



# Packaging, Transferring, and Shipping Hazardous Materials

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# Why Do We Need To Be Trained?

- SAFETY!
- IT'S THE LAW!
- PROTECTION FROM CIVIL AND CRIMINAL LIABILITIES



# Why Do We Need To Be Trained?

- A violation of any hazardous materials regulation, including training, may result in a civil penalty of up to \$55,000 for each violation and, in certain cases, criminal penalties of up to \$110,000 and imprisonment up to 10 years in any case which resulted in death or bodily injury.

-49 CFR 107.329 and 49 CFR 107.333

# Why Do We Need To Be Trained?

- May 11<sup>th</sup>, 1996
- ValuJet Flight 592 was flying from Miami International Airport to Hartsfield-Jackson Atlanta International Airport
- Plane crashed into the Everglades shortly after take-off due to a fire in the cargo
- Killed all 110 people on board



# Why Do We Need To Be Trained?



- Investigators concluded that the fire started because of oxygen canister in the cargo hold
- They were improperly labeled and packed without safety caps
- Mauro Valenzuela certified that these canisters had been properly removed and replaced, causing them to be loaded on the Jet
- A 24-count indictment against SabreTech and its employees was filed, though most charges were dropped

# Applicability

- Shipping regulations are applicable (under most circumstances), when a person or organization ships or transports hazardous materials by:



# Who Regulates Shipping/Transfers?

## Shipping:

- UNCOE United Nations Committee of Experts
- ICAO International Civil Aviation Organization
- ■ IATA International Airline Transport Association
- ■ 49 CFR U.S. Government (Federal Register)
- ■ DOT Department of Transportation
- USPS U.S. Postal Service (Domestic Mail Manual) DMM
- TDGR Transport of Dangerous Goods Regulations (Canada)
- IMDGC International Maritime Dangerous Goods Code

## Transfers imports/exports:

- USDA U.S. Department of Agriculture
- CDC Centers for Disease Control and Prevention
- FDA Food and Drug Administration
- Dept. of Commerce
- U.S.-Custom Service



# Who Regulates Shipping?

- 49 CFR parts 100-185
  - These are the legally enforceable regulations on shipping in the United States
- IATA regulations are the most important, most stringent, and most widely used regulations throughout the rest of the world

# Training

- Mandatory for ANYONE offering, preparing for transport, packaging or transporting
  - 49 CFR: certification valid for 3 years.
    - Employer must keep records for duration of employment plus 90 days
  - IATA and ICAO: certification valid for 2 years.
    - Employer must keep records for 2 years after training
- If you ship internationally, must observe the IATA 2 year limit on certification



# Important Points To Remember

- The Federal Aviation Administration investigates random, normal packages, and also all “leakers”
- Any evidence of an infectious substance leak in a cargo compartment requires disinfection of entire compartment
- Any release of infectious substance (Cat A, or Cat B) must be reported to DOT
- Carriers (FedEx, UPS, etc) have right to inspect all packages
- Carriers, aircraft cargo handlers, and pilots have the right to reject packages
- Even if believed shipment will go via ground, it must be packaged and labeled in accordance with air regs

# Important Points to Remember

- If a shipment leaks and causes damage due to improper packaging:
  - The shipper is responsible for all costs, fees, and expenses incurred in connection with the cleanup and disposal of the package
  - There may be a fine assessed against the shipper
- The carrier is required by law to report improperly declared or under-declared shipments of dangerous goods to the DOT
  - Penalties for such shipments may include fines up to \$500,000.00 and five years in jail



# Important Definitions

- **TRANSPORT / TRANSPORTATION:**
  - Shipping of the materials/goods by air, land, or sea, usually by a commercial carrier.
- **TRANSFER:**
  - The process of exchanging the materials between facilities.
- **CONSIGNOR:**
  - The university, company or healthcare facility that is responsible for the shipment.
- **CONSIGNEE:**
  - The end receiver of the shipment, e.g. a reference laboratory, another healthcare facility.

# The Shipper

Usually an employee of a University, Company or Healthcare facility.

## Responsibilities:

- Properly classify the material(s)
- Properly identify the material(s)
- Properly package the material(s) \*
- Properly mark the package
- Properly label the package
- Properly document the package for shipment
  - \* includes knowledge of “overpacks” and of dry ice (solid CO<sub>2</sub>)  
Must be adequately trained and must be certified in these responsibilities.
- The shipper is the only individual who is authorized and trained to complete and sign the Shipper’s Declaration for Dangerous Goods.

# Operator/Carrier

- The individual, or the courier, or the shipping company, or the airline that transports the package from the point of origin to the point of destination.
- Their responsibilities include examination of the documentation, inspection of the package, storage, loading and transport, and delivery of the package.
- The carrier has the right to open a package for inspection or request a signed statement that a shipment is not dangerous goods, and has the right to reject any package
- Carrier relies on shipper to be in complete compliance



# Dangerous Goods

- IATA DGR Section 1.0:
  - “ .....substances which are capable of posing a significant risk to health, safety, or property when transported by air and which are classified according to Section 3.”

1.	Explosives	6.	Toxic/Infectious Substances Div 6.1- Toxic substances Div 6.2 Infectious substances
2.	Gases	7.	Radioactive Materials
3.	Flammable Liquids	8.	Corrosives
4.	Flammable Solids	9.	Miscellaneous (dry ice)
5.	Oxidizing Substances and organic peroxides		

# Division 6.2 – Infectious Substances

- “ substances known to contain, or reasonably expected to contain, pathogens... microorganisms (including bacteria, viruses, rickettsia, parasites, and fungi) or recombinant microorganisms ... that are known, or reasonably expected, to cause infectious disease in humans or animals... subject... only if they are capable of spreading disease when exposure to them occurs”.

# Important Div 6.2 Definitions

- DIAGNOSTIC SPECIMEN:
  - “Any human or animal material including, but not limited to excreta, secreta, blood and its components, tissue, and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live animals”.
- BIOLOGICAL PRODUCTS:
  - “... products derived from living organisms, that are (legally) manufactured and distributed .... and are used for either prevention, treatment, or diagnosis of disease of humans or animals, or for development, experimental, or investigational purposes. (e.g. vaccines and diagnostic products)”.
- GENETICALLY MODIFIED ORGANISMS ( GMO ):
  - “....microorganisms... in which genetic material has been purposefully altered through genetic engineering in a way that does not occur naturally”.

# Risk Groups of Pathogenic Organisms

- The World Health Organization (WHO) defines four Risk Groups for infectious substances based on pathogenicity, mode and ease of transmission, degree of risk to individuals and to communities, and reversibility (treatment) of the disease through known and effective preventative agents and treatment.
- These Risk Groups are very similar to those used by the US National Institutes of Health (NIH), and to the CDC's BioSafety Levels (BSL's)
  - \*Risk Groups are not critical to classification of items prior to shipping

# Permits

- Shipment or Transport of infectious agents may require a permit from the U.S. Public Health Service, Department of Commerce, the United States Department of Agriculture (USDA), or the U.S. Animal Plant Health Inspection Service (APHIS).
- The Shipper is responsible for obtaining authorization, the required permits, and for ensuring that the material is packaged in compliance with applicable regulations.
- Copies of permit applications for the CDC and the USDA are available online (Shipments and transfers should be accompanied by a copy of permit)

# USDA Permits

- Generally, a USDA veterinary permit is needed for materials derived from animals or exposed to animal-source materials. Materials which require a permit include animal tissues, blood, cells, cell lines, RNA/DNA extracts, hormones, enzymes, monoclonal and polyclonal antibodies, anti-sera, immunoassay components/kits, transgenic mice, and microorganisms including bacteria, viruses, protozoa, and fungi.
- Exceptions to this requirement are human and non-human primate tissues, serum, and blood. However, if the human or non-human primate materials are cell culture derived or have been exposed to animal serum, a USDA permit is required.

# USDA Permits

- Contact EHRS to assist you in obtaining USDA permits
- Import permit applications will be obtained through the Automated Document Retrieval System by calling area code (301) 734-4952 or by writing to:
  - Animal Products Program:  
USDA, APHIS, VS, NCIE  
Products Program  
4700 River Road, Unit 40  
Riverdale, MD 20737-1231
- For further information please contact the Animal Products Program at (301) 734-7830 or (301) 734-8695. Dial o at the recorded message to speak to a person. FAX: (301) 734-8226

# Remember

- Final copies of permits must be retained in EH&RS
- Contact EH&RS (419-530-3600) for questions on Permits.



# WHO Risk Groups of Infectious Substances

- Note that an organism may appear in more than one risk group, depending on the amount of organism present

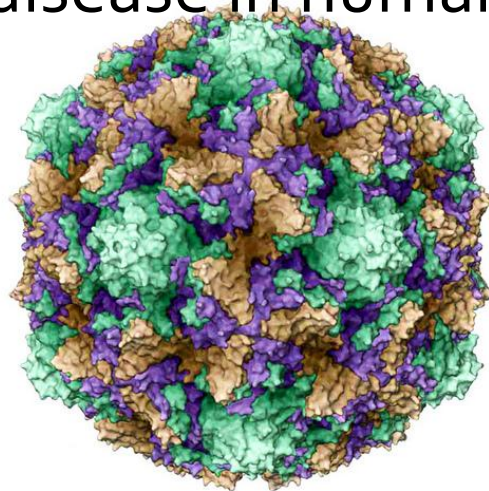
Risk Group	Individual Risk	Community Risk	Examples
4	High	high	Ebola, <i>Mtb</i> in CULTURE smallpox virus, <i>Y. pestis</i>
3	High	low	sputum for AFB, serum for HIV, HCV, <i>B. anthracis</i>
2	Moderate	low	Enteric Gram-negative rods, most routine clinical bacteria
1	no/low	no/low	<i>B. cereus</i> , normal flora

# Classifying the Materials

- One of the most difficult parts of the whole procedure –confusion over what is “infectious”
  - OSHA requires us to consider blood, serum and many other body fluids as “potentially infectious”.
  - IATA, 49 CFR, etc DO NOT require this
    - – hence the categories of “infectious substance” and “diagnostic specimen”.

# DOT 49 CFR

- DIVISION 6.2 (INFECTIOUS SUBSTANCE):
  - A material known or reasonably expected to contain a pathogen. A pathogen is a micro-organism (including bacteria, viruses, rickettsia, parasites, fungi) or other agent, such as prions, that can cause disease in humans or animals.



# Infectious Substances

## Category A

- An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.
- Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.
- Proper Shipping Names:
  - Infectious Substance, Affecting Humans (UN2814)
  - Infectious Substance, Affecting Animals (UN2900)

# Infectious Substances

## Category B

- An infectious substance not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.
- This includes Category B infectious substances transported for diagnostic or investigational purposes. (Less restrictions, easier to ship)
- The proper shipping name and identification number:
  - Biological Substance, Category B, UN3373

# Definitions in DOT 49 CFR

## ■ CULTURE:

- An infectious substance containing a pathogen that is intentionally propagated.
- Culture does not include a human or animal patient specimen as defined below.

## ■ PATIENT SPECIMEN:

- Human or animal materials collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease prevention.
- Patient specimen includes excreta, secretions, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g. transport swabs, culture media, and blood culture bottles).



# Definitions in DOT 49 CFR

- BIOLOGICAL PRODUCT:
  - Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings or animals.
- Mark packaging for these with UN 3373 when they contain a biological product known or reasonably expected to contain a pathogen that meets the definition of a Category B infectious substance.

# Exceptions

1. Blood collected for transfusions or the preparation of blood products.
2. Tissues / organs intended for transplantation.
3. Sanitary waste and sewage.
4. Animal waste generated in animal husbandry or food production.
5. Environmental microbiological samples collected to evaluate occupational and residential risks (except possible agents of bioterrorism).
6. Agricultural and food products, including foodstuffs suspected of being, or known to be, contaminated with disease-causing bacteria, e.g. in food borne disease outbreaks
7. Division 6.2 materials transported by private or contract motor carriers in dedicated vehicles. However, they must be “properly secured” in the transport vehicle.

# Classifying the Materials

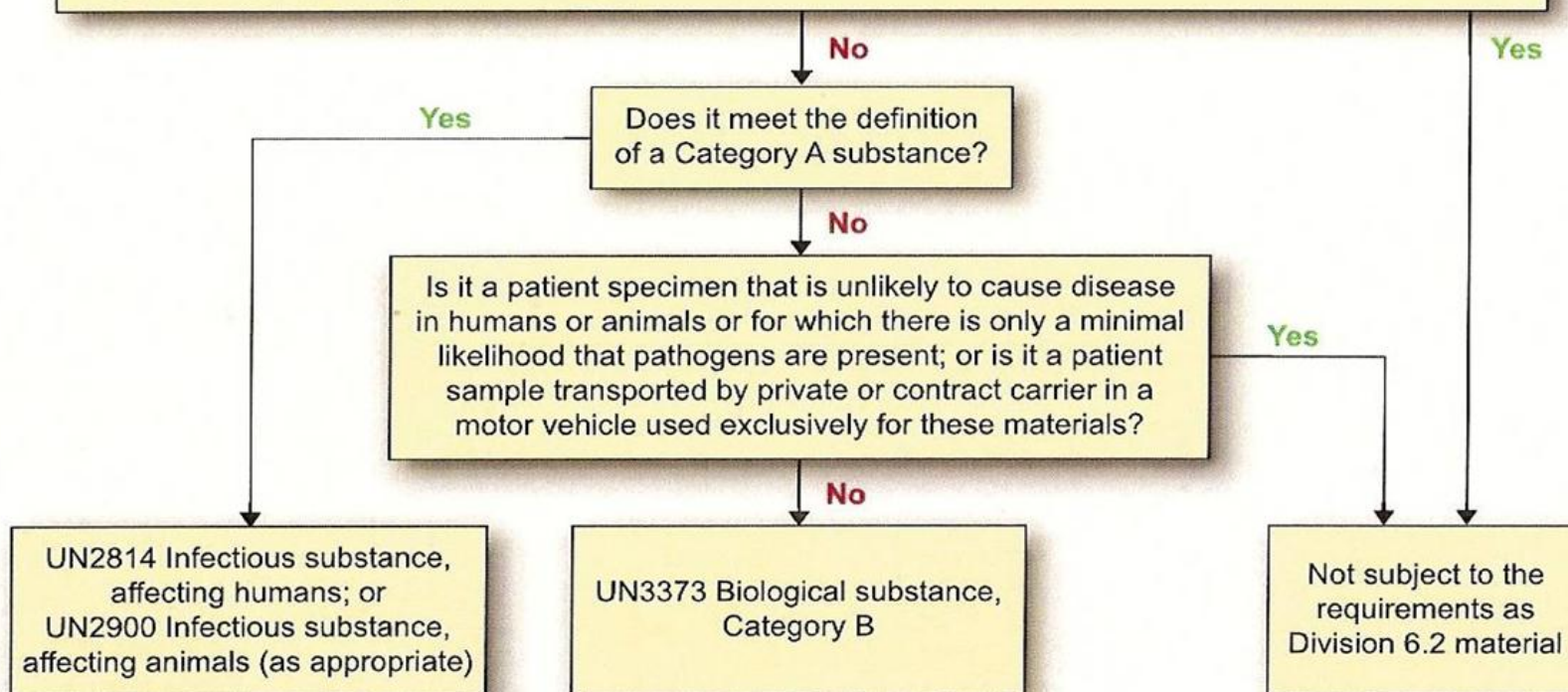
- Issues appear to include:
  - Questions as to if or when do Category B organisms become Category A organisms – based mainly on the amount of organism in the material – and a definition of what is a “culture” of an organism.
    - IATA definition of culture: the result of a process by which microorganism are intentionally propagated: applies to typical clinical isolates grown in broth and on solid media.
  - Category A list “is not exhaustive” – what about other known pathogens that are not specifically mentioned?

# Classifying the Materials

- Many (not all) shippers have used the following as their guidelines:
  - A culture of a microorganism, or a specimen/sample known to contain a microorganism, or a blood/serum sample to be tested for a named microorganism = infectious substance, even if the serum is being sent to determine if it contains antibodies to a microorganism
  - A blood/serum sample to be tested for, e.g. glucose, cholesterol, etc. is a diagnostic specimen.
    - Labeling requirements are very different, e.g. a Shipper's Declaration for Dangerous Goods is not required for a diagnostic specimen.

## Substance for classification

- Is it known **NOT** to contain an infectious substance?
- Are any micro-organisms present non-pathogenic to humans and animals?
- Have the pathogens present been neutralized or inactivated so they no longer pose a health risk?
- Is it an environmental sample (e.g., food or water) that is not considered to pose a significant health risk?
- Is it a biological product or a biological material (e.g., blood product, tissue, or organ) subject to U.S. Department of Health and Human Services or U.S. Department of Agriculture regulation?
- Is it a dried bloodspot or fecal occult blood?
- Is it laundry or medical equipment, or a used health care product that conforms to 29 CFR 1910.1030?
- Is it forensic material that complies with U.S., state, local, or Indian tribal government regulations?
- Is it an agricultural product or food defined under the federal Food, Drug, and Cosmetics Act?
- Is it intended for transplant/transfusion?



# Scenario 1

- A blood sample known or reasonably suspected to contain Ebola Virus

1) Check bulleted questions on page 11

**NO**

2) Does it meet the definition of a Category A Substance? (check form)

**YES**



Infectious Substance,  
affecting humans, UN2814

# Scenario 2

- A blood sample taken from a patient known or suspected to have a Hepatitis B

1) Check bulleted questions on page 11

NO

2) Does it meet the definition of a Category A Substance? (check form)

NO

3) Is it a patient sample transported by private or contract carrier in a motor vehicle used exclusively for these materials?

YES

Not subject to the  
requirements as Division 6.2  
material

NO

Biological Substance,  
Category B, UN3373



# Scenario 1

- A blood sample not known to contain pathogens collected for routine testing
  - 1) Check bulleted questions on page 11

**NO**

- 2) Does it meet the definition of a Category A Substance? (check form)

**NO**

Not Subject to the requirements as  
Division 6.2 material

# The Importance of Correct Classification

## CATEGORY A

- PACKING INSTRUCTIONS 602
- SPECIALLY CERTIFIED OUTER BOX (MEETS UN 6.2 SPECIFICATIONS)
- MUST HAVE SHIPPER'S DECLARATION OF DANGEROUS GOODS
- OUTER BOX MUST CONTAIN ITEMIZED LIST OF CONTENTS (SHIPPING NAME AND NUMBER) AND A LIST INSIDE THE PACKAGE
- OUTER BOX MUST BE MARKED BY THE MANUFACTURER WITH THE UN LABEL "UN 4G/CLASS 6.2"
- OUTER BOX MUST HAVE THE WHITE INFECTIOUS SUBSTANCE ( 6 ) LABEL

## CATEGORY B

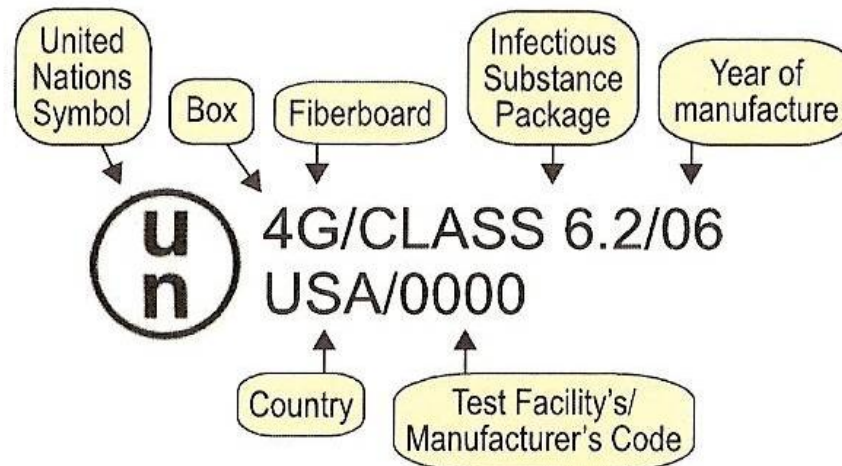
- PACKING INSTRUCTIONS 650
- OUTER BOX NEED MEET LESS DEMANDING SPECIFICATIONS THAN UN 6.2
- NO NEED FOR SHIPPER TO DECLARE DANGEROUS GOODS (UNLESS WITH DRY ICE)
- OUTER BOX MUST BE IN GOOD SHAPE
- MUST BE LABELLED BIOLOGICAL SUBSTANCE CATEGORY B and HAVE PACKAGE MARK UN 3373
- NO REQUIREMENT TO NOTIFY CONSIGNEE IN ADVANCE

# Packing and Labeling of: Category A

## PACKAGING FOR A CATEGORY A INFECTIOUS SUBSTANCE

- Must meet the test standards of §178.609 and must be marked in conformance with §178.503(f)
- Is a triple packaging consisting of
  - Primary watertight receptacle
  - Watertight secondary packaging
  - Rigid outer packaging

## SAMPLE OF UN PACKAGE CERTIFICATION MARK



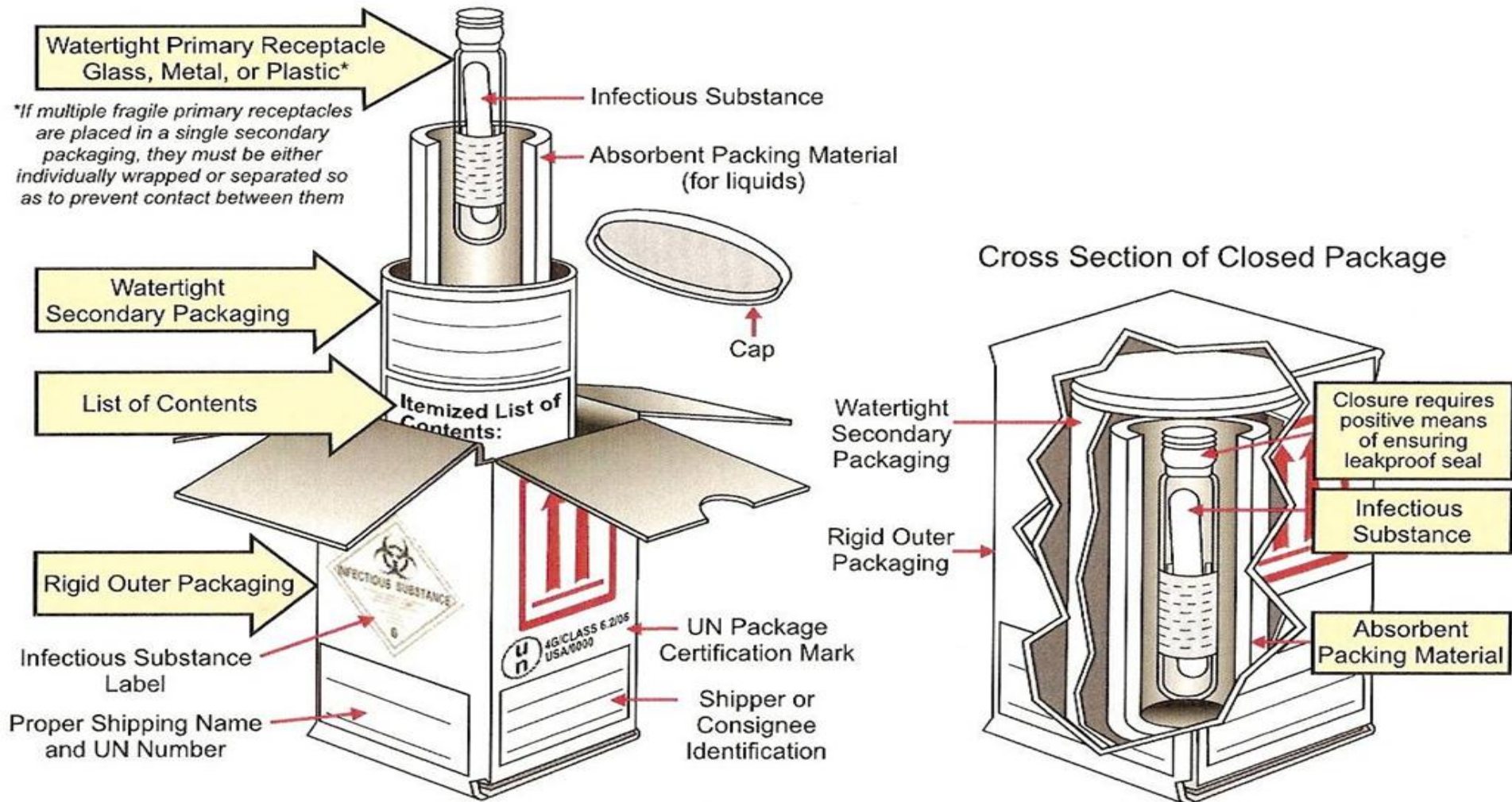
# Package Testing Standards

Measure	IATA and 49 CFR
Min. Dimensions	at least 4" (100mm) in smallest dimension
Leakproof	1° and 2° must not leak
Absorbent	between 1° and 2°; MUST BE ABLE TO ABSORB ALL LIQUID BEING SHIPPED IN 1° CONTAINER
Pressure Test	infect subs: withstand i.p.d. of 13.8 lb/in <sup>2</sup>
Drop Test	wet box; dropped from 27 ft (30 ft for 49 CFR)
Puncture Test	7kg bar dropped from 1m
Quality Assurance	QA program required (not for 49 CFR)

## Category "A"

**Packaging you use for PI 602 MUST meet these testing standards!**

# Infectious Substances: Category A



- Note 1:** The smallest external dimension of the outer packaging must not be less than 100 mm (3.9 inches)
- Note 2:** The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa
- Note 3:** Follow package manufacturer's closure instructions

# Packing and Marking: Category B

## §173.199 Category B infectious substances.

Revised



Required marking on outer package of Category B infectious substance adjacent to proper shipping name "Biological substances, Category B"

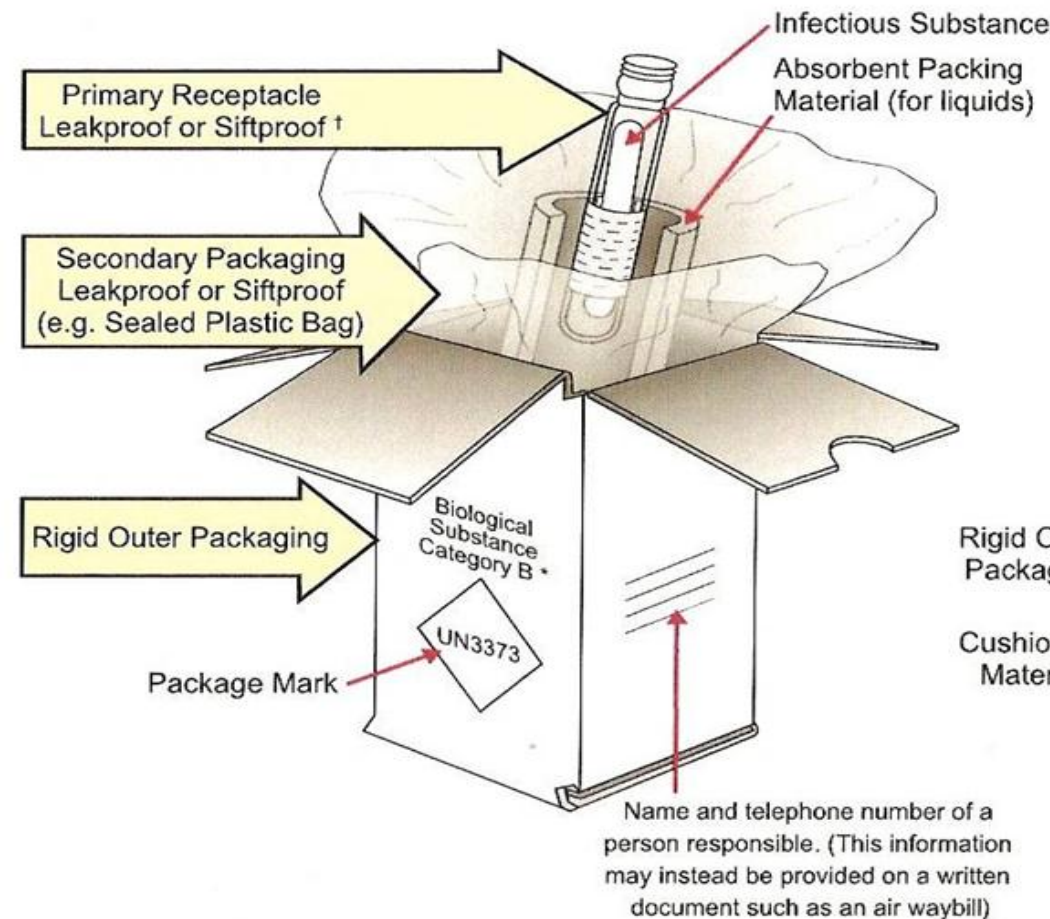


**UN3373**

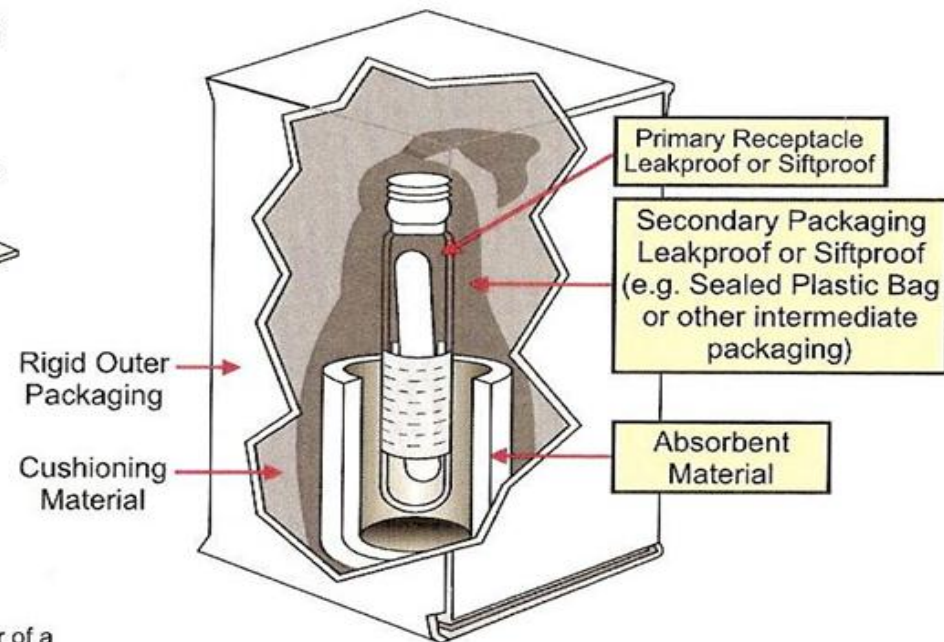
**Note 1:** At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (3.9 inches)

**Note 2:** For liquid shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa

# Infectious Substances: Category B



Cross Section of Closed Package



\* The proper shipping names "Biological Substance, Category B"; "Clinical Specimen"; and "Diagnostic Specimen" are authorized until December 31, 2006. From January 1, 2007 only the proper shipping name "Biological Substance, Category B" will be authorized.

† If multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact

**Note:** Follow package manufacturer's closure instructions

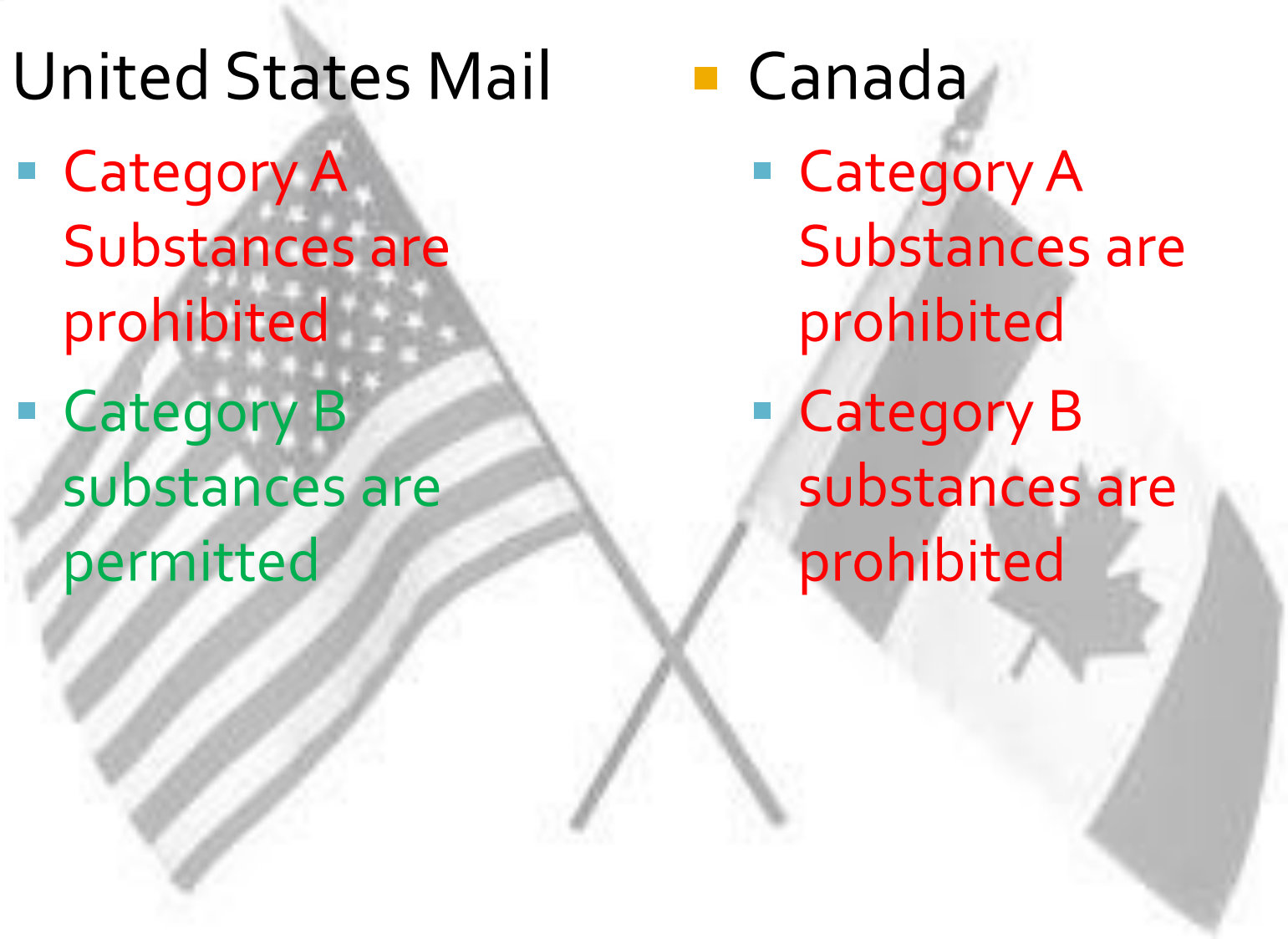
# Sending Div. 6.2 by USPS

## ■ United States Mail

- Category A  
Substances are prohibited
- Category B  
substances are permitted

## ■ Canada

- Category A  
Substances are prohibited
- Category B  
substances are prohibited



# Sending Div. 6.2 by USPS

Material classified as Biological **Substance Category B** (UN 3373) can be sent as First-Class Mail, Priority Mail, or Express Mail. Must be so marked on the outer shipping container.

Many of the 6.2 requirements are needed:

- Must be triple-packaged.
- Primary container must be leak proof.
- Adequate absorbent material present
- Secondary container must be leak-proof and meet the same pressure requirements.
- Outer shipping container must be rigid, but NOT required to meet the 6.2 standards.
- Outer shipping container must show name and telephone number of a person knowledgeable about the shipment.
- There are volume and weight limits
  - basically < one Liter /1y and <4 L total in the 2y container.

# Select Agent Rule 42 CFR part 73

- “Additional Requirements for Facilities Transferring or Receiving Select Agents”
  - Antiterrorism and Effective Death Penalty Act of 1996 requires Secretary of HHS to regulate transfer of certain biological agents ( “select agents” ) harmful to humans
  - CDC is responsible for the implementation of this regulation
- If you have select agents or toxins in your lab you are required to disclose this information to Environmental Health and Radiation Safety per 42 CFR part 73

# IATA Division 3.9

## Miscellaneous Dangerous Goods (Dry ice)

- Shippers **MUST** be aware of this as it includes dry ice – solid carbon dioxide (  $\text{CO}_2$  ).
  - Dry ice will become gaseous as its temperature increases (inevitable in transport): the gas **MUST** be allowed to escape from the package.
- If used to cool infectious substance(s) (Cat A) – **MUST** be declared on the dangerous goods shipping declaration form (follow ALL the requirements) – see later.
- If used to cool Category B specimen(s) – **does NOT** need the dangerous goods declaration form, but its presence **MUST** be indicated on the outer packing and on the airbill
- **NEVER SEAL DRY ICE IN AN AIR-TIGHT (LEAK-PROOF) CONTAINER.**
  - The pressure increase could cause the container to explode.
- Package **MUST** always be marked with net weight (in kilograms) of the initial amount of dry ice used, and **MUST** be marked as containing dry ice.
- For specimen integrity, it is advisable to ship so that package does not arrive on weekends.

# Dangers of Packing Dry Ice Improperly

## **Virus package explodes at Columbus airport**

**COLUMBUS —** A package labeled as containing the West Nile virus exploded at a Federal Express facility, and about 50 workers were evacuated.


Fire officials said dry ice used to preserve tissue samples containing live virus may have caused the shoebox-sized package to burst Tuesday at the FedEx office near Port Columbus International Airport.

The package contained brain and kidney tissue from a bird that had tested positive for the virus, said Jay Carey, spokesman for the Ohio Department of Health. The department was sending the material to the University of Texas.

The virus was live but the samples were frozen and unlikely to become airborne, Mr. Carey said.

# IATA Dangerous Goods List

- 14 columns
- Need to know proper packing, shipping, and documentation
- >3,000 proper shipping names
- Only 8 names apply to shipping infectious substances



# Identification

UN/ ID No.	Proper Shipping Name/Description	Class or Div.	Sub Risk	Hazard Label(s)	PG	Passenger and Cargo Aircraft				Cargo Aircraft Only		S.P. see 4.4	ERG Code		
						Ltd Qty		Pkg Inst	Max Net Qty/Pkg	Pkg Inst	Max Net Qty/Pkg				
						Pkg Inst	Max Net Qty/Pkg								
A	B	C	D	E	F	G	H	I	J	K	L	M	N		
	Diagnostic specimens with a low probability of containing pathogens in Risk Groups 2 or 3 †			None		—	—	650	4 L	650	4 L	A14	6L		
1845	Dry ice †	9		Miscellaneous	III	—	—	904	200 kg	904	200 kg	A48	9L		
2814	Infectious substance, affecting humans * (liquid)	6.2		Infectious subst.		—	—	602	50 mL	602	4 L	A81	6L		
2814	Infectious substance, affecting humans * (solid)	6.2		Infectious subst.		—	—	602	50 g	602	4 kg	A81	6L		
2900	Infectious substance, affecting animals * only (liquid)	6.2		Infectious subst.		—	—	602	50 mL	602	4 L	A81	6L		
2900	Infectious substance, affecting animals * only (solid)	6.2		Infectious subst.		—	—	602	50 g	602	4 kg	A81	6L		
3245	Genetically modified micro-organisms	9		Miscellaneous		—	—	913	No Limit	913	No Limit	A47	9L		
3291	Medical waste, n.o.s.	6.2		Infectious subst.	II	—	—	622	No Limit	622	No Limit	A117	6L		

# IATA Dangerous Goods List

Column	Information
<b>A</b>	UN number (“UN” must precede number)
<b>B</b>	proper shipping name -- copy <b>EXACTLY!</b> technical name goes into ( )
<b>C</b>	class/division of dangerous goods
<b>D</b>	subsidiary risk (N/A to infectious substances)
<b>E</b>	applicable hazard label
<b>F</b>	packing group (N/A to infectious substances)

# IATA Dangerous Goods List

Column	Information
<b>G-H</b>	packing instructions for dangerous goods with quantity limitations (N/A for infectious substances)
<b>I-J</b> (passenger/cargo)	<b>I</b> packing instructions to follow (602, 650, 622, or 913) <b>J</b> net quantity allowed per package
<b>K-L</b> (cargo only)	<b>K</b> packing instructions to follow (602, 650, 622, or 913) <b>L</b> net quantity allowed per package
<b>M</b>	special provisions
<b>N</b>	ICAO Emergency Response Drill codes

# IATA Dangerous Goods List

UN # A	Proper Shipping Name B	Class C	Pk. Inst I
3373	Biological substance Category B		650
1845	Dry ice	9	904
2814	Infectious substance, affecting humans (liquid) *	6.2	602
2814	Infectious substance, affecting humans (solid) *	6.2	602
2900	Infectious substance, affecting animals only (liquid) *	6.2	602
2900	Infectious substance, affecting animals only (solid) *	6.2	602
3245	Genetically modified micro-organisms	9	913
3291	Medical waste, n.o.s.	6.2	622

# IATA Dangerous Goods List

UN # A	Proper Shipping Name B	Class C	Pk. Inst I
2814	Infectious substance, affecting humans ( * )	6.2	602
2900	Infectious substance, affecting animals only ( * )	6.2	602
	NOTE: If affecting both humans and animals, use UN 2814		
	( * ) NOTE: must be followed with the organism(s) technical name(s) – and always in ( )		

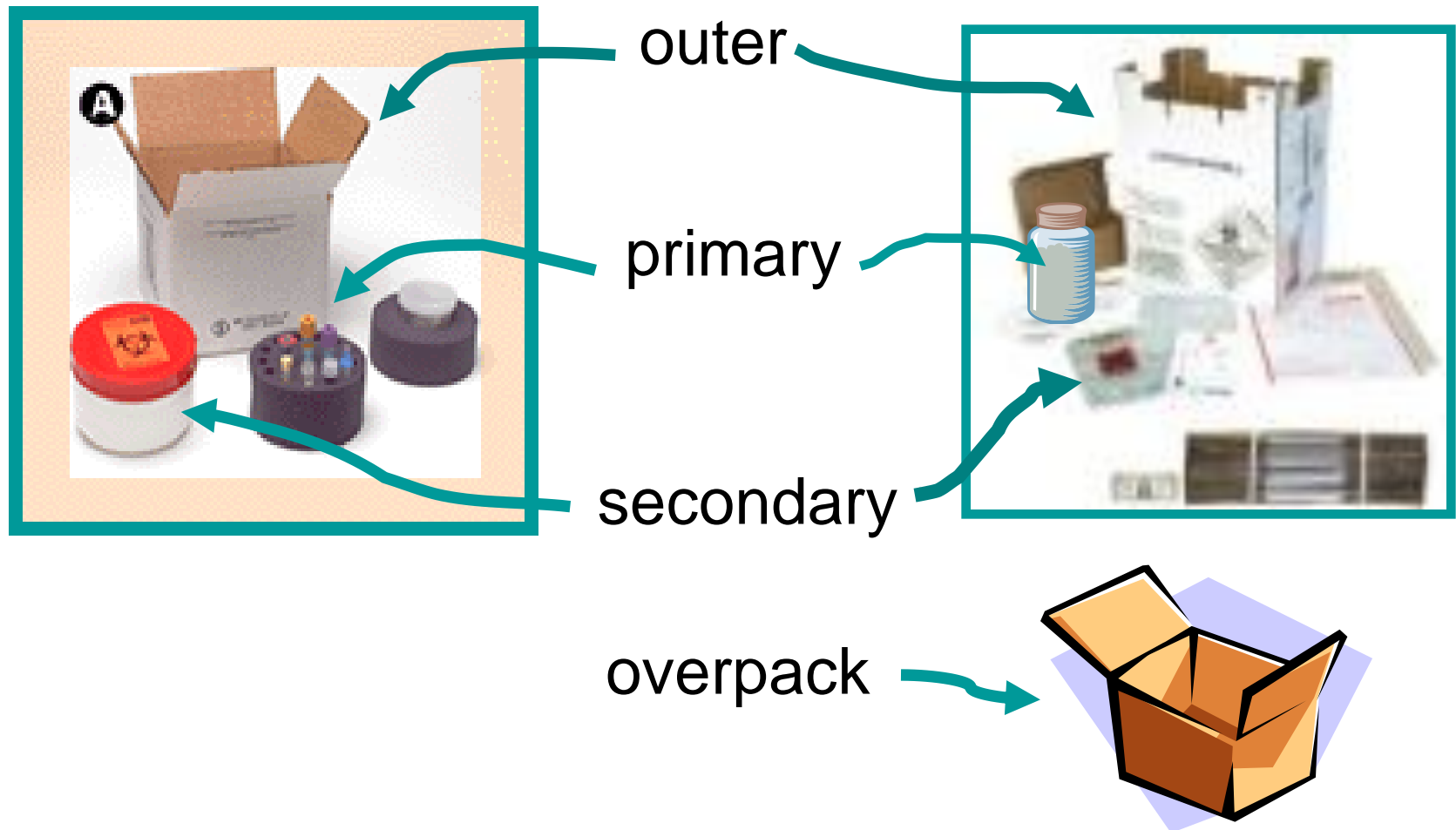
# Proper Packaging/Dimensions

- It is illegal to mix manufacturers' secondary and outer packages
- IATA and 49 CFR regulations specify that the smallest dimension be 100mm (4.0 inches).

HOWEVER - note that individual carriers can require larger minimum dimensions – e.g. large enough for the shipping form to be attached.



# PACKAGING TERMS (CONTAINERS)



# Packaging Requirements

- Primary Receptacle or Container:
  - In an healthcare setting, usually will be a blood collection tube, other fluid collection tube, or a tube that the clinical specimen has been transferred to.
    - Will usually contain fluid or tissue.
    - May be a culture tube of an organism.
- Petri dishes/plates CANNOT be shipped as primary containers.
  - Primary container must be watertight - CFR 173.96
- Tubes with screw type closures MUST be secured with adhesive tape.
- If more than one primary container is shipped, they MUST be cushioned from each other
  - bubble wrap.
- The primary container MUST be surrounded with sufficient absorbent material to capture the entire liquid contents of the primary container should leakage occur.
  - The piece of absorbent provided by the manufacturer of the pack may not always be sufficient.

# Recent Update to 49 CFR

- Biological substances Category B must be packaged in triple packaging, consisting of a primary receptacle, a secondary packaging and an outer packaging.
- Liquid diagnostic specimens: "For shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95kPa (0.95 bar, 14 psi)."
  - NOTE: very few primary receptacles pass this requirement, necessitating the use of a tested secondary container.
  - This means that all (air) shipments of noninfectious liquid specimens must be in a triple package, and if the primary is not capable of passing the pressure test, the secondary must be.

# Packaging Requirements






- If you use a certified (pressure) container as primary or secondary container for infectious substances it must meet “same manufacturer” requirement for the outer packaging box.
  - OVERPACK container (if used) can be from different source
- The outer box properties are different:
  - for PI 602 – MUST be certified to meet UN Class 6.2
- For PI 650 – need only meet IATA 4 foot drop test
- Documentation is different

# Sources for Shipping and Packaging Supplies

- Exakt-pak
  - [www.exaktpak.com](http://www.exaktpak.com)
- Saf-T-Pak
  - [www.saftpak.com](http://www.saftpak.com)
- Com-Pac International
  - [www.com-pac.com](http://www.com-pac.com)

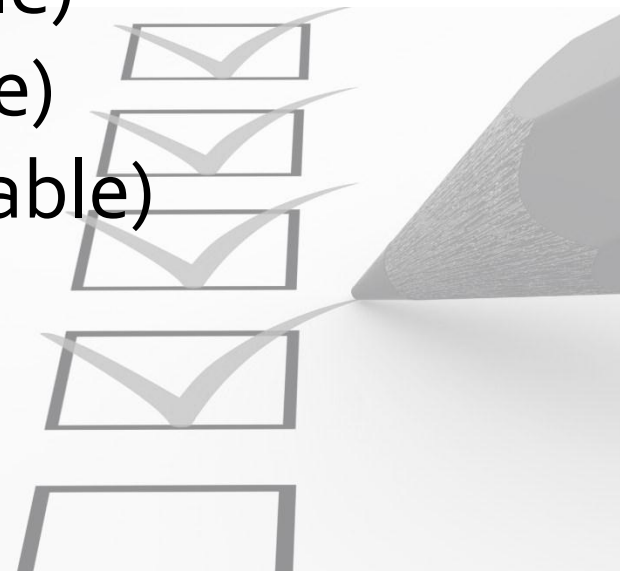


# Required Labels and Markings on Outer Container

	<p>This orientation label should clearly mark which side is "Up". Two labels are required on all boxes with each one on opposite sides of the package.</p>
<p><b>Inner Packages Comply With Prescribed Specifications</b></p>	<p>This marking must appear on an overpack when the regulations require the use of packages bearing UN Specification Markings.</p>
	<p>This marking is required when shipping patient/diagnostic specimens.</p>
	<p>This label is required when shipping a substance or specimen on dry ice.</p>
	<p>This label is required when shipping infectious substances. Please note when shipping infectious substances you must use UN certified 6.2 Infectious Substance Packaging.</p>
	<p>This label is required when shipping <math>\geq 50</math> ml of an infectious substance.</p>

# Marking Requirements

- Proper shipping name and technical name when applicable
- Identification number
- Consignee or consignor name and address
- DOT Special Permit (if applicable)
- Orientation arrows (if applicable)
- Net quantity of dry ice(if applicable)

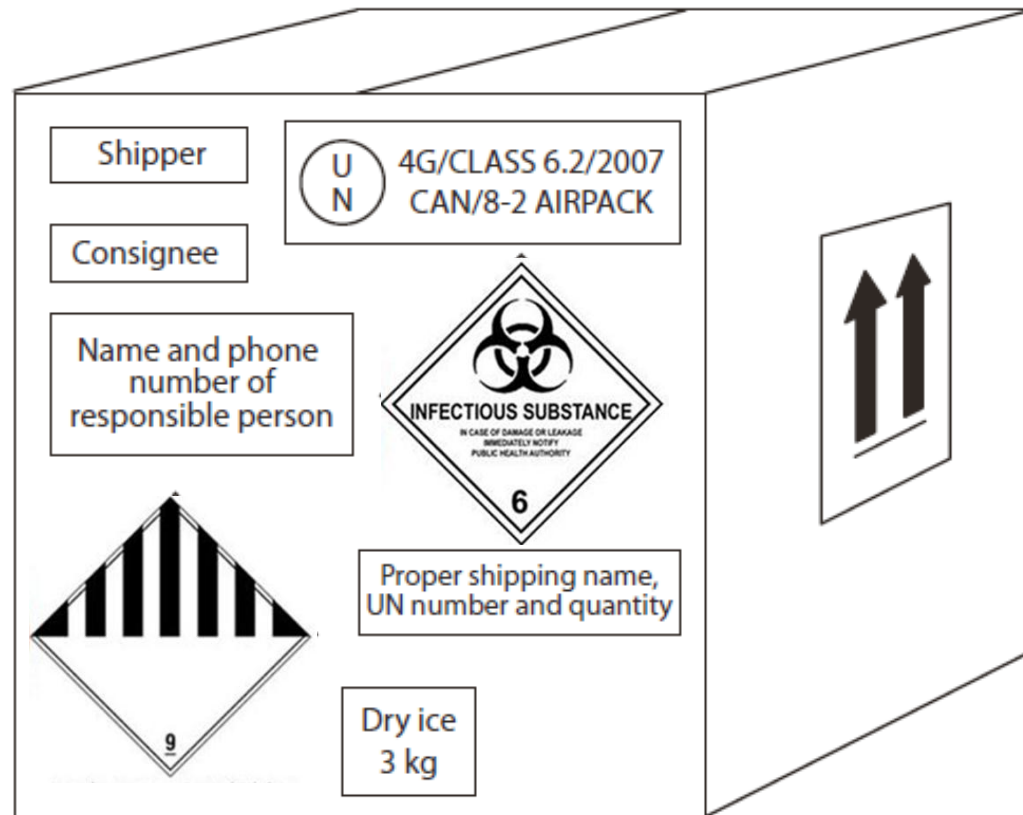


# Proper Shipping Names and Identification Numbers

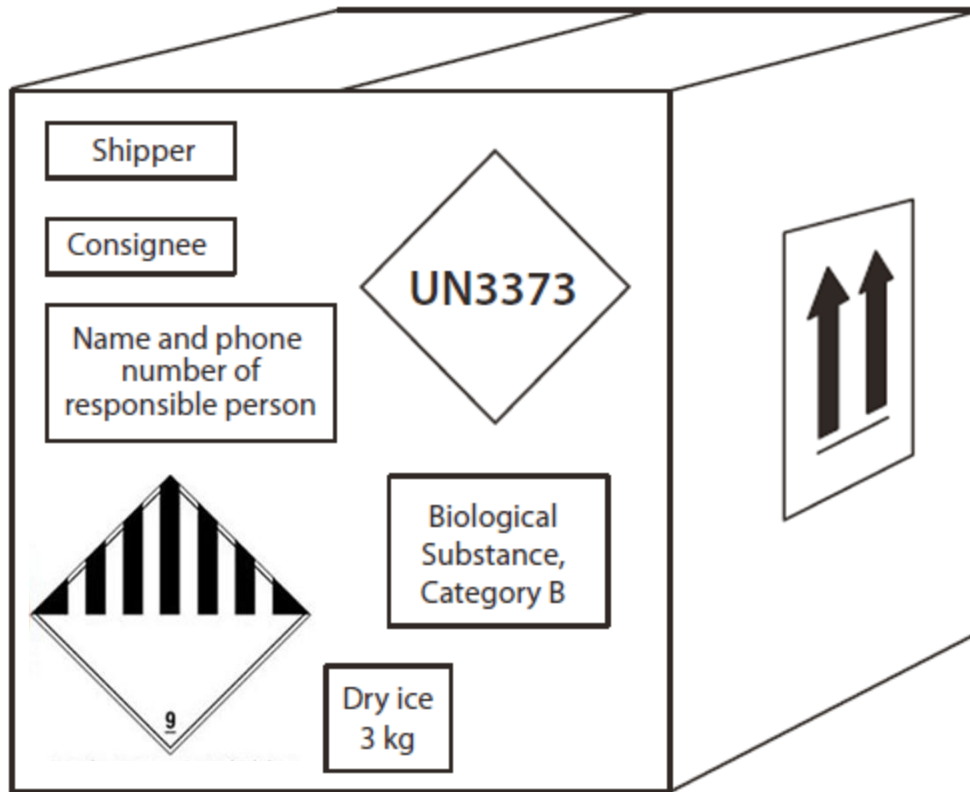
- Category A infectious substance:
  - Infectious substances, affecting animals, only, UN2900
  - Infectious substances, affecting humans, UN2814
- Biological substance, Category B, UN3373

# Marking and Labeling Requirements Category A

- Category A
  - Proper shipping name, UN 2814 or UN 2900 (as applicable)
  - Shipper or Consignee identification
  - Infectious Substance Label
  - Orientation arrows (as applicable)
  - Dangerous Goods Label (if dry ice)



# Marking and Labeling Requirements Category B



- **Category B**
  - Proper shipping name
  - UN 3373 marking
  - Name and telephone number of responsible person (may be placed on separate document such as air waybill)
  - Orientation arrows (as applicable)
  - Dangerous Goods Label (Dry Ice)

# Changes in Labeling (Oct. 2014)

Per the DOT regulations, the Class 6 Infectious Substance label with the text 'In U.S.A. Notify Director-CDC, Atlanta, GA 1-800-232-0124' will no longer be allowed.



Do not use this version of the Class 6 label, effective Oct. 1, 2014.



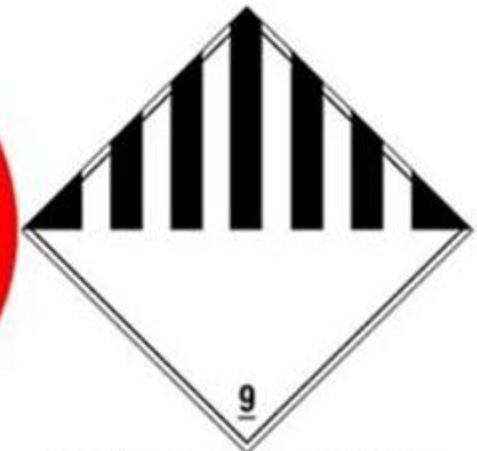
Use the new version, which has the "In U.S.A. Notify Director-CDC, Atlanta, GA 1-800-232-0124" removed.

## Effective October 1, 2014

Per DOT regulations, Class 9 hazard labels with the horizontal line will no longer be accepted.



Do not use this version of the Class 9 label, effective Oct. 1, 2014.



Use the new version, which has the horizontal line removed.

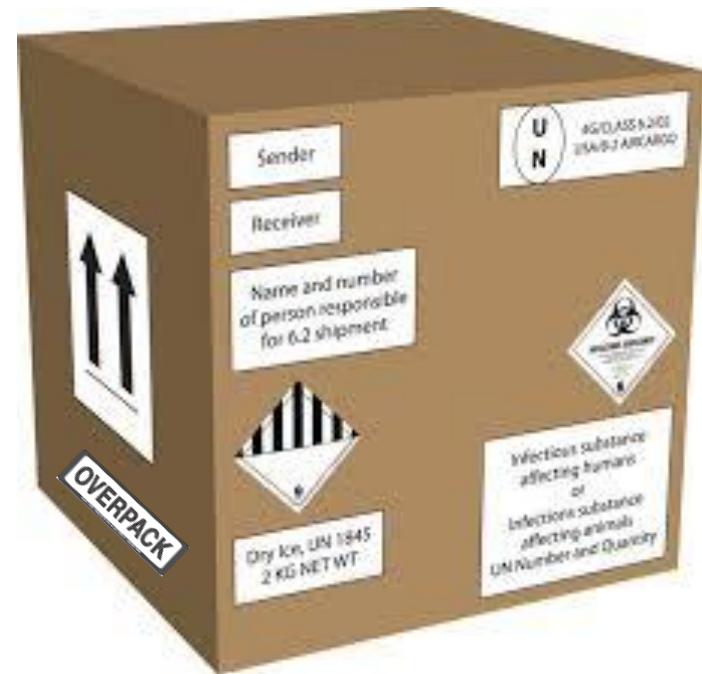
# Cargo Aircraft Only Label

- Attach if  $\geq 50$  ml of an Infectious Substance



# Shipping with Overpacks

- An overpack can save money by consolidation in a noncertified fiberboard
- MUST bear all markings and labels applicable to the inner containers



# Declaration of Dangerous Goods

- If the document is not 100% correct, it's....

**WRONG!**

- DOT fines a minimum of \$6,200 for using a shipping name and class that is incorrect, and \$1,300 for placing a hazard label on a package that does not contain Hazardous Materials

# Shipper's Declaration for Dangerous Goods

- AN EXTREMELY IMPORTANT FORM.
- Forms are often supplied by manufacturers of shipping containers.
- Must have red hashed marks down both sides.
- NOTE: Form may or may not have ruled columns with headings.

If using a form with ruled columns, do not run into next column, use another line.

If using a form without columns, BE SURE to keep correct (required) sequence.

# Shipper's Declaration for Dangerous Goods

Review Handout

SHIPPER'S DECLARATION FOR DANGEROUS GOODS					(Provide at least two copies to the airline.)			
Shipper  <b>A</b>			Air Waybill No.  Page      of      Pages Shipper's Reference Number (optional)					
Consignee  <b>B</b>								
Two completed and signed copies of this Declaration must be handed to the operator			<b>WARNING</b> 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.					
<b>TRANSPORT DETAILS</b> This shipment is within the limitations prescribed for: (delete non-applicable) <table border="1"><tr><td>PASSENGER AND CARGO AIRCRAFT</td><td>CARGO AIRCRAFT ONLY</td></tr></table>			PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	Airport of Departure  <b>C</b>			
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY							
Airport of Destination:			Shipment type: (delete non-applicable) <table border="1"><tr><td>NON-RADIOACTIVE</td><td>RADIOACTIVE</td></tr></table>				NON-RADIOACTIVE	RADIOACTIVE
NON-RADIOACTIVE	RADIOACTIVE							
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b>								
Dangerous Goods Identification								
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization	
<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>	<b>H</b>	<b>I</b>	<b>J</b>	<b>K</b>	
Additional Handling Information  <b>L</b>							<b>M</b>	
24 hr. Emergency Contact Tel. No. _____								
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.						Name/Title of Signatory  Place and Date  Signature (see warning above)		

# Shipper's Declaration for Dangerous Goods Form

- Must be typed or a computer printout – do not write by hand (except signature), and possibly airport names
- If computer printout – make enough copies – usually 3.
- Shipper (and carrier) must keep a copy for 375 days after the date the shipment was accepted by the carrier
- If typed – cannot use correction fluid (e.g. “white out” )
- Where deletions of preprinted descriptions are required – strike over completely with “xxxxxxx” or “=====”.

# Shipper's Declaration for Dangerous Goods Form

## SHIPPER

- Name, address, telephone number
- Needs FULL address
  - NOTE: some businesses only list the company name here – no individual
- Box 11 must be the phone number of shipper
  - If not, must be that of someone familiar with the material who can accept responsibility for it,
  - Or someone who has direct access to someone who has relevant information about the material
- Phone must be monitored entire time shipment is in transport
- Beepers and pagers are NOT considered “direct access”
- NOTE: If the shipment includes class(es) of dangerous goods other than Div 6.2 – e.g. flammable, toxic, corrosive, oxidizing substances – the 24 hour telephone contact person will be expected to have rapid access to the relevant SDS

# Shipper's Declaration for Dangerous Goods Form

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## CONSIGNEE

- Name, address, telephone number
- If the shipment is being sent to a company or a reference laboratory , a person at that company MUST be identified here

# Shipper's Declaration for Dangerous Goods Form

## AIR WAYBILL NUMBER:

- This may be entered or changed by the shipper, shipper's agent, the airline or the airline's handling agent.
- (Page \_\_\_ of \_\_\_ pages: this must be entered by the shipper.

## Shipment Type

- Delete, with strike through, one of the boxes.
  - Will usually delete "RADIOACTIVE"

# Shipper's Declaration for Dangerous Goods Form

- Dangerous Goods Identification
  - The order of the first four columns printed on the shipper's declaration form MUST be as follows (left to right)
- Proper shipping name
- Class/division
- UN number
- Packing group
  - N/A for infectious substances

# Shipper's Declaration for Dangerous Goods Form

## Proper Shipping Name

- Write in: Infectious Substance, Affecting Humans  
(specify organism name)
  - If more than one microorganism involved:
    - some recommend listing all by name
    - some recommend listing the two highest risk organisms
  - IF PACKAGE CONTAINS DRY ICE THIS MUST BE LISTED HERE ALSO
  - Organizations offering proficiency testing samples to laboratories need only use generic microbiological descriptions such as bacteria, fungus, viral, mycobacteria
  - Minor errors on the Shipping Declaration form are acceptable if such errors DO NOT compromise safety

# Shipper's Declaration for Dangerous Goods Form

## CLASS OR DIVISION

- For infectious substance, affecting humans, enter 6.2
- If the shipment includes dry ice – enter 9 on the dry ice line

## UN or ID Number

- UN 2814 for infectious substance affecting Humans
- UN 2900 for infectious substances affecting Animals
- UN1845 if shipment contains dry ice

## Packing Group

- Leave blank for infectious substances – does not apply
- If dry ice is being shipped – enter III in this column

## SUBSIDIARY RISK

- Leave blank for infectious substances and dry ice

# Shipper's Declaration for Dangerous Goods Form

## CLASS OR DIVISION

### ■ QUANTITY AND TYPE OF PACKING:

- Enter the total quantity being shipped.
  - List the individual amounts X the number of primary containers.
- Enter the type of packing.
  - E.g. One fiberboard box OR # of fiberboard boxes – overpack used
- If dry ice is included – enter the dry ice weight (kilograms) and enter that an overpack used

# Shipper's Declaration for Dangerous Goods Form

## PACKING INSTRUCTIONS

- Enter 602 for the infectious substance
- Enter 904 if dry ice is being shipped

## AUTHORIZATION

- Leave blank – unless shipped materials EXCEED the maximum limits for passenger aircraft, then enter A81
- Check with carrier first – to make sure they accept the recently revised maximum limits (see earlier slides)

## NAME/TITLE OF SIGNATORY PLACE AND DATE SIGNATURE

- Must agree with shipper

# Shipper's Declaration for Dangerous Goods Form

## REMEMBER – KEEP A COPY

- DOT amended the HMR to require that the shipper keep a copy (or an electronic image thereof) of the original shipping paperwork (Dangerous Goods Declaration form) for 375 days AFTER the hazardous material is accepted by the carrier.

# Transfer of Materials Across Borders

- State and International Borders
  - DO NOT TRANSPORT IN YOUR PERSONAL VEHICLE
  - Consult with EH&RS prior to any shipments leaving or coming into this state and country
  - U.S. Customs Department will stop and hold you and your packages

# Shipping Software

- FedEx Ground will require ALL hazardous materials paperwork to be completed and submitted electronically using a FedEx® electronic shipping solution or a FedEx® Compatible Solutions Program application that has the ability to transmit shipping information electronically.
- FedEx Recognized Dangerous Goods Vendor Software
  - Most recognized dangerous goods software vendors offer both stand-alone software and online internet-based programs. S
- Some vendors allow a one-time shipment option for those who only ship occasionally. Additional dangerous goods software companies may be recognized in the future.

# Shipping Software

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- If the dangerous goods software you use is not on the recognized list, please contact the FedEx Dangerous Goods/Hazardous Materials Hotline.

To view a current list of approved vendors, go to [www.Fedex.com](http://www.Fedex.com)

# TEST TIME!

