

Infectious substances

Category B

Transport Regulation

Compliance & Packaging



US DOT
PHMSA



Definitions
&
Classification



Packaging
&
Labeling



Packaging
Scenarios



Tara J. Schnell

HazMat/ Dangerous Goods Transportation Training Specialist
Biological Research Safety Training, University of Wisconsin-Madison

Today's Topics



- ✓ Overview of HazMat Transport Regs
- ✓ Infectious Substances Classification
- ✓ Packaging Basics
- ✓ Category B Packaging
- ✓ WSLH Category B Shipping
- ✓ Dry Ice with Category B
- ✓ Specimens with Preservatives
- ✓ Hands-On Practice
 - ✓ Classification & Packaging
 - ✓ Packaging Scenarios

What is HazMat?

- Hazardous Materials are defined as any substance or material that is capable of posing an unreasonable risk to health, safety and property when transported in commerce.
- Called "Dangerous Goods" in the International Air Transport/ Cargo regulations



U.S. Department of Transportation

**Pipeline and Hazardous Materials
Safety Administration**



ICAO

Nine Classes of Hazardous Materials

Class 1: Explosives

Divisions: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6



Class 6: Toxic and Infectious Substances

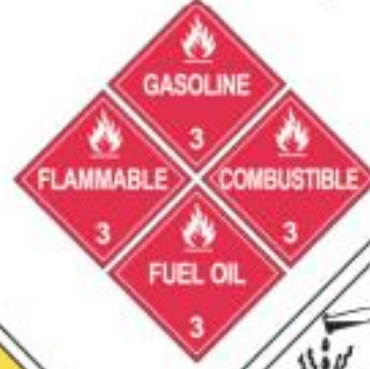
Class 2: Gases

Divisions: 2.1, 2.2, 2.3



Class 7: Radioactive

Class 3: Flammable Liquid and Combustible Liquid



Class 8: Corrosive



Class 4: Flammable Solid, Spontaneously Combustible, and Dangerous When Wet

Divisions 4.1, 4.2, 4.3



Class 9: Miscellaneous



Class 5: Oxidizer and Organic Peroxide

Divisions 5.1, 5.2



Dangerous



Revised 04/13

Federal Motor Carrier
Safety Administration

U.S. Department of Transportation
www.fmcsa.dot.gov

Nine Regulated Hazard Classes



Classification:

CFR49 USDOT-PHMSA

Section 173.134 Class 6, *Division 6.2 Infectious Substances*

Material known or reasonably expected to contain a pathogen

Pathogen is a microorganism that can cause disease in humans and/or animals:

- Bacteria
- Viruses
- Parasites
- Fungi
- Prions proteinaceous infectious particles
- other agents

Must be assigned one of these IDs appropriate:

UN2814

UN2900

UN3373

UN3291

Infectious Substances Affecting Humans

Infectious Substances Affecting Animals

Category B

Category C

Category D

Category E

Category F

Category G

Category H

Category I

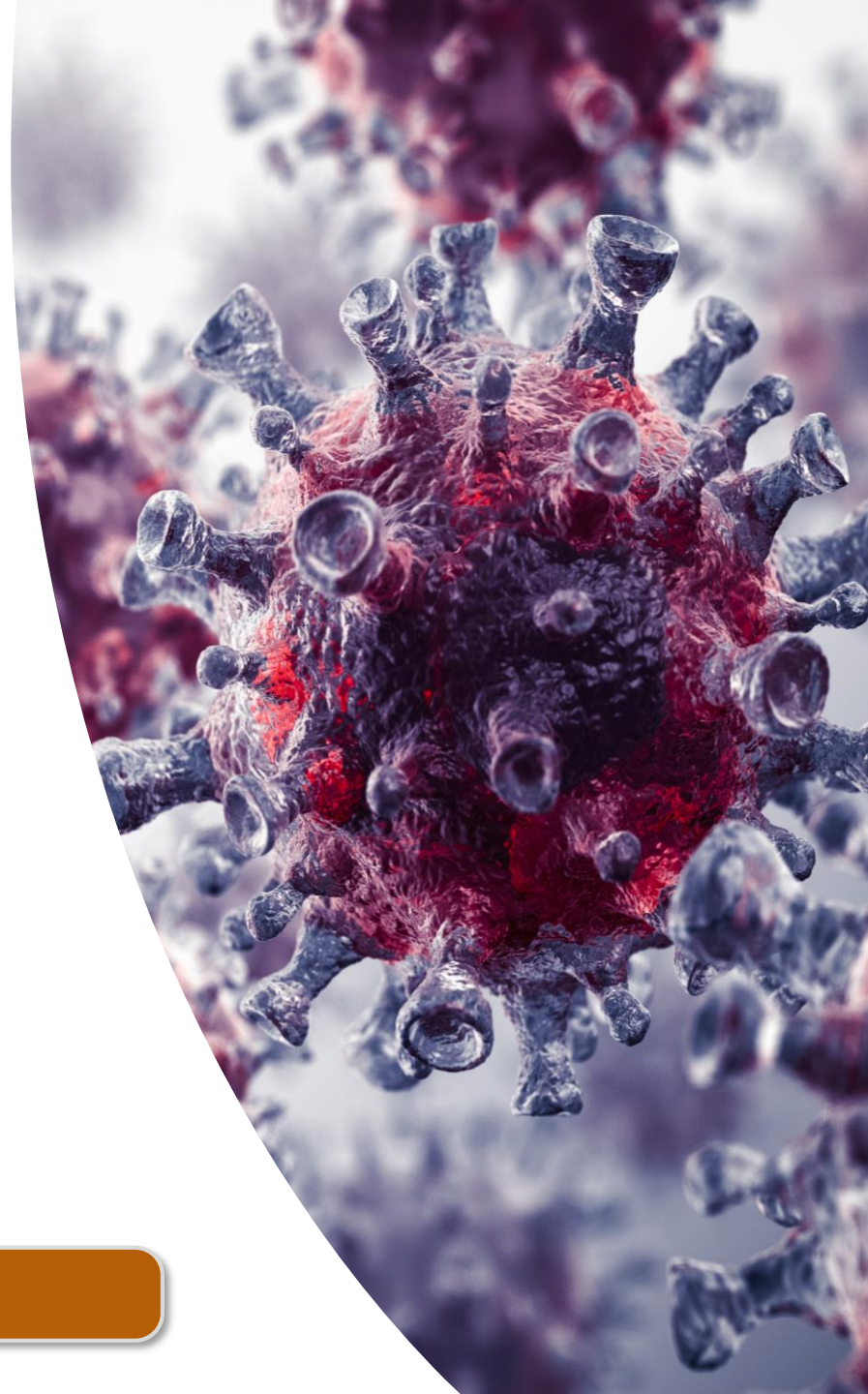
Category J

Category K

Category L

Category M

Category N



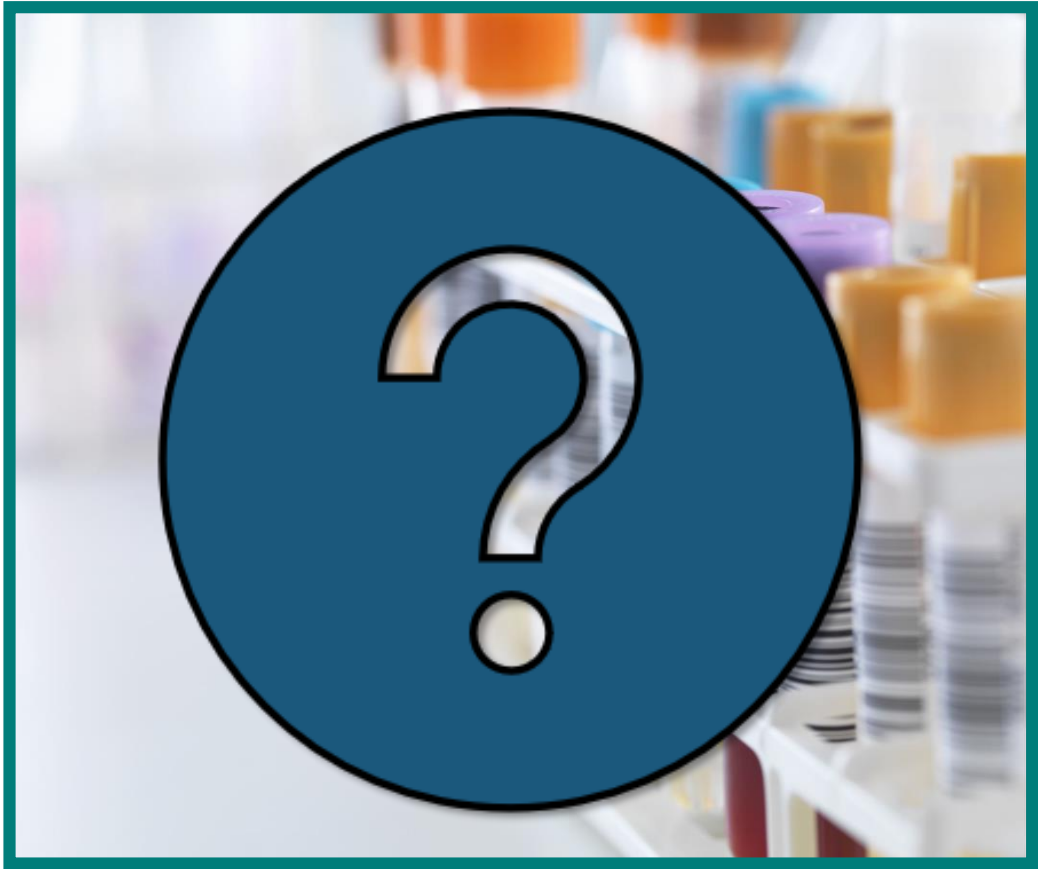
Infectious Substances subgroups

Category A

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.

Category B

Infectious substance that is 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.



UN number and Proper Shipping Name (PSN)

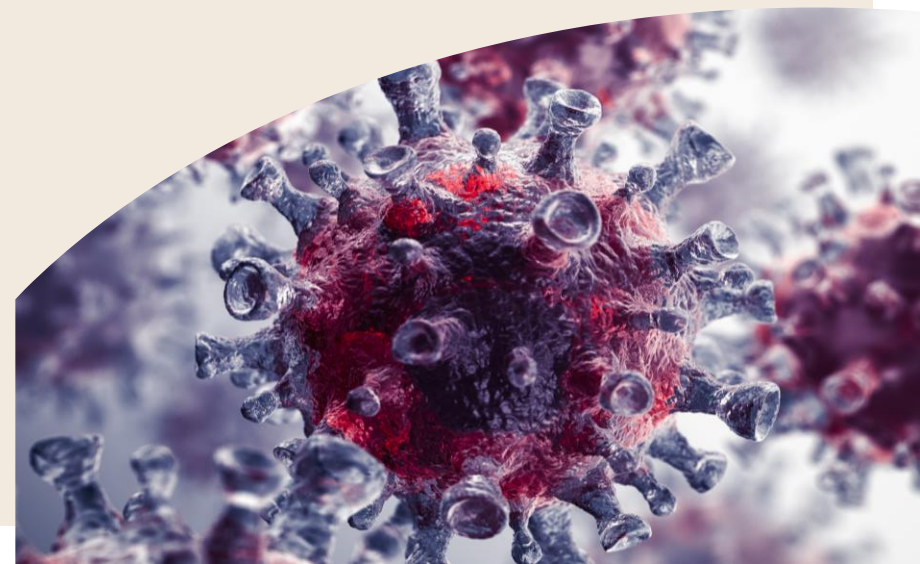
Category A

UN2814 "Infectious substance affecting humans"
(humans only, humans and animals)

UN2900 "Infectious substance affecting animals"
(animals only)

Category B

UN3373 "Biological Substance, Category B"



Category A

Highest consequence
pathogens

Majority will also require
permits, customs documents

Exposure/Release in
Transport = FULL HazMat
Response



Category A Challenges



- ✓ Training & Proficiency Requirement
 - Only trained persons classify, package, papers, ship
 - Renew every 24 months
 - Maintain knowledge
- ✓ Compliance
 - Full Federal DOT regulations for Hazardous Materials
 - Document retention rules
 - Subject to inspections & document audits
 - International regulations are separate!
- ✓ Noncompliance Penalties



Ralph, this specimen needs to be shipped off for testing!

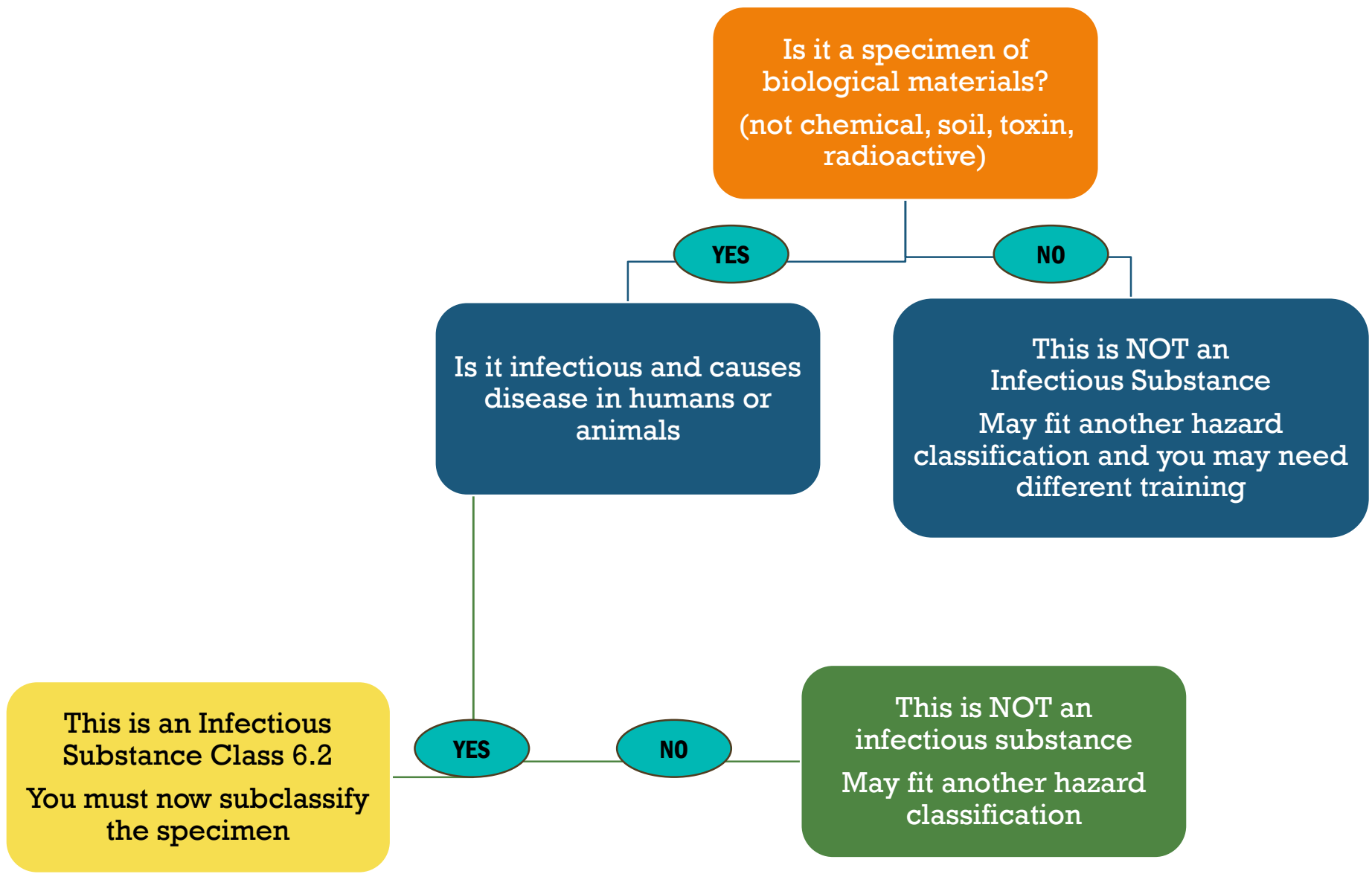
Gee, Sam, where on earth do we find out how to do that?

Wait, we did this training...



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Ralph, We have an infectious substance. How do we package this thing?

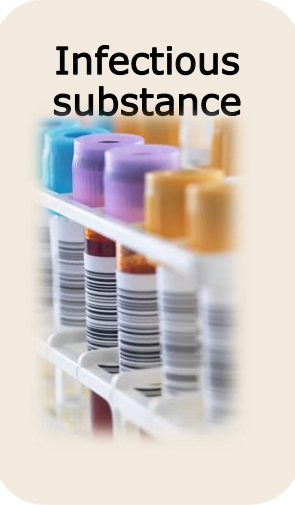
Sam, if it's Category B we can package it, easily.

How can we tell if it is A or B?

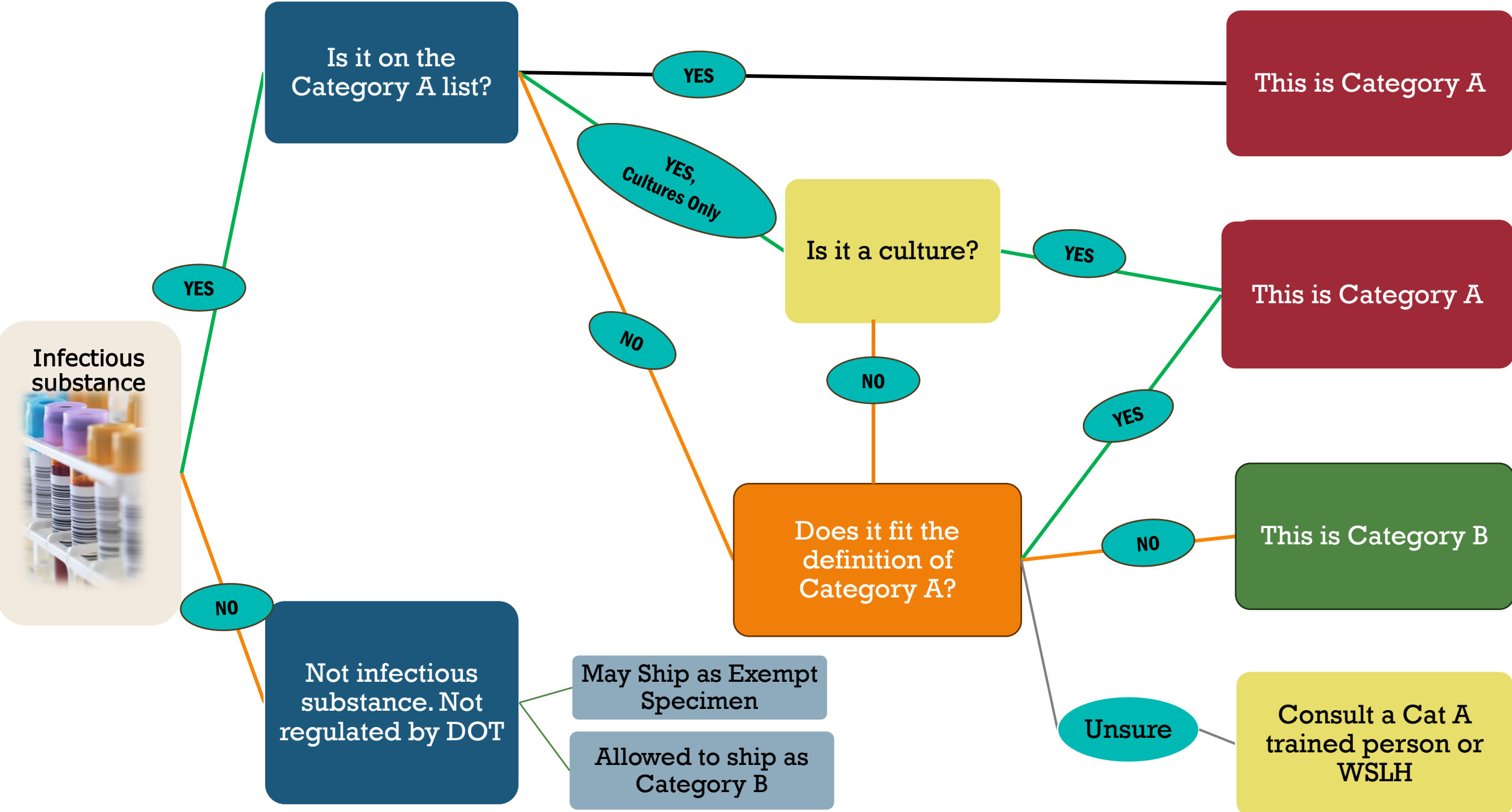


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Infectious substance



Is it on the Category A list?

YES

This is Category A

YES, Cultures Only

Is it a culture?

YES

This is Category A

NO

Does it fit the definition of Category A?

NO

This is Category B

YES

NO

Not infectious substance. Not regulated by DOT

May Ship as Exempt Specimen

Allowed to ship as Category B

NO

Unsure

Consult a Cat A trained person or WSLH

Category A Example List

Source: *Transporting Infectious Substances Safety*, www.phmsa.dot.gov

UN2814 Infectious substances affecting humans

Bacillus anthracis (cultures only)

Brucella abortus (cultures only)

Brucella melitensis (cultures only)

Brucella suis (cultures only)

Burkholderia mallei–Pseudomonas mallei–Glanders (cultures only)

Burkholderia pseudomallei–Pseudomonas pseudomallei (cultures only)

Chlamydia psittaci–avian strains (cultures only)

Clostridium botulinum (cultures only)

Coccidioides immitis (cultures only)

Coxiella burnetii (cultures only)

Crimean-Congo haemorrhagic fever virus

Dengue virus (cultures only)

Eastern equine encephalitis virus (cultures only)

Escherichia coli, verotoxigenic (cultures only)

Ebola virus

Flexal virus

Francisella tularensis (cultures only)

Guanarito virus

Hantaan virus

Hantavirus causing hemorrhagic fever with renal syndrome

Hendra virus

Hepatitis B virus (cultures only)

Herpes B virus (cultures only)

Human immunodeficiency virus (cultures only)

Highly pathogenic avian influenza virus (cultures only)

Japanese Encephalitis virus (cultures only)

Junin virus

Kyasanur Forest disease virus

Lassa virus

Machupo virus

Marburg virus

Monkeypox virus

Mycobacterium tuberculosis (cultures only)

Nipah virus

Omsk haemorrhagic fever virus

Poliovirus (cultures only)

Rabies virus (cultures only)

Rickettsia prowazekii (cultures only)

Rickettsia rickettsii (cultures only)

Rift Valley fever virus (cultures only)

Russian spring-summer encephalitis virus (cultures only)

Sabia virus

Shigella dysenteriae type 1 (cultures only)

Tick-borne encephalitis virus (cultures only)

Variola virus

Venezuelan equine encephalitis virus (cultures only)

West Nile virus (cultures only)

Yellow fever virus (cultures only)

Yersinia pestis (cultures only)

UN 2900 Infectious substances affecting animals

African swine fever virus (cultures only)

Avian paramyxovirus Type 1–Velogenic Newcastle disease virus (cultures only)

Classical swine fever virus (cultures only)

Foot and mouth disease virus (cultures only)

Goatpox virus (cultures only)

Lumpy skin disease virus (cultures only)

Mycoplasma mycoides–Contagious bovine pleuropneumonia (cultures only)

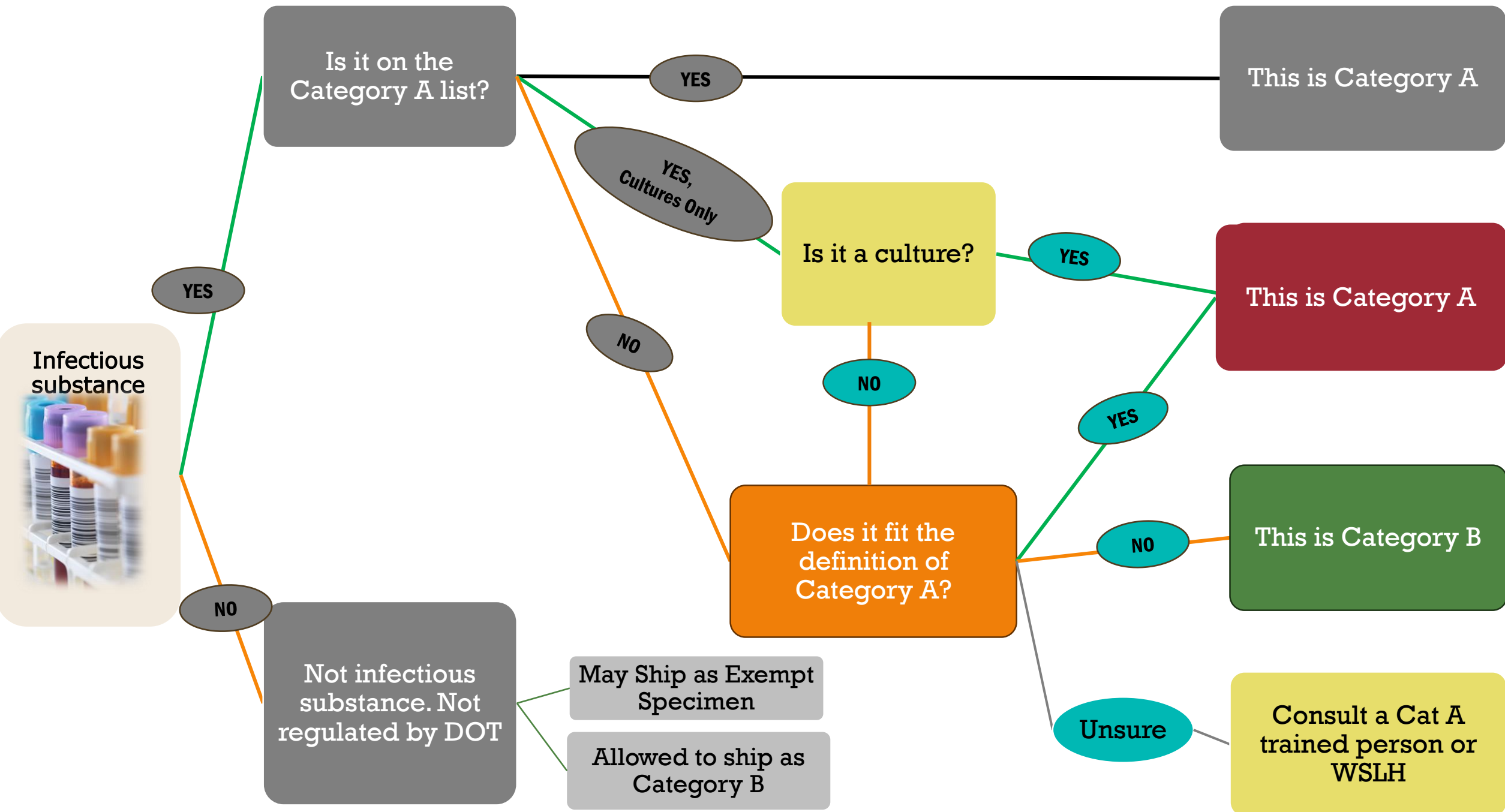
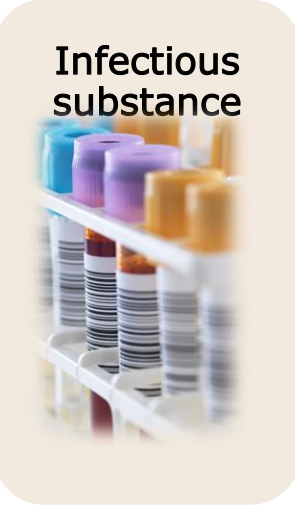
Peste des petits ruminants virus (cultures only)

Rinderpest virus (cultures only)

Sheep-pox virus (cultures only)

Swine vesicular disease virus (cultures only)

Vesicular stomatitis virus (cultures



UN number and Proper Shipping Name (PSN)

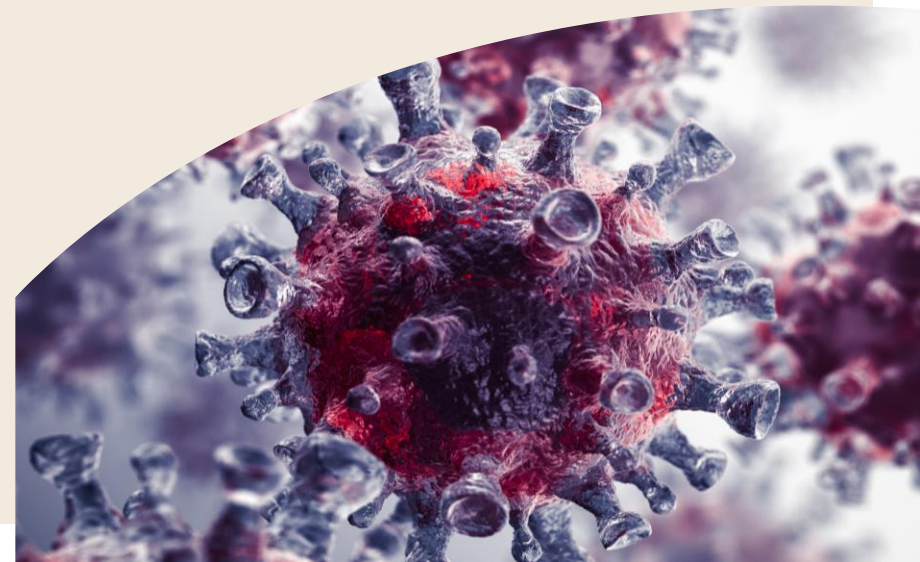
Category A

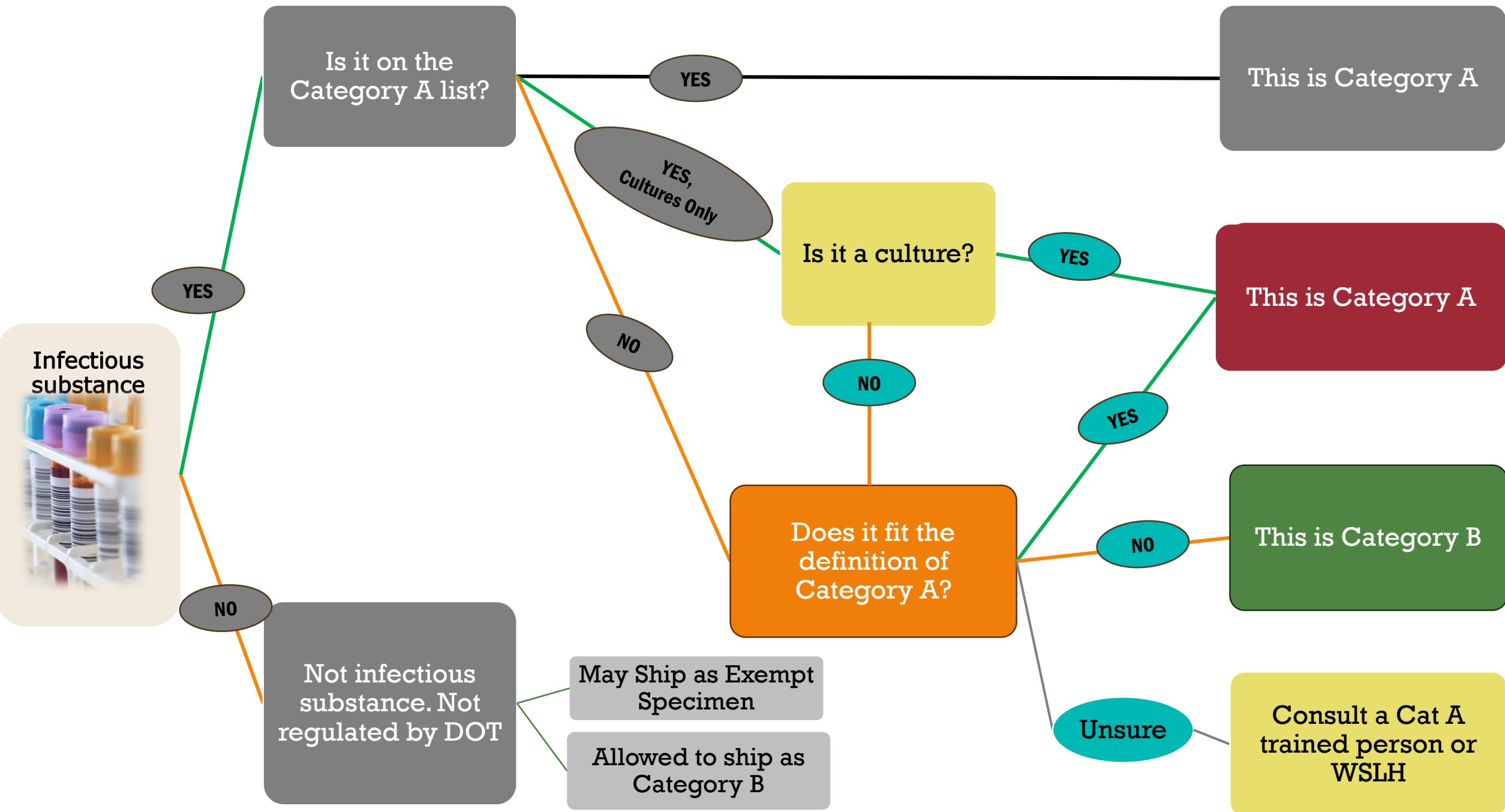
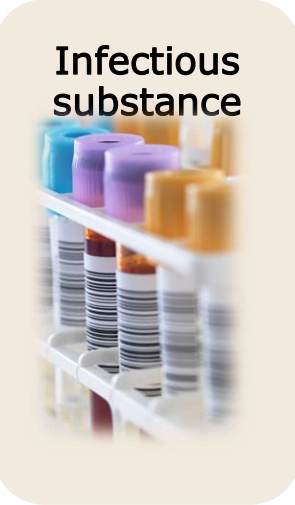
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UN3373 "Biological Substance, Category B"





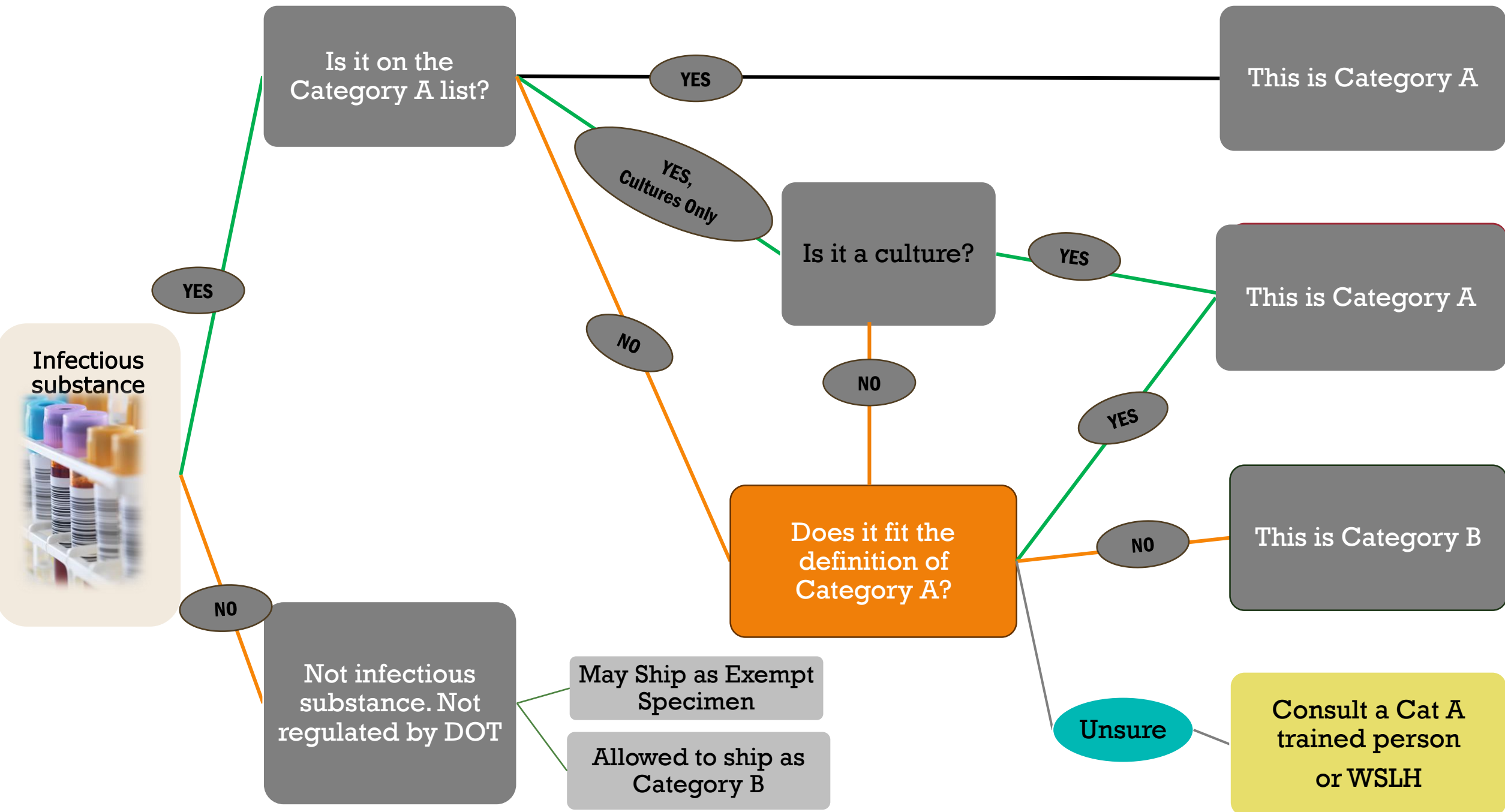
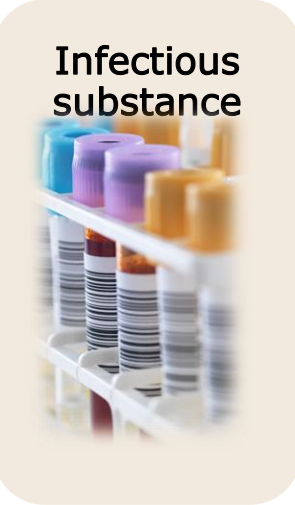


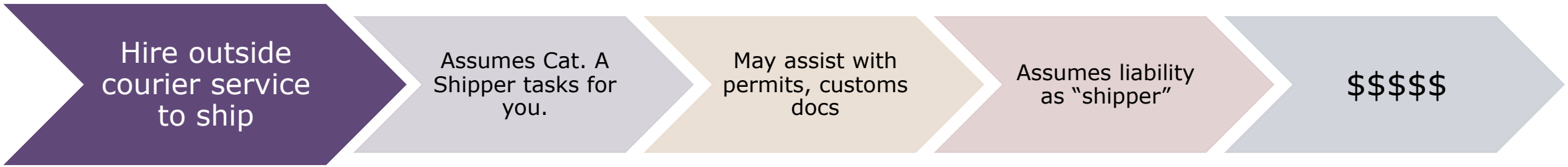
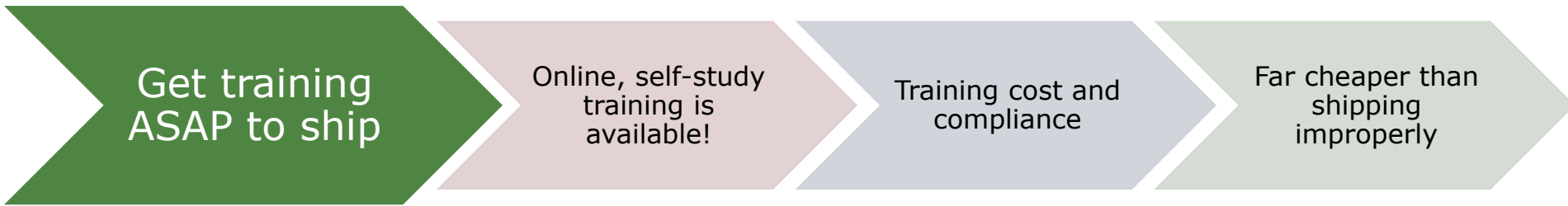
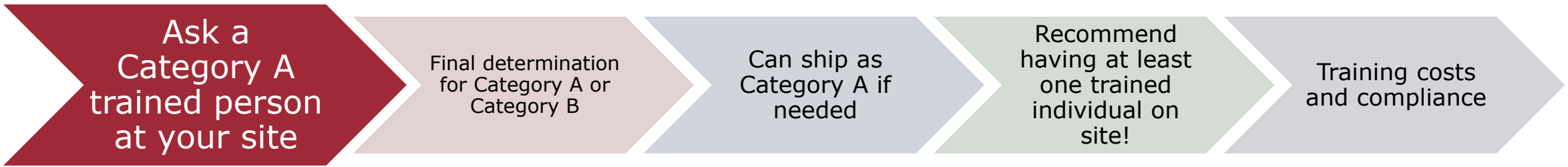
Sam, maybe if we aren't sure we should ship Category A all the time.

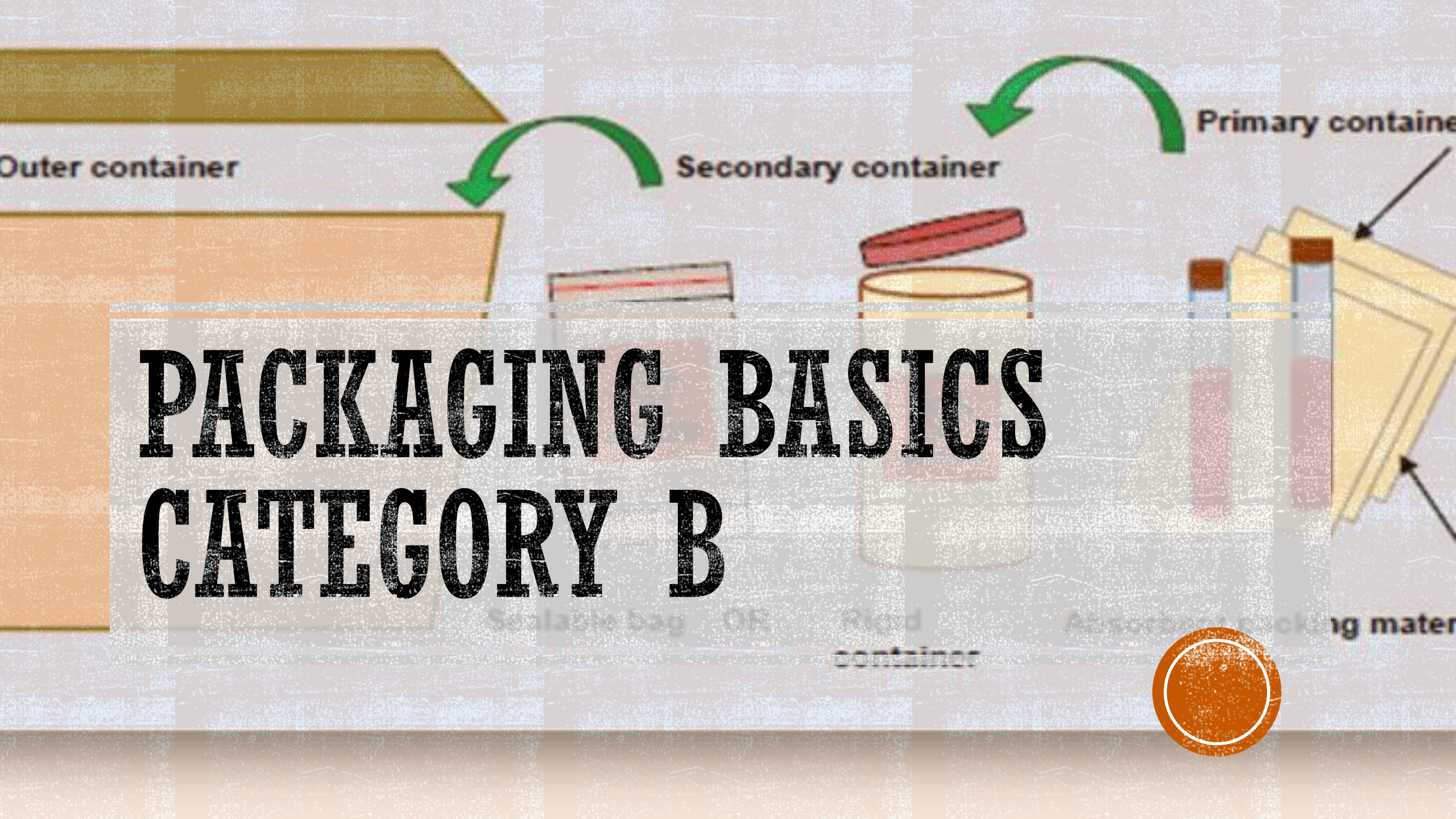
Ralph, If we aren't sure it is better to ask somebody, but who?

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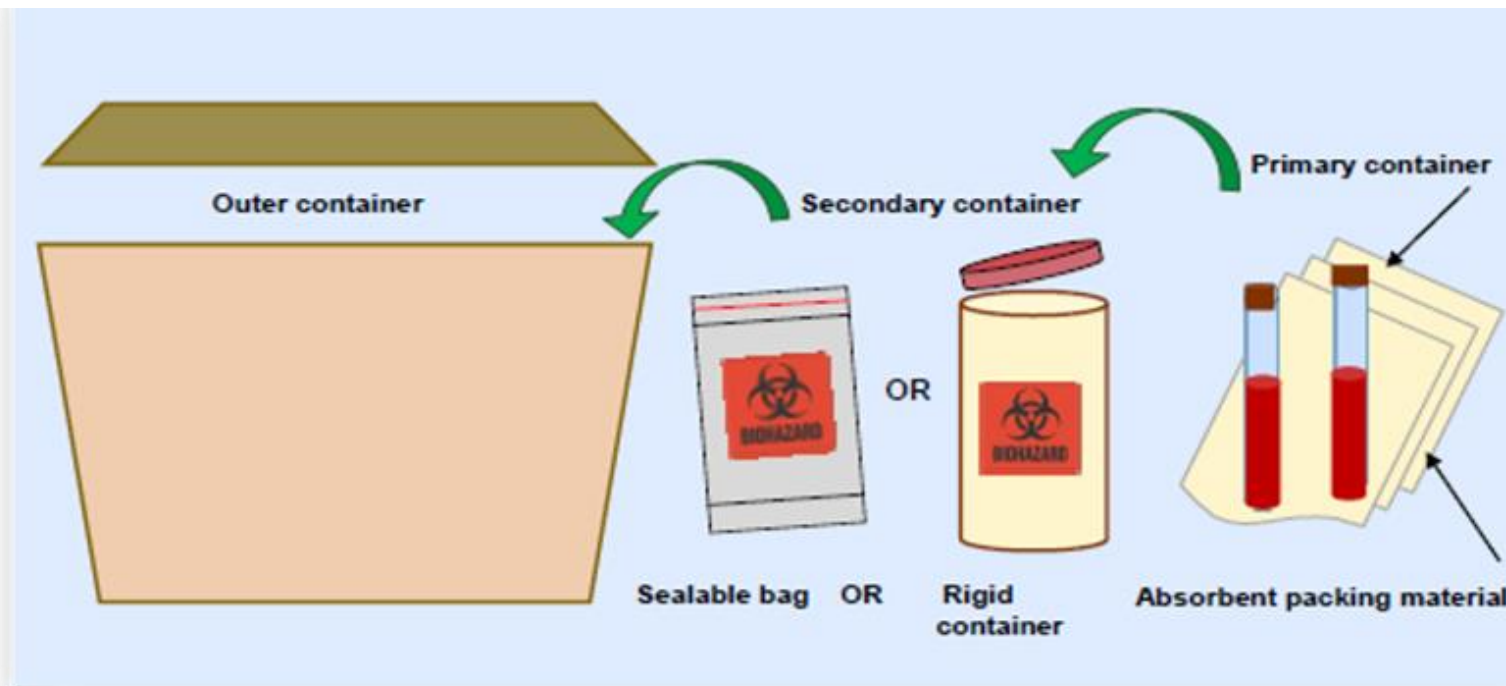




PACKAGING BASICS

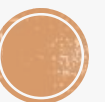
CATEGORY B



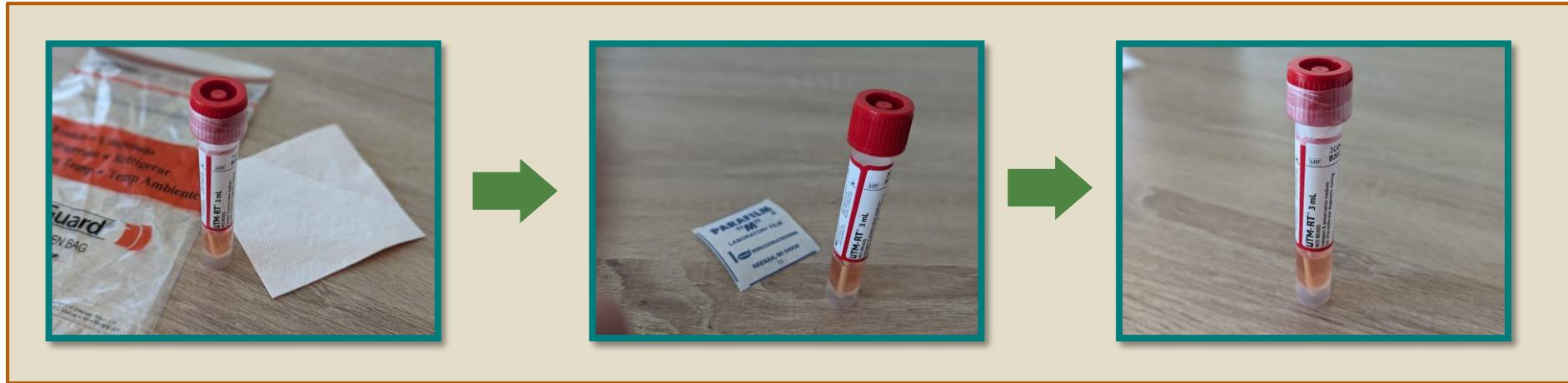


Packaging Basics Category B

- **3-Layer Packaging**
 - Leak-proof Inner = Primary + Secondary containers
 - Secure Outer container
- **Durability standards matter**
 - Test package to DOT standard OR
 - Purchase kits with secondary & outer together
- **Packaging can be re-used**
- Different packaging air transport or international



Inner packing



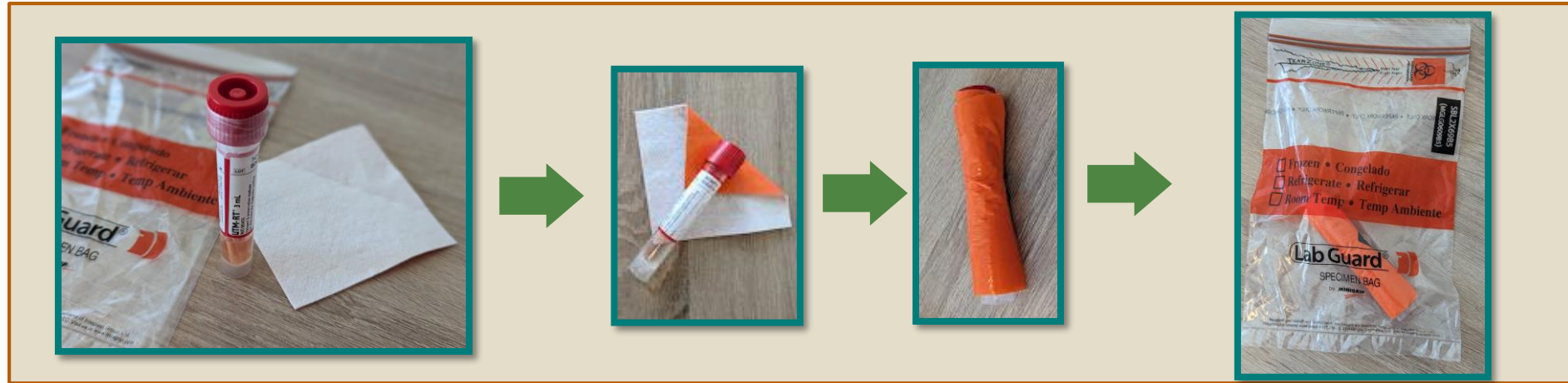
Primary Container

No leaks under normal transport conditions

- ✓ Screw-cap containers
 - ✓ If not leakproof, secure with parafilm (WSLH specimens no parafilm!)
 - ✓ Prevent caps hitting
 - ✓ Add an extra layer
-
- Ground transport: some weather, altitude may affect specimen
 - Air transport: withstand air pressure, temp changes



Inner packing



Secondary Container

No leaks under transport conditions

Ground:

- ✓ Zipper closure plastic bags
- ✓ Screw-cap containers

Air:

- ✓ Zipper closure plastic bags
- ✓ Screw-cap containers

Add cushioning & absorbent material

- ✓ Prevent shifting, breakage, caps loosening
- ✓ Absorbent required for liquids or frozen liquids
- ✓ Enough to absorb entire specimen contents



To Wrap or NOT To Wrap?



Adding Absorbent & Cushioning

Wrapping a specimen is good practice when:

- ✓ More than one specimen in the secondary container
- ✓ Recipient is OK with the practice
- ✓ Small number of tubes in shipment
- ✓ Simple procedure
 - ✓ Single wrap layer
 - ✓ minimal tape
 - ✓ add extra padding in secondary or around secondary container to prevent shifting

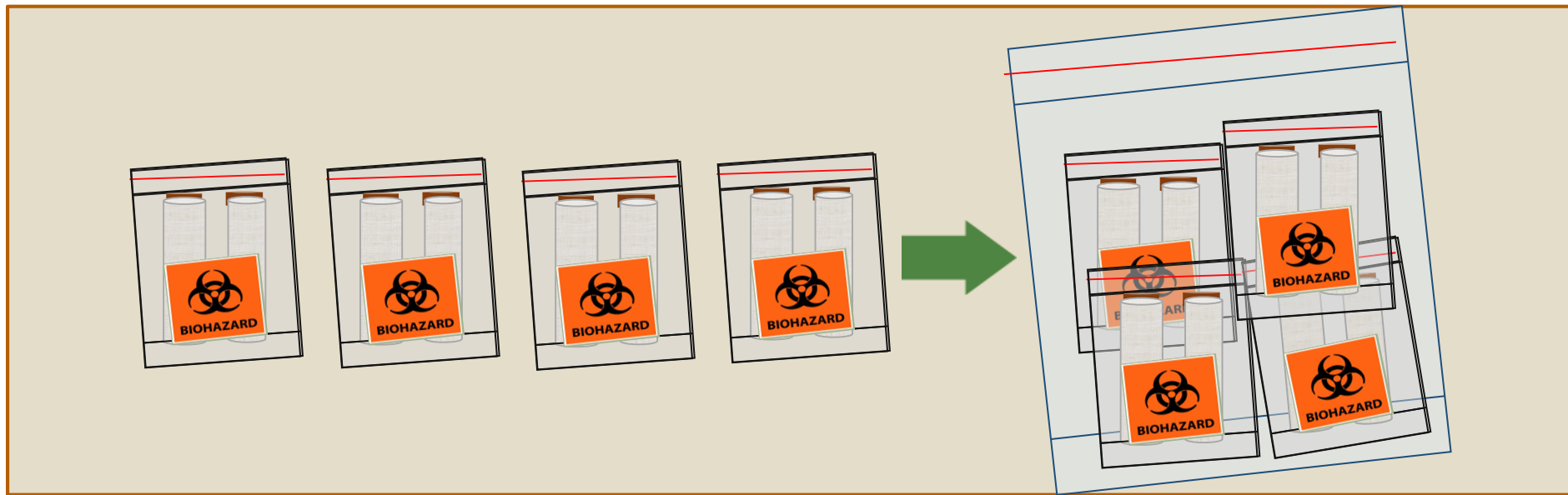
When NOT to wrap each specimen:

- ✓ Recipient does NOT want them wrapped [WSLH]
- ✓ Several specimens in the shipment and it would be cumbersome to pack or unpack
- ✓ Only one specimen per secondary container

What to do instead:

- ✓ add extra padding in or around secondary container to prevent shifting
- ✓ Bundle multiple secondary contains together then pack into outer container with padding





Bundling for Large Quantities

Combine multiple secondary containers prior to packing into outer container

- ✓ Useful when shipping large quantities, small specimen containers or specimens of differing sizes
- ✓ Easier to:
 - ✓ pack and unpack
 - ✓ clean-up if outer box breaks - Pick up 24 small biohazard-marked zip bags vs. pick up 3 large bags containing zip bags

What can be used?

- ✓ Large zip bags, twist-tie bag, plastic canister
 - ✓ Don't use red bags, autoclave bags
- ✓ Needs a secure closure to prevent spill
 - ✓ Does not need to be leak-proof
- ✓ Disinfect exterior, just like secondary container
- ✓ Visible biohazard label (clear or add biohazard label)
- ✓ Multiple bundles OK - Must fit in outer box

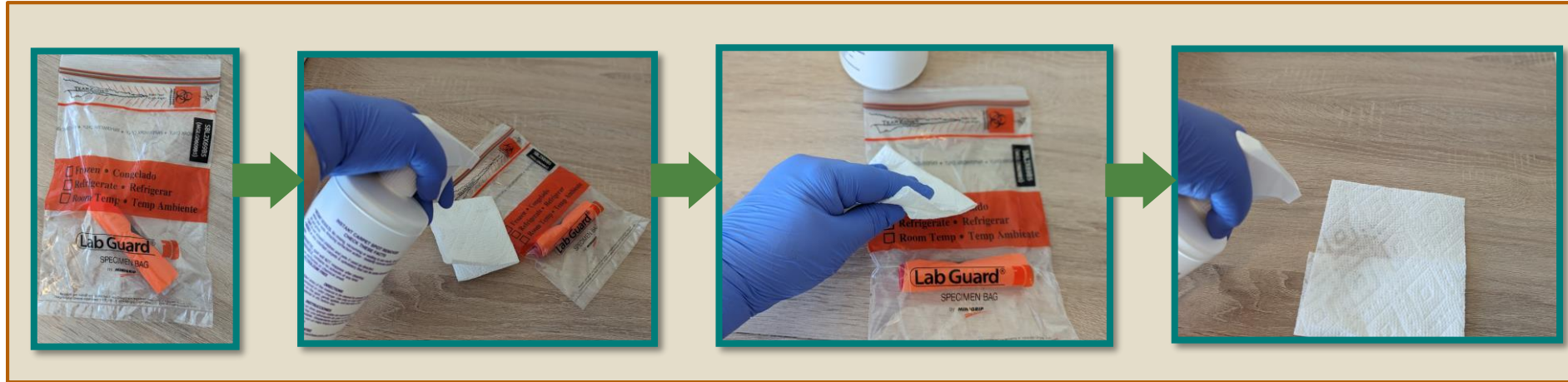


OSHA Biohazard Label

- Typically, on secondary container
- Complies with OSHA BBP for human specimen containers
- Hazard communication to recipient
- Clear communication if outer package breaks in public area
- Why not on outer package?
- Biosecurity concerns
- Not necessary for transport communication
- Conveys inaccurate message to bystanders



Close it. Clean it. Change it.



- ✓ Close the secondary container
- ✓ Disinfect the exterior
- ✓ Disinfect work surface or move to clean area
- ✓ Change or remove your PPE

Remaining package elements **MUST** stay clean enough to handle with bare hands (without PPE)



Outer Package



Rigid container (e.g., cardboard, plastic)



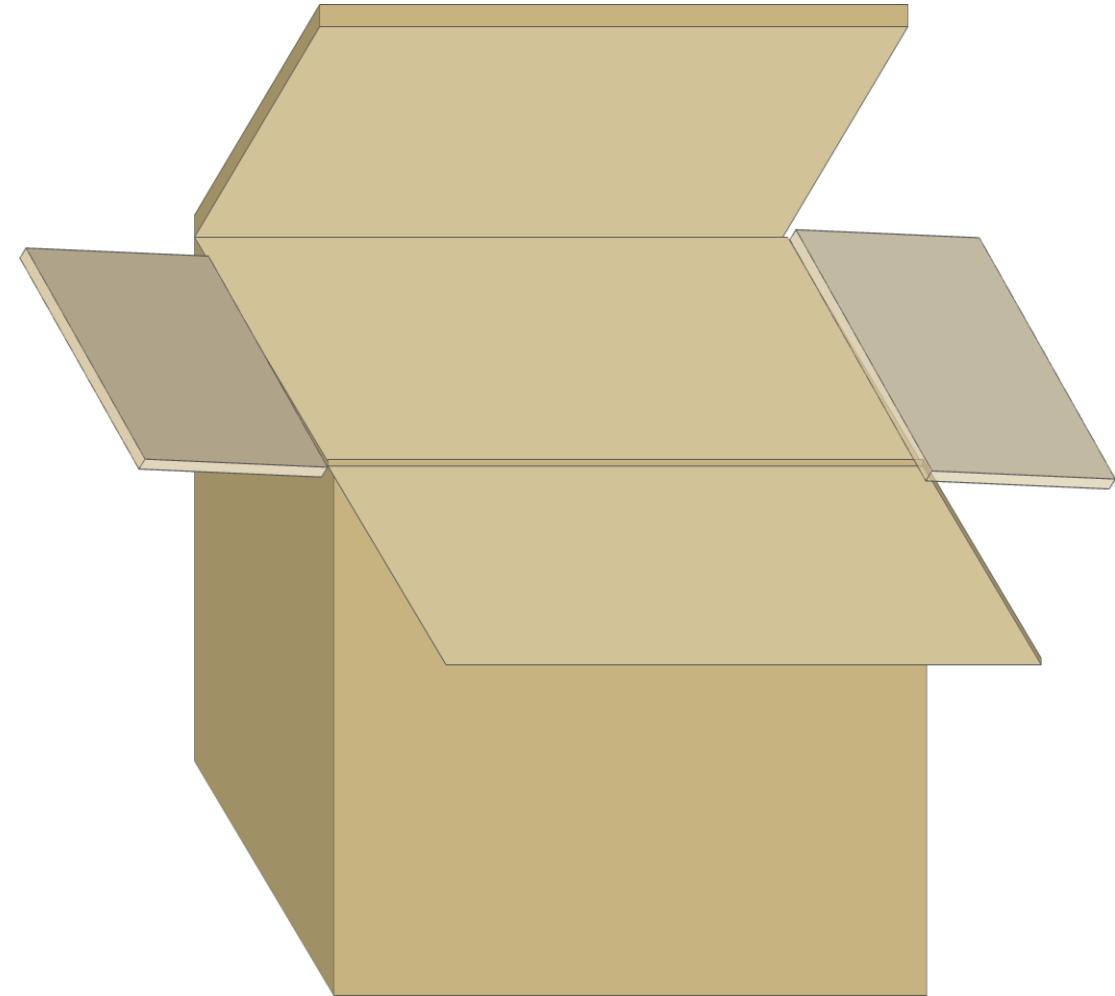
Compatible with secondary container to meet durability standards for Category B
Test or purchase a kit!



Secure Closure



UN#, PSN, To/From Addresses, Responsible person



WSLH Packaging is compliant!



Labels & Markings



UN 3373 Diamond
(Replaces a hazard diamond)



PSN: Biological Substance, Category B



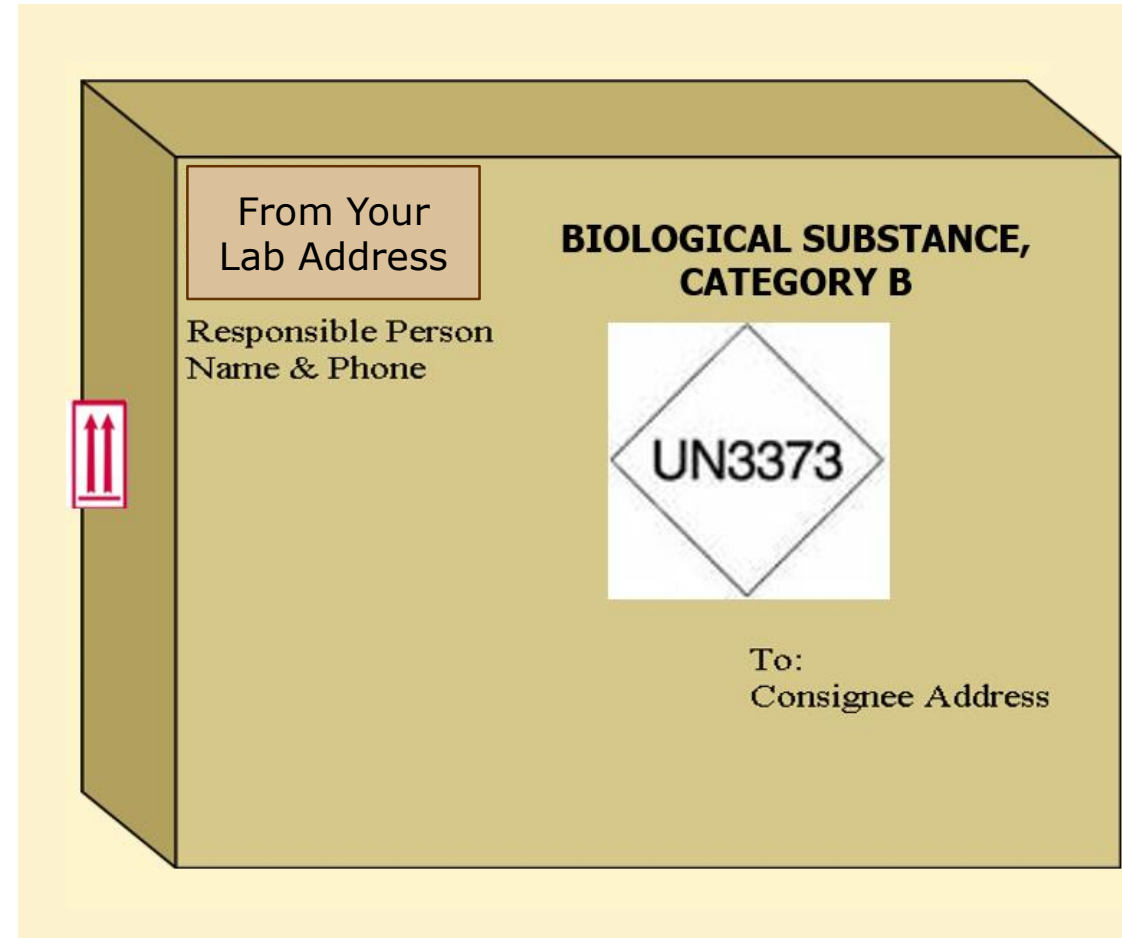
To Address
May be printed or hand-written



From Addresses
May be printed or hand-written



Responsible Person Name & Phone
(on box or paperwork)



WSLH Packaging is compliant!



WSLH Labels & Markings



UN 3373 Diamond
(Replaces a hazard diamond)



PSN: Biological Substance, Category B



To Address
May be printed or hand-written



From Addresses
May be printed or hand-written



Responsible Person Name & Phone
(on box or paperwork)



Category B With Dry Ice Packing



Same Category B primary container



Secondary container must be compatible with dry ice



Secondary & outer containers must function together to meet Category B durability standards
Test or purchase a kit!



Don't use dry ice as packing material to stabilize secondary container



Close Styrofoam box and secure (1-2 pieces of tape)
DO NOT SEAL AIR-TIGHT



WSLH Packaging is compliant!



Category B With Dry Ice Labels & Markings



All Category B labels & markings
To/ From Addresses



PSN: Dry Ice OR
Carbon Dioxide, solid



UN 1845



Quantity of dry ice in package (kg)



Responsible Person Name & Phone
(on box or paperwork)



WSLH Packaging is compliant!



Dry Ice – Ground Only, US DOT

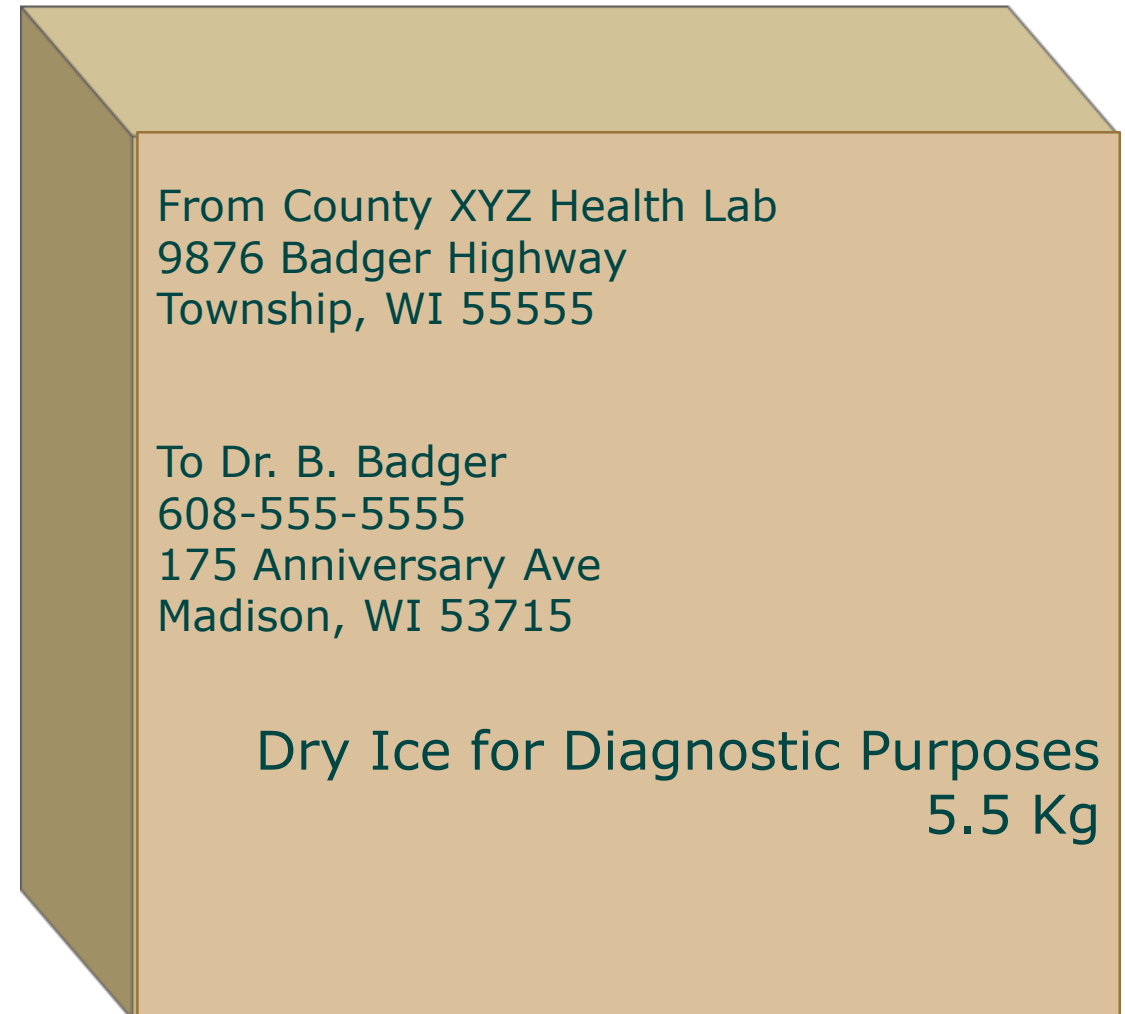
Diagnostic or medical treatment purpose

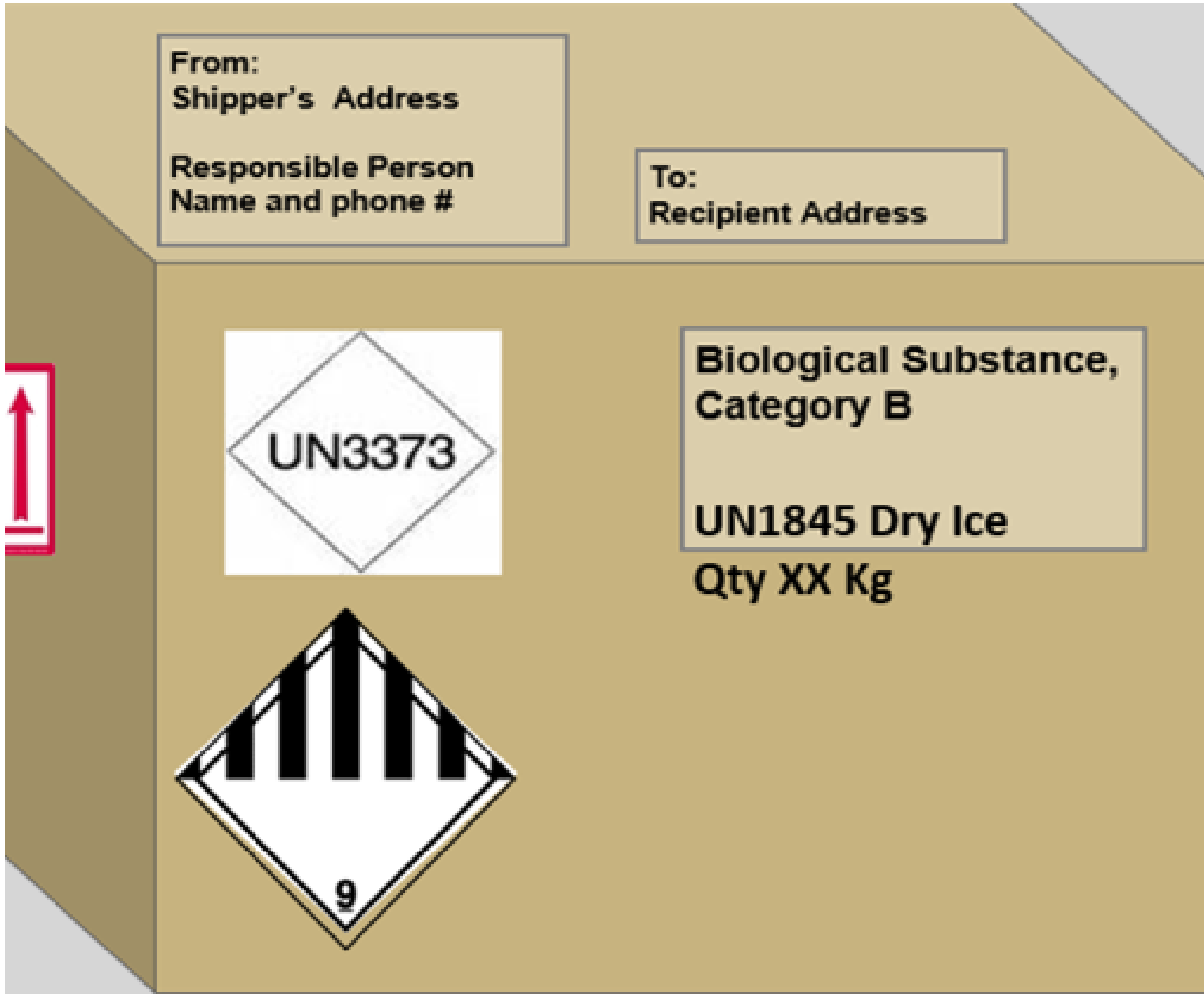
Mark the outer package with:

- "Dry Ice for Medical Purposes" or "Dry ice for Diagnostic Purposes"
- Quantity of dry ice contained in the package
- No other paperwork is required

Not Required:

- No HazMat Shipping Papers
- No UN number
- No Class 9 Diamond label
- No package durability standard





Box Exterior Rules

All labels must be on a single side or adjacent sides

All hazard labels must be on a single side

Cannot overlap, obscure or cover a required label

All diamonds must be diamonds

Orientation Arrows recommended for liquid shipments (cannot obscure if already on box)

Labels must be pristine & intact. White space must remain white.

Box must be in good condition

Not enough room?
GET A BIGGER BOX

WSLH Packages: All On One Side

Category B
they all fit on an end



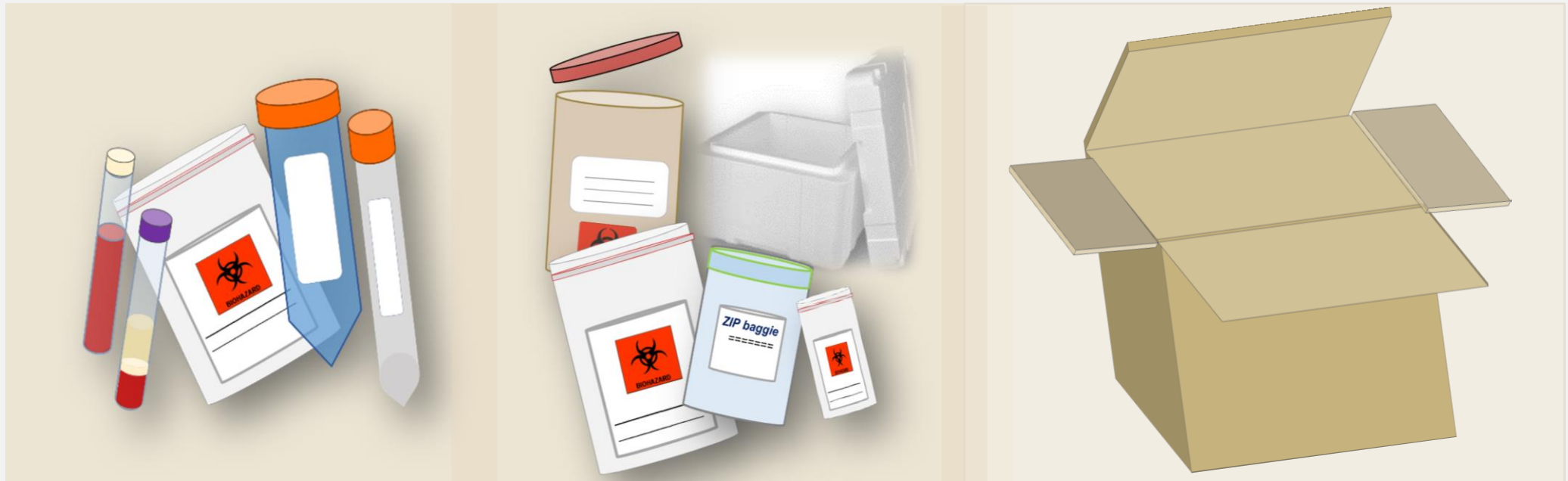
Category B with Dry ice
They all fit all on the top



Resources

Packaging Materials

- Recipient Lab
- Fisher
- VWR
- Saf-T-Pak
- LabelMaster
- ULine



Category B Packing Info

USPS

- Infectious Substances Category B
- <https://postalpro.usps.com/product-classification/infectious-substances>

FedEx

- How to Ship Hazardous Materials
- <https://www.fedex.com/en-us/service-guide/hazardous-materials/how-to-ship.html>

UPS

- Shipping Hazardous Materials
- <https://www.ups.com/us/en/support/shipping-support/shipping-special-care-regulated-items/hazardous-materials-guide.page>

US DOT
Guidance

- Transporting Infectious Substances Safety Guidance
- <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/Transporting-Infectious-Substances-Safely.pdf>





Preservatives with Infectious Substances

Special allowance for specimens in preservative solutions

- Formaldehyde solutions $\leq 10\%$ (formalin usually OK)
- Isopropanol
- Ethanol
- Not regulated: Agar, blood agar, nutritive solutions, anticoagulants
- Other haz chemicals in solution may require different training

Specimen preparation

- 30 mL per specimen container
- Screw-top lids, secure with parafilm or tape
- Inside two layers of heat-sealed plastic bag
- No more than 1.0 ml per package

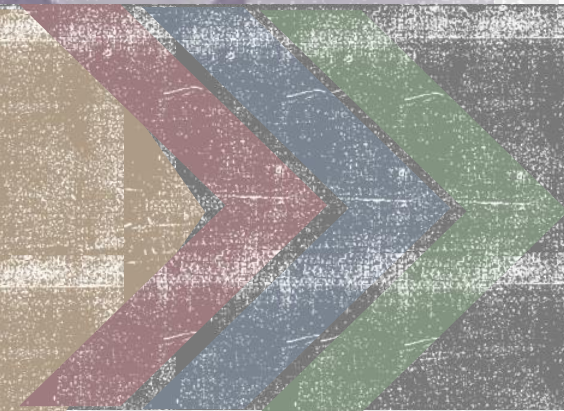
Add to box & paperwork:

"Scientific research specimens, 49 CFR 173.4b applies."



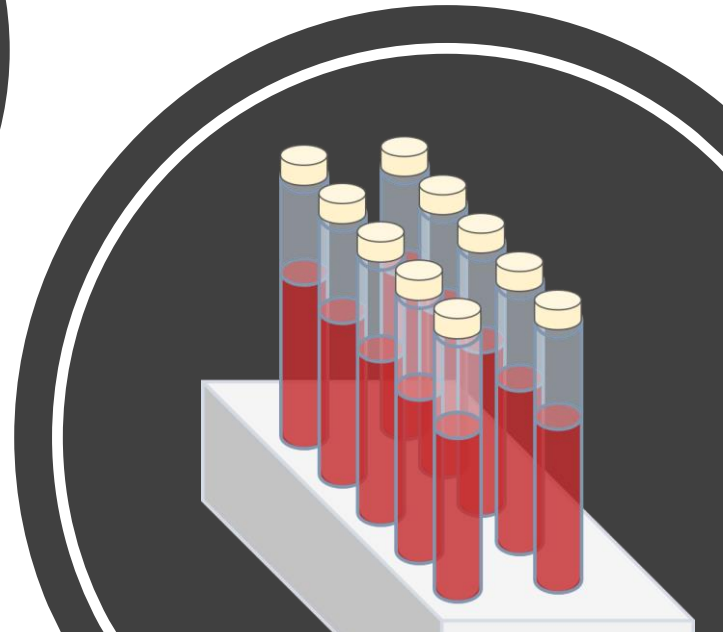
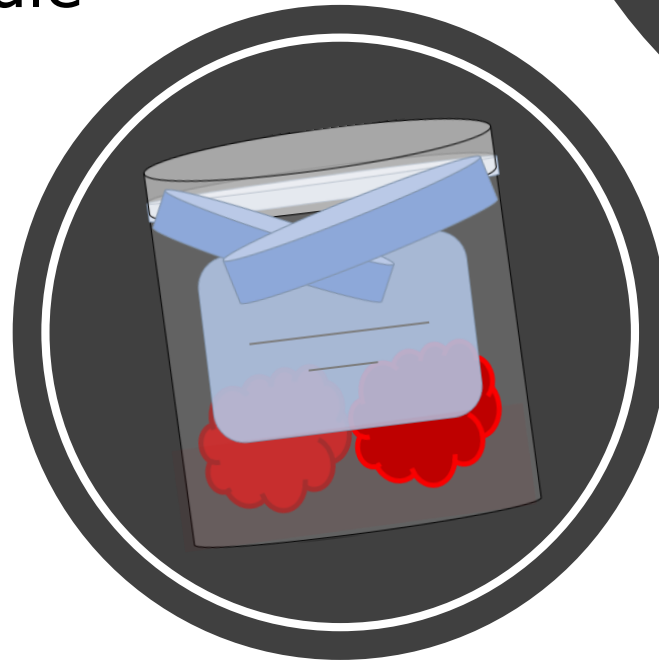
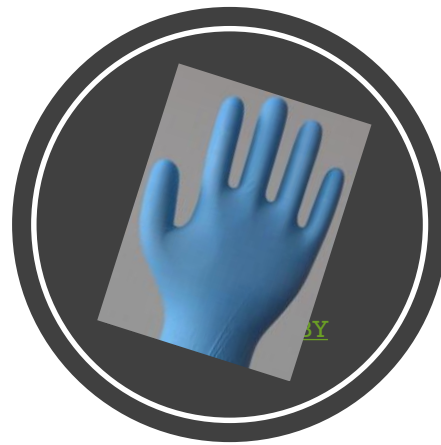


Packaging Practice



Primary Container Options?

- ✓ Conical tubes
- ✗ Syringe with taped capped needle
- ✗ Twist-close sample bags
- ✓ Screw-cap vials
- ✓ Snap-cap microtubes
- ✗ Agar plates, taped closed
- ✗ Slide-zip baggies
- ✗ Inverted nitrile glove
- ✓ ETDA purple-top tubes





DO'S AND DON'TS

- ❌ Diamond labels must be fully intact
- ❌ Diamond labels must be oriented as diamonds
- ❌ Labels & markings should be organized and oriented in the same reading direction
- ❌ Old labels must be completely obscured if not relevant to shipment
- ❌ No Responsible person info
- ✅ Hand-written markings must have lettering at least 6 mm tall or greater
- ✅ Hand-writing must be clearly legible
- ✅ All labels describing the hazard must be on the same side



Sender Address

WISCONSIN STATE LAB OF HYGIENE
CDD SPECIMEN RECEIVING
2601 AGRICULTURE DR
MADISON WI 53718

LABEL MASTER
L8908
UN3373

BIOLOGICAL SUBSTANCE
CATEGORY B

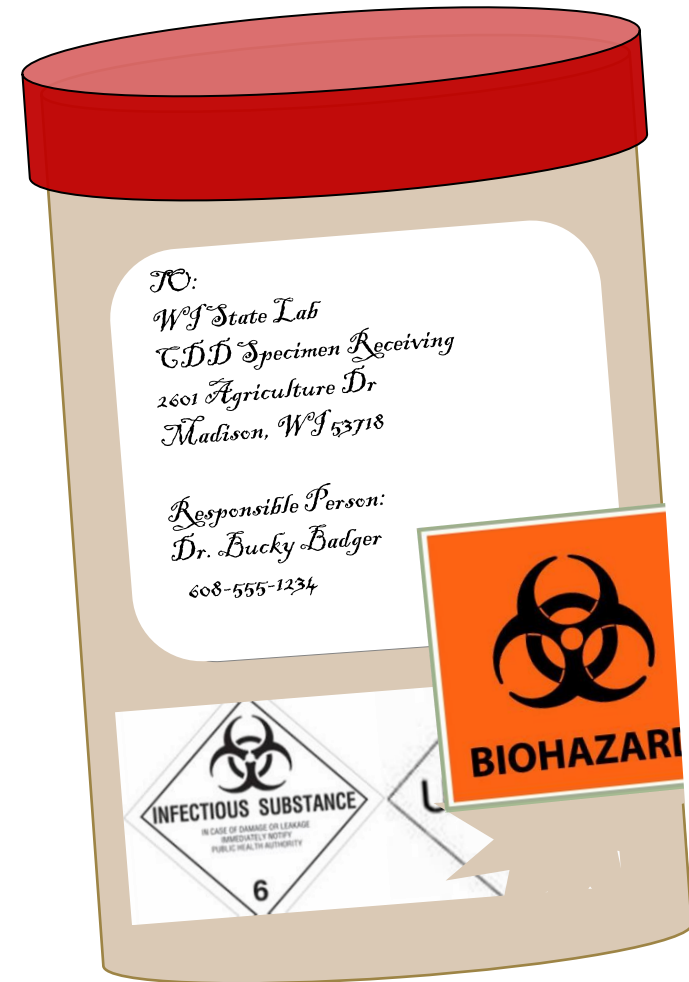
54819

EXEMPT HUMAN SPECIMEN

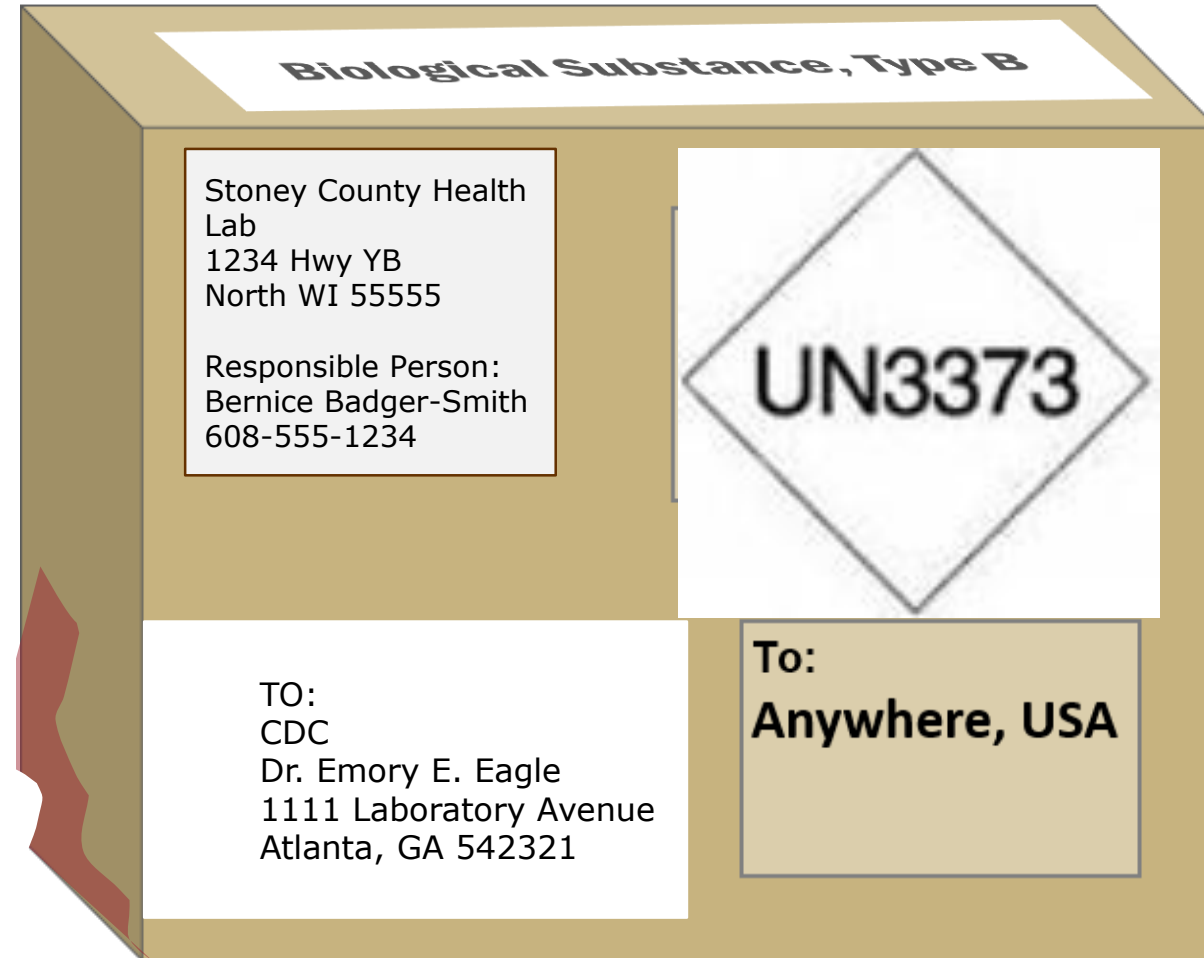
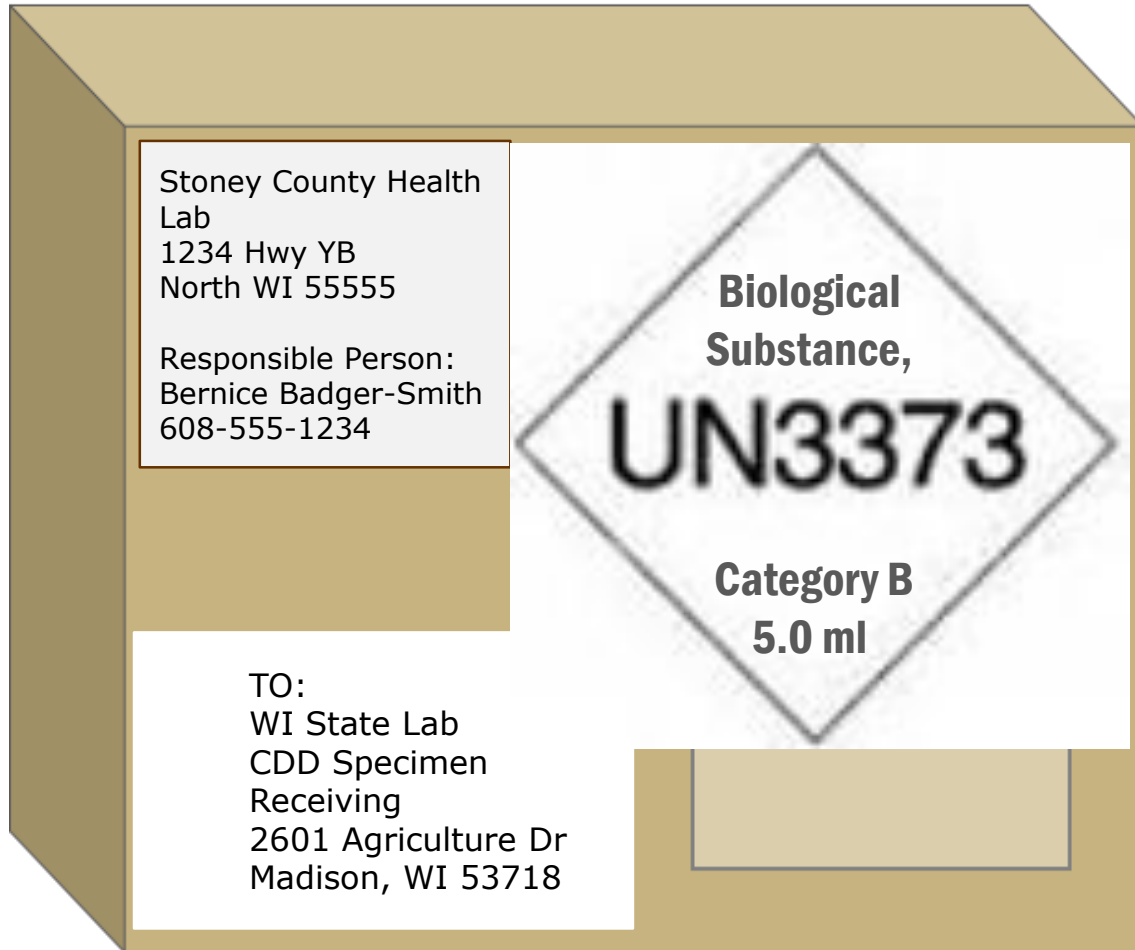
www.therapak.com

Do's and Don'ts

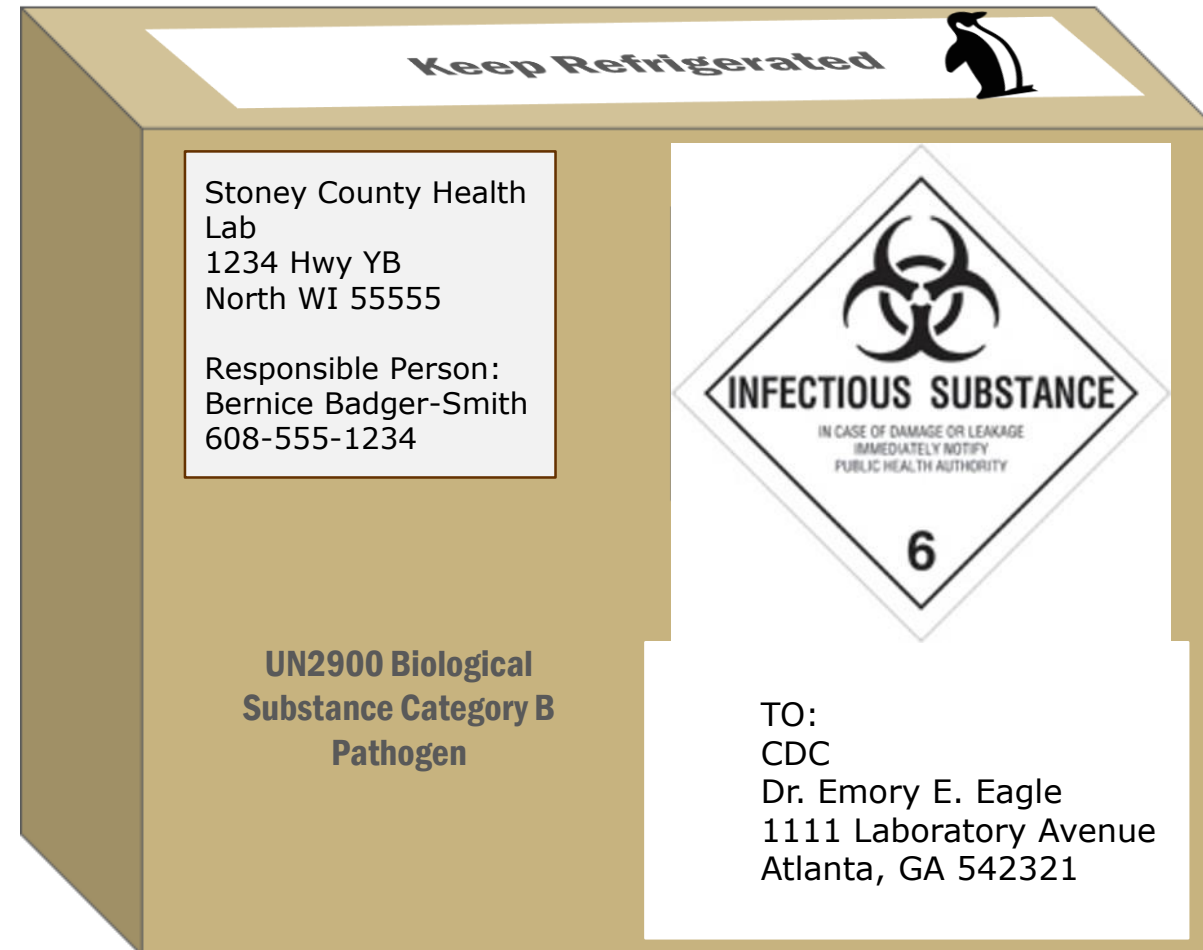
What is Wrong With These Packages?



What is Wrong With These Packages?



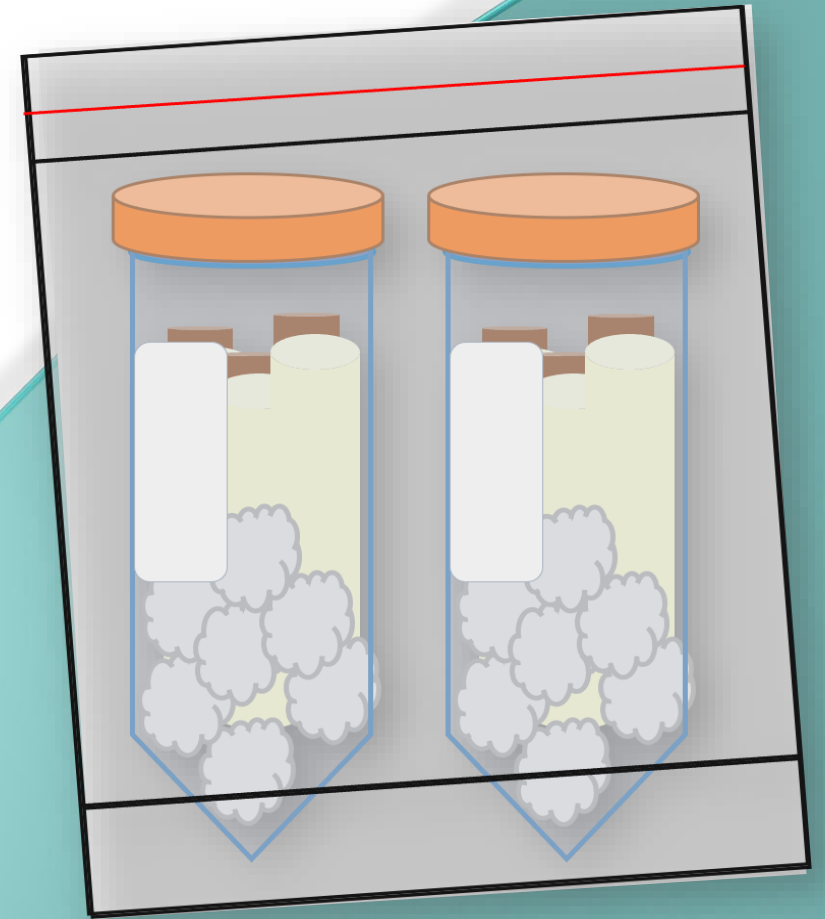
What is Wrong With These Packages?



Is This Secondary Container Acceptable?

Description:

- Specimen vials wrapped in paper towels
- 3 wrapped tubes with cushioning packed inside larger capped plastic tubes
- Two large tubes within a zipped bag
- The zipped bag + a box is part of a Category B shipping kit





SCENARIO A

- Shipment of 25 tubes human whole blood and 25 vials urine to WSLH
- Patients had accidental exposures to chemical vapors
- Some present with coughing, vomiting, and/or skin rash
- Classify the specimens
- Determine shipment temperature
- Package & label





SCENARIO B

- Ship 10 vials human blood to WSLH for STI testing
- Patients are each symptomatic or requested testing
- Classify the specimens
- Determine shipment temperature
- Package & label



SCENARIO C

- Send 10 tubes of human stool to WSLH
- All patients attended a family event
- 4 patients with diarrhea, fever and abdominal pain
- *Shigella dysenteriae* type 1 is suspected based on patient exams
- Classify the specimens
- Determine shipment temperature
- Pack and Label



Scenario D

Sending samples using WSLH Category B packing kit. You need to keep specimens cold and do not have a refrigerant pack.

What can you use?

- ❑ Ice cubes in a zipper-lock freezer bag, wrapped in paper towels
- ❑ 2 packs of frozen peas
- ❑ A freezer pack from the First Aid kit
- ❑ Reusable plastic ice packs that are frozen
- ❑ Reusable plastic ice packs that have been refrigerated
- ❑ Dry ice in a zipper-lock freezer bag, wrapped in paper towels



Packaging Problems....



Packaging Problems....



From:
Shipper's Address

Responsible Person
Name and phone #

To:
Recipient Address



Biological Substance
Category B

UN1845 Dry Ice
Qty XX Kg



Questions?

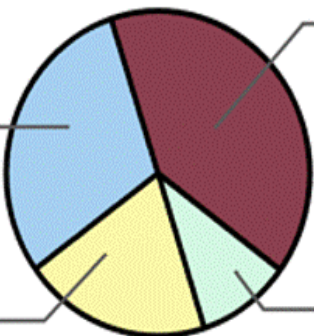


To feel science-y

Surprise
sponsor/safety
inspector visit

Hide the fact
you're wearing
the same clothes
as yesterday

It's too cold
in the lab



Why people wear
lab coats



*Thank you for
your
participation*

