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Sandia National Laboratories

International Biological Threat Reduction Program

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SAND No. XXXX

Sandia National Laboratories

International Biological Threat Reduction

Innovative solutions for countering biological threats globally

- **Promote the responsible use of biological agents, equipment, and expertise globally.**
- **Strengthen capacities to safely, securely, and responsibly detect, handle, and control dangerous biological agents.**
- **Improve understanding and management of the risks associated with accidental and deliberate misuse of biological agents.**

IBTR Core Capabilities

- **Laboratory biorisk management**
  - Biorisk management standards and regulatory frameworks
  - Core biorisk management program documents
  - Lab design / programming expertise
  - Facility specific biosafety and biosecurity threat, vulnerability, and risk assessments
  - Biorisk (biosafety and biosecurity) upgrades
  - OIE Collaborating Center
- **Biothreat identification and analysis**
  - Global analysis
  - Country and regional analyses
- **Capacity building and outreach**
  - Biorisk management training
  - Training centers
  - Law enforcement
- **Building inherently safer and more secure biomedical capabilities**
  - Surveillance and control
  - Public and vet health
  - Incident detection and response

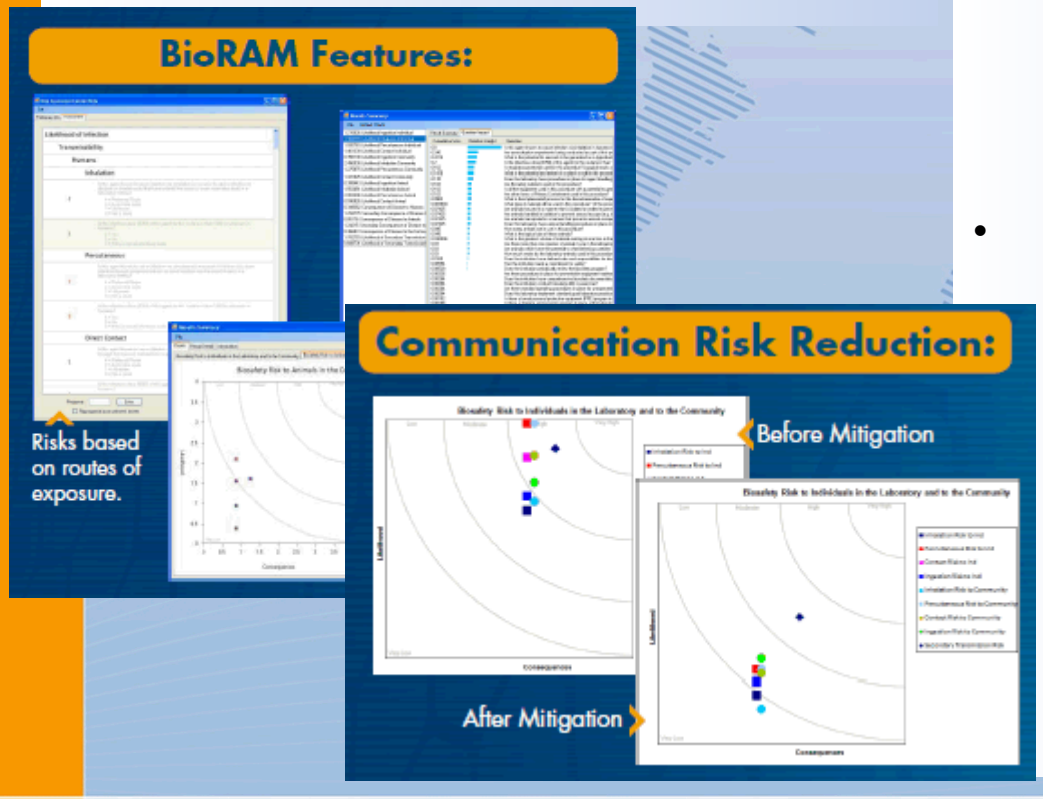
IBTR's Global Experience

DTRA's Lead Biorisk Implementer

- Primarily support new country engagement
- Technical assistance in:
  - Biological Risk Assessment and Prioritization
  - Global Biorisk Management Curriculum and training
  - Biorisk Core Documents
  - Laboratory planning / programming / biorisk management
  - Tabletop and full scale exercises to assess disease detection and response capabilities

IBTR's Biosafety and Biosecurity Risk Assessment Methodology (BioRAM)

- BioRAM Vision
  - Create a standardized approach to risk assessment.
  - Create a tool for understanding prioritization and communication in a laboratory environment.



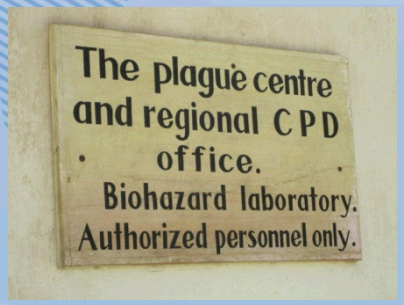
- Biosafety
  - Likelihood: The likelihood of infection by the agent and the likelihood of exposure through an infectious route based on the procedures and work practices.
  - Consequences: The consequences of disease from accidental exposure.
  - Risks: The risks to laboratory workers, risk of accidental exposure to human and animal community, and risks of secondary infection.
- Biosecurity
  - Likelihood: The likelihood of targeting a laboratory based upon the agent's potential for malicious use and the likelihood of successful acquisition of the agent from the laboratory.
  - Consequences: The consequences of disease from malicious release.
  - Risks: The risks to the human and animal community.

Example: Building Veterinary Capacity to Control Infectious Diseases

- **Training veterinary sector in provinces to detect and control infectious diseases of livestock**
  - Clinical training in the provinces
- **Sample transportation systems**
  - Support to identify and develop transportation networks from provinces to a country's national veterinary laboratory
  - Training and IATA certification for infectious materials transportation
- **Systems to aid with laboratory diagnostics**
  - Training and technical support to implement molecular diagnostics
  - Technical assistance on laboratory biosafety and biosecurity to ensure veterinary laboratories are capable of handling the samples they receive
- **Detection and control of infectious diseases**
  - Engaging public and private sector veterinary partners to develop and pilot the implementation of strategic control plans

Example: Technical Assistance to Bioscience Facilities

- **Biosafety and biosecurity risk assessments**
  - **Partnering with facility biosafety and biosecurity officers and/or institutional biosafety committees to conduct risk assessments**
- **Comprehensive lab biorisk management**
  - **Technical assistance in alignment with international standards, including as identified through risk assessments and gap analyses:**
    - *Institutional policies and procedures*
    - *Inventory systems*
    - *Personnel management programs*
    - *Physical security upgrades*
    - *Reviews of laboratory designs by lab planners and architectural and engineering specialists*



Example: Building Human Capacity to Address Biorisks

- **Global Biorisk Management Curriculum**
  - Develop and maintain a customizable library of courses designed based on international best practices in biorisk management and sustainable training techniques
    - *Catalog: http://biosecurity.sandia.gov/gbrmc/catalog.html*
  - Network of trainers to provide document and quality control and to offer a platform for shared experiences and problem solving
- **Conduct training for different stakeholders**
  - Policy makers, lab workers, biosafety/biosecurity officers, lab directors, law enforcement
  - Topics include: biorisk management, molecular diagnostics, infectious substance shipping, and biothreat identification and response
  - Training platforms include: classroom, distance-learning, lab, tabletop exercises, and full-scale field exercises
- **Development of regional training centers**
  - Physical training centers and regional consortia
  - Train-the-Trainer programs
- **Support to international organizations' human capacity efforts, including WHO, OIE, and INTERPOL**

Shipping Infectious Substances & Biological Specimens

Military Consultative Committee Engagement with the Pakistan Armed Forces

December 2014

Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

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

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

Key Messages

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

Key Messages, continued

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

Biorisk Management: the AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

Key Components of Biorisk Management

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

Key Components of Biorisk Management

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

Key Components of Biorisk Management

- **Performance**
  - The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

Preview Exercise

What went wrong?

- In your groups, take 10 minutes to discuss the possible reasons why this happened and -
- List at least five things that should have been done to prevent this
- Put your answers on your flip chart

Preview Exercise

Expected Answers - Failure to:

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

Small Group Exercise – Part 1

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?

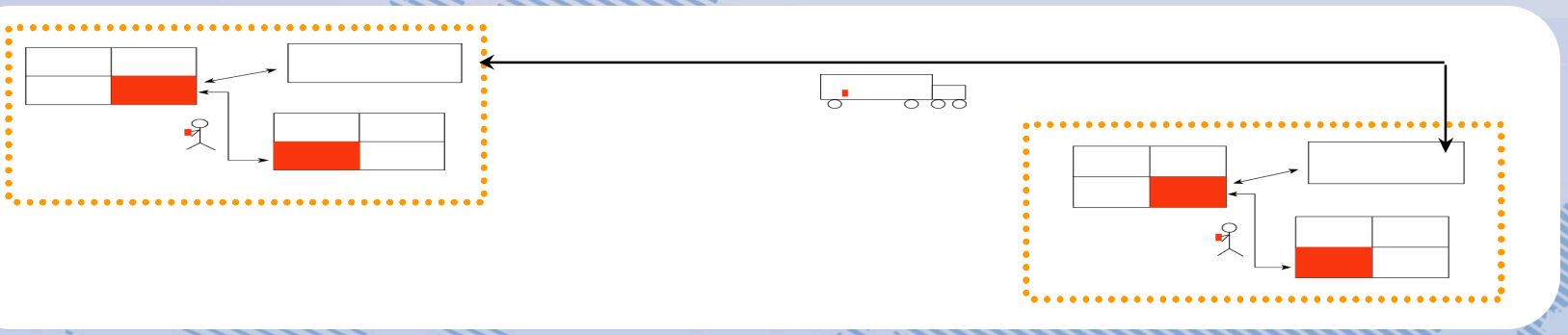
Be prepared to share one or two examples with the class

Small Group Exercise – Part 2

In your group, spend 10 minutes to discuss the following questions:

- What obstacles or challenges have you encountered shipping samples?
  - Domestically
  - Internationally
- What options have been identified to address these challenges?

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

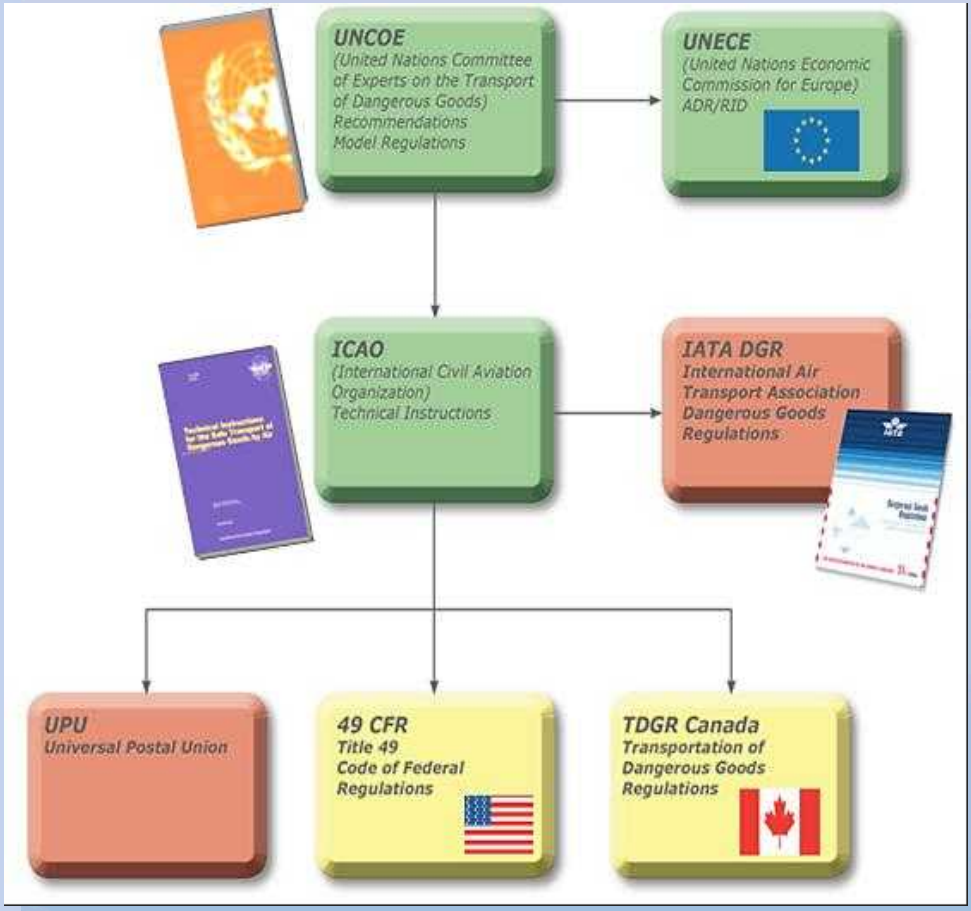
Transport can occur

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

Transport outside of a facility can occur by road, sea, rail, post, or air

Shipping & Transport 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 meet the criteria of one or more of the nine UN hazard classes

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

- 6.1 Toxic Substances and
- **6.2 Infectious Substances**

Class 7 Radioactive Material

Class 8 Corrosives

Class 9 Miscellaneous Dangerous Goods

Key Components of Biorisk Management

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

Shipping Risk Assessment

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

Shipping Risk Assessment

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?

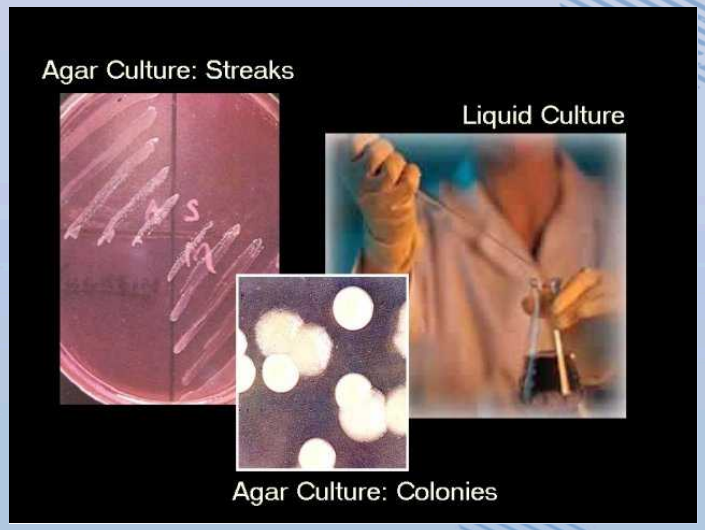
Identify 2 or 3 key differences in biological material that would alter the associated risks; put these on your flip chart.

- 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.

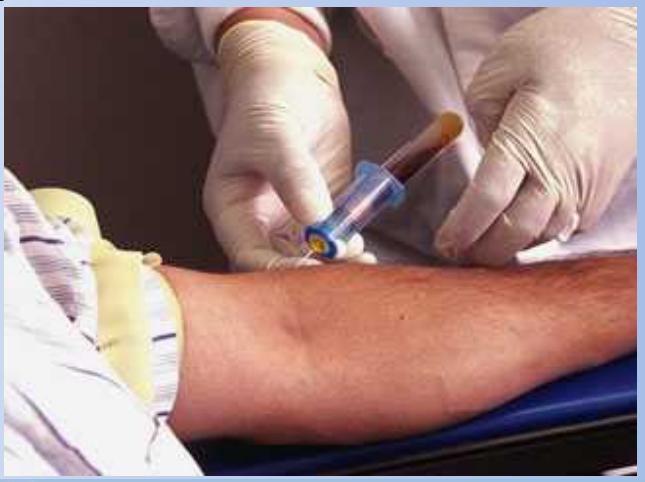
Definitions: Cultures



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

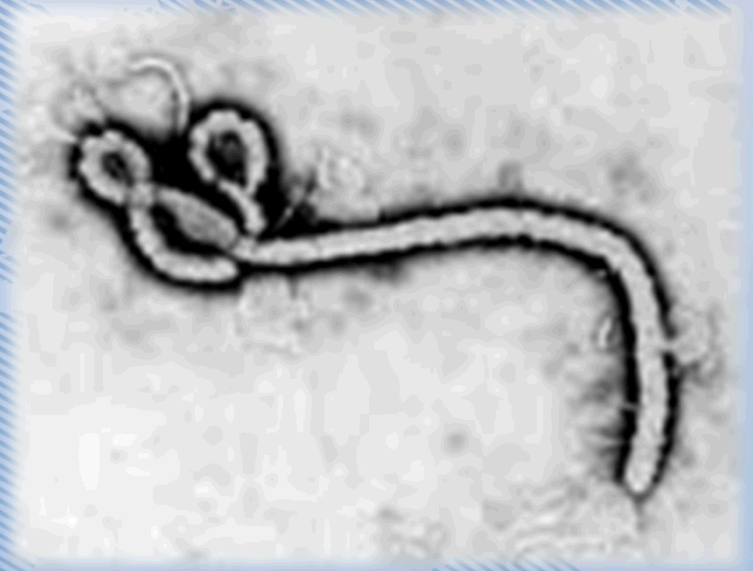
Definitions: Patient Specimens

- 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 lists examples and is not exhaustive
- New or emerging pathogens meeting the same criteria should be classified as Category A
- Cultures may be Category A or B depending on the microorganism

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 2814	*Bacillus anthracis* (cultures only)
Infectious substance	*Brucella abortus* (cultures only)
affecting humans	*Brucella melitensis* (cultures only)
	Brucella suis (cultures only)
	Burkholderia mallei – *Pseudomonas mallei* – Glanders (cultures only)
	Burkholderia pseudomallei – *Pseudomonas pseudomallei* (cultures only)
	Chlamydia psittaci – avian strains (cultures only)
	Clostridium botulinum (cultures only)
	Coccidioides immitis (cultures only)
	Coxiella burnetii (cultures only)
	Crimean-Congo hemorrhagic fever virus
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	Escherich
	Ebola viru
	Flexal viru
	Francisell
	Guanarito
	Hantaan v
	Hantaviru
	Hendra vi
	Hepatitis
	Herpes B
	Human im
	Highly pat
	Japanese
	Junin viru
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus
	Marburg virus
	Monkeypox virus
	Mycobacterium tuberculosis (cultures only)
	Nipah virus
	Omsk hemorrhagic fever virus
	Poliovirus (cultures only)
	Rabies virus (cultures only)
	Rickettsia prowazekii (cultures only)
	Rickettsia rickettsii (cultures only)
	Rift Valley fever virus (cultures only)
	Russian spring-summer encephalitis virus (cultures only)
	Sabia virus
	Shigella dysenteriae type 1 (cultures only)
	Tick-borne encephalitis virus (cultures only)
	Variola virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus (cultures only)
	Yellow fever virus (cultures only)
	Yersinia pestis (cultures only)
UN 2900	African swine fever virus (cultures only)
Infectious substances	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
affecting animals	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Goatpox virus (cultures only)
	Lumpy skin disease virus (cultures only)
	Mycoplasma mycoides – Contagious bovine pleuropneumonia (cultures only)
	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)

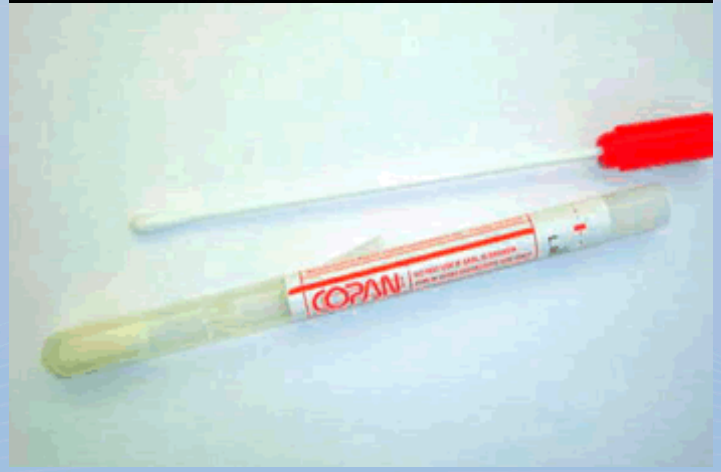
Definitions: Exempt Patient Specimens

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

Anthrax Bioterrorism Scenario



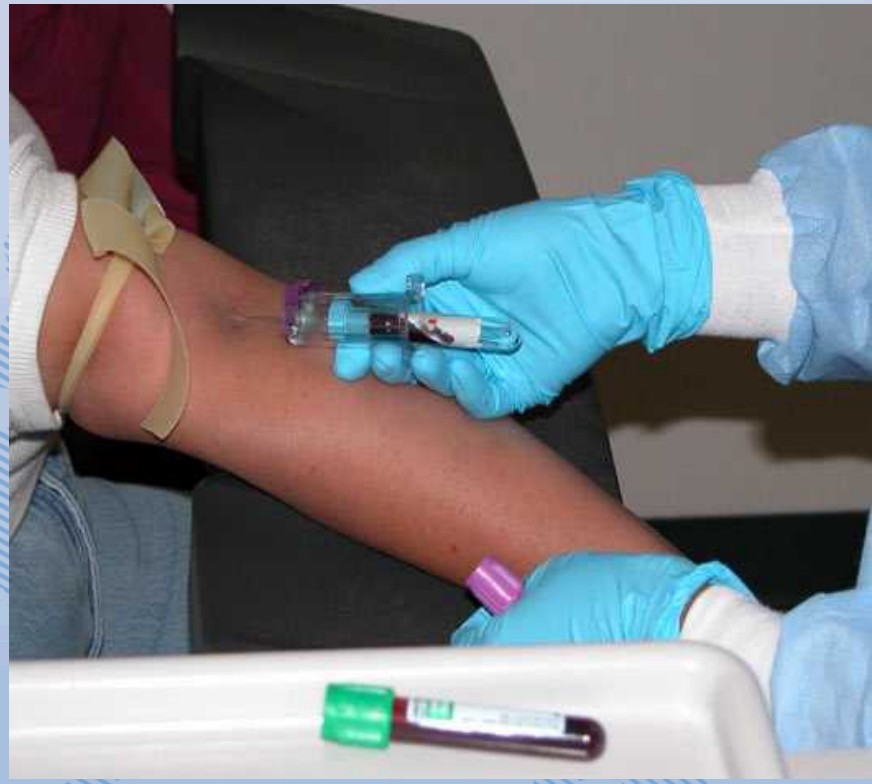
- Nasopharyngeal swabs are collected from potentially exposed office workers
- The swabs will be transported to local clinical laboratory for analysis
- Are they infectious substances?
- Would you classify these as Category A or B?

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

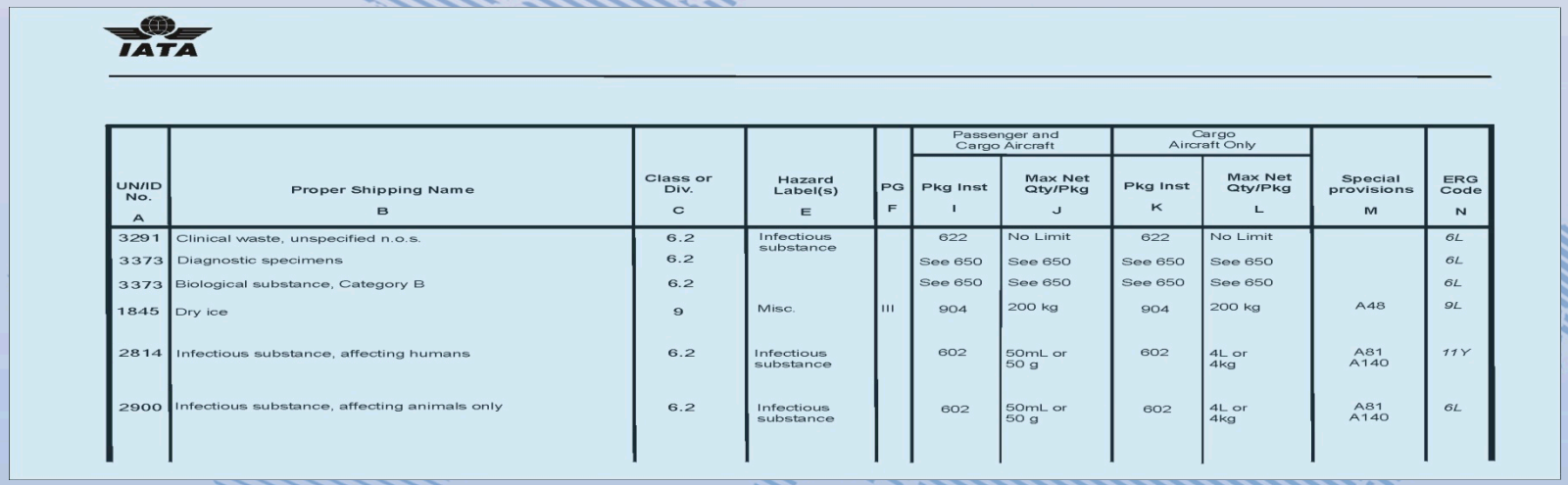
The samples will fall into one of four categories:

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



IATA

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

- 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

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

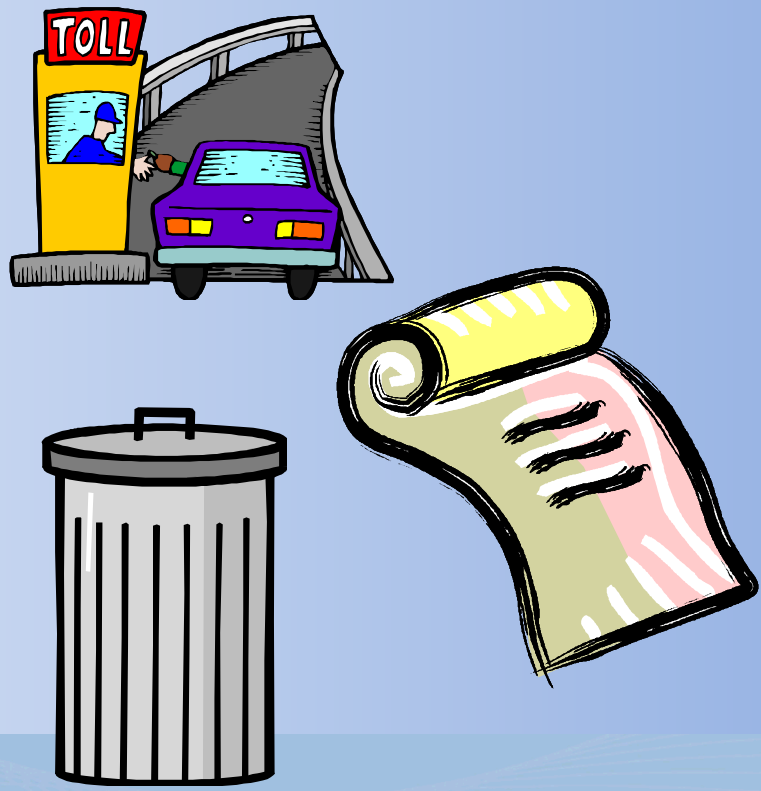
- Exempt human specimen
- Exempt animal specimen

Key Components of Biorisk Management

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

How Do Mitigate the Risks Associated with Shipping?

- Through Mitigation Control Measures:
  - Engineering Controls
  - Administrative Controls
  - Practices and Procedures
  - Elimination



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

Shipping Risk Mitigation 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

Shipping Risk Mitigation
Group Activity – Expected Responses

Engineering Controls

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

Administrative Controls

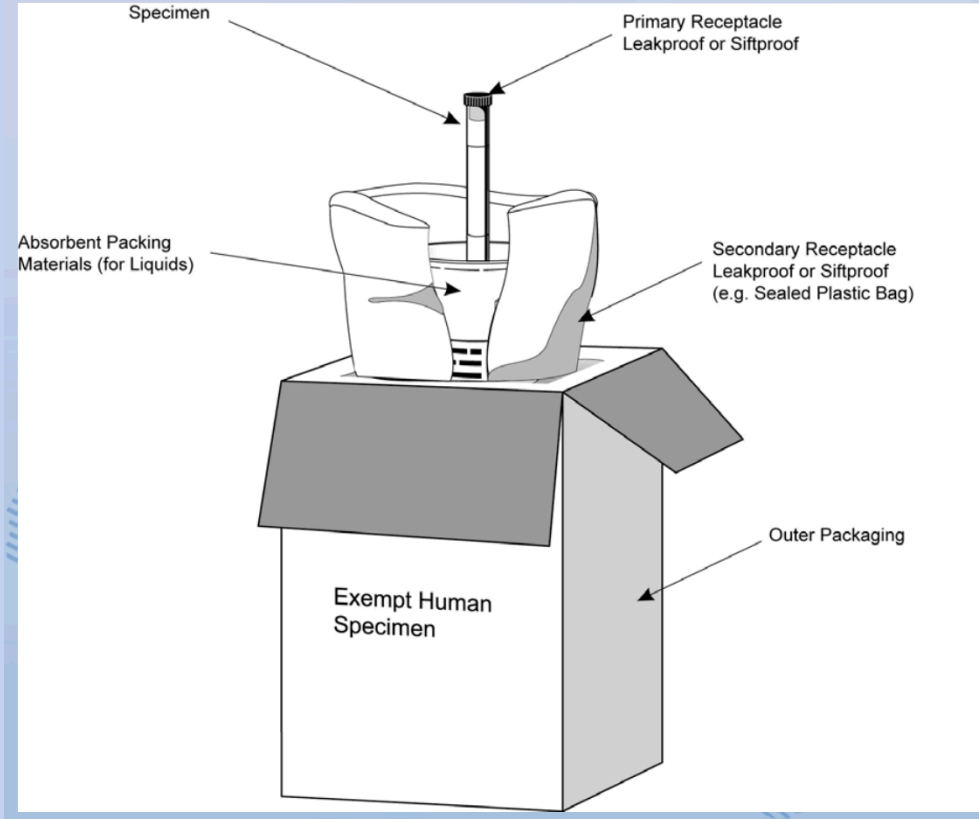
- Authorizing shipments
- Material Transfer Agreements
- Import and Export licenses
- Carrier selection and requirements

Practices and Procedures

- Training
- Tracking of materials

Principles of Packaging

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



Overview of Packaging

Triple packaging required for Category A, B, and Exempt

Primary receptacle

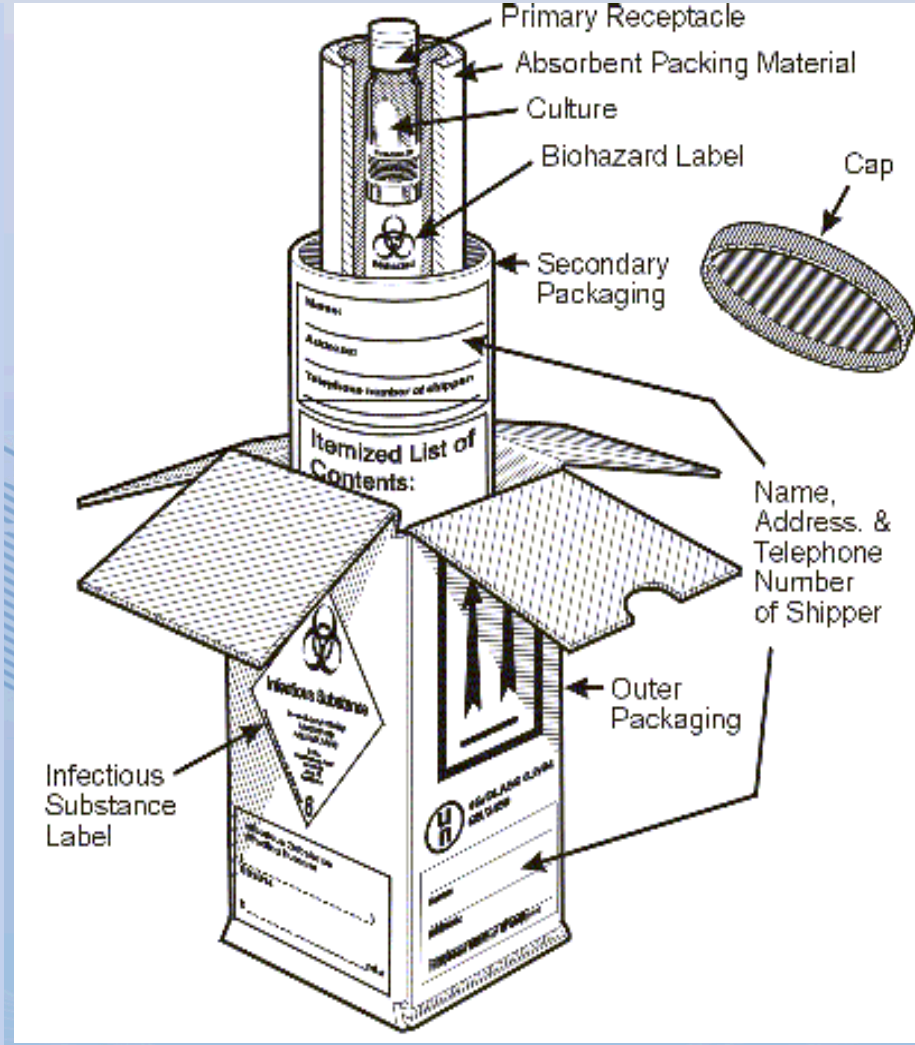
- A primary watertight, leakproof receptacle containing the specimen

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

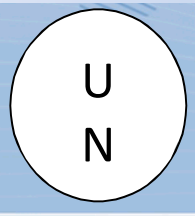
- Secondary packagings are placed in outer packagings with cushioning material
- Outer packagings protect their contents from physical damage while in transit
- At least one external surface with a minimum dimension of 10x10 cm



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



4G/Class 6.2/2010
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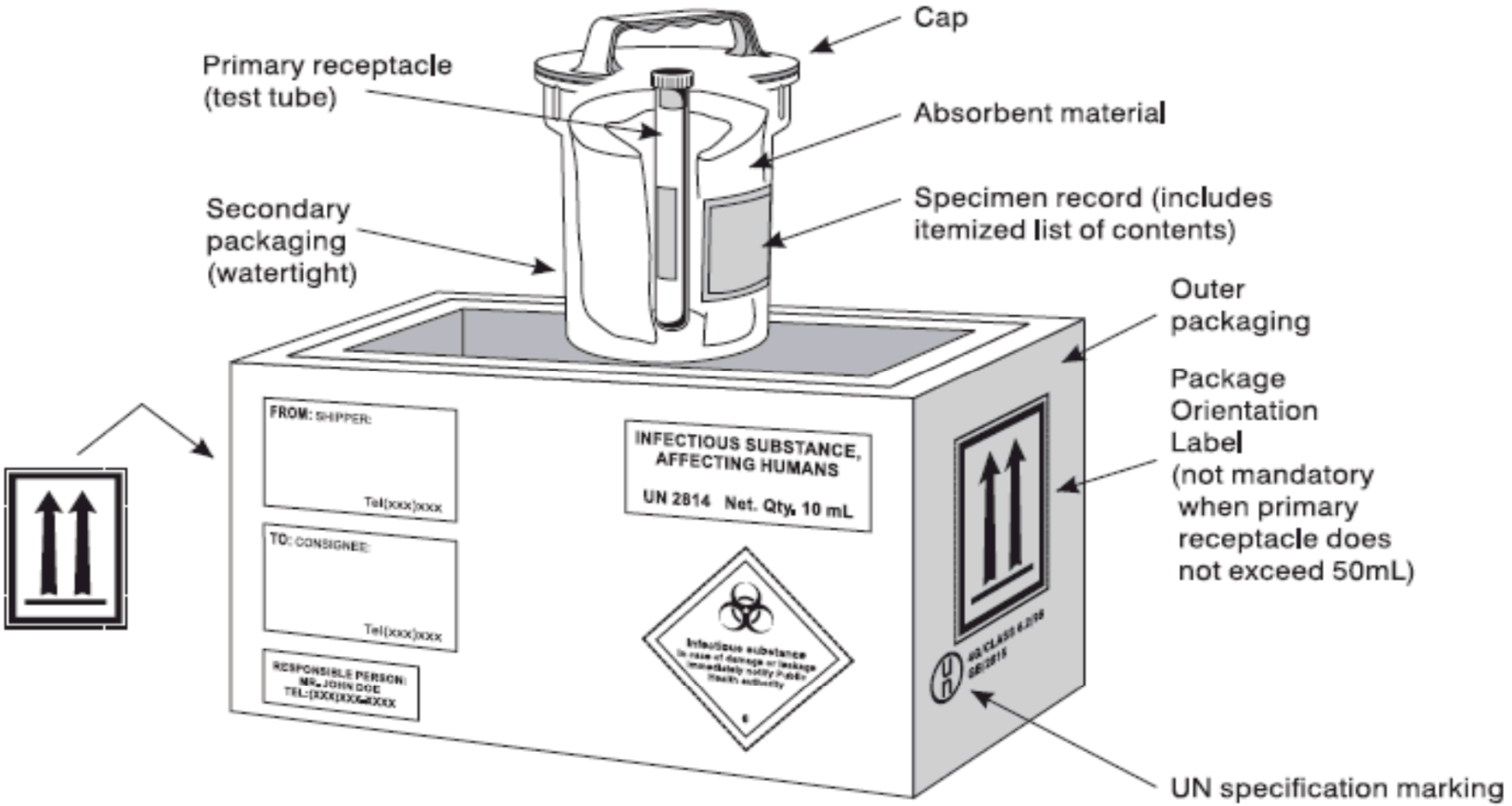
Category A Packaging

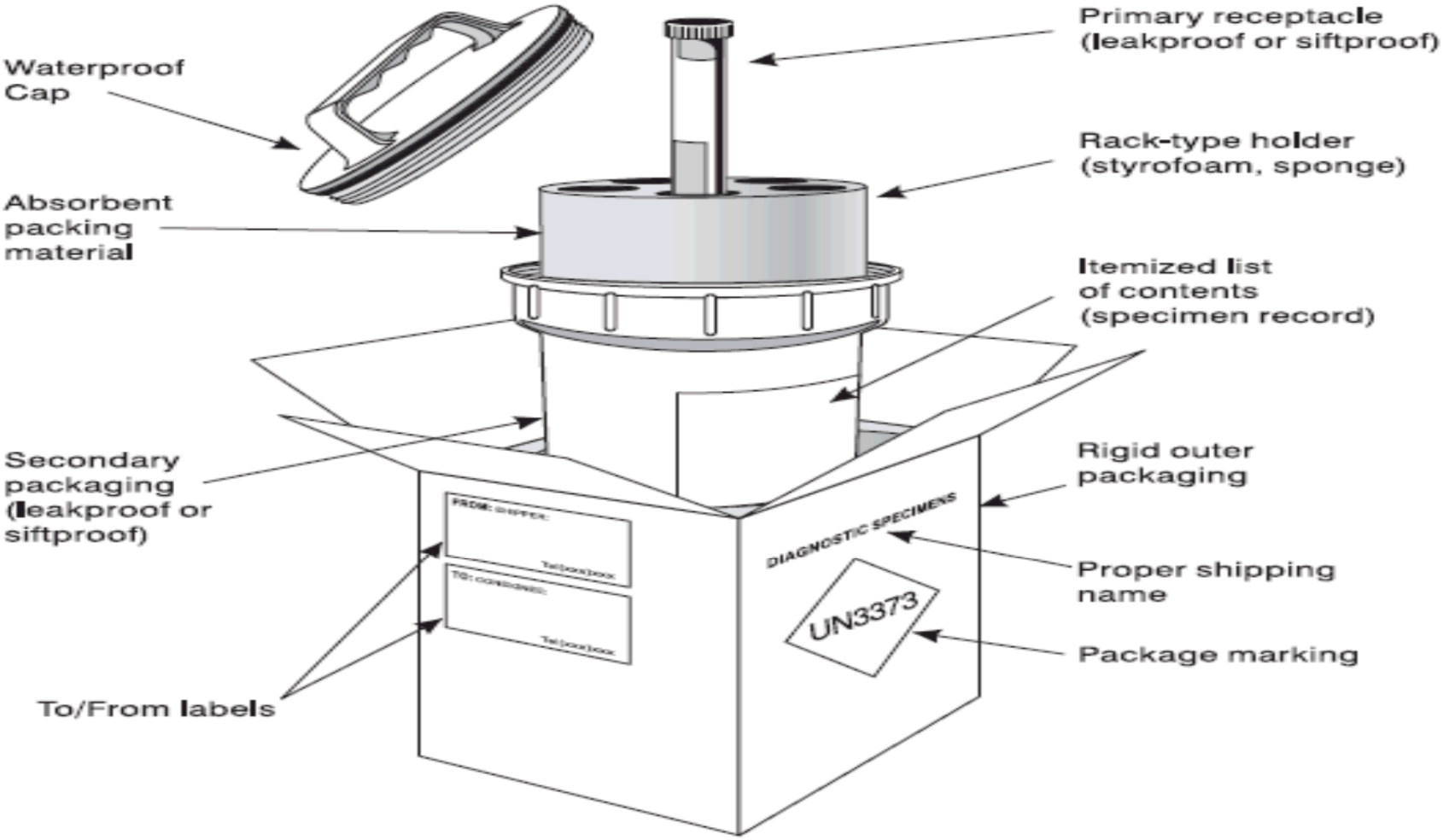


Category B Packaging: IATA PI 650

- ✓ Good quality
- ✓ Leakproof/siftproof primary (1 L max)
- ✓ Leakproof/siftproof secondary
- ✓ Absorbent
- ✓ Multiple fragile primaries wrapped individually
- ✓ Pressure capable primary or secondary

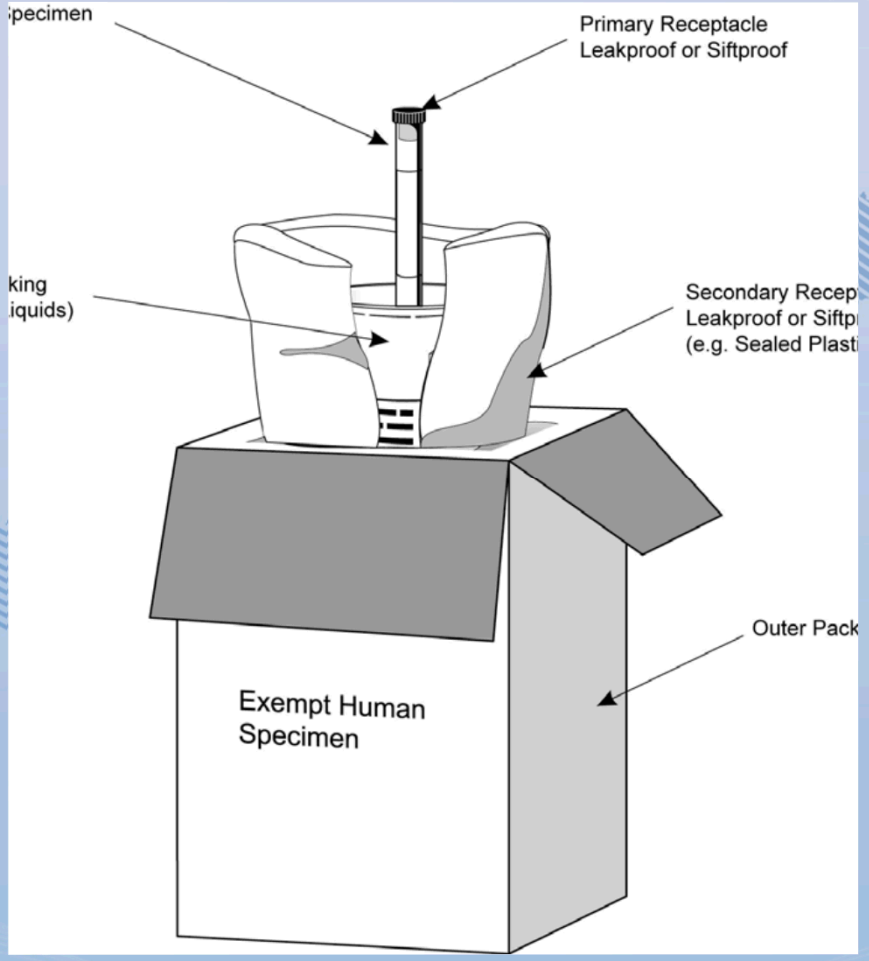
- ✓ Itemized list
- ✓ Rigid outer packaging
- ✓ Two sides at least 4 in.
- ✓ Qty. less than 4L or 4kg
- ✓ Name and telephone # marked on package or airwaybill
- ✓ NO spec marks but 1.2m drop

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"



Exercise with Packaging Options

Read the scenarios provided by the instructor. Discuss in your group and determine the:

- Proper Shipping Name and UN number for the material to be shipped
- Kind of packaging to use (some options are available to work with)
- Shipping conditions (ambient, cold, frozen, etc.) required and how this will be done

Take 10 minutes. Capture your answers on the flip chart provided.

Be prepared to discuss your results with the rest of the class.

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?

Packaging Availability

Available from a variety of suppliers around the world.

- Internet search for suppliers
- IATA regulations handbook lists (hard copy provided)

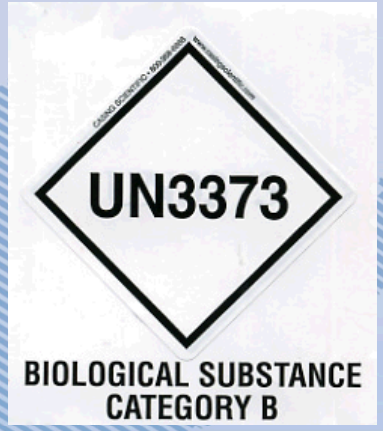
Marking & Labeling Overview

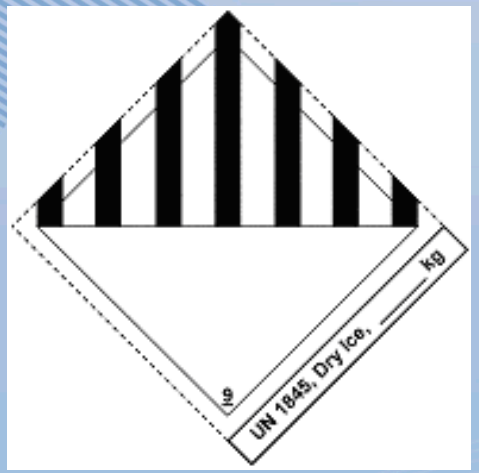
Markings provide information on

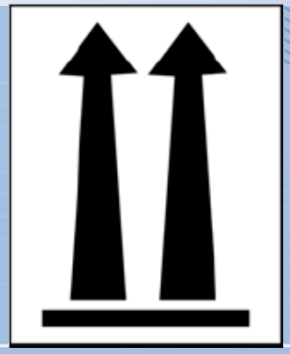
- Contents of package
- Nature of hazard
- Applicable packaging standards
- Must be clearly visible

Labels – two types

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

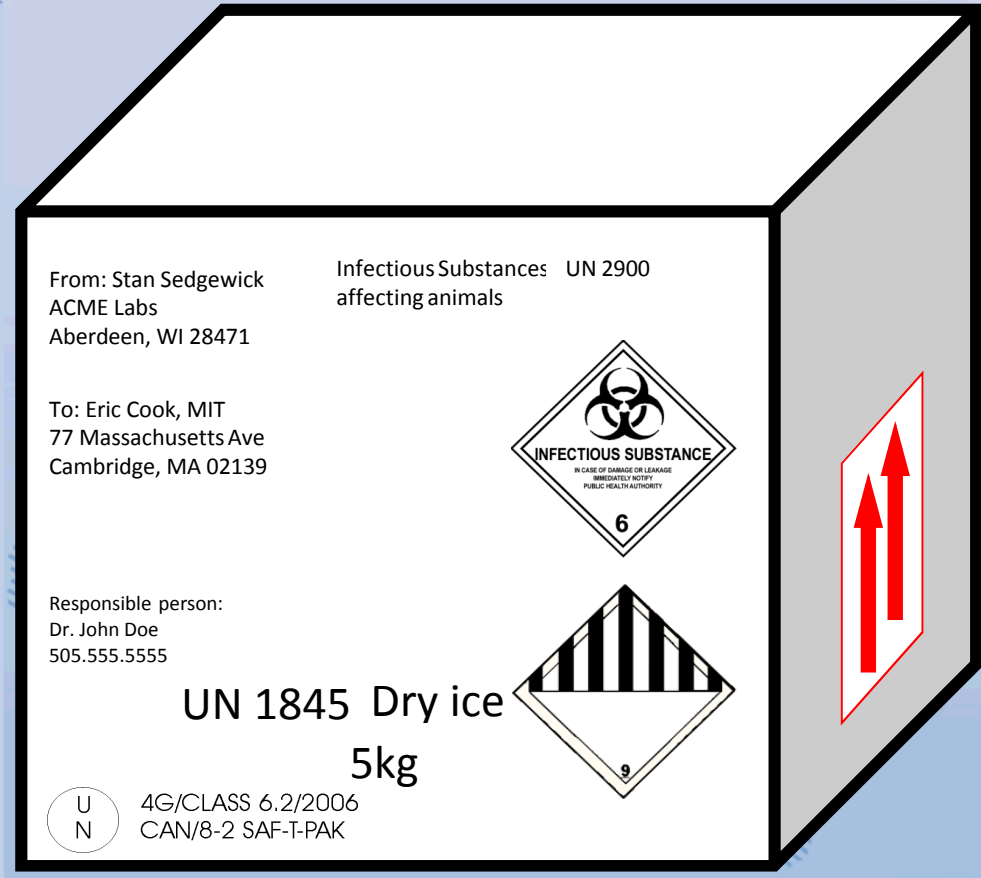






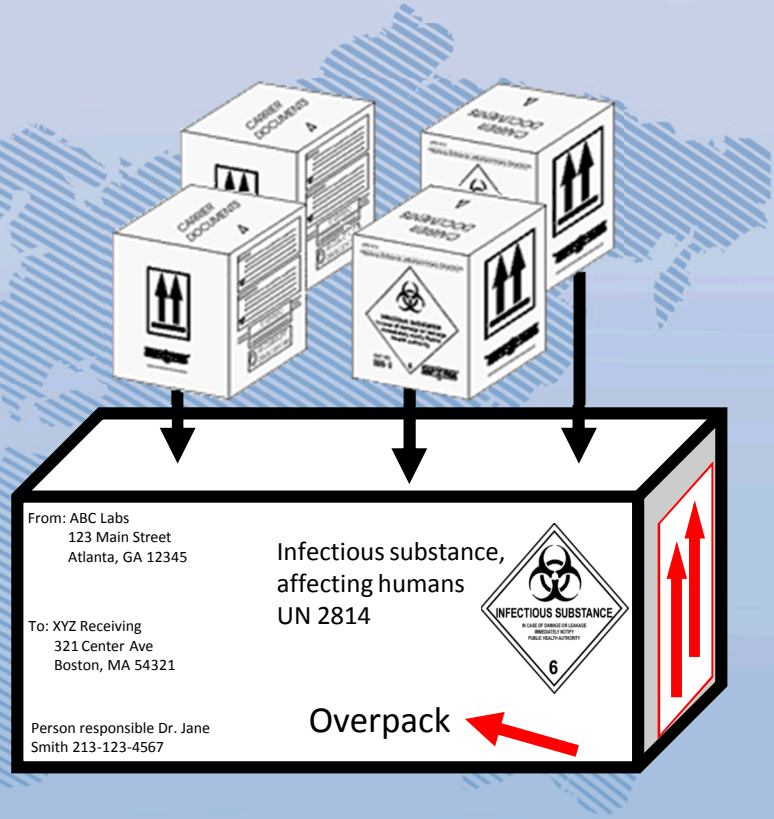
Marking & Labeling

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



Shipping with Overpacks

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



Required Documentation

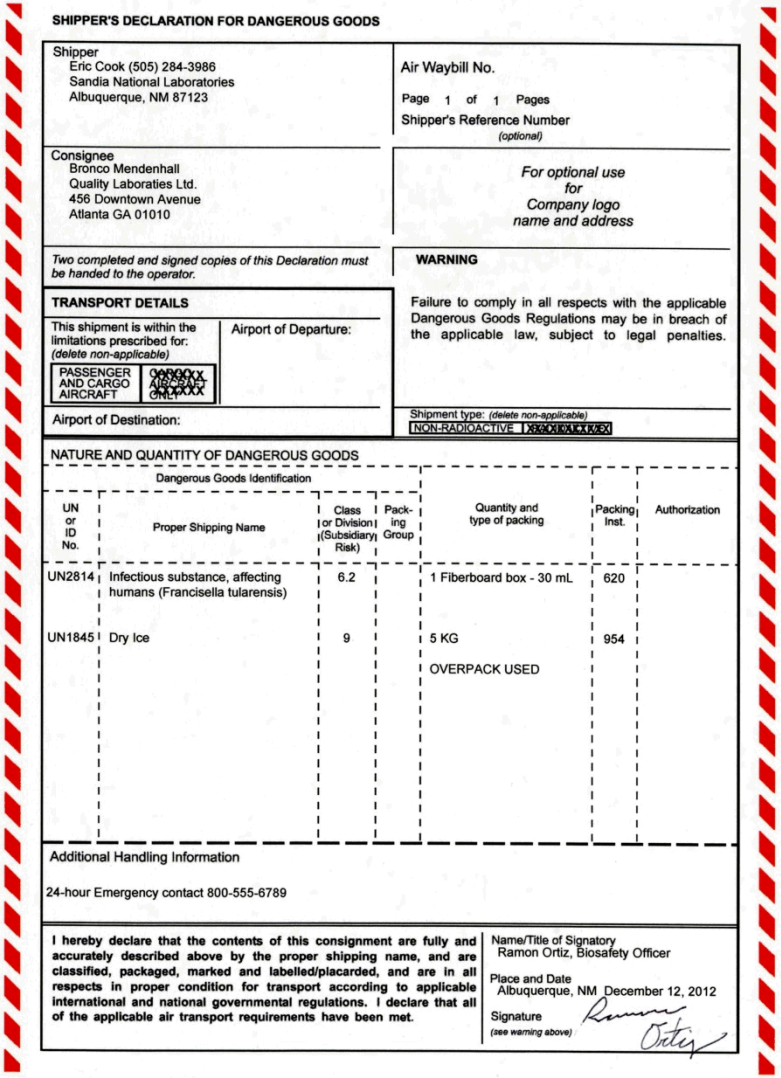
1. Packing list / proforma invoice, which includes
   - Receiver's address
   - Number of packages
   - Detail of contents
   - Weight
   - Value (for customs purposes, indicate a minimal value if items supplied free of charge)

2. Shipping waybill

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

4. Category A packages also require
   - Shipper's Declaration for Dangerous Goods

Shipper's Declaration



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper
Eric Cook (505) 284-3986
Sandia National Laboratories
Albuquerque, NM 87123

Air Waybill No.

Page 1 of 1 Pages

Shipper's Reference Number *(optional)*

Consignee
Bronco Mendenhall
Quality Laboraties Ltd.
456 Downtown Avenue
Atlanta GA 01010

For optional use for Company logo name and address

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.

TRANSPORT DETAILS

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

PASSENGER AND CARGO AIRCRAFT / CARGO AIRCRAFT ONLY

Airport of Departure:

Airport of Destination:

Shipment type: *(delete non-applicable)*

NON-RADIOACTIVE / 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 (Francisella tularensis)	6.2		1 Fiberboard box - 30 mL	620	
UN1845	Dry Ice	9		5 KG OVERPACK USED	954	

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 labelled/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.

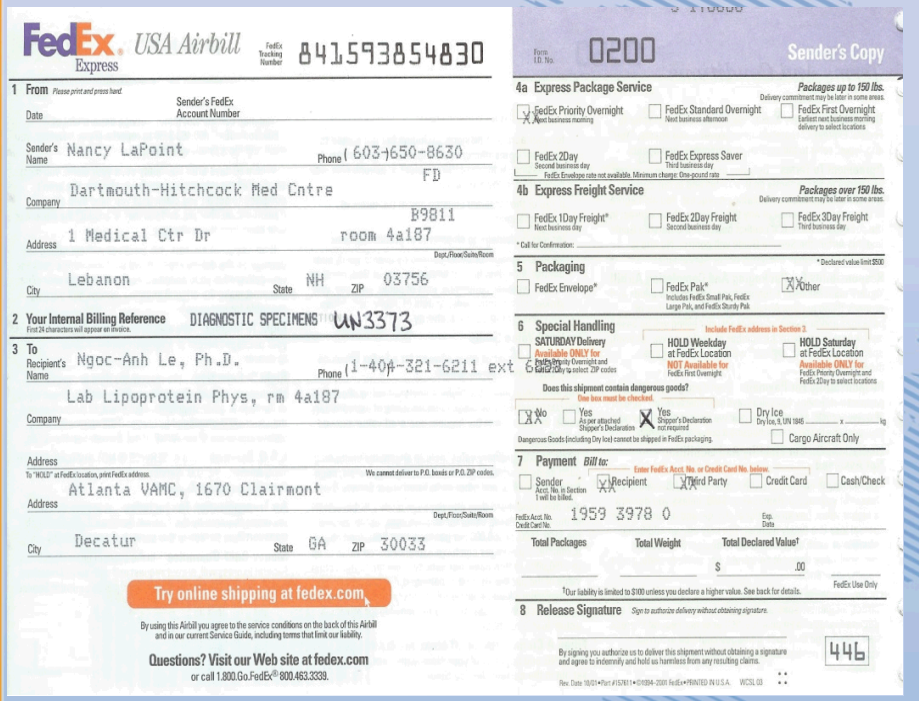
Name/Title of Signatory
Ramon Ortiz, Biosafety Officer

Place and Date
Albuquerque, NM December 12, 2012

Signature *(see warning above)*

- 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

Documentation for Category B (Air waybill)



FedEx Express USA Airbill 841593854830

1 From — Sender's Name: Nancy LaPoint; Phone: (603)650-8630; Company: Dartmouth-Hitchcock Med Cntre; Dept: FD; Address: 1 Medical Ctr Dr; Room: B9811 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 6[illegible]; Company: Lab Lipoprotein Phys, rm 4a187; Address: Atlanta VAMC, 1670 Clairmont; City: Decatur; State: GA; ZIP: 30033

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® 800.463.3339.

Form I.D. No. 0200 Sender's Copy

4a Express Package Service — Packages up to 150 lbs.: X FedEx Priority Overnight; FedEx Standard Overnight; FedEx First Overnight; FedEx 2Day; FedEx Express Saver

4b Express Freight Service — Packages over 150 lbs.: FedEx 1Day Freight; FedEx 2Day Freight; FedEx 3Day Freight

5 Packaging: FedEx Envelope*; FedEx Pak*; X Other

6 Special Handling: SATURDAY Delivery; HOLD Weekday at FedEx Location; HOLD Saturday at FedEx Location

Does this shipment contain dangerous goods? X No; Yes; X Yes Shipper's Declaration not required; Dry Ice, Dry Ice, 9, UN 1845 x kg; Cargo Aircraft Only

7 Payment Bill to: Sender; X Recipient; X Third Party; Credit Card; Cash/Check — FedEx Acct. No. 1959 3978 0

Total Packages; Total Weight; Total Declared Value† $ .00

8 Release 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"

Authorizing Shipments

- 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?

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?

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

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

Training Requirements

Shippers are responsible for fully complying with IATA regulations when offering a consignment of dangerous goods to IATA Member and associated Member airlines.

- Must be trained or have training verified prior to performing activity
- A test must be provided following dangerous good training to verify understanding of the regulations
  - Training record must contain evidence that test completed satisfactorily, organization providing training, and training materials used to meet training requirement.
- Recurrent training provided within 24 months of previous training.

Some Training Resource Options

- Sandia National Laboratories International Biological Treat Reduction Program
  - Awareness Training
  - Certification course on Shipping Infectious Substances and Biological Agents –IATA (2 day)
  - 5 day Shipping course with Program Management, Train-the-Trainer, and Laboratory focus tracks

- Pakistan Biological Safety Association

  Non-profit, non-governmental professional organization dedicated to the provision of comprehensive knowledge related to Biosafety issues in Pakistan.

  Website: http://www.pakbiosafety.com/index.htm

  Email: pbsa.pak@gmail.com

- International Federation of Biosafety Associations

  It's mission is to support and promote biosafety on a national and international level through collaboration among national and regional biosafety organizations worldwide

  http://internationalbiosafety.org

- IATA Dangerous Good Authorized Training Centers in Pakistan
  - Pakistan International Airline

    Email: ptc.iatatraining@piac.aero

    Website: www.piac.com.pk

  - Global Aviation Institute

    Email: info@gai.com.pk

    Website: www.gai.com.pk

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

Review

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

What did we learn?	What does it mean?	Where do we go from here?

Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

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

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

Thank You!

Don’t forget to complete your evaluation!