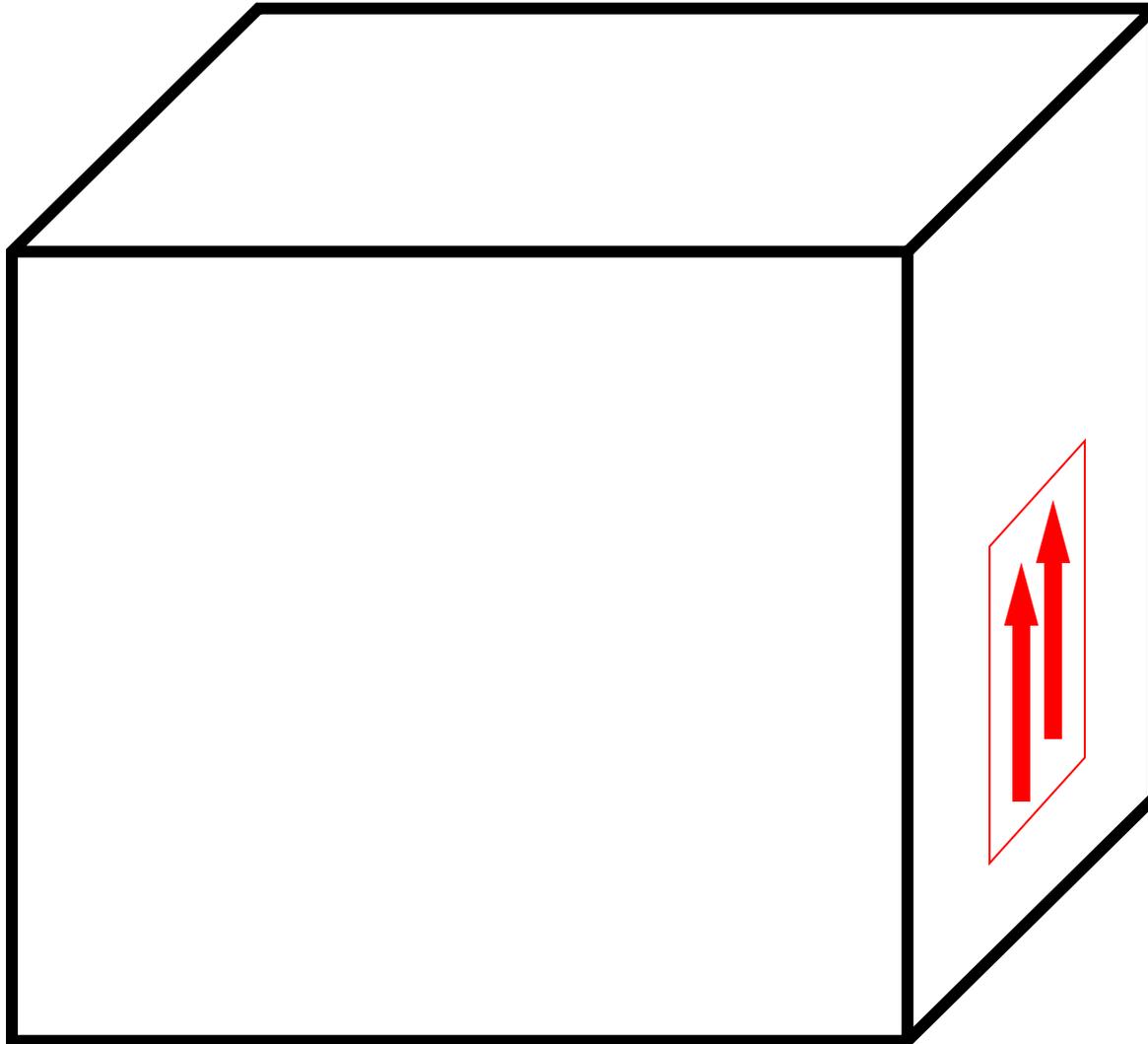
Class Exercise: What marks and labels?

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?





From: Stan Sedgewick ACME Labs, Magagoni Rd Dar es Salaam United Republic of Tanzania	UN 2814 Infectious Substances, affecting humans	
To: Evangelo Cromwell HPA Porton Down Centre Gibbet Hill Road Coventry, UK CV4 7AL	10 ml	
Person Responsible: Dr. John Smith 214-123-4567		
	4G/CLASS 6.2/2006 CAN/8-2 SAF-T-PAK	





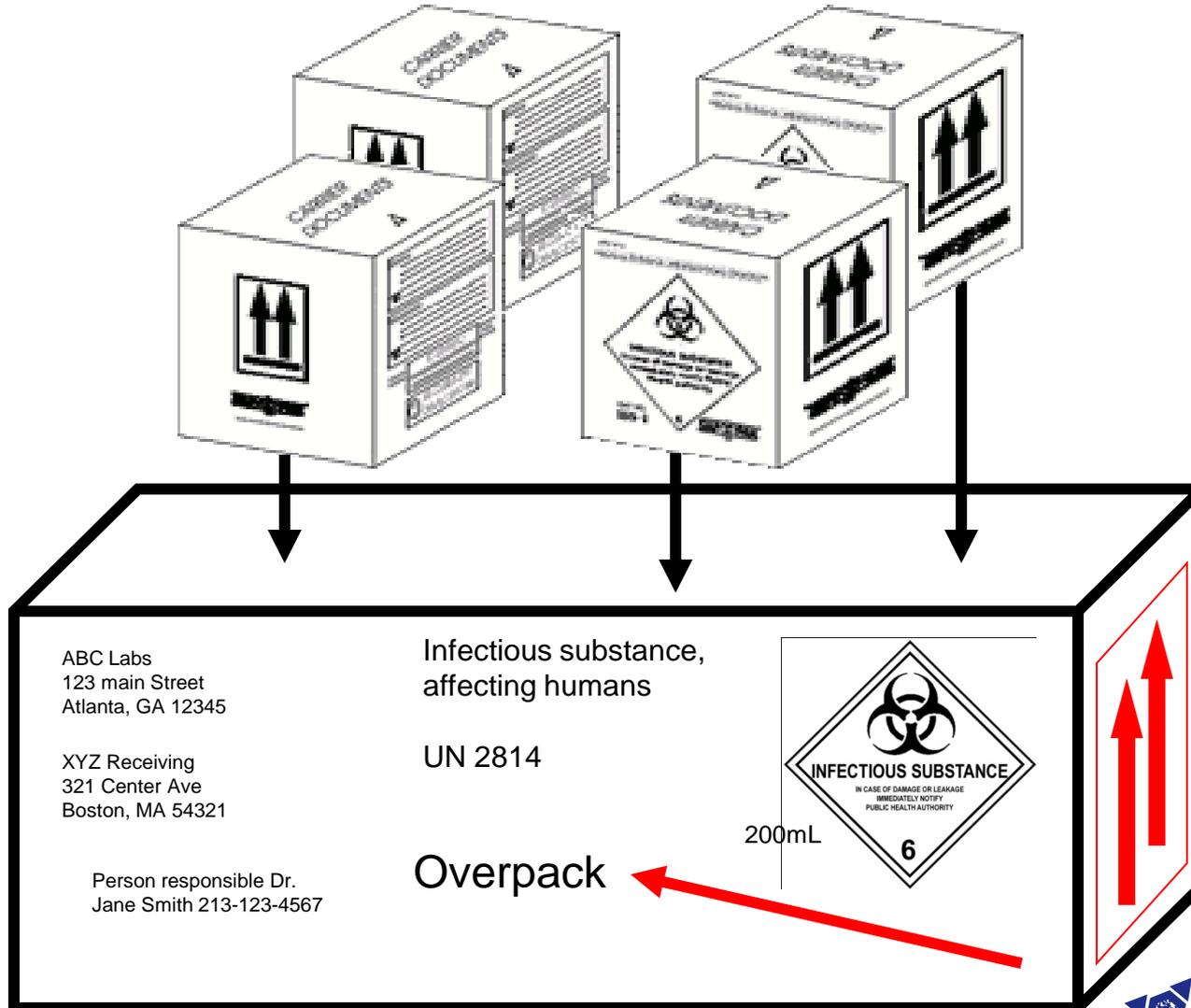
Shipping with Overpacks

- 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 outer box





Multiple small packages in an Overpack





Shipping Infectious Substances with Dry Ice

- **Two options**
 - “All packed in one fibreboard box”
 - **UN Specification Box that holds both the samples and the dry ice in one outer package. UN Specification markings are visible on outside of this box**
 - “Overpack used”
 - **Infectious substances packaged in a smaller UN Specification Box that does not hold the dry ice**
 - **This smaller UN Specification Box is placed in an outer box or overpack that can hold the dry ice**
 - **Overpack is not a UN Specification Box but must be marked**
 - All markings and labels on inside box must also be on overpack
 - Outside box must be marked with word “overpack”
- **Remember, dry ice is a Class 9 dangerous good**

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.





Break



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

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 0002 <i>(optional)</i>				
Consignee Quality Laboratories Ltd. 456 Downtown Avenue Atlanta GA 01010 <small>Name and Number of Person Responsible for class 6.2 shipment: Dr. John Smith 1-555-111-9999</small>						
<small>Two completed and signed copies of this Declaration must be handed to the operator.</small>		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: <i>(delete non-applicable)</i>		Airport of Departure: _____ Airport of Destination: _____				
PASSENGER AND CARGO AIRCRAFT <input type="checkbox"/> <input checked="" type="checkbox"/> PASSENGER AIRCRAFT <input checked="" type="checkbox"/> <input type="checkbox"/>		Shipment type: <i>(delete non-applicable)</i> NON-RADIOACTIVE <input checked="" type="checkbox"/> <input type="checkbox"/>				
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  <small>(see warning above)</small>				

- 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



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

NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification					Quantity and type of packaging	Packing Instruction	Authorization
UN or ID No.	Proper Shipping Name	Class Division	Pack- ing Group	Subsi- diary Risk			
UN 2814	Infectious substances affecting humans (Hepatitis B virus)	6.2			1 fiberboard box X 25 ml	602	
UN 1845	Dry Ice	9	III		2 kg OVERPACK USED	904	
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 Cambridge, MA Aug 9, 2010		
					Signature (see warning above) <i>Eric Cook</i>		



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		
<table border="1"><tr><td><input checked="" type="checkbox"/> PASSENGER AND CARGO AIRCRAFT</td><td><input checked="" type="checkbox"/> CARGO AIRCRAFT ONLY</td></tr></table>	<input checked="" type="checkbox"/> PASSENGER AND CARGO AIRCRAFT	<input checked="" type="checkbox"/> CARGO AIRCRAFT ONLY	
<input checked="" type="checkbox"/> PASSENGER AND CARGO AIRCRAFT	<input checked="" type="checkbox"/> 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							
UN or ID No.	Proper Shipping Name	Class Division	Pack-ing Group	Subsi-dary Risk	Quantity and type of packaging	Packing Instr.	Authorization
UN 2814	Infectious substances affecting humans (Hepatitis B Virus)	6.2			1 fiberboard box X 25 ml	602	
UN 1845	Dry Ice	9	III		2 kg OVERPACK USED	904	
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 Cambridge, MA June 30, 2010		
					Signature (see warning above) <i>Eric Cook</i>		

Must be trained and certified



Documentation for Category B (Air waybill)

FedEx USA Airbill Express Tracking Number: 841593854830

1 From Please print and press hard. Sender's FedEx Account Number:
 Date:
 Sender's Name: Nancy LaPoint Phone: 603-650-8630
 Company: Dartmouth-Hitchcock Med Centre
 Address: 1 Medical Ctr Dr room 4a187
 City: Lebanon State: 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 4a187
 Address: Atlanta VAMC, 1670 Clairmont
 City: Decatur State: GA ZIP: 30033

4a Express Package Service Packages up to 150 lbs.
 FedEx Priority Overnight Next business morning
 FedEx Standard Overnight Next business afternoon
 FedEx 2Day Second business day
 FedEx Express Saver Third business day
 FedEx First Overnight Business next business morning delivery to select locations

4b Express Freight Service Packages over 150 lbs.
 FedEx 1Day Freight* Next business day
 FedEx 2Day Freight Second business day
 FedEx 3Day Freight Third business day

5 Packaging
 FedEx Envelope*
 FedEx Pak*
 Other

6 Special Handling
 SATURDAY Delivery Available ONLY for packages over 250 lbs.
 HOLD Weekday at FedEx Location Available ONLY for FedEx First Overnight and FedEx 2Day to select locations
 HOLD Saturday at FedEx Location Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations

7 Payment Bill to:
 Sender FedEx bill to Shipper
 Recipient
 Third Party
 Credit Card
 Cash/Check

8 Release Signature
 Signature: 446

- 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”



Class Activity: Completing a Shipper's Declaration for Dangerous Goods

- **Dr. Treponema has asked you to help him with the following shipment since 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



Class Activity: Documentation

- **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***





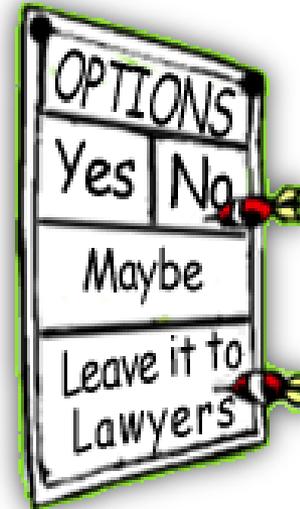
Break



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?





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?

- **Selection of an appropriate carrier that can provide appropriate security**
 - Ensuring reliable and trustworthy people handle the package
 - Controlling access to transport facilities, docks, and vehicles
 - Tracking shipping progress
 - Providing ongoing security training for employees
- **Verification that recipient receives package as expected**
 - Email or fax preferred since receipt is documented



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~~, ~~VUC-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 as 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 are listed in 2.9.4 and apply to:

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



- **The dangerous goods regulations require *all personnel involved in transport* to undergo appropriate training**
 - Training for Shipping of Category A infectious substances
 - **Successful completion of a training course that includes an exam**
 - Training for shipping of Category B infectious substances:
 - **Clear instructions should be supplied to the user**
- **Security training**
 - Security awareness training
 - Specific training as appropriate based on job duties
- **Institutions must keep training records that include**
 - Employee's name
 - Date of most recent training (every 24 months)
 - Description, copy, or location of training materials
 - Record of Exam
 - Name and address of trainer
 - Certificate of successful completion



- **As discussed at beginning, institutions need systems to:**
 - Ensure appropriate approvals and paperwork in place prior to shipping
- **Ensure that 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**
 - Classification, Packaging, Labeling, Marking, Documentation
- **Control of samples prior to shipping**
 - Which personnel are authorized to have access to the materials and information
 - Limited access to packages prior to hand over to carrier
 - E.g. secure storage for packages waiting to be picked up by carrier
 - Using a chain of custody (CoC) may be appropriate for transport of higher security risk materials
 - Record all individuals who have contact with the dangerous pathogens and toxins up until moment package turned over to carrier



Program Management

- **Institutions have a range of responsibilities related to the shipment of infectious substances**
 - From approvals prior to shipment through verification that sender receives the shipment
- **To support those responsibilities, institutions need to have**
 - Appropriate training
 - Maintenance of records
 - Written security and safety plans for transport
 - **Based on assessment of transportation safety and security risks**
 - **Address personnel, unauthorized access, en route security, training requirements, institutional requirements**



Class Activity: Prepare a Shipping Checklist

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



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





Break



EXAM TIME!