



Packaging & Shipping for the Clinical Laboratory



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Packaging and Shipping for the Clinical Laboratory

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Course Objectives

- General Familiarization: Recognize and Classify Hazards of Clinical Samples
- Identify and apply applicable regulations and requirements for transportation of Clinical Samples
- Determine proper packing and shipping of Clinical Samples



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Who am I? Why am I here?

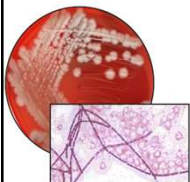
- Medical Laboratory Scientist and Microbiologist
- Experienced In Dangerous Goods Shipping
- Hazardous Waste Operations Certified
- Bioterrorism Training Coordinator
- Enhance cooperation between Clinical and Public Health Laboratories
- Ensure that any interested party can transport clinical samples
- Ensure samples and cultures can be shared in a safe and effective manner



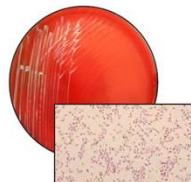
BIOTHREAT AGENTS



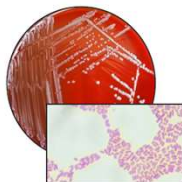
AMERICAN
SOCIETY FOR
MICROBIOLOGY



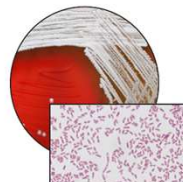
ANTHRAX
Bacillus anthracis



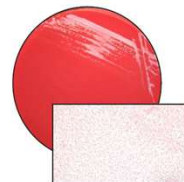
BRUCELLOSIS
Brucella spp.



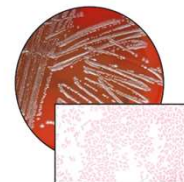
GLANDERS
Burkholderia mallei



MELIOIDOSIS
Burkholderia pseudomallei



TULAREMIA
Francisella tularensis



PLAGUE
Yersinia pestis

2

Who are you? Why are you here?

If you fit anywhere into this flow of shipping infectious materials this class is for you!



<https://www.aphl.org/aboutAPHL/publications/Documents/QSA-2021-Pack-Ship-Training-Requirements-Job-Aid.pdf> - For an in-depth discussion on training requirements please visit the link provided. This APHL Training Job Aid breaks down job functions and their required training level.



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Importance of Packing and Shipping

- Safety - Damaged or leaking specimens. Accidental release or exposure. - No illness reported to date due to release
- Legal - Fines (Civil Penalties) and prosecutions.
 - As of July 2019, if an individual or institution is found noncompliant with regulatory requirements, they are subject to a civil penalty, with a maximum penalty of \$81,993 for each violation. The maximum increases to \$191,316 if the violation results in death, substantial property damage, serious illness or severe injury to any person (49CFR 107.329) The minimum civil penalty for training violations is \$493. In situations where a person willfully or recklessly violates the hazardous material regulations the person may be subject to criminal investigation, with the potential of 5 years imprisonment (49CFR 107.333).
 - For current violations list and common fines see 49CFR 107 Appendix A-D
- Impetus for inspections.
- Rejection by courier - Delay in testing



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Training Requirements

Two Time Frames of Training

- Initial
 - Required within 90 days
 - May perform job functions under direct supervision
 - DOT considers 91st day without initial training to be NON-Compliant!
 - On-Demand Trainings:
 - CDC Lab Training: cdc.gov/labtraining
 - MDHHS BOL: MiTrain Course number 1094582
 - Mayo Clinic: [Dangerous Goods Training \(mayocliniclabs.com\)](https://mayocliniclabs.com)
- Recurrent
 - Every 2 years for shipments by Air - IATA
 - Every 3 years for shipments by ground - DOT 49 CFR
 - If job functions change significantly



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Training Requirements

Two Levels of Training:

- Non-Certified
 - Only ship Category B substances
 - Less than 5.5lbs of Dry Ice
 - Still must be aware of packaging instructions and hazard classification
- Certified
 - Ship Category A infectious substances
 - Greater than 5.5lbs of Dry Ice



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Training Requirements

Training:

- Even if you don't package and ship Category A by law you still need awareness and training in dangerous goods shipping.
- Easier to train everyone to a higher level
- Anyone shipping infectious substances must have "knowledge and training"

49 CFR 172.704

(a) Hazmat employee training must include the following:

(1) **General awareness/familiarization training.** Each hazmat employee shall be provided general awareness/familiarization training designed to provide familiarity with the requirements of this subchapter, and to enable the employee to recognize and identify hazardous materials consistent with the hazard communication standards of this subchapter.



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Employer Responsibilities in Dangerous Goods Shipping

Employers are responsible for ensuring final training:

(49CFR 172.702) It is the employer's responsibility to ensure their employees are trained. Only the hazmat employer can certify that an employee has been trained and tested.

- Function Specific Training on Dangerous Goods
 - Verify job specific hazardous goods training
- Retain training records - certify employees are competent
 - MDHHS BOL, will save training records and documents

Federal Hazmat transportation law 49 CFR, Part 172, Subpart H requires training all hazmat employees. Training must include:

- General Awareness Training/Familiarization
- Safety
- Function Specific
- Security Awareness



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Employer Responsibilities in Dangerous Goods Shipping

At the end of this training, you'll take a competency quiz and, if you pass, receive a certificate with applicable training information.

- Your supervisor must sign certificate to be valid
- Employer will store records for 3 years (IATA, DOT).
 - MDHHS maintains class lists and records, but the official documentation should be kept on site
- DOT requires employers to save records for 90 day after employee departure



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What's in this Training

General awareness/familiarization training on dangerous goods packaging and shipping

4 Step Approach to Packaging and Shipping

1. Determine the mode of transportation
 2. Classify the hazards you are shipping
 3. Package your material
 4. Label and mark package
- Prepare shipping documentation



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This booklet was supported by the Public Health Emergency Preparedness Cooperative Agreement number NU90TP922062, funded by the Centers for Disease Control and Prevention (CDC) and distributed by MDHHS Bureau of Laboratories. Its contents are solely the responsibility of the author and do not necessarily represent the official views of the CDC or the Department of Health and Human Services



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Step 1. Determine the mode of transportation

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Determine the mode of transportation

Mode of transportation will determine Regulations to follow

- Air
- Land
- Courier & Materials of Trade



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Governing Agencies

****Definition:**

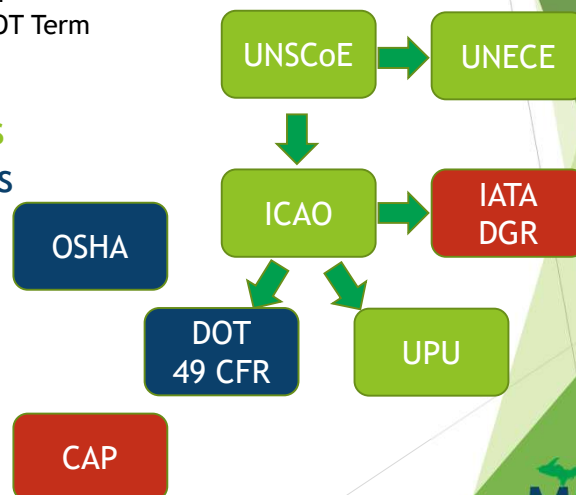
All the same thing

Dangerous Goods = International Term

Hazardous Material = U.S. Federal, DOT Term

- Also called "Hazmat"

- International Regulations
- United States Regulations
- Association Regulations



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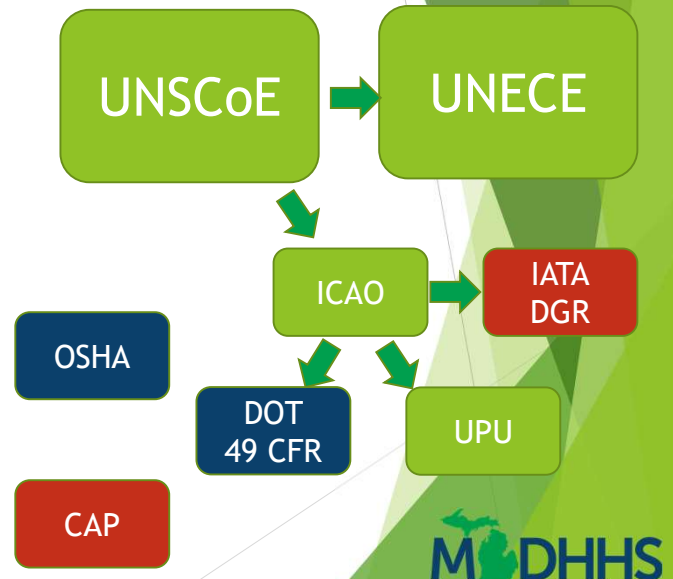
Governing Agencies

United Nations Subcommittee of Experts on the Transportation of Dangerous Goods

- Recommendations and Model Regulations

International Regulator -
Provides Harmonization to
labeling - 4-digit number system

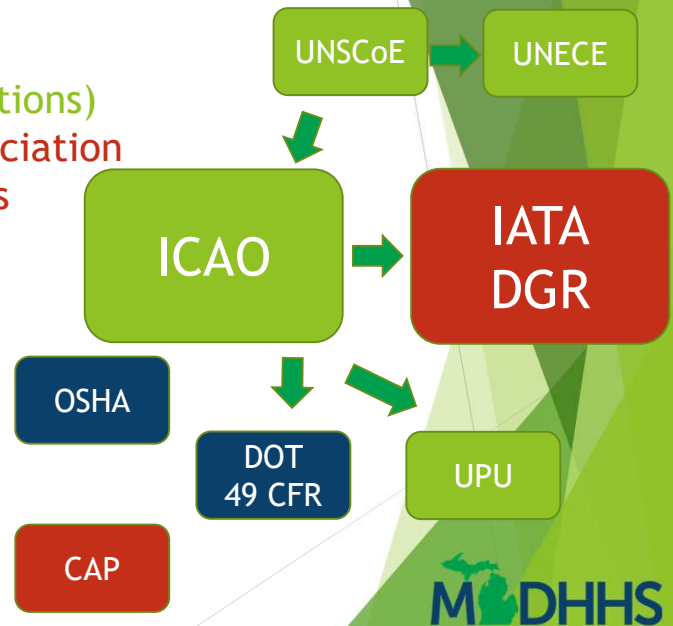
UN####



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Governing Agencies

International Civil Aviation
Organization (Technical Instructions)
International Air Transport Association
• Dangerous Goods Regulations



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Governing Agencies

Universal Postal Union - Postal Service

- Publication 52

Pipeline and Hazardous Materials Safety Administration (PHMSA):

Department of Transportation

- Code of Federal Regulations Title 49



OSHA

CAP

DOT
49 CFR

UPU

UNSCoE

UNECE

ICAO

IATA
DGR

MDHHS

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Governing Agencies

Occupational Safety and Health Administration

- 29 CFR Part 1910.1030 - Bloodborne Pathogen

College of American Pathologists

- GEN.40512 & GEN.40515
- Specimen Transport and Tracking



COLLEGE of AMERICAN
PATHOLOGISTS

OSHA

CAP

DOT
49 CFR

UPU

UNSCoE

UNECE

ICAO

IATA
DGR

MDHHS

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Enforcement Agencies

Who's going to inspect you?

*Verify compliance, inspect records

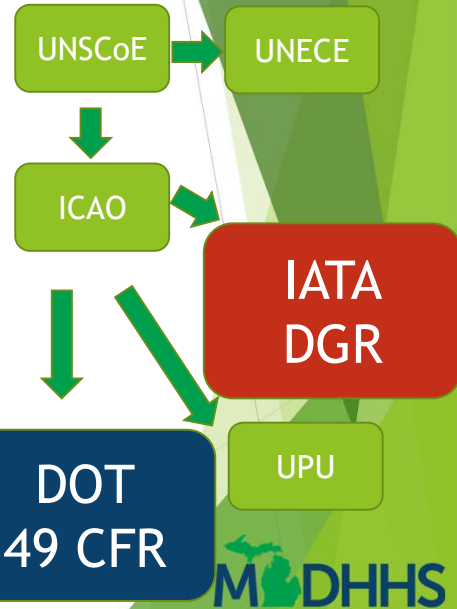
- DOT
- FAA (IATA DGR and DOT 49CFR)
- CAP
- OSHA



OSHA

CAP

DOT
49 CFR



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Couriers & Material of Trade

Courier

- Infectious and biological substances “Materials of Trade” are patient specimens carried by private motor carrier.
- Must follow 49 CFR 173.6 (4)
 - Private Vehicles used exclusively to transport medical samples/supplies (Exclusively means Point A to Point B, not other stops, no other purposes. At other times the vehicle can be used for different purposes)
 - Operator of vehicle must be informed of the presence of the hazardous material
- Staff and institutions utilizing a courier still need to be trained in classifying and packaging dangerous good per 49CFR, 172.700
 - Still transported on public highway
 - Safety is still an issue

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Couriers & Material of Trade

Courier

- The packaging must be the manufacturer's original packaging or a package of equal or greater strength and integrity
- The packaging must be marked with a common name or proper shipping name (such as "exempt human specimen", "diagnostic specimen", or "Dry ice")
 - Packages are exempted from placarding labeling
- For Class 6, Division 6.2, Category B materials, OSHA requires that a biohazard label be placed on the outer or inner packaging
- Material that contains blood or is visibly contaminated with blood must have the biohazard symbol on the outer or inner packaging
- The aggregate gross weight of all materials of trade on a motor vehicle may not exceed 200 kg



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Couriers & Material of Trade

Couriers & Dry Ice

- Dry Ice, when transported over the roadway, is not subject to the regulations; however, the container must be designed and constructed to permit the release of carbon dioxide gas in order to prevent a buildup of pressure that could rupture. Also, the package must be marked "Carbon dioxide, solid" or "Dry ice"
- Material should be placed in the truck, if possible, otherwise roll down a window to allow fresh air to circulate

Spill Kit

- OSHA requires that there be a spill kit in each vehicle suitable for cleaning up the materials that are being transported. In general, this would consist of personal protective equipment (e.g. gloves, eye protection), absorbent materials, broom and dustpan, and bags to contain clean-up debris. If refrigerant is used during the transport, then the operator should have a pair of cryogenic gloves available in the vehicle.



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Couriers & Material of Trade

Courier

- Packaging requirements
 - Leak-proof, Tightly capped
 - Combo-packaging: Inner packaging, strong, tight, protective outer packaging, absorbent material to absorb entire contents
 - Secured against movement
 - Exempted from Packing and Labeling requirements for Category B only. (Only requires Inner and Outer packing, no placarding)
 - All Category A substances must follow regulations (No 49CFR 173.6 exceptions for Category A)



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Transport Regulations

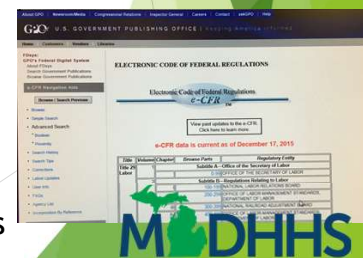
Regulations can change: Keep up to date

- Subject to interpretation
- DGR is sold in book form, CFRs are all free online: e-CFR
- Regulations are mostly harmonized and very similar. In cases where there are differences DOT and IATA have language in their regulations that state to follow the more stringent version:

49 CFR 171.22 -

Authorizes, with certain conditions and limitations, the offering for transportation and the transportation in commerce of hazardous materials in accordance with:

- ICAO - Air Transport
- IMDG - International Maritime Dangerous Goods Code
- Transport Canada TDG Regulations - Canadian Regulations

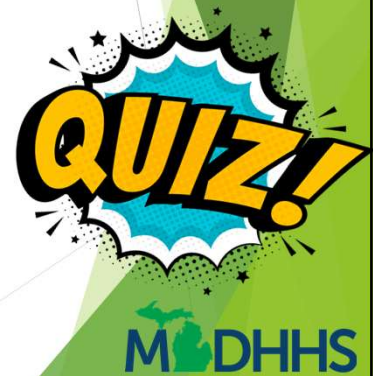


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Training and Transport Comprehension

Packaging and Shipping Training is required every 2 years by IATA and every 3 years by DOT:

True or False?



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Training and Transport Comprehension

To complete your packaging and shipping certification your Employer must provide:

- a. Bloodborne pathogen training
- b. Security Training
- c. Function Specific Training
- d. All of the above



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Training and Transport Comprehension

A UN number is a 4-digit number used to identify:

- a. Bacteria
- b. Shipping containers
- c. Hazardous Materials
- d. Regulatory Publication Versions



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Training and Transport Comprehension

Regulatory agencies with the power to inspect your packaging and shipping program are:

- a. DOT
- b. FAA (following IATA DGR)
- c. CAP
- d. OSHA
- e. All of the above



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Step 2: Classify Hazard

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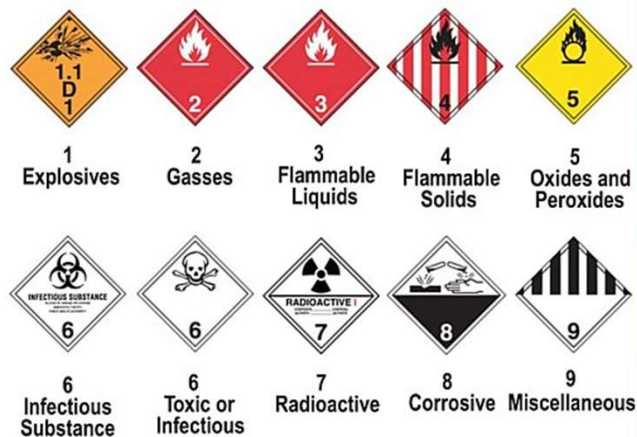
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Classify Hazard

9 Hazard Classes

1. Explosive
2. Flammable Gases
3. Flammable Liquids
4. Flammable Solids
5. Oxides
6. Infectious
7. Radioactive
8. Corrosive
9. Miscellaneous



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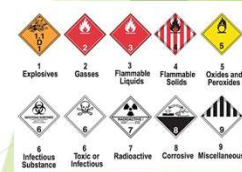
Classify Hazard

Hazard Class 6

- 6.1 - Toxins
- 6.2 - Infectious Substances
 - Category A
 - Category B

Hazard Class 9

- Miscellaneous
- Dry Ice



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Classify Hazard

Infectious substances

- Infectious substances are anything known or reasonably expected to contain a pathogen

Can be shipped 1 of 2 ways:

- Culture

“ . . . are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient specimens as defined . . . ”



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Classify Hazard

Infectious substances

- Infectious substances are anything known or reasonably expected to contain a pathogen

Can be shipped 1 of 2 ways:

- Specimen

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



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Classify Hazard

Category A infectious substance

“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.”

*Transporting Infectious Substances Safely
U.S. Department of Transportation

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Classify Hazard

Category A Indicative list:
UN2814 - Affecting Humans
UN2900 - Affecting Animals

NOT All inclusive - Emerging Pathogens, etc.

Dependent on form of infectious substance:
Culture vs. Specimen

IATA and DOT Indicative Category A List	
CATEGORY A PATHOGENS, INDICATIVE OF INFECTIOUS SUBSTANCES, AFFECTING HUMANS (UN2814) WHEN TRANSPORTED IN ANY FORM UNLESS OTHERWISE INDICATED:	
<i>Bacillus anthracis</i> (cultures only)	<i>Japanese encephalitis virus</i> (cultures only)
<i>Brucella abortus</i> , <i>Brucella melitensis</i> , <i>Brucella suis</i> (cultures only)	<i>Junin virus</i>
<i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i> (cultures only)	<i>Kyasanur Forest disease virus</i>
<i>Chlamydia psittaci</i> avian strains (cultures only)	<i>Lassa virus</i>
<i>Coccidioides immitis</i> (cultures only)	<i>Marburg virus</i>
<i>Coccidioides immitis</i> (cultures only)	<i>Monkeypox virus</i>
<i>Coxsackievirus B1</i> (cultures only)	<i>Mycobacterium tuberculosis</i> (cultures only)
<i>Crimean-Congo hemorrhagic fever virus</i>	<i>Nipah virus</i>
<i>Dengue virus</i> (cultures only)	<i>Onkox virus</i>
<i>Eastern equine encephalitis virus</i> (cultures only)	<i>Polioma virus</i> (cultures only)
<i>Ebola virus</i>	<i>Rabies virus</i> (cultures only)
<i>Escherichia coli</i> , verotoxinogenic (cultures only)	<i>Rickettsia prowazekii</i> , <i>Rickettsia rickettsii</i> (cultures only)
<i>Flavivirus</i>	<i>Rift Valley fever virus</i> (cultures only)
<i>Francisella tularensis</i> (cultures only)	<i>Russian spring-summer encephalitis virus</i> (cultures only)
<i>Guarania virus</i>	<i>Sabia virus</i>
<i>Hantaan virus</i>	<i>Shigella dysenteriae</i> type 1 (cultures only)
<i>Hantavirus causing hemorrhagic fever with renal syndrome</i>	<i>Tick-borne encephalitis virus</i> (cultures only)
<i>Hebilla virus</i>	<i>Varicella virus</i>
<i>Hepatitis B virus</i> (cultures only)	<i>Venezuelan equine encephalitis virus</i> (cultures only)
<i>Herpes B virus</i> (cultures only)	<i>West Nile virus</i> (cultures only)
<i>Highly pathogenic avian influenza virus</i> (cultures only)	<i>Yellow fever virus</i> (cultures only)
<i>Human immunodeficiency virus (HIV)</i> (cultures only)	<i>Yersinia pestis</i> (cultures only)
CATEGORY A PATHOGENS INDICATIVE OF INFECTIOUS SUBSTANCES, AFFECTING ANIMALS (UN2900) WHEN TRANSPORTED IN ANY FORM UNLESS OTHERWISE INDICATED:	
<i>African swine fever virus</i> (cultures only)	<i>Mycoplasma mycoides</i> -Contagious bovine pleuropneumonia (cultures only)
<i>Avian paramyxovirus Type 1-Velogenic Newcastle disease virus</i> (cultures only)	<i>Peste des petits ruminants virus</i> (cultures only)
<i>Classical swine fever virus</i> (cultures only)	<i>Rinderpest virus</i> (cultures only)
<i>Foot and mouth disease virus</i> (cultures only)	<i>Sheep-pox virus</i> (cultures only)
<i>Girapox virus</i> (cultures only)	<i>Swine vesicular disease virus</i> (cultures only)
<i>Lumpy skin disease virus</i> (cultures only)	<i>Vesicular stomatitis virus</i> (cultures only)

Note: This is an indicative list and not an all-inclusive list. Please note that at times, the names of new and emerging pathogens may not always be included and published immediately on regulatory lists. Shippers should also consult the HHS/USDA Select Biological Agents and Toxins list available at www.selectagents.gov for the shipment of any potential select agent organism or toxin. Confirmed Select Agents must always be shipped as Category A, and potential or suspect Select Agents as "Suspected Category A". Always refer to public health authorities (e.g., CDC, WHO, or other state or local public health agencies) for guidance when transporting a new or emerging pathogen.

Adapted from APHL Clinical Laboratory Preparedness and Response Guide

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Classify Hazard

Category B substances infectious substance:
NOT in a form generally capable of causing permanent disability or **life threatening or fatal disease** when exposure occurs.

Examples of Category B: UN3373

All other infectious substances NOT classified as Category A. Basically, everything else infectious.

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Classify Hazard

“Exempt Human Specimen” or “Exempt Animal Specimen”

- IATA and United States Postal Service (USPS)
- Not a “Dangerous good” No UN####
- Specimens that are known NOT to harbor a pathogen or have a minimal likelihood that a pathogen is present
- Specimens transported for routine testing NOT related to diagnosis of infectious disease.
- Professional judgement

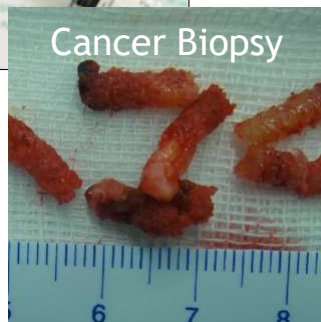


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Classify Hazard

Examples of Exempt



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Classify Hazard

DOT “Not subject to Regulation”

- Does NOT mean no regulations
- Does NOT meet criteria for Category A or Category B.
- Minimal likelihood pathogens are present
- Something has been done to render it non-infectious
- Biological Products
 - Transfusion blood products, vaccines
 - Tested for infectiousness



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Classify Hazard

Examples of Non-Regulated

- Transfusion/Transplant material
- Dried Blood spots and Fecal occult cards



Tested Negative for infectious substances

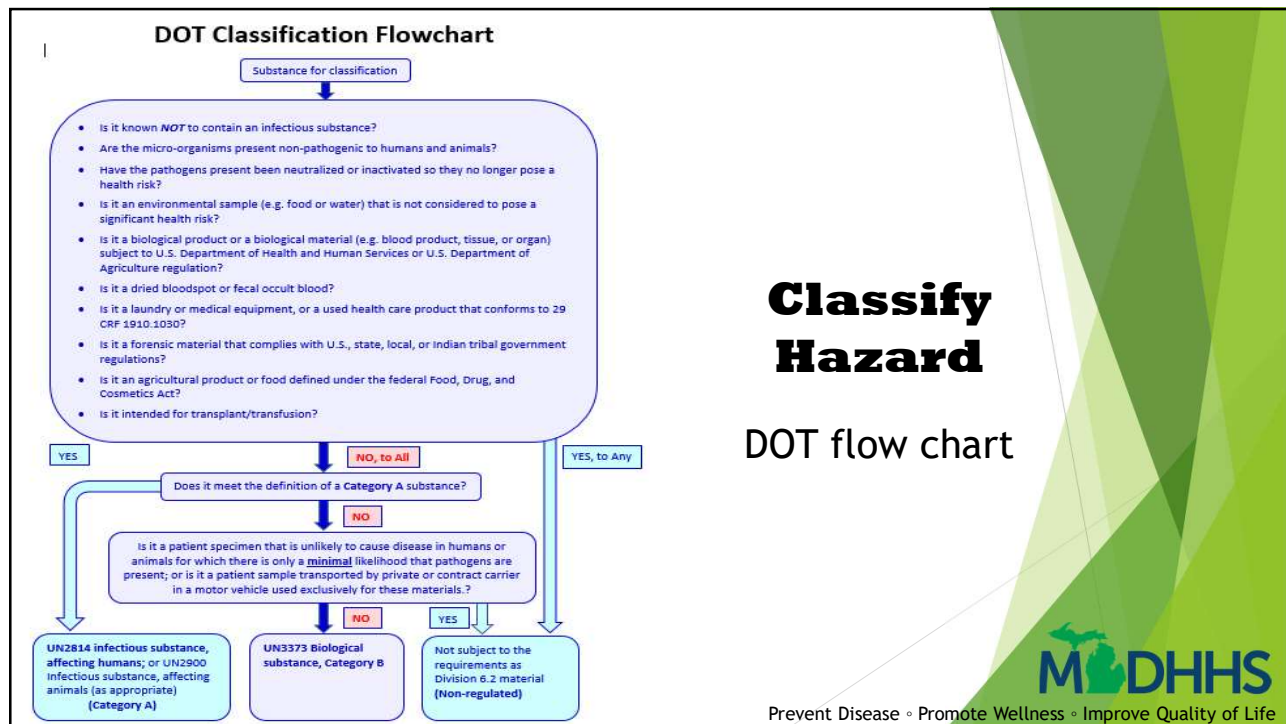


Rendered Negative for infectious substances

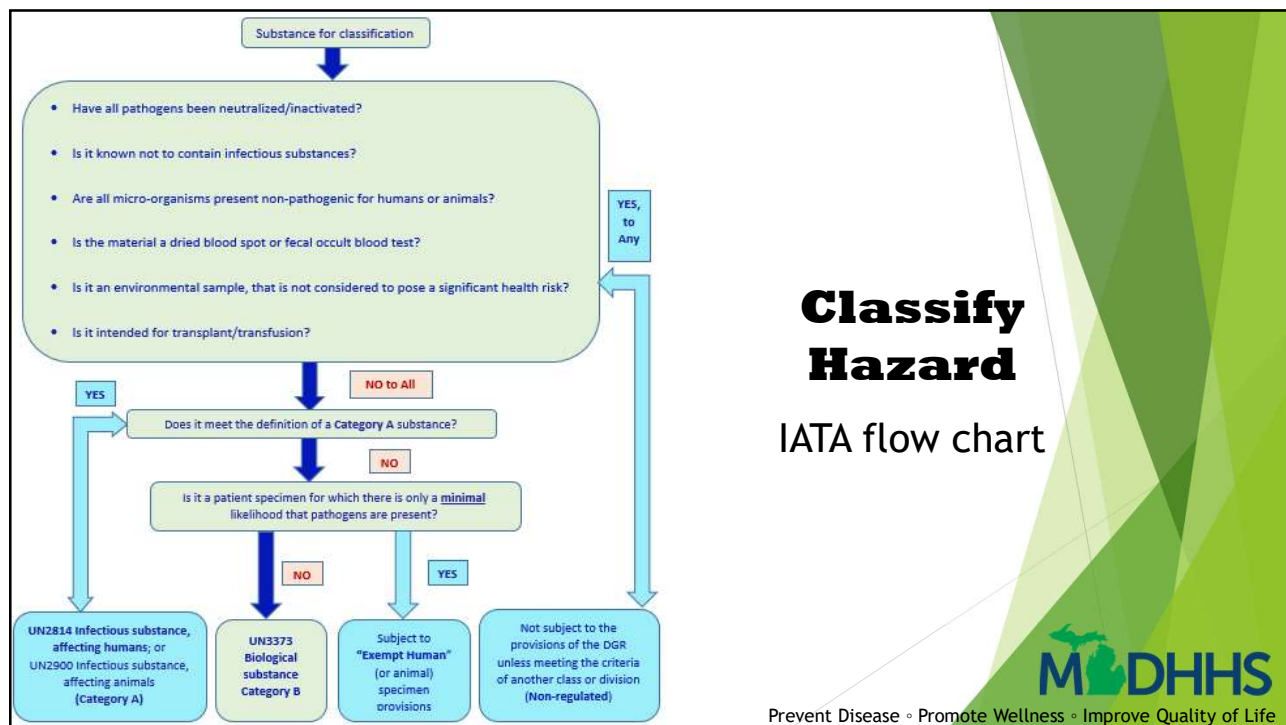


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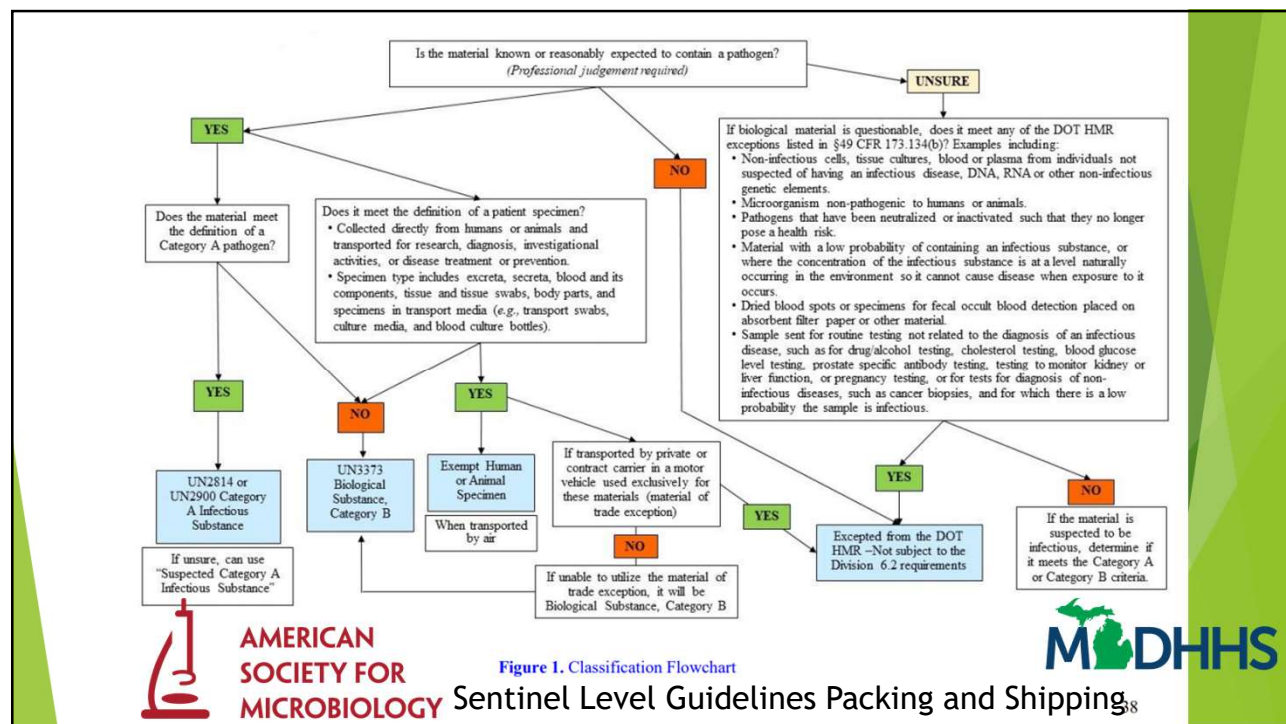
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Classification of Infectious substances

Category A	Category B	Exempt
In a form on the indicative list of Category A Infectious Substances	All pathogens not classified as Category A	Specimens taken directly from a patient that have minimal likelihood of containing a pathogen
Causes severe disease in healthy humans and animals	Patient specimens with an unknown medical history	Medical history indicates no pre-existing pathogens
Deadly pathogens which are easily transmitted from one host to another	Patient samples of unknown origin	Patient does not display any symptoms of disease at time sample is obtained
New and emerging pathogens with traits similar to established Category A substances	Patient specimens sent for diagnostic testing of pathogens	No local outbreaks of disease at time sample obtained
Pathogen recognized as bioterrorism threats	Potentially pathogenic environmental samples	Screened specimens used for clinical trials

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Classify Hazards Practice and Comprehension

There are ____ Hazard classes for Dangerous Goods

- a. 6
- b. 7
- c. 9
- d. 12



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Classify Hazards Practice and Comprehension

Category A infectious substances are given the UN number:

- a. UN2814 or UN2900
- b. UN3373
- c. 6.2
- d. 867-5309
- e. 42



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Classify Hazards Practice and Comprehension



Classify the following examples

1. Cerebral spinal fluid sample from a patient with suspected Eastern Equine Encephalitis virus.
2. Bacterial culture of *Mycobacterium tuberculosis*.
3. Urine sent as part of clinical trial.
4. Throat swab collected to test for Strep Throat (*Streptococcus pyogenes*).
5. Blood culture bottles collected at doctor's office
6. White powder for Anthrax



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Classify Hazard

Class 9 - Miscellaneous

- Dry Ice
- Dry Ice is a Dangerous Good - UN1845

Hazard relates to extreme temperature and the nature of sublimation - solid to gas. Dry Ice releases large volumes of carbon dioxide gas as it sublimates.

Contact Hazard: Dry Ice can cause severe frostbite upon contact with unprotected skin



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pngitem.com

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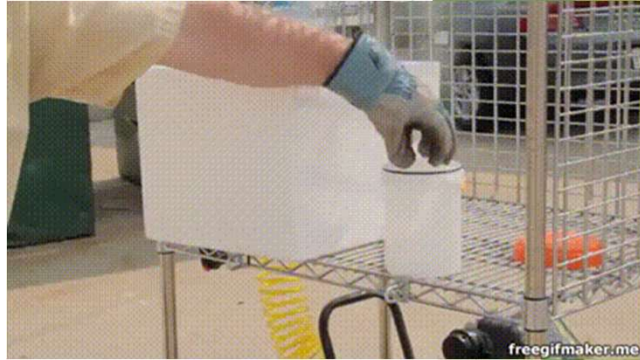


Classify Hazard

Hazards of Dry Ice

Explosive Hazard:

If packaged in a container that does not allow the gas to escape the package will pressurize. The package may explode causing injury or property damage.



Youtube Video from Saf-T-pak

MICHIGAN DHHS

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Classify Hazard

Hazards of Dry Ice

Asphyxiant

Suffocation Hazard:

A large volume of carbon dioxide released into a confined space may displace oxygen and create an oxygen deficient environment.

NEVER transport Dry ice in the same confined space as people, i.e. place Dry Ice in the trunk of a vehicle, not the back seat.

Dry ice linked to death of Washington woman traveling in Dippin' Dots' deliveryman's car

Ashley May USA TODAY
Published 10:49 a.m. ET Jul. 31, 2018



Dry ice is a solid form of carbon dioxide. It can cause asphyxiation. Erika Parfenova, Getty Images/Stockphoto.com

A Washington woman died and another is in serious condition after a freak accident caused by dry ice inside a new car.

Pierce County officials say the wife of a Dippin' Dots deliveryman was driving home late Thursday night when fumes from dry ice in the car created a toxic mix, [The News Tribune](#) reports.

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Dry Ice Recommendations

- Shipments are generally recommended to contain 5-10lbs of dry ice per 24hrs of transit time
- Refer to manufacture's recommendations
- Consider weekends and holidays when shipping Dry Ice.
- Secure samples so that when the dry ice sublimates the samples will NOT move freely inside the package.
- A Styrofoam box should NOT be reused if it is cut, cracked, torn, or stained.
- IATA Packaging instructions P954
- DOT Packaging instructions 49 CFR 173.217



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Dry Ice Recommendations

Documentation:

Appropriate documentation should discuss the presence of dry ice

- For Category A this information will be included in the Dangerous Goods Declaration.
- For Category B and Exempt packages this information should be provided on the Air Waybill.



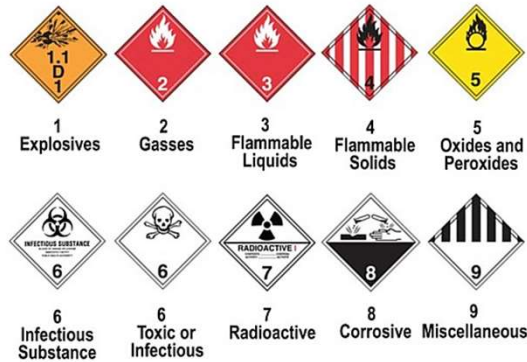

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Other Hazards

Hidden hazards

- Stop and think, is there something here I'm missing from the other hazard classes?



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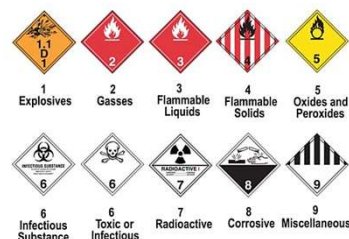
53

Other Hazards

Hidden Hazards:

Be on the lookout for:

- Dry Ice
- Reagents
 - Flammable
 - Reactive
- Specimen preservatives
 - I.e., Alcohol or Formalin



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Excepted and De minimis

Dangerous Goods exceptions

- Quantity-based for certain dangerous goods.
 - Can NOT be applied to infectious substances.

De minimis: 49 CFR 173.4b

- <1mL for Liquids, <1g for solids
- No marking or labeling requirements
- Must be packaged securely without leakage

Excepted:

- IATA Special Provision A180
- 30mL or less of common preservatives. Alcohols (ethanol, isopropanol)
- Total quantity must NOT exceed 1L
- Secure packaging, leakproof

Excepted Labeling:

- Outer package **MUST** be marked with:
 - “Scientific research specimens, not restricted, Special Provision A180 applies.”
- When a waybill is used the text, “not restricted” and A180 must appear in the description of the substance

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Other Hazards

Formaldehyde and Formalin

Special Provision A180 can be used for shipping non-infectious substances with <30ml of formalin by air

Percentage	Classification
<10% formaldehyde	Not regulated by transport regulations
<10% formaldehyde with alcohol	Class 8 Corrosive Liquid UN1198 Formaldehyde solution, flammable
10-25% formaldehyde	Class 9 Miscellaneous Dangerous Goods UN3334 Aviation Regulated Liquid N.O.S.
≥25% formaldehyde	Class 8 Corrosive Liquid UN2209 Formaldehyde solution

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Other Hazards

Medical waste

- UN3291
- If waste contains Category A substances, then **MUST** be classified and packaged as UN2814 Category A
- Decontaminated medical waste is not subject to dangerous goods regulations

Regulations for Medical Waste:

- Exceptions for Division 6.2 Packing: Regulated Medical Waste.
 - 49 CFR 173.134(b), 49 CFR 173.134(c)
- Regulated Medical Waste.
 - 49 CFR 173.197

NOTE: Medical Waste is outside the scope of this course. For additional resources or assistance contact MDHHS BOL Bioterrorism Training Coordinator.



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Additional Thoughts on Hazards



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Step 3: Package Material



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Package Material

Package material based on mode of transport and hazard classification.
Find and apply packing requirements

Mode of Transport	Regulations/Standards	Packing Requirements
Air	IATA DGR	Category A = PI 620 Category B = PI 650 Dry Ice = PI 954
Ground—US mail	USPS Publication 52 (39 CFR)	
Ground—Motor vehicle courier, train, or cargo ship	DOT HMR (49 CFR Parts 100-185)	Category A = 49 CFR 173.196 Category B = 49 CFR 173.199 Dry Ice = 49 CFR 173.217



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Package Material

Triple Packing:

1. Primary receptacle
2. Secondary Packaging
3. Outer Packing



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Triple Packing

Primary receptacle: Specimen container

- Leakproof (siftproof for solids)
 - Positive means of sealing - tape, parafilm
 - Receptacle may vibrate in transit and become loose
 - Required for Category A, Highly recommended for all others
- Packaged so they can NOT break or leak into secondary packaging
- Primary receptacle must be glass, metal, or plastic

MDHHS **Strongly** discourages shipping agar plates (Petri dish)

- Fragile
- Difficult to make leakproof



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Triple Packing

Secondary Packaging

- Must include cushioning around primary receptacle to prevent breaking
 - If multiple primary receptacles, they must be individually wrapped to prevent contact
 - Bubble wrap individually if needed
- Must contain sufficient absorbent to absorb entire volume of sample
- Must also be leakproof in case primary containment fails.



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Triple Packing

Secondary Packaging

- When shipped by aircraft, either Primary or Secondary must withstand internal pressure of 95kPa
 - 95kPa Bag or Cylinder



BARRIAPOUCH Pressure Test
Youtube Video

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Triple Packing

Outer Packing

- Rigid outer packing (at least one side of 4 inches)
- Must consist of corrugated fiberboard, wood, metal or rigid plastic
 - Outer packing can NOT be Styrofoam. Styrofoam should be placed within another rigid container.
- Dry ice, or ice packs can be placed between secondary and outer package

****Diligence in selecting the proper packaging will safeguard your shipment and reduce your liability in case of shipping accident.**



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Triple Packing

Outer Packing Testing Requirements 49 CFR 178.609

Requirement		Category A	Category B	Exempt Patient Specimen
Drop Test Conditioning	Water Spray	Yes	Yes	No
	-18°C	Yes	Yes	
Drop Test Height		9 meters	1.2 meters (4 feet)	No
Puncture Test		7kg Rod	No	No
Stacking Test		Yes	No	No

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Triple Packing

The complete package must withstand damage as prescribed by IATA and DOT



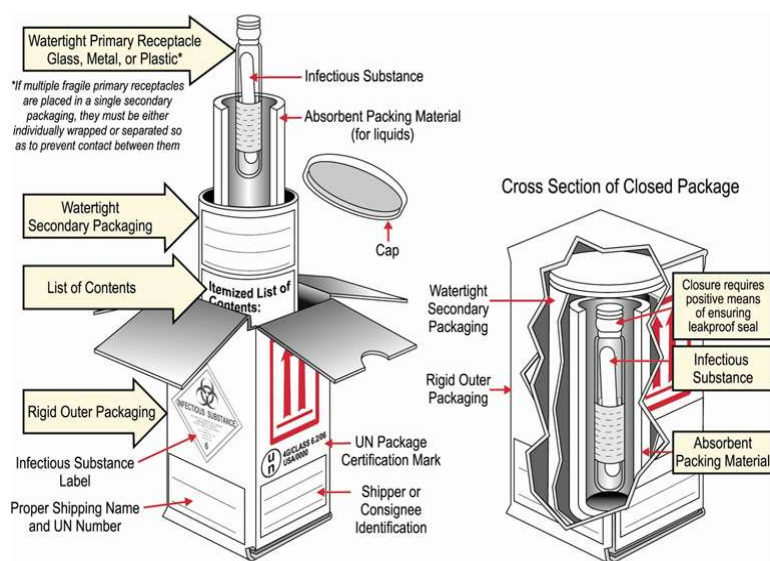
Youtube Video from Saf-T-pak



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Category A Packaging



cdc.gov

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Category A Packaging

Packing Instructions

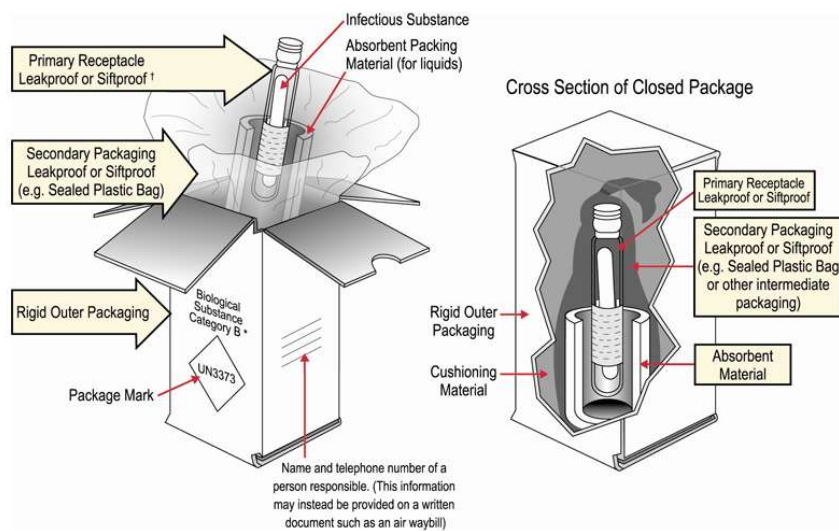
- IATA: 620
- DOT: 49 CFR 173.196
- Box: UN Specific 4G
- UN Number: UN2814, or UN2900
- Proper Shipping Name:
 - Infectious substance, affecting humans
 - Infectious substance, affecting animals



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Category B Packaging



cdc.gov

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Category B packing

Packing Instructions

- IATA: 650
- DOT: 49 CFR 173.199

According to IATA packing instruction 650, your package must:

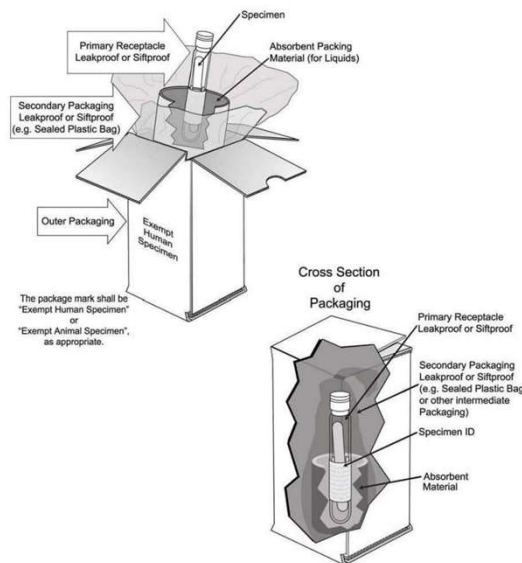
- Withstand 95kPa of pressure and temperatures between 40°F-130°F
- Contain no more than 4 liters in the outer packaging, excluding ice
- Include an itemized list of contents between the secondary and outer packaging
- Be marked with the proper shipping name, "Biological Substance, Category B"
- Display the name and telephone number of a responsible contact person on the exterior or the paperwork
- Be labeled with the UN3373 marking



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Exempt Human Specimen Packaging



thermh.org.au

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Exempt Packing

Packing Instructions:

- IATA 3.6.2.3.8
- Correct Naming: “Exempt Human Specimen”
- No UN#



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Triple Packing

Overpack

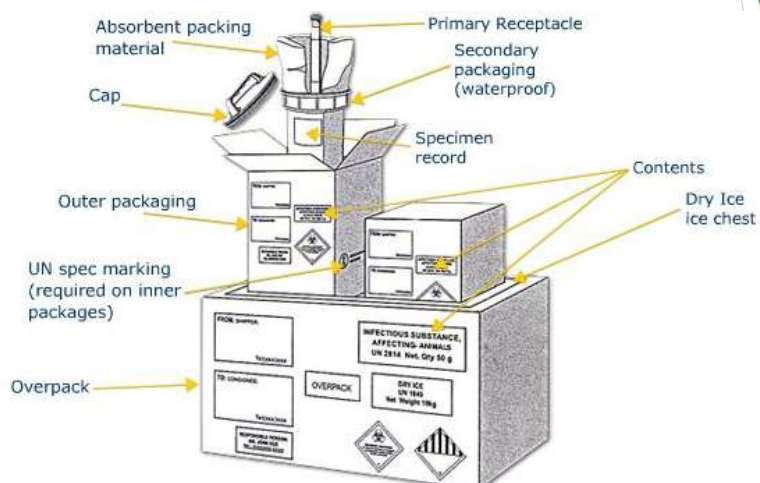
- Container used to ship multiple packages
- Supplemental to required Triple Packaging
 - No specific testing or requirements
- NOT considered package component
- Therefore, all interior packages need proper handling and labeling
- Dry ice or Ice packs can be placed between interior packages and overpack
 - If wet ice is used the package **MUST** be leakproof
 - The use of wet ice is strongly discouraged!!!



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Overpack Packaging



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Dry Ice

Packing Instructions

- IATA 954 DOT 173.217
- UN1845
- Proper Shipping name:
 - Dry Ice
 - Carbon Dioxide, solid

When shipping dry ice the package **MUST** be sealed in a way to allow the gas to vent



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Aircraft Quantity Limits

	Category A	Category B	Dry Ice
Passenger Aircraft	50mL	1L	200kg
Cargo Aircraft	4L	4L	200kg

****Special provision A81:** No quantity limits on body parts, organs, or whole bodies.
Special provision A81 must be declared on shipping papers

TRANSPORT DETAILS

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

PASSENGER AND CARGO AIRCRAFT ONLY

Airport of Departure:

Airport of Destination:



TRANSPORT DETAILS

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

PASSENGER AND CARGO AIRCRAFT ONLY

Airport of Departure:

Airport of Destination:

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Important Tips

- Do NOT mix and match packaging components
- Packing supplies are tested together to work as a unit
- Follow manufacturer's instructions

Absorbent material - small square can soak up 50mL

- Absorbent material is NOT the requisition



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Packaging Comprehension

When packing infectious material in a Triple Pack where does the absorbent material go?

- a. No absorbent material needed
- b. Between the Primary and Secondary container
- c. Between the Secondary and Outer container
- d. Taped to the outer package



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Packaging Comprehension

The primary receptacle, or the specimen container must be:

- a. Vented, so the bacteria can breathe
- b. Leakproof and sealed in a positive manner
- c. Made of metal
- d. Taped to the outer package



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Packaging Comprehension

If specimens are shipped on wet ice or gel packs the outer package must be leakproof:

True or False



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Step 4: Marking, Labeling, and Documentation



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Markings - In depth

Marking and Labeling

- Durable - Securely affixed
- Visible - Printed on contrasting background
- Legible - MUST not fold over comers of package - writing MUST not smudge
- Correct size - use premade stickers or preprinted package
- Correct location
 - Hazard label and supplemental information on the same side
- If reused package - irrelevant marking MUST be removed or obliterated
 - Reused outer package must be clean and undamaged
 - Regulation state reused packages must be in "good condition."
 - Vague, open to interpretation, use professional judgement.
 - Only reuse a box if you can personally verify it is not contaminated
- Net Quantity, or Weight - If applicable
 - Category A and Dry Ice



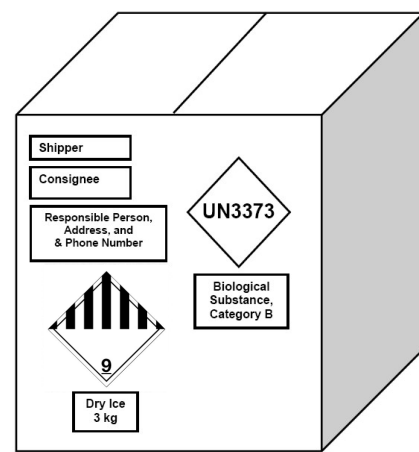
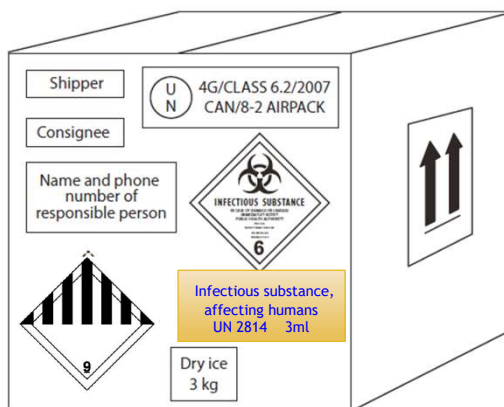
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Markings - In depth

Category B Packaging

Category A Packaging



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Markings - In depth

Shipper, Consignee
MUST appear on dangerous goods packages

► Shipper

Name
Address

► Consignee

Name
Address



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Markings - In depth

Responsible Person Contact

- Required for dangerous goods packages
- Person who is aware of package and contents
 - Category B: Responsible Person Contact information on either written documents or the outer package.
 - Category A: Responsible Person Contact information on BOTH written documents and the outer package.



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Markings - In depth

Category A Package

Who sent it:
(Shipper)

Where its going:
(Consignee)

Who is aware of
package:
(Responsible Person)

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Markings - In depth

Category A shipment:

24/7 contact - Emergency Contact

- Code USG-12
- Often confused with Responsible Person
- Responsible Person NOT necessarily 24/7 contact
 - But can be the same person
- Contact MUST be a monitored phone line for immediate access information
 - Must be a live person! NOT an answering machine
- Can be a contract company
- Note:
 - 24/7 Emergency Contact goes on the shipping papers, not the package

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Markings - In depth

Category A Infectious Substance Label

- Diamond shaped label
- Text: “In case of Damage or Leakage, immediately Notify Public Health Authority” MUST appear
- Proper shipping name and UN # (UN2814) MUST appear



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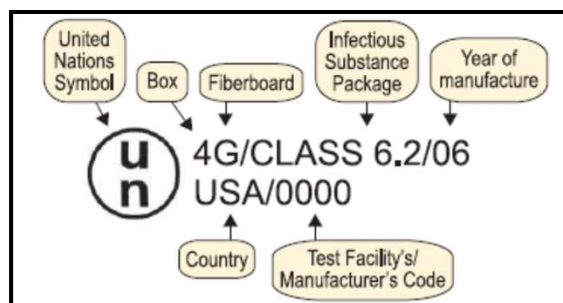
89

Markings - In depth

UN Certification Mark

MUST be on Category A packages

This label is proof from the manufacture that the package has passed all applicable Category A tests. It can NOT be covered up by other labeling.



Placed by the Manufacture (you can NOT add this to any box)

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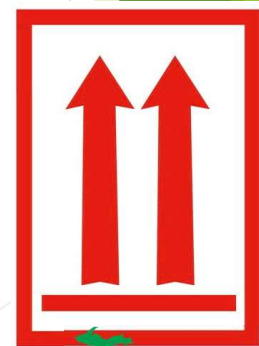
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Markings - In depth

Orientation Label

- Orientation Arrows
 - 2 available styles, black or red on white background. Must have two arrows and appear similar to the example pictures
- Required if >50ml per receptacle
 - Although orientation arrows are not always required to help with proper handling it is recommended to add them to all Category A packages
- When required must have 2 labels per package, and **MUST** be placed on opposite sides of package



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Markings - In depth

Category B Infectious Substance

- Diamond shaped label
- Text: “Biological Substance, Category B” **MUST** appear along with UN# UN3373



**BIOLOGICAL SUBSTANCE
CATEGORY B**

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Markings - In depth

Biohazard Symbol

- OSHA requires a biohazard symbol on primary or secondary packaging that contains blood or is contaminated with human blood or other possible infectious substances
- USPS requires a biohazard symbol on secondary packaging for Category B.
- Independent of Hazmat classification
- Do NOT place on outer package unless required



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Markings - In depth

Exempt human or animal specimen

- Specimens transported by air for routine testing NOT related to an infectious disease.

EXEMPT HUMAN SPECIMENS	<input type="checkbox"/>
EXEMPT ANIMAL SPECIMENS	<input type="checkbox"/>

34959 QADOC 583 Rev 1

SAFOPAK

STP-819



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Markings - In depth

Dry Ice

Must have three pieces of information:

- Class 9 Miscellaneous Dangerous Goods label
- Proper shipping name ("Dry Ice" or "Carbon dioxide, solid") and UN number, UN1845
- Net weight in kilograms (kg) (NOT pounds, lbs)
- Dry Ice Font Size regulated by volume:
 - 12mm or larger (>30kg)
 - 6mm or larger (5-30kg)
 - Of adequate size (<5kg)



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Markings - In depth

Dry Ice - Important reminders

- Must NEVER be placed in sealed container
 - Package must be taped in a way to vent CO₂ gas



- Special labels are NOT needed for ice packs, gel packs, or wet ice
 - But the package MUST be leak proof
 - The use of wet ice is **Strongly** discouraged
 - Ice melts and makes a mess!!



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Markings - In depth

Overpack

- Marking when an overpack is for multiple packages sent to the same recipient.
- Must have all the same markings as inner packages
- Inner packages must be marked properly
- Label at least 12mm high

OVERPACK



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Markings - In depth

Cargo only label (air transport)

Net quantity > 50 gm/ml Category A

200kg dry ice

Affix near other hazard labels - Same side of package



TRANSPORT DETAILS	
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>	
<input checked="" type="checkbox"/> PASSENGER AND CARGO AIRCRAFT	<input type="checkbox"/> CARGO AIRCRAFT ONLY
Airport of Departure:	
Airport of Destination:	

TRANSPORT DETAILS	
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>	
<input type="checkbox"/> PASSENGER AND CARGO AIRCRAFT	<input checked="" type="checkbox"/> CARGO AIRCRAFT ONLY
Airport of Departure:	
Airport of Destination:	

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Markings – In depth

Proper shipping name

- The specific name from the list of dangerous goods used to describe the hazard properties

Proper shipping names include:

- **UN2814 Infectious substance, affecting humans****
- **UN2900 Infectious substance, affecting animals *only*****
- **UN3373 Biological substance, Category B**
- **Carbon dioxide, solid *or* Dry ice**

****Select UN2814 if the substance affects both humans and animals.**

- We worry more about Humans



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Documentation

Itemized list:

* DOT and IATA do NOT describe in detail information required for the itemized list, nor do they provide a template.

- Laboratory Requisition most often fulfills requirement
 - Must be sent with diagnostic specimens anyway
- Between secondary and outer package
- IATA requires list for Category A and B
- DOT only requires list for Category A
 - Better idea to always include an itemized list

Not Documented, Not Done



cpahalltalk.com

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Documentation

Airway bill -

Not based on DOT or IATA regulation but required by air carriers. Therefore, each carrier will have carrier specific forms to use such as the proprietary software used to generate shipping labels with FedEx's Ship Manager

- Contract between the shipper and the carrier airline
- Required for **all** shipments of dangerous goods by air
- Must be attached to the outer packaging often within affixed pouch

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Documentation

Airway bill -

In the case of Dry Ice and Category B shipments the completed airway bill could be your only documentation of the shipment. Therefore, you must save these documents for 2 years per IATA/FAA regulations.

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Documentation

Shipper's Declaration - Dangerous Goods Form

- Requirement for packages containing Category A substances or shipments with Dry Ice
- Two formats: information in columns and a non-columnar format. Both forms can be found on [IATA's website](#).

NOTE: FedEx requires the use of FedEx Ship Manager® software when generating a Shipper's Declaration. Other non-FedEx software must be [FX-18 compliant](#).

Shipper **MUST** retain copy for 2 years - 49 CFR and IATA
Provide carrier with 2 **signed** copies
(Print/prepare 3 total copies for processing)



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Shipper's Declaration

Even seemingly minor errors can cause your package to be disqualified and returned

Don't forget to sign and date the bottom!

Step by Step instructions provided in the resources section of booklet

Currently NO fully electronic version. You **MUST** provide paper copies.

The form is titled "SHIPPER'S DECLARATION FOR DANGEROUS GOODS" and includes a warning section. It is divided into several sections: "TRANSPORT DETAILS", "NATURE AND QUANTITY OF DANGEROUS GOODS", and "Additional Handling Information". The form includes fields for Shipper, Consignee, Transport Details, and a table for Dangerous Goods Identification. The form is numbered 1 through 22, indicating key areas for attention.

UN No.	Proper Shipping Name	Class	Pack	Quantity and type of packaging	Packing	Authorization
9	10	11	12	13	14	15
16				17		

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Shipper's Declaration

1 and 2: Shipper and
Consignee

Full Names and complete
address

Phone number with area code

SHIPPER'S DECLARATION FOR DANGEROUS GOODS			
Shipper		3	
1			
Consignee			
2			
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)		Airport of Departure	
6		7	
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY		
Airport of Destination:			

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Shipper's Declaration

6 and 7: Transport Details

XXXX out the Passenger or
Cargo box as needed

Airport: Either provide full
name of the airport or city

- Do NOT use airport codes
- OK to leave blank if unsure
- Carrier can enter airport information

Consignee			
2			
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)		Airport of Departure	
6		7	
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY		
Airport of Destination:			
NATURE AND QUANTITY OF DANGEROUS GOODS			
Dangerous Goods Identification			
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group
9	10	11	12

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Shipper's Reference Number		5	
This space will have variable content depending on the carrier and method used to create this form.			
WARNING			
Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.			
Shipment type: (delete non-applicable)		8	
NON-RADIOACTIVE		RADIOACTIVE	
Quantity and type of packaging	Packing Inst.	Authorization	
13	14	15	

Shipper's Declaration

8: Radioactive

XXXX option that DOES NOT apply

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Shipper's Declaration

9-17: This section can be Columns or Non-columnar

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification				Quantity and type of packaging	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Secondary Risk)	Packing Group			
9	10	11	12	13	14	15
	16			17		

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Shipper's Declaration

Completed Dangerous Goods Section:
And IATA Special Provision A140 - Unconfirmed or Unknown

FIGURE 8.1.J
Shipper's Declaration Completion—Example 6

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Hazard)	Packing Group			
UN2814	Infectious substance, affecting humans (Dengue virus)	6.2		1 Fibreboard box x 25 g	620	
UN1845	Dry Ice	9		20 kg Overpack used	954	

A way to show an infectious substance shipment packed in a UN Class 6.2 specification package surrounded by dry ice contained in an overpack meeting Packing Instruction 954 requirements.

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Shipper's Declaration

The proper shipping name for Category A Infectious substances **MUST** have the technical name listed on the Shipper's Declaration.

- The technical name should NOT appear on the outside of the package - "Lost in Crowd"
- Technical name written in parentheses after Proper Shipping name

49 CFR 172.203(k) state in part, "A material classed as Division 6.2 and assigned UN2814 or UN2900 that is suspected to contain an unknown Category A infectious substance must have the words "suspected Category A infectious substance" entered in parentheses in place of the technical name as part of the proper shipping description. For additional technical name options, see the definition for "Technical name" in § 171.8. A technical name should not be marked on the outer package of a Division 6.2 material (see § 172.301(b))."

FIGURE 8.1.J
Shipper's Declaration Completion—Example 6

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Hazard)	Packing Group			
UN2814	Infectious substance, affecting humans	6.2		1 Fibreboard box x 25 g	620	
UN1845	(Suspected Category A infectious substance)			20 kg Overpack used	954	

A way to show an infectious substance shipment packed in a UN Class 6.2 specification package surrounded by dry ice contained in an overpack meeting Packing Instruction 954 requirements.

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Documentation

Common Errors

- Incorrect Technical Name
 - NO abbreviations
- Missing Emergency response info: 24/7 Contact
- Packing Description: Fiberboard NOT 4G, or “Box”
- Sign Form

Correct Format	Incorrect Format
Infectious substance, affecting humans	Inf. Sub. Affecting humans
Carbon dioxide, solid or use “Dry ice”	CO ₂ , solid

CHECK YOUR WORK!

Errors can lead to rejection and delays



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Carrier Specific Reminders

USPS:

- Will not accept Category A packages.
- Non-Regulated Substances (DOT classification) need Category B packing requirements
 - Omitting UN3373 label and proper shipping name.

FedEx:

- Will accept Category A packages but not select agents.
- Requires the use of FedEx software (Ship Manager®) when generating a Shipper's Declaration.
 - Or software must be FX-18 compliant.



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IATA Dangerous Goods Table

UN/ID no.	Proper Shipping Name/ Description	Class or Div. (Sub Risk)	Hazard Label	PG	Passenger & Cargo Aircraft				Cargo Aircraft Only		S.P. see 4.4	ERG Code	
					EQ see 2.6	LTD Qty		Pkg Inst	Max Net Qty/Pkg	Pkg Inst			Max Net Qty/Pkg
						Pkg Inst	Max Net Qty/Pkg						
3373	Biological substance, Category B	6.2			E0	Forbidden		see 650		see 650			11L
1845	Dry Ice†	9	Miscellaneous		E0	Forbidden		954	200 kg	954	200kg	A48 A151 A805	9L
2900	Infectious substance, affecting animals	6.2	Infectious Subst.		E0	Forbidden		620	50 ml	620	4 L	A81 A140	11Y
2814	Infectious substance, affecting humans	6.2	Infectious Subst.		E0	Forbidden		620	50 ml	620	4 L	A81 A140	11Y

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DOT Hazardous Materials Table

UN/ID no.	Proper Shipping Name/ Description	Class or Div. (Sub Risk)	Hazard Label	PG	EQ see 2.6	Special Provisions (§ 172.102)	(8)			(9)		(10)	
							Passenger & Cargo Aircraft			Quantity Limitations (see §§ 173.27 and 175.75)		Vessel Stowage	
							Excep- tions	Non- bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Loca- tion	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	Biological substance, Category B	6.2	UN3373			A82	134	199	None	4 L or 4 kg	4 L or 4 kg	A	40
A W	Carbon dioxide, solid or Dry ice	9	UN1845		None		217	217	240	200 kg	200 kg	C	40
G	Infectious substances, affecting animals only	6.2	UN2900		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg	B	40
G	Infectious substances, affecting humans	6.2	UN2814		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg	B	40

Adapted from 49 CFR Section 172.101 website:
<https://www.phmsa.dot.gov>

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US Postal Service Pub 52 Packaging Standards

Material Being Mailed	Nonregulated	Category A	Category B
Blood for Transfusion	346.325	Non-Mailable (nm)	346.321
Biological Product	346.325	nm	346.321
Culture or Stock	346.325	nm	346.321
Patient Specimen	346.325	nm	346.321
Exempt Human or Animal Specimen	346.326	n/a	n/a
Forensic Material	346.325	nm	346.324
Regulated Medical Waste	346.322	nm	346.322
Sharps Waste	346.322	nm	346.322
Toxin ²	346.31	nm	346.321
Treated Medical Waste	346.325	n/a	n/a
Used Health Care Product	346.323	nm	346.323

Exhibit 346.327 Packaging References for Mailable, Infectious Substances
(Hazard Class 6, Division 6.2)

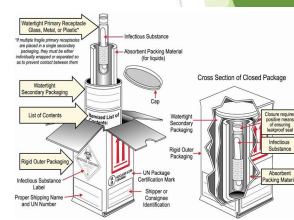
https://pe.usps.com/text/pub52/pub52c3_023.htm

115

Final Overview

Category A Overview:

- Leakproof primary receptacle
- Leakproof secondary packaging
- Biohazard symbol on primary or secondary packaging
- Cushioning and absorbent
- Rigid outer packaging with UN specification mark
- Infectious Substance hazard label
- Proper shipping name
- Shipper and consignee addresses
- Responsible person contact information
- Itemized list of contents
- Shipping Papers with 24/7 emergency contact
- Package Orientation label (if primary receptacle exceeds 50 ml of liquid)
- Air Waybill (air transport only)
- Shipper's Declaration with 24/7 emergency contact (air transport only)



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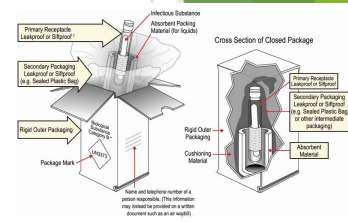
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Final Overview

Category B

- Leakproof primary receptacle
- Leakproof secondary packaging
- Biohazard symbol on primary or secondary packaging
- Cushioning and absorbent materials
- Rigid outer packaging
- UN3373 mark
- Proper shipping name
- Shipper and consignee addresses
- Responsible person contact information on outer packaging or written documentation
- Itemized list of contents (air transport only)
- Air Waybill (air transport only)
- Primary receptacle or secondary packaging must be capable of withstanding an internal pressure of 95 kPa without leakage (USPS and liquids by air transport)



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Final Overview

Exempt - IATA designation

- Leakproof primary receptacle
- Leakproof secondary packaging
- Cushioning and absorbent materials for liquid samples that can absorb the entire volume of the substance
- Outer packaging of adequate strength for capacity, mass, and intended use
- Shipper and consignee addresses
- Exempt human specimen or exempt animal specimen label
- Air Waybill
- Biohazard symbol on secondary packaging (USPS only)

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Final Overview

Non-Regulated - DOT designation

Not subject to DOT regulations packages must include:

- Shipper and consignee addresses
- USPS use of DOT's Category B triple packing requirements, omitting the UN3373 label and biological substances, Category B proper shipping name



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**What to do if it all
goes wrong and
where to find answers**



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Emergency Procedures

- ▶ If damage occurs
 - ▶ Avoid further handling
 - ▶ Inspect package and adjacent packages
 - ▶ Notify:
 - ▶ Shipper and Consignee
 - ▶ Public Health authorities
 - ▶ CDC
 - ▶ Use proper PPE
 - ▶ Follow clean up protocols
 - ▶ Provide first aid if necessary



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Emergency Procedures

Resources:

49 CFR

https://www.ecfr.gov/cgi-bin/text-idx?SID=646df6509d863ec6d12f6283bb15f693&mc=true&tpl=/ecfrbrowse/Title49/49cfrv2_02.tpl#0

IATA

<https://www.iata.org/publications/dgr/pages/index.aspx>

DOT

<https://www.transportation.gov/>

FAA

<https://www.faa.gov/hazmat/>

Select Agents

<https://www.selectagents.gov/SelectAgentsandToxinsList.html>

American Society of Microbiology - Packing and Shipping

<https://asm.org/guideline/Packing-and-Shipping-Infectious-Substances>

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Responsibilities



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Responsibilities

Shipper (Consignor)	Operator (Carrier)	Receiver (Consignee)
Training	Training	Training
Classification	Inspection	Verification of itemized list
Identification (of Hazard)	Acceptance or Rejection	Inspection before opening
Select Proper Packaging	Storage	Incident reporting
Packing	Transportation	
Marking and Labeling	Incident Reporting	
Documentation		*Recommended only Professional Responsibility

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Be Prepared!

► Take what you've learned and apply it!

► Plan:

- Take a mock sample through your process

► Prepare:

- Procedures, Job Aids, Checklists, Competency

► Perform:

- Resources: Send photos to MDHHS



Your First Hands-On
Category A Package
shouldn't be a patient sample



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Be Prepared!

► New IATA Regulation

- CBTA - Competency Based Training and Assessment

- Begins January 2023

► Employer shall confirm employees are competent

- In conjunction with passing training course, training such as this.
- Function specific on the job evaluation

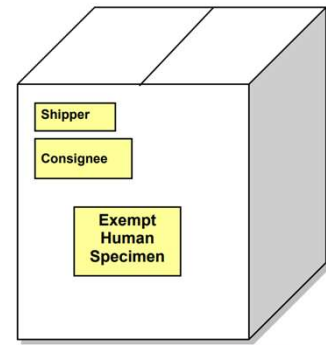
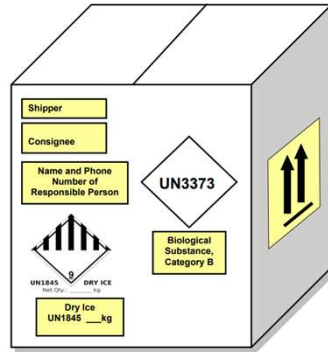
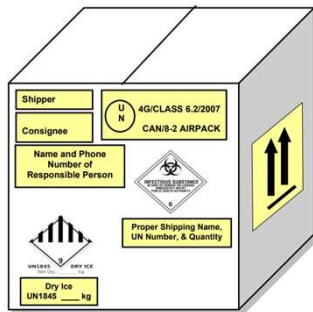


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Scenarios

- ▶ Blood from a patient infected with Lassa virus - Sent Frozen with Dry Ice
- ▶ Classify?
- ▶ Package



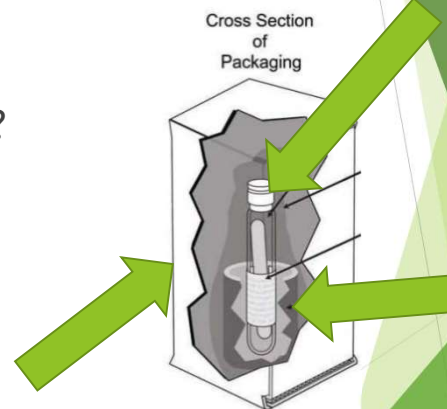
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Scenarios

- ▶ Blood for glucose testing
- ▶ Classify?
- ▶ UN #####?
 - ▶ Triple packing requirements?
 - ▶ 1
 - ▶ 2
 - ▶ 3



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Scenarios

- ▶ Nasopharyngeal swab for COVID-19 testing
- ▶ Classify
- ▶ Package
- ▶ Biohazard Label

When MUST a 95kPa container be used?



Primary Receptacle



Secondary Container

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Scenarios

- ▶ Sputum known or reasonably expected to contain *Mycobacterium tuberculosis*
- ▶ Culture of *Neisseria meningitidis*
- ▶ Culture of *E. coli*
- ▶ Placard and UN Number?



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Resource Information for



Packaging & Shipping

Helpful Resources Affecting Transport of Division 6.2 Infectious Substances

Department of Transportation (DOT): 49 CFR Part 171-180, Hazardous Materials Regulations (HMR)

U.S. DOT Hazardous Material Regulations (HMR), Title 49 CFR § 100 – 185

- **DOT's Hazardous Materials Information Center:** The DOT Hazardous Material Information Center exists to promote compliance and does not report to enforcement branch. Contact for compliance questions:
 - Phone Number: 1-800-467-4922 Monday-Friday 9am-5pm EST
 - Email: infocntr@dot.gov
- https://www.ecfr.gov/cgi-bin/text-idx?SID=1d49a3b137cb1b6fc45251074e634b44&tpl=/ecfrbrowse/Title49/49tab_02.tpl
- <https://www.fmcsa.dot.gov/regulations/hazardous-materials/how-comply-federal-hazardous-materials-regulations>
- www.phmsa.dot.gov/hazmat
- Emergency response requirements 49 CFR § 172, Subpart G.
- Emergency Response Guidebook
 - <https://www.phmsa.dot.gov/hazmat/erg/emergency-response-guidebook-erg>
- Hazardous Material Transportation Security Requirements
 - <https://www.phmsa.dot.gov/training/hazmat/security-requirements-brochure-english>

International Air Transport Association (IATA):

- IATA Dangerous Goods Hotline: Technical support and question:
 - Phone Number: 1-800-716-6326
 - Email: dangood@iata.org
- Dangerous Goods Regulations (DGR)
- Online store to purchase document: <http://www.iata.org/publications/Pages/index.aspx>
- Blank Fillable Shipper's Declaration Forms:
 - <http://www.iata.org/whatwedo/cargo/dgr/Pages/shippers-declaration.aspx>

United States Postal Service (USPS): <https://pe.usps.com/text/pub52/welcome.htm>

Occupational Health & Safety Administration (OSHA): 29 CFR Part 1910.1030 <https://www.osha.gov/>

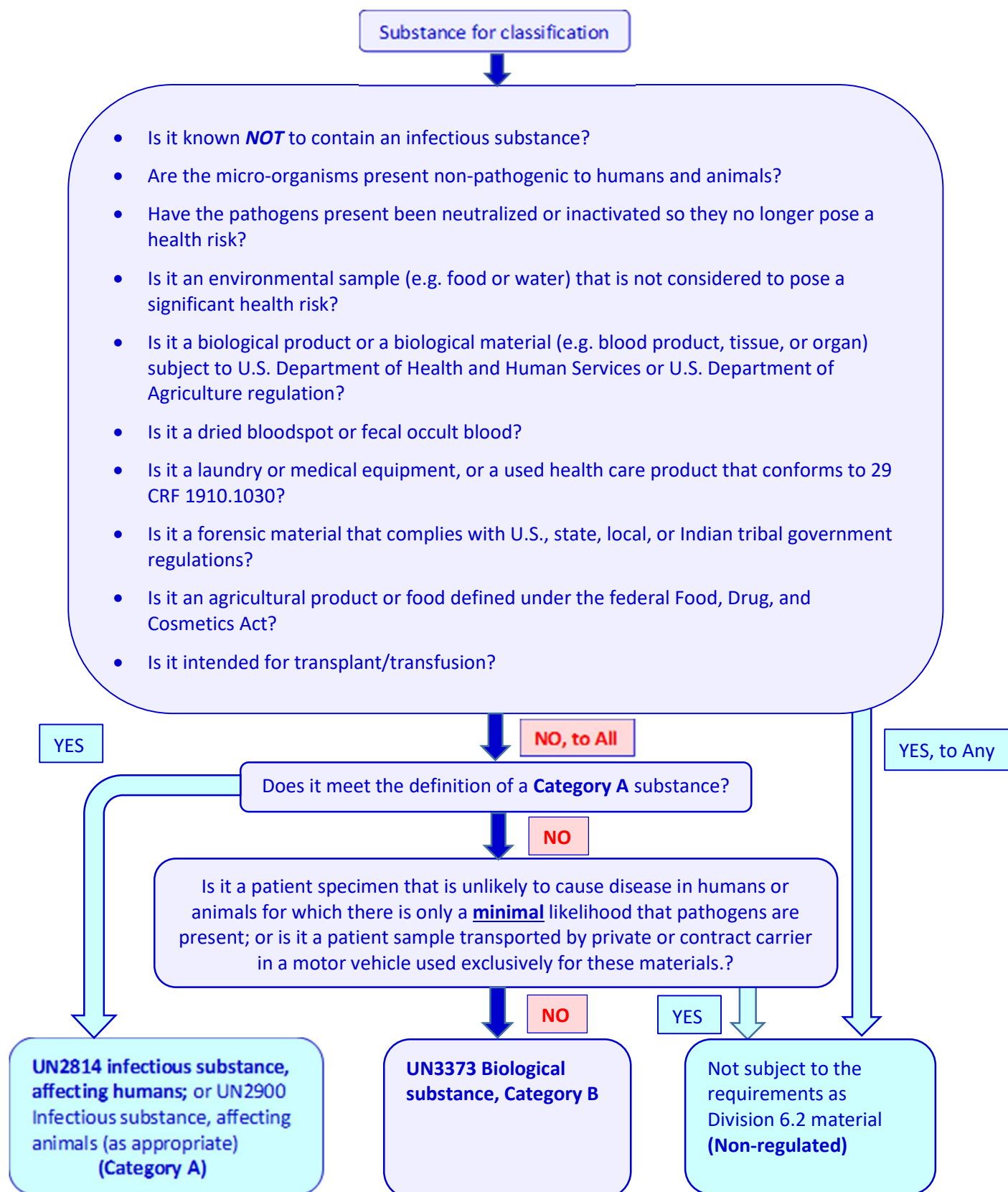
American Society for Microbiology (ASM) Laboratory Response Network (LRN) Sentinel Level Clinical Laboratory Protocols:

- <https://asm.org/Articles/Policy/Laboratory-Response-Network-LRN-Sentinel-Level-C>
- Packing and Shipping Infectious Substances
 - <https://asm.org/Guideline/Packing-and-Shipping-Infectious-Substances>

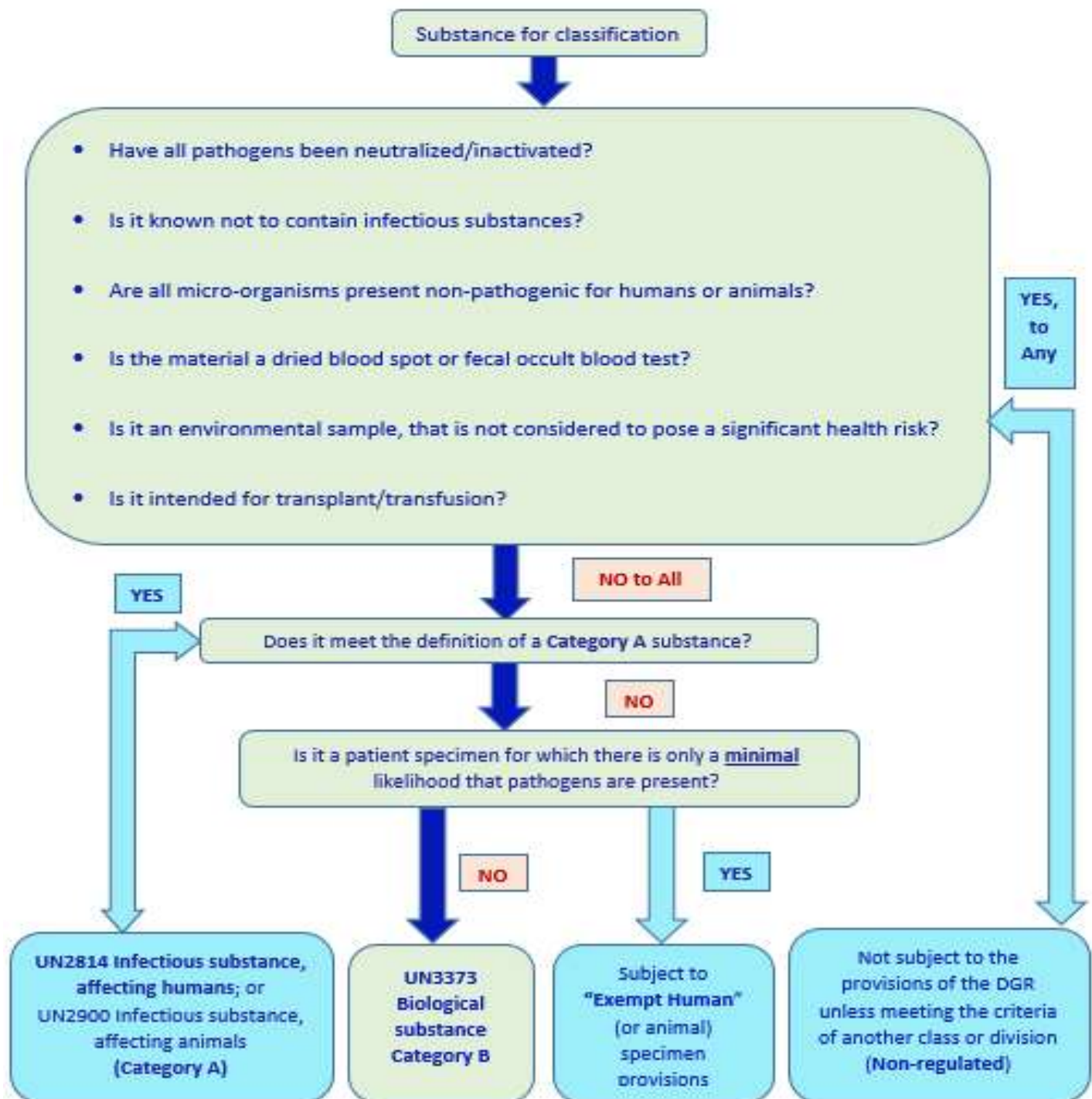
Association of Public Health Laboratories (APHL) Packaging & Shipping Toolkit

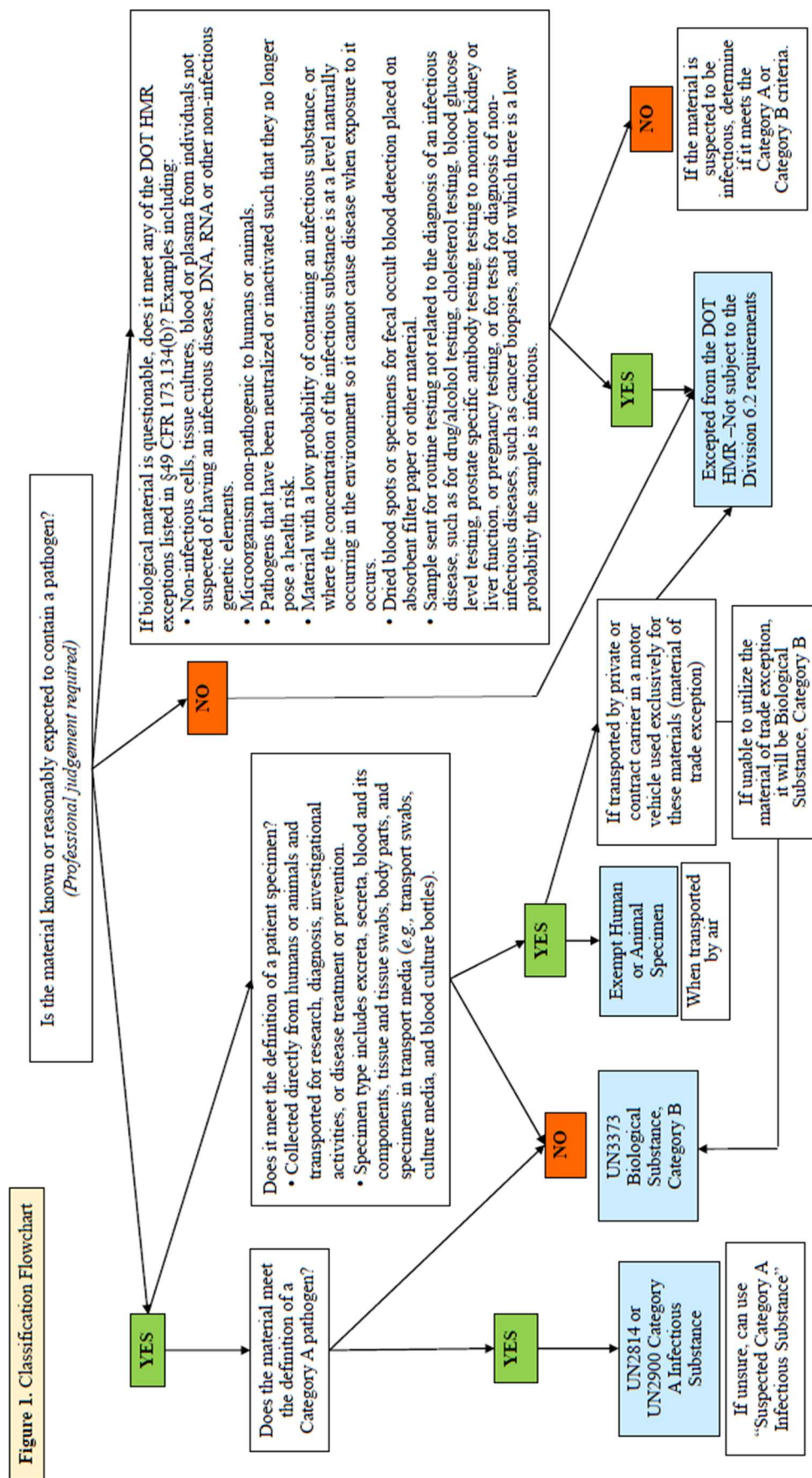
https://www.aphl.org/programs/infectious_disease/Pages/ID-Packaging-and-Shipping-Toolkit.aspx

DOT Classification Flowchart



IATA & US Postal Service Classification





IATA and DOT Indicative Category A List

CATEGORY A PATHOGENS, INDICATIVE OF INFECTIOUS SUBSTANCES, AFFECTING HUMANS (UN2814) WHEN TRANSPORTED IN ANY FORM UNLESS OTHERWISE INDICATED:

<i>Bacillus anthracis</i> (cultures only)	Japanese encephalitis virus (cultures only)
<i>Brucella abortus</i> , <i>Brucella melitensis</i> , <i>Brucella suis</i> (cultures only)	Junin virus
<i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i> (cultures only)	Kyasanur Forest disease virus
<i>Chlamydia psittaci</i> avian strains (cultures only)	Lassa virus
<i>Clostridium botulinum</i> (cultures only)	Machupo virus
<i>Coccidioides immitis</i> (cultures only)	Marburg virus
<i>Coxiella burnetii</i> (cultures only)	Monkeypox virus
Crimean-Congo hemorrhagic fever virus	<i>Mycobacterium tuberculosis</i> (cultures only)
Dengue virus (cultures only)	Nipah virus
Eastern equine encephalitis virus (cultures only)	Omsk hemorrhagic fever virus
Ebola virus	Polio virus (cultures only)
<i>Escherichia coli</i> , verotoxigenic (cultures only)	Rabies virus (cultures only)
Flexal virus	<i>Rickettsia prowazekii</i> , <i>Rickettsia rickettsii</i> (cultures only)
<i>Francisella tularensis</i> (cultures only)	Rift Valley fever virus (cultures only)
Guanarito virus	Russian spring-summer encephalitis virus (cultures only)
Hantaan virus	Sabia virus
Hantavirus causing hemorrhagic fever with renal syndrome	<i>Shigella dysenteriae</i> type 1 (cultures only)
Hendra virus	Tick-borne encephalitis virus (cultures only)
Hepatitis B virus (cultures only)	Variola virus
Herpes B virus (cultures only)	Venezuelan equine encephalitis virus (cultures only)
Highly pathogenic avian influenza virus (cultures only)	West Nile virus (cultures only)
Human immunodeficiency virus (HIV) (cultures only)	Yellow fever virus (cultures only)
	<i>Yersinia pestis</i> (cultures only)

CATEGORY A PATHOGENS INDICATIVE OF INFECTIOUS SUBSTANCES, AFFECTING ANIMALS (UN2900) WHEN TRANSPORTED IN ANY FORM UNLESS OTHERWISE INDICATED:

African swine fever virus (cultures only)	<i>Mycoplasma mycoides</i> – Contagious bovine pleuropneumonia (cultures only)
Avian paramyxovirus Type 1-Velogenic Newcastle disease virus (cultures only)	Peste des petits ruminants virus (cultures only)
Classical swine fever virus (cultures only)	Rinderpest virus (cultures only)
Foot and mouth disease virus (cultures only)	Sheep-pox virus (cultures only)
Goatpox virus (cultures only)	Swine vesicular disease virus (cultures only)
Lumpy skin disease virus (cultures only)	Vesicular stomatitis virus (cultures only)

Note: This is an indicative list and not an all-inclusive list. Please note that at times, the names of new and emerging pathogens may not always be included and published immediately on regulatory lists. Shippers should also consult the HHS/USDA Select Biological Agents and Toxins list available at www.selectagents.gov for the shipment of any potential select agent organism or toxin. Confirmed Select Agents must always be shipped as Category A, and potential or suspect Select Agents as “Suspected Category A”. Always refer to public health authorities (e.g., CDC, WHO, or other state or local public health agencies) for guidance when transporting a new or emerging pathogen.

DOT Hazardous Materials Table

Adapted from 49 CFR Section 172.101

UN/ID no.	Proper Shipping Name/Description	Class or Div. (Sub Risk)	Hazard Label	PG	EQ see 2.6	Special Provisions (§ 172.102)	(8)			(9)		(10)	
							Passenger & Cargo Aircraft			Quantity Limitations (see §§ 173.27 and 175.75)		Vessel Stowage	
							Exemptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	Biological substance, Category B	6.2	UN3373			A82	134	199	None	4 L or 4 kg	4 L or 4 kg	A	40
A W	Carbon dioxide, solid or Dry ice	9	UN1845		None		217	217	240	200 kg	200 kg	C	40
G	Infectious substances, affecting animals only	6.2	UN2900		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg	B	40
G	Infectious substances, affecting humans	6.2	UN2814		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg	B	40

IATA DGR (61st Edition 2020)

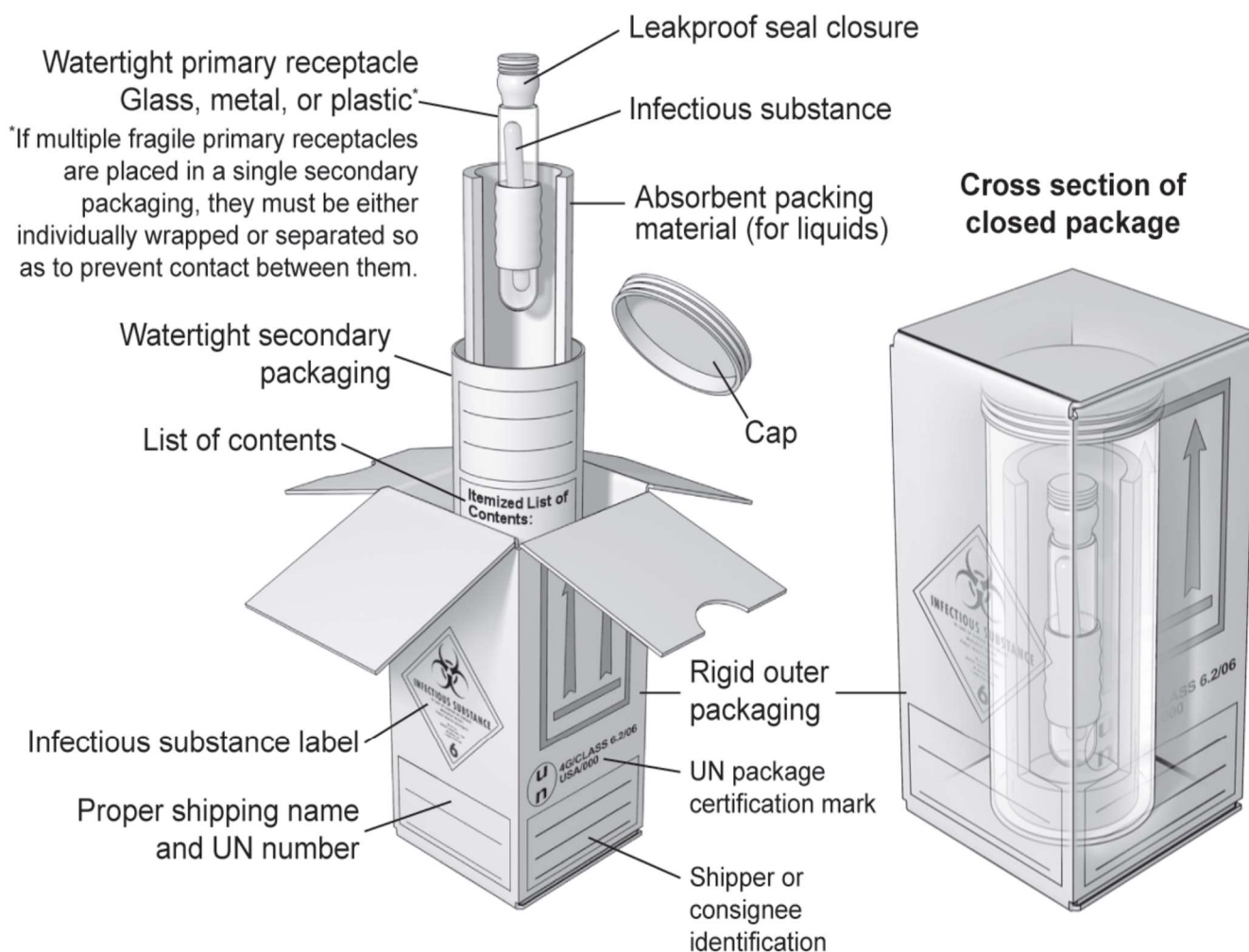
UN/ID no.	Proper Shipping Name/ Description	Class or Div. (Sub Risk)	Hazard Label	Passenger & Cargo Aircraft				Cargo Aircraft Only		S.P. see 4.4	ERG Code	
				EQ see 2.6	LTD Qty		Pkg Inst	Max Net Qty/Pkg	Pkg Inst			Max Net Qty/Pkg
					Pkg Inst	Max Net Qty/Pkg						
3373	Biological substance, Category B	6.2		E0	Forbidden		see 650		see 650			11L
1845	Dry Ice†	9	Miscellaneous	E0	Forbidden		954	200 kg	954	200kg	A48 A151 A805	9L
2900	Infectious substance, affecting animals	6.2	Infectious Subst.	E0	Forbidden		620	50 ml	620	4 L	A81 A140	11Y
2814	Infectious substance, affecting humans	6.2	Infectious Subst.	E0	Forbidden		620	50 ml	620	4 L	A81 A140	11Y

US Postal Service Pub 52

https://pe.usps.com/text/pub52/pub52c3_023.htm

Material Being Mailed	Nonregulated	Category A	Category B
Blood for Transfusion	346.325	nm	346.321
Biological Product	346.325	nm	346.321
Culture or Stock	346.325	nm	346.321
Patient Specimen	346.325	nm	346.321
Exempt Human or Animal Specimen	346.326	n/a	n/a
Forensic Material	346.325	nm	346.324
Regulated Medical Waste	346.322	nm	346.322
Sharps Waste	346.322	nm	346.322
Toxin ²	346.31	nm	346.321
Treated Medical Waste	346.325	n/a	n/a
Used Health Care Product	346.323	nm	346.323

Category A Triple Packaging (cdc.gov)



Category A Infectious Substance With Dry Ice Outer Packaging





Do not use these 2 labels if dry ice is not used
(Refer to arrows)



Diagram 1: Numbered Dangerous Goods Shipper's Declaration Form

SHIPPER'S DECLARATION FOR DANGEROUS GOODS				(Provide at least three copies to the airline.)		
Shipper		Air Waybill No.				
1		3		Page of Pages 4		
Consignee		Shipper's Reference Number 4				
2		This shipper's declaration was prepared using a FedEx Express template. It must be used ONLY for: * Class 7 radioactive shipments * Shipments using an 023 air waybill (IP1, IXF or ATA service) * Shipments originating from a non-US location				
Two completed and signed copies of this Declaration must be handed to the operator		WARNING				
TRANSPORT DETAILS		Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.				
This shipment is within the limitations prescribed for: (delete non applicable)		Airport of Departure				
6		PASSENGER AND CARGO AIRCRAFT		CARGO AIRCRAFT ONLY		7
Airport of Destination:		Shipment type: (delete non-applicable)				
		NON-RADIOACTIVE RADIOACTIVE 8				
NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification				Quantity and type of packaging	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Pack-ing Group			
9	10	11	12	13	14	15
	16			17		
Additional Handling Information						
18		Emergency Telephone Number: 19				
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		
				Place and Date 20 21		
				Signature (see warning above) 22		
Emergency Telephone Number						
FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT. ADR EUROPEAN TRANSPORT STATEMENT: CARRIAGE IN ACCORDANCE WITH 1.1.4.2.1						

Category A Checklist for Dangerous Goods Form


	Item	Complete		Item(s) in Need of Follow Up / Notes
		Yes	N/A	
Note 1	Itemized list of contents included (e.g., test request form)			
Note 2	*Multiple copies of Dangerous Goods Form (3 with pkg. & 1 keep in-house)			
1	Completed Shipper info (Full name, complete address and phone number)			
2	Completed Recipient info (Full name, complete address and phone number)			
3	If used, Airway Bill number listed on Shipper's Declaration			
4	*Page 1 of 1 completed			
5	(Optional) Sample/Specimen number listed as "Specimen Reference Number"			
6	*Passenger (Up to 50ml) vs. Cargo only selected (>50ml) <ul style="list-style-type: none"> Use Orange cargo label on Box only if cargo selected 			
7	(OK to leave blank) Airport of departure & airport of destination listed			
8	*Radioactive vs. non-radioactive selected			
9	UN hazard identification(s) listed <ul style="list-style-type: none"> UN 2814 or UN 2900 (Category A) UN 1845 (if dry ice included) 			
10	Proper shipping name listed (either) <ul style="list-style-type: none"> For UN2814: Infectious Substance, Affecting Humans For UN2900: Infectious Substance, Affecting Animals For UN1845: Dry Ice 			
10	" Suspected Category A, Infectious Substance " Note: Use Technical name of organism(s) listed after proper shipping name if ID is confirmed			
11	Class or Division listed <ul style="list-style-type: none"> Use 6.2 for Category A Use 9 for Dry Ice 			
12	Leave blank Packing group for 6.2 material, and for dry ice			
13	Quantity and type of packaging listed (e.g., Fibreboard box, 5mL solid).			
14	Packing Instruction (PI) listed <ul style="list-style-type: none"> Category A = 620 ; Dry ice = 954 			

Category A Checklist for Dangerous Goods Form


	Item	Complete		Item(s) in Need of Follow Up / Notes
		Yes	N/A	
15	<u>Leave blank</u> Authorization			
16	If more than one organism or dry ice is included, they are each listed here			
17	Type of packaging and volume listed for 2 nd item (e.g., " fibreboard box " volume, if dry ice must be in kg "Overpack used" (if overpack used i.e. w/dry ice)			
18	Additional handling information provided (e.g., "Attention to" or list the Responsible Person info)			
19	24-hour emergency contact listed (name and number include area code)			
20	Name/Title of signatory listed			
21	Place and date listed			
22	Signed by trained & certified personnel that packaged sample			

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to UPS.)

Shipper: MATT BASHORE MDHHS BUREAU OF LABORATORIES 927 TERMINAL RD LANSING, MI 48906, United States (US)		Air Waybill No. 1Z4505550155857278 Page 1 of 1 Page(s) HAZ+ Shipper's Reference Number (optional)			
Consignee: HOMER SIMPSON SIMPSON DOUGHNUT CO 7523 LOONEY TUNE BLVD OWOSSO, MI 48867, United States (US)					
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)		Airport of Departure:			
<table border="1"> <tr> <td>PASSENGER AND CARGO AIRCRAFT</td> <td>XXXXX</td> </tr> </table>		PASSENGER AND CARGO AIRCRAFT	XXXXX	Airport of Destination:	
PASSENGER AND CARGO AIRCRAFT	XXXXX				
Shipment type: (delete non-applicable)		Non-Radioactive XXXXXX			
NATURE AND QUANTITY OF DANGEROUS GOODS UN Number or Identification Number, Proper Shipping Name, Class or Division, Packing Group (if required), number of packages, and all other required information. UN2814, INFECTIOUS SUBSTANCE, AFFECTING HUMANS, (SUSPECTED CATEGORY A INFECTIOUS SUBSTANCE), 6.2, // 1 Fiberboard Box x 20 ml // 620, RESPONSIBLE PARTY : MATT BASHORE (517)335-8373					



Additional Handling Information Emergency Contact 24-Hour Number: 1-800-633-8253 PERS CUSTOMER 8780	
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 KIRK ANNIS LABORATORY TECHNICIAN Place and Date LANSING, MI 03-Mar-2017 Signature (see warning above) 

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to airline.)

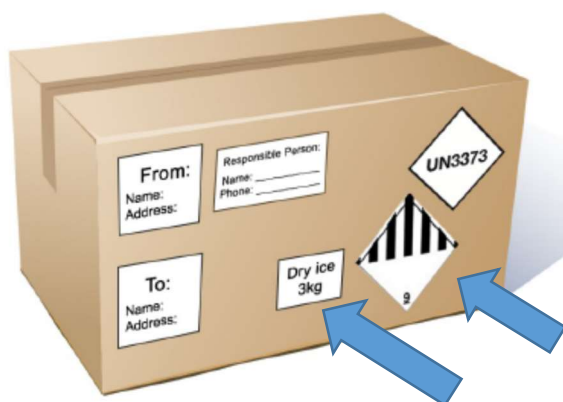
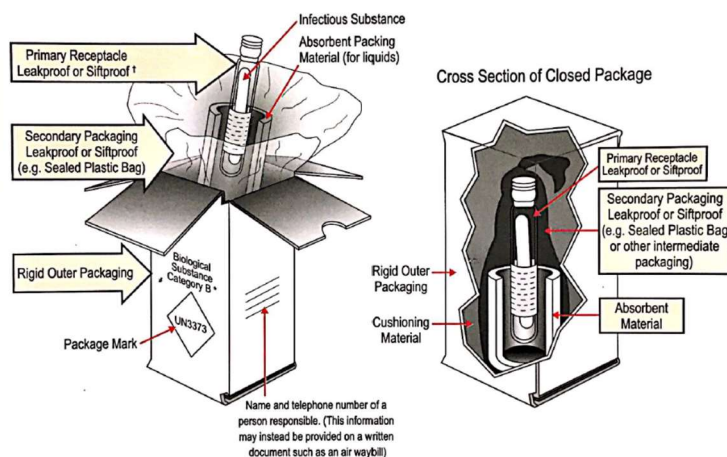
SCN 10/9 5622518 80001

Shipper Kirsten Gallagher MDHHS - Bureau of Laboratories 3350 N. Martin Luther King Jr. Blvd Lansing MI 48906 US		Air Waybill No. 658740351173 Page 1 of 1 Page(s) Shipper's Reference Number (optional)	
Consignee MATT BASHORE 5176489804 CENTERS FOR DISEASE CONTROL CENTERS FOR DISEASE CONTROL 1600 CLIFTON RD NE ATTN STAT LAB UNIT ATLANTA GA30329 US		FX 18 Compliant  CAFE3211	
Two completed and signed copies of this Declaration must be handed to the operator		WARNING Failure to comply with 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) <div style="border: 1px solid black; padding: 2px; display: inline-block;">PASSENGER AND CARGO AIRCRAFT</div>		Airport of Departure Lansing	
Airport of Destination: ATLANTA TWMULA		Shipment type: (delete non applicable) <div style="border: 1px solid black; padding: 2px; display: inline-block;">NON-RADIOACTIVE</div>	
NATURE AND QUANTITY OF DANGEROUS GOODS UN Number or identification Number, proper shipping name, Class or Division (subsidiary risk), packing group (if required), and all other required information. UN 2814, Infectious substance, affecting humans(SUSPECTED CATEGORY A INFECTIOUS SUBSTANCE),6.2//1 FIBERBOARD BOX X 10 ml//620			
Additional Handling Information 24/7 EMERGENCY PHONE NUMBER 800-123-4567			
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 KIRSTEN M GALLAGHER/LAB TECH Place and Date LANSING, MI 03/08/2019 Signature KIRSTEN M GALLAGHER (see warning above) 	
8006338253 Emergency Telephone Number			
FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS OR TREATMENT. ADR EUROPEAN TRANSPORT STATEMENT: CARRIAGE IN ACCORDANCE WITH 1.1.4.2.1			

Category B Example With Dry Ice Outer Packaging

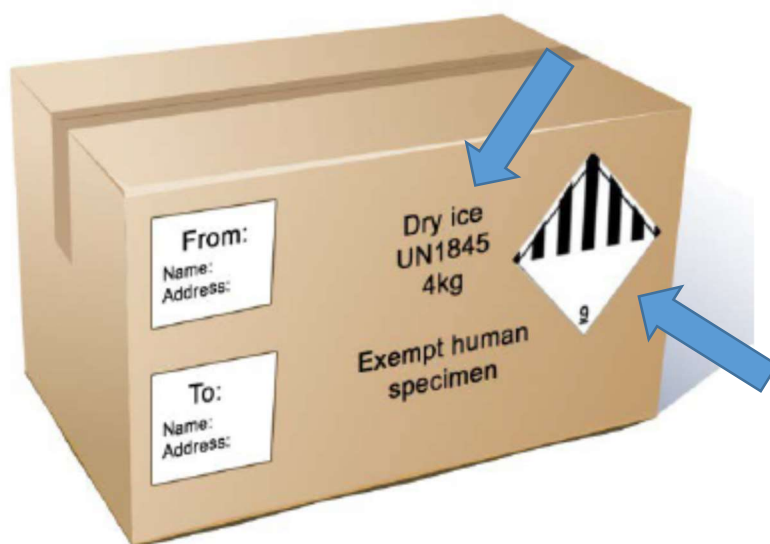
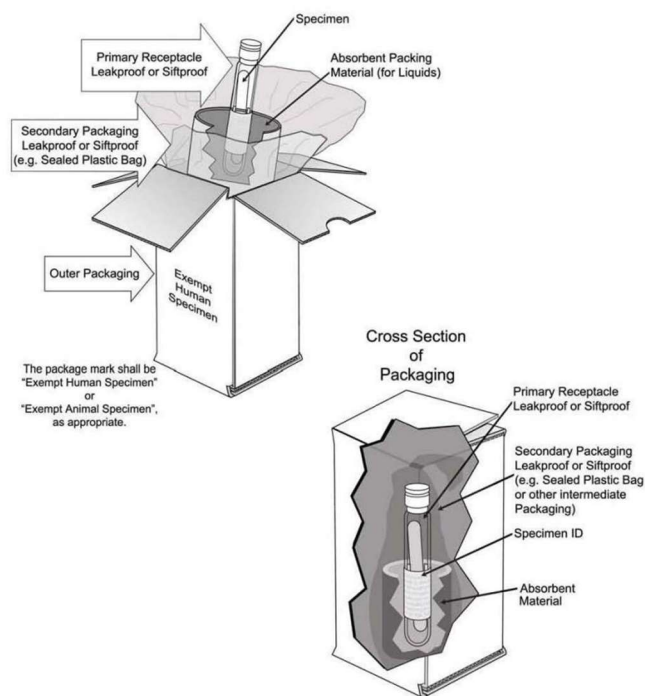


BIOLOGICAL SUBSTANCE CATEGORY B



Do not use these 2 labels if dry ice is not used
(Refer to arrows)

Exempt Human Specimen With Dry Ice Outer Packaging



Do not use these 2 labels if dry ice is not used
(Refer to arrows)