

Introduction

Welcome to the **Shipping Biological Substances, Category B (OHS_BIO201)** training course. This course is **required** for anyone that will be shipping samples considered Biological Substances, Category B Genetically Modified Organisms (GMOs), Exempt Human or Animals Specimens.

UAB **requires** additional shipping training for anyone that will be packing:

- Materials shipped on Dry Ice: **Shipping with Dry Ice (OHS_BIO200)**
- Infectious substances capable of causing disease in humans or animals: **Shipping Infectious Substances, Category A (OHS_BIO202)**



Failure to properly pack and ship materials is a **violation** of the law and is punishable with fines and/or imprisonment.

Objectives

At the conclusion, participants should be able to:

1. Identify and properly classify Biological Substances, Category B, Genetically Modified Organisms (GMO), or Exempt Human or Animal Specimens intended for shipment.
2. Pack samples correctly with appropriate primary and secondary containment.
3. Mark and Label any shipping packages correctly.
4. Properly complete the appropriate shipping documents and/or permits.
5. Follow necessary safety guidelines to avoid any accidents or injuries.

Overview

When shipping Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens, you are bound by regulations that come from several International and National agencies. These regulatory bodies ensure that infectious substances or materials are transported as safely as possible, most notably, by air.

Regarding the shipping and receiving of Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens, the University of Alabama at Birmingham follows both the:

- [International Air Transportation Association Dangerous Goods Regulations \(IATA-DGR\)](#)
- [United States Department of Transportation Hazardous Materials Title 49 Code of Federal Regulations Parts 171-180](#)

Shipper Responsibilities

When shipping packages containing Biological Substances, Category B, Genetically Modified Organisms (GMOs), Exempt Human or Animal Specimens, from UAB, you have the responsibility to properly:

- Classify the substance or material
- Identify the substance or material
- Select the appropriate packaging system
- Pack the substance or material
- Mark and Label the package correctly

Classification

Classification is necessary in order to follow both International and National regulations. Classification of an item to be shipped is used to identify the **actual** hazard and **not** the substance itself.

Biological Substances, Category B

Samples that **do not meet** the criteria for Infectious Substances, Category A may qualify for classification as Biological Substances, Category B. This means that your specimen is not known or reasonably expected to contain pathogens. Use this [Classification Flowchart](#) to assist you.

Exempt Human or Animal Specimens

If your sample is **not** Category A or B, it may fall under the definition of an Exempt Human or Animal Specimen. These Exempt Human or Animal Specimens are those which have minimal likelihood of pathogens being present.

Do not assume your sample is an Exempt Human or Animal Specimen. Professional judgement is required to determine if a substance is exempt. Any professional judgment made should be based on known medical history, symptoms, and the likelihood of pathogens present in the local population from which the sample was obtained. If professional judgement is not available the specimen **must not** be shipped as Exempt Human or Animal Specimen. If you have questions, please call the UAB Occupational Health and Safety (OH&S) at (205) 934-2487 to get further clarification.

Examples of Exempt Human or Animal Specimens often include:

- Blood or urine to monitor:
 - Cholesterol levels
 - Blood glucose
 - Hormone levels
- Biopsies to detect cancer and test specimens to monitor organ function in humans and animal with non-infectious diseases.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Genetically Modified Organisms (GMO)

Genetically Modified Organisms that do not meet the definition of Category A or B Infectious Substances are assigned to Class 9 (Miscellaneous Hazard). Check with your carrier if you are unsure or have questions.

Identification

UN and PSN

United Nation (UN) Number

These numbers are taken from the [List of Dangerous Goods](#), and are used to identify a substance or group of substances. This UN Number always precedes the Proper Shipping Name (PSN):

- UN 3373 Biological Substances, Category B
- UN 3245 Genetically Modified Micro-Organisms or Genetically Modified Organisms (GMOs)
- Exempt Human or Animal Specimens **do not** have a UN Number

Proper Shipping Name (PSN)

The Proper Shipping Name (PSN), is assigned by IATA, ICAO, or 49 CFR, and is the name used on shipping documents to describe substances.



The words **diagnostic specimen** and **clinical specimen** are **no longer allowed** as Proper Shipping Names (PSN).

Packaging System

Selecting the Proper Packaging

Biological Substances, Category B

Packaging components for Biological Substances, Category B must pass testing requirements as a system, so mixing and matching packaging components from different manufacturer's is **not allowed**. For example, you cannot ship Biological Substances, Category B in an EXAKT-PAK™ secondary container and in a SAF-T-PAK™ outer container (fiberboard box).



Disposable components of a packaging system **must** be replaced by components from the same vendor that have been tested and certified for **that** packaging system. **Substituting alternative products is a violation of the law!**

Outside Packaging

The recommended outside packaging must be **sturdy** and **rigid**. The outside packaging is typically corrugated fiberboard box and should be the appropriate size for the intended content. The box also serves as a surface for displaying clear Marks, Labels, and other important information.

You should **always** use boxes that meet approved standards. Always look for the UN mark. It indicates that the box has been tested and meets standards. If you have questions about which boxes are approved, please call UAB OH&S at (205) 934-2487.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Inside Packaging

To be precise:

- Biological Substances, Category B are shipped using Packing Instructions 650 (or PI 650).
- Exempt Human Specimens **do not** have designated Packaging Instructions so they should be triple-packed (Primary Container → Secondary Container → Tertiary Container) to prevent any release or leak of substance. Non-infectious Genetically Modified Organisms (GMOs) are packed using PI 959.
- Any substances identified as UN 3373 must be **triple packaged** in approved boxes only.
- Shipping liquids are of special concern when traveling by air due to air pressure changes that may occur during a flight. If the shipment is liquid, then the primary or secondary container must be able to withstand air pressure changes without leakage. Documentation of testing is available from the manufacturer.



All packaging components for Biological Substances, Category B **must** be assembled per the manufacturer's closing instructions specific to the packaging system purchased.

Marks and Labels

General Information

Marks and Labels are used to provide information about the contents of the package, the nature of the hazard, and any special handling requirements. Any Marks and Labels should be:

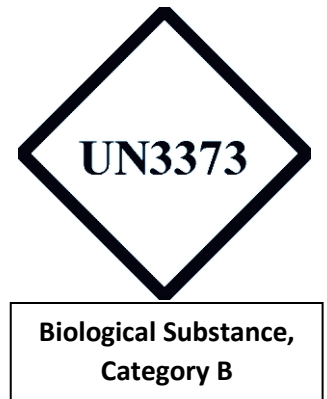
- Durable
- Placed so that they are completely visible
- Not obscured by any other Labels or Markings
- Placed all on the same face of the package, if possible

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Biological Substances, Category B

Biological Substances, Category B shipments require the labels described below.

- A Biological Substances, Category B black & white Diamond-on-Point label
- Proper Shipping Name and UN Number (which is “UN3373 Biological Substances, Category B”)
- Complete name **and** address of the Shipper **and** Consignee (Receiver)
- Name and telephone number of a responsible person. This must be a reliable and responsible person that will answer the phone (**no** voicemail and **no** answering machines). They should be able to answer any questions about the content, shipper, recipient details, and/or permit inquiries.



Exempt Human or Animal Specimens

Packages containing Exempt Human or Animal Specimens must be:

- Packed to prevent leakage
- Include the complete name **and** address of the Shipper **and** Consignee
- Marked with the Proper Shipping Name either
 - Exempt Human Specimen
 - Exempt Animal Specimen

**EXEMPT
HUMAN
SPECIMEN**

**EXEMPT
ANIMAL
SPECIMEN**

Do not use a UN 3373 Diamond-on-Point Label. Remember to remove or completely cover any irrelevant Marks or Labels.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Genetically Modified Organisms (GMO)

Packages containing Genetically Modified Organisms (GMO) should include:



- The complete name **and** address of the Shipper **and** Consignee (Receiver)
- The name and telephone number of a responsible person
- The UN 3245 Genetically Modified Organisms mark
- Remove or completely cover any irrelevant Marks or Labels



If you have any questions about the appropriate required Marks and Labels, contact UAB OH&S at 205-934-2487.

Documentation

No Shipper's Declaration is required for Biological Substances, Category B. You must include the following information on the waybill:

- UN Number
- Proper Shipping Name
- The Class or Division Number: 9
- The number of packages
- The Net Weight of the Dry Ice in each package, if appropriate

Appendix B at the end of this course material has examples of Waybill information.

Permits

Additional documentation (i.e., permits or certificates) may be required when shipping any biological substance, particularly those designated Infectious Substances. Federal permits are required to import/export disease causing agents for humans and animals, vectors for those agents, animal products, plants, plant products, and plant pests. Chemically inactivated agents are exempt from Dangerous Goods Regulations, but

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

may still require permits for receipt and/or transfer. Permits may also be required for domestic transport of some agents. The recipient of the material must obtain any required permits.

If you are the shipper, request a copy of any applicable permits from the recipient and include a copy of the permit with the shipping documents.

The U.S. receiver (importer) is responsible for the package being sent to them from a foreign country. The receiver must assure that the foreign shipper has packed and labeled the material according to U.S. Public Health Service and IATA regulations. The importer must send the proper shipping labels and a copy of their import permit to the shipper. Complying with foreign import regulations should prevent packages from being held at customs or denied entry.

USDA/APHIS Import/Transport Permits:

The USDA/APHIS (Animal and Plant Health Inspection Service) regulates transport of materials that could potentially harm U.S. agricultural products including livestock, poultry and crops. APHIS permits may be required for import, export, and interstate transport of animal or plant pathogens, pathogen vectors, animals, animal products, plants, plant products, and the introduction of genetically modified organisms into the environment. See: [USDA/APHIS Import/Export links](#)

USDA/APHIS Import/Transport permits:

- must be obtained by the intended receiver of the material before shipment is made
- are good for one year and are amendable/renewable

The application can be found [here](#). The application form is for foreign import or interstate transfer. This application requires 6 to 8 weeks for processing.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Animal related:

- USDA/ APHIS permits are required for imports/ exports and inter-state transport of:
 - animal or plant pathogens including challenge material from the USDA
 - specimens reasonably believed to contain animal or plant pathogens*
 - vectors of animal or plant disease*
 - potentially hazardous animal or plant products

Plant Related:

USDA/APHIS regulation 7 CFR Part 330 Federal Plant Pest Regulations covers the transport of plant pests.

Genetically Modified Organisms (GMOs):

To determine if a permit is needed to import or transport a GMO, contact the APHIS Biotechnology permit branch via a letter of notification.

**USDA/APHIS regulation 9 CFR Animals and Animal Products Parts 94, 95, and 122 covers transport of organisms or vectors that can cause infectious diseases of animals. The regulation defines material requiring a permit as, "(d) Organisms. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry). (e) Vectors. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease." http://www.access.gpo.gov/nara/cfr/waisidx_03/9cfrv1_03.html.*

Centers for Disease Control (CDC) Import/Transport Permits:

The Department of Health and Human Services, through the CDC, regulates the transport of biological materials that could cause illness in humans, including pathogens and biological toxins. In general, a permit is needed for any infectious agent known or suspected to cause disease in humans that you wish to import into the United States. In some cases acquisition and/or subsequent distribution of an agent (e.g., viruses requiring BSL-3 or BSL-4 containment) is prohibited within the United States and requires CDC authorization/permit prior to transfer to another location within the U.S. Select Agent permits may only be obtained through UAB's Responsible Official, in coordination with the Federal Select Agent Program. A list of Select Agents and Toxins can be found [here](#). Domestic transport may or may not require a permit. To determine if your shipment requires a permit visit the CDC [Import Permit Program website](#).

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Foreign imports of the following materials require a Permit to Import or Transport Agents or Vectors of Human Disease:

- etiologic agent
- arthropod or other animal host or vector of human disease
- exotic living arthropod or other animal capable of being a host or vector of human disease
- Non-human primate material - all non-human primate material (e.g., blood, plasma, tissue, urine, feces) requires an import permit, unless it has been specifically treated and rendered non-infectious.

Department of Commerce Export Permits:

Exports of designated biological agents and toxins that have the potential to pose a threat to human, animal or plant life may require a license from the U.S. Department of Commerce, Bureau of Industry and Security (BIS). The scope of items subject to this licensing requirement is broader than “select agents,” and researchers must consult with the University's Export Controls Officer to conduct a separate review to determine if a BIS export license is required.

Export Control at UAB is mediated through the [University Compliance Office](#). BIS may require a license for the export of:

- Designated human, animal and plant pathogens, zoonoses and toxins
- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with the pathogenicity of a controlled organism or that code for a controlled toxin
- genetic material and products which might be used for culture of large amounts of agents

For further guidance on whether or not the agents you are shipping/receiving require permits, please contact OH&S at 934-2487.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Example

Appendix A at the end of this document contains pictures showing the correct shipping label requirements for each one below:

- Shipping Nonhazardous or Exempt Specimens
- Shipping Genetically Modified Organisms
- Shipping Biological Substances, Category B

Operator (or Carrier) Responsibilities

Not all couriers/carriers will transport all Biological Substances, Category B, **and** not all countries or states in the U.S. accept Biological Substances, Category B.

Where there are variations (restrictions) by state/country or courier/carrier, they may be more restrictive than the IATA DGR or ICAO TI, but never less restrictive.

Commercial Courier

The airline industry is very strict about transporting biological materials. You **cannot** carry these materials/samples onto a passenger plane no matter how it is packaged. You **must** use commercial couriers such as UPS, USPS, FedEx, or DHL. There are quantity limitations, depending on the samples being shipped, and on the courier's method of transport. For more information, please check with OH&S and/or your courier.

Security



Security of the package is the shipper's responsibility until it is handed off to the authorized carrier!

After preparing the package for shipment, the package must remain under the **direct control** of trained personnel until it is handed over to the carrier. This reduces the chances of tampering, theft, destruction, or invalidating the shipper's signature that signifies the package has been prepared in accordance with 49 CFR/IATA regulations.



If you suspect a package has been tampered with, notify UAB OH&S **immediately** at (205) 934-2487!

Before handing the package over to the carrier for shipment, it is the shipper's responsibility to ensure that all Federal and International regulations are met. International shipments may require additional permits.

Receiver (or Consignee) Responsibilities

If you are expecting to receive packages containing Biological Substances, Category B at UAB, you have the responsibility to:

- Inspect the documents
- Inspect the package
- Get an import permit if necessary
- Report any damages to the shipper and UAB Biosafety
- Notify the sender that the package has arrived
- Keep all shipping documents for a minimum of three years

Conclusion

This concludes the **Shipping Biological Substances, Category B (OHS_BIO201)** training course. This course has the following parts:

1. Shipping Dangerous Goods Module
2. Shipping Dangerous Goods Attestation
3. Shipping Biological Substances, Course Material
4. Reality Check: This Reality Check presents challenges and scenarios from real life examples related Biological Substances, Category B. You should answer any scenario from the information that is presented in this course material.
5. Assessment: 90% or higher is considered passing. You have three chances to successfully complete the assessment. Failing all three attempts means that you fail the course and must start over.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Want to Learn More?

OH&S has many training courses available to all UAB active employees and students. This includes topics such as in depth radiation training, biosafety, bloodborne pathogens, chemical safety, Controlled Substances, building life safety, hazardous and medical waste, universal waste, PPE, Hazard Communication, etc.

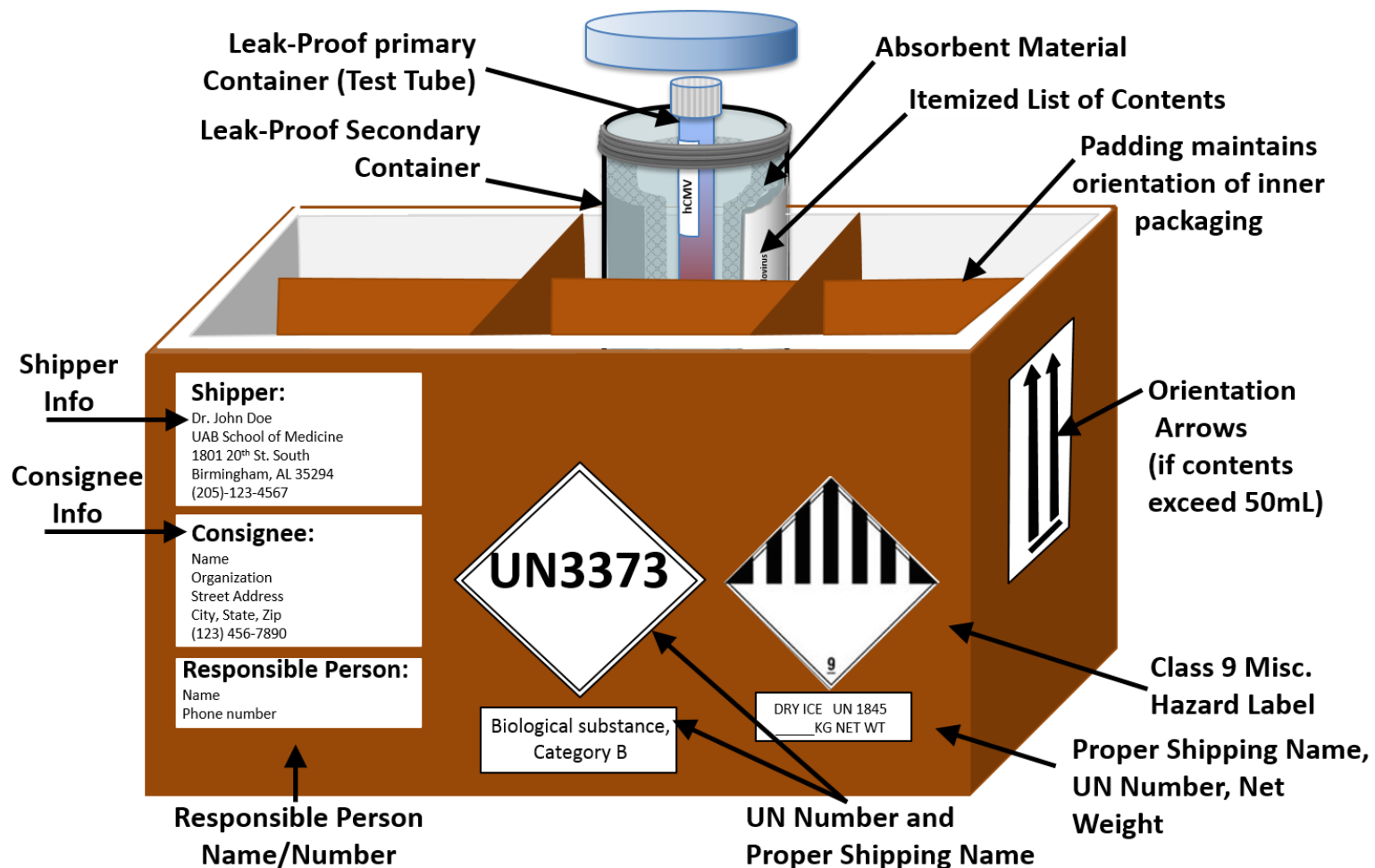
We have a [decision tree](#) to assist you in choosing the right course to match the knowledge/skills you may need at work every day as well.

If you have any questions or comments, please feel free to contact OH&S at (205) 934-2487.

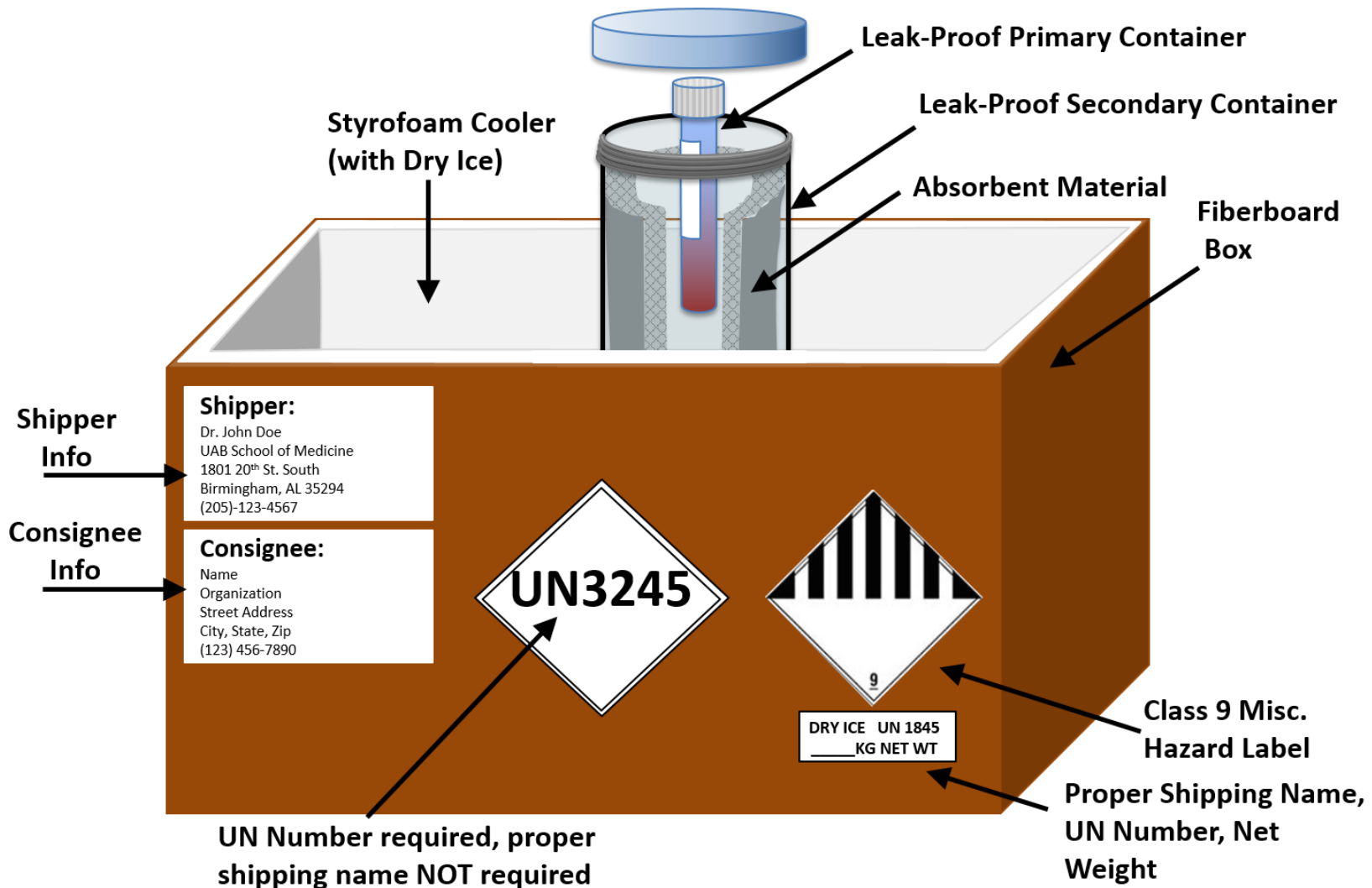
Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Appendix A: Shipping Label Requirements

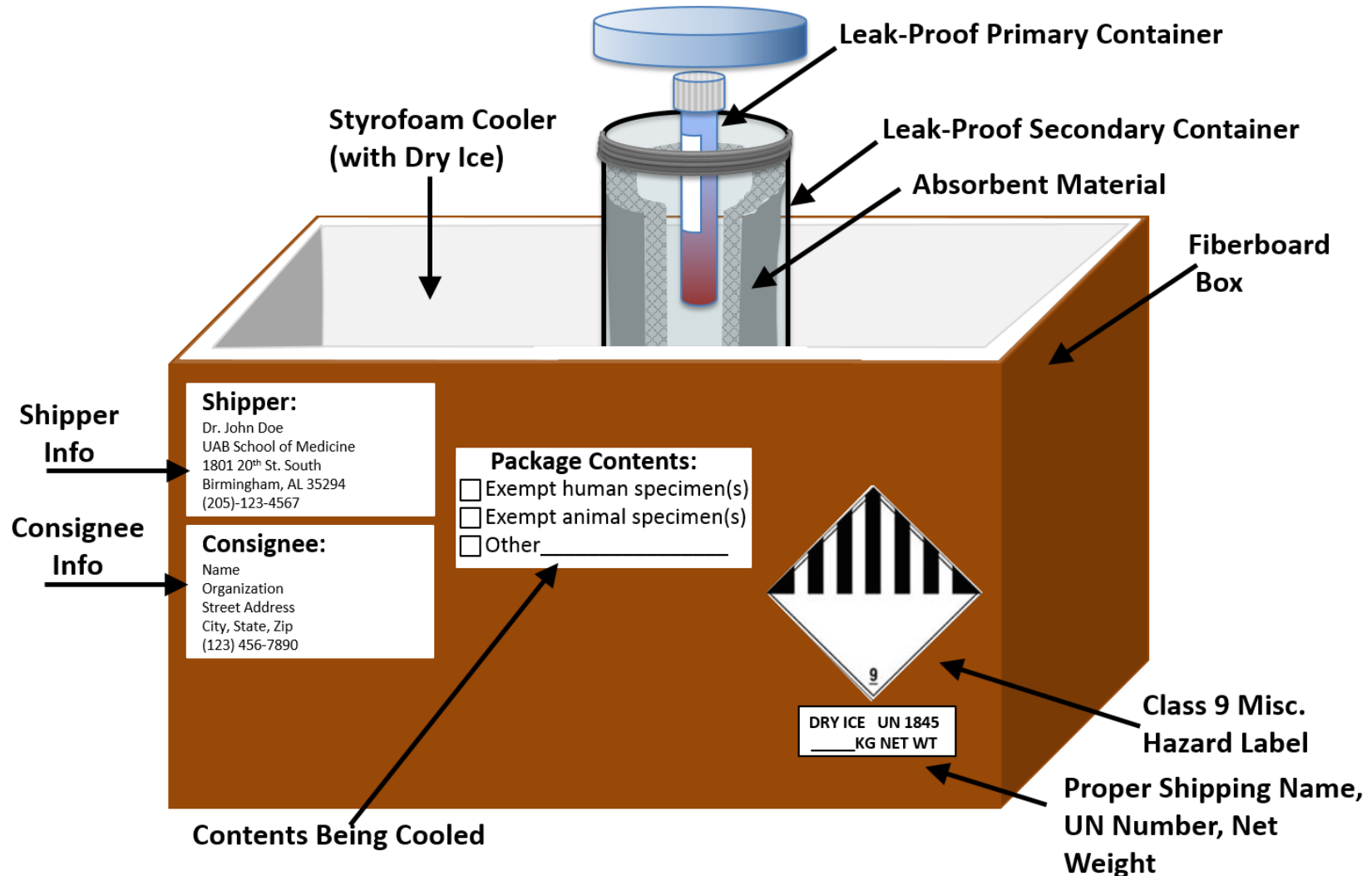
Shipping Biological Substances, Category B, on Dry Ice Follow Commercial System Instructions; IATA Packaging Instructions 650 & 954



Shipping Genetically Modified Organisms on Dry Ice Follow IATA Packaging Instructions 959 & 954



Shipping Nonhazardous or Exempt Specimens on Dry Ice Follow IATA Packaging Instruction 954



Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Appendix B: Examples of Waybill Information

UN3373 Biological Substances, Category B

FedEx Express US Airbill Tracking Number: 0987654321

1 From Please print and press hard.
Date: 5/19/17 Sender's FedEx Account Number: 1234-5678-90123
Sender's Name: Angelise Esilegna Phone: (567) 890-1234
Company: UAB
Address: 1720 2nd Ave S Oncology BMX 34
City: 1720 2nd Ave S State: AL ZIP: 35294

2 Your Internal Billing Reference
First 24 characters will appear on invoice.

3 To
Recipient's Name: John Doe Phone: (123)-456-7891
Company: ACME Bio
Recipient's Address: 1234 Main S. Biochemistry Bldg 605
City: Mayberry State: MO ZIP: 63664

4a Express Package Service
☐ FedEx Priority Overnight
☐ FedEx Standard Overnight
☐ FedEx 2Day
☐ FedEx Express Saver
☐ FedEx 1 Day Freight
☐ FedEx 2Day Freight
☐ FedEx 3Day Freight

4b Express Freight Service
☐ FedEx 1 Day Freight
☐ FedEx 2Day Freight
☐ FedEx 3Day Freight

5 Packaging
☐ FedEx Envelope
☐ FedEx Pak
☐ FedEx Box
☐ FedEx Tube
☐ Other

6 Special Handling
☐ SATURDAY Delivery
☐ HOLD Weekend at FedEx Location
☐ HOLD Saturday at FedEx Location

Does this shipment contain dangerous goods?
☐ No ☐ Yes As per attached Shipper's Declaration ☒ Yes Shipper's Declaration not required
☒ Dry Ice Dry Ice, 9, UN 1845 1 x 1.2 kg
☐ Cargo Aircraft Only

7 Payment Bill to: ☐ Sender ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

8 Residential Delivery Signature Options
☐ No Signature Required
☐ Direct Signature
☐ Indirect Signature

Total Packages 1 **Total Weight** **Total Declared Value** \$.00

Does this shipment contain dangerous goods?
☐ No ☐ Yes As per attached Shipper's Declaration ☒ Yes Shipper's Declaration not required
☒ Dry Ice Dry Ice, 9, UN 1845 1 x 1.2 kg
☐ Cargo Aircraft Only

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

UN3245 Genetically Modified Organism

FedEx US Airbill Tracking Number: 0987654321

1 From Please print and press hard
 Date: 5/19/17 Sender's FedEx Account Number: 1234-5678-90123
 Sender's Name: Angelise Esilegna Phone: (567) 890-1234
 Company: UAB
 Address: 1720 2nd Ave S Oncology BMX 34
 City: 1720 2nd Ave S State: AL ZIP: 35294

2 Your Internal Billing Reference
 Print 38 characters will appear on invoice.

3 To
 Recipient's Name: John Doe Phone: (123)-456-7891
 Company: ACME Bio
 Recipient's Address: 1234 Main S. Biochemistry Bldg 605
 Address: Mayberry State: MO ZIP: 63664

4a Express Package Service
☐ FedEx Priority Overnight
☐ FedEx Standard Overnight
☐ FedEx 2Day
☐ FedEx Express Saver

4b Express Freight Service
☐ FedEx 1Day Freight
☐ FedEx 2Day Freight

5 Packaging
☐ FedEx Envelope
☐ FedEx Pak
☐ FedEx Box
☐ FedEx Tube
☐ Other

6 Special Handling
☐ SATURDAY Delivery
☐ HOLD Weekday at FedEx Location
☐ HOLD Saturday at FedEx Location

Does this shipment contain dangerous goods?
☐ No ☐ Yes As per attached Shipper's Declaration ☒ Yes Shipper's Declaration not required
☒ Dry Ice Dry Ice, 9, UN 1845 1 x 1.2 kg
☐ Cargo Aircraft Only

7 Payment Bill to:
☐ Sender ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

8 Residential Delivery Signature Options
☐ No Signature Required
☐ Direct Signature
☐ Indirect Signature

Total Packages 1 **Total Weight** **Total Declared Value** \$.00

Does this shipment contain dangerous goods?
 One box must be checked
☐ No ☐ Yes As per attached Shipper's Declaration ☒ Yes Shipper's Declaration not required
☒ Dry Ice Dry Ice, 9, UN 1845 1 x 1.2 kg
☐ Cargo Aircraft Only

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Exempt Human/Animal Specimens

FedEx Express US Airbill Tracking Number: 0987654321

Form ID No. 0215 **Sender's Copy**

1 From Please print and press hard.
 Date: 5/19/17 Sender's FedEx Account Number: 1234-5678-90123
 Sender's Name: Angelise Esilegna Phone: (567) 890-1234
 Company: UAB
 Address: 1720 2nd Ave S Oncology BMX 34
 City: 1720 2nd Ave S State: AL ZIP: 35294

2 Your Internal Billing Reference
 First 34 characters will appear on invoice.

3 To
 Recipient's Name: John Doe Phone: (123)-456-7891
 Company: ACME Bio
 Recipient's Address: 1234 Main S. Biochemistry Bldg 605
 Address: Mayberry State: MO ZIP: 63664

4a Express Package Service
☐ FedEx Priority Overnight Next business morning ** Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.
☐ FedEx Standard Overnight Next business afternoon ** Saturday Delivery NOT available.
☐ FedEx 2Day Second business day ** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.
☐ FedEx Express Saver Third business day ** Saturday Delivery NOT available.

4b Express Freight Service
☐ FedEx 1 Day Freight* Next business day ** Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.
☐ FedEx 2Day Freight Second business day ** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

5 Packaging
☐ FedEx Envelope* ☐ FedEx Pak* ☐ FedEx Box ☐ FedEx Tube ☐ Other
*Declared value limit \$500.

6 Special Handling
☐ SATURDAY Delivery NOT available for FedEx Standard Overnight, FedEx Priority Overnight, FedEx Express Saver, or FedEx 2Day.
☐ HOLD Weekday at FedEx Location NOT available for FedEx Priority Overnight and FedEx 2Day to select locations.
☐ HOLD Saturday at FedEx Location Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations.

Does this shipment contain dangerous goods?
☐ No ☐ Yes (per attached Shipper's Declaration) ☒ Yes (Shipper's Declaration not required)
 Dangerous goods (including dry ice) cannot be shipped in FedEx packaging.
☒ Dry Ice Dry Ice, 9, UN 1845 1 x 1.2 kg
☐ Cargo Aircraft Only

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.
☐ Sender Acct. No. is linked. ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

8 Residential Delivery Signature Options If you require a signature, check Delivery Signature.
☐ No Signature Required Package may be left without obtaining a signature for delivery.
☐ Direct Signature Someone at recipient's address may sign for delivery. Fee applies.
☐ Indirect Signature If no one is available at recipient's address, someone at a neighboring address may sign for delivery. Fee applies.

Total Packages 1 **Total Weight** **Total Declared Value** \$.00

Does this shipment contain dangerous goods?
 One box must be checked
☐ No ☐ Yes As per attached Shipper's Declaration ☒ Yes Shipper's Declaration not required
☒ Dry Ice Dry Ice, 9, UN 1845 1 x 1.2 kg
☐ Cargo Aircraft Only