

Shipping Infectious Substances, Category A (OHS_BIO202) Course Material

Introduction

Welcome to the **Shipping Infectious Substances, Category A (OHS_BIO202)** training course. This course is **required** for anyone that will be shipping samples that are considered Infectious Substances, Category A.

Any UAB employee who participates in the shipping process for Infectious Substances, Category A, **must complete** training every two years **or** if regulations change. The shipping process can include packaging, preparing the paperwork, assembling the package, labeling, or any other activity associated with transport. This is required by the International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA).

Additional shipping training is **required** for anyone that will be working with:

- Materials shipped on Dry Ice: **Shipping with Dry Ice (OHS_BIO200)**
- Biological Substances (This includes Genetically Modified Organisms and Exempt Human or Animal Specimens): **Shipping Infectious Substances, Category A (OHS_BIO201)**



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 Infectious Substances, Category A.
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 Infectious Substances, Category A, you are bound by regulations that come from several International and National agencies. Even though there are multiple agencies and regulations, these regulatory bodies ensure that infectious substances or materials are transported as safely as possible (specifically by air).

Regarding the shipping of Infectious Substances, Category A, the University of Alabama at Birmingham follows both the:

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

Shipper's Responsibilities

When shipping Infectious Substances, Category A, from UAB, you have the responsibility to properly:

- Classify the substance or material
 - Identify the substance or material
 - Select the appropriate packaging
 - Pack the substance or material
 - Mark and Label the package correctly
 - Complete documentation
 - Make arrangements with your chosen courier and receiver. This includes obtaining permits if required.
- For example, both the USDA and CDC have permit requirements.

Classification

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

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Infectious Substances, Category A

Infectious Substances, Category A are those which are capable of posing a risk to health and safety. These substances are capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Work with these substances **requires** high containment.

You can use the terms in the [Shipping Glossary](#), [Examples of Infectious Substances in Category A or B Job Aid](#), and the [Classification Flowchart](#) to help properly classify your sample.

Genetically Modified Organisms (GMO)

If your sample happens to be a Genetically Modified Organism (GMO) **and** meets the classification of an Infectious Substance, Category A, then it **must** be classified and shipped as an Infectious Substances, Category A. Check with your carrier if you are unsure or have questions.

Identification

UN and PSN

United Nations (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 2900 Infectious Substances, affecting animals
- UN 2814 Infectious Substances, affecting humans

Proper Shipping Name (PSN)

The Proper Shipping Name (PSN) is assigned by IATA, ICAO, 9 CFR, and is the name used on Shipping Documents to describe substances. Infectious Substances, Category A have two Proper Shipping Names – one refers to Infectious Substances affecting animals and the other affecting humans.

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- The PSN, **Infectious Substances, affecting animals** (along with the preceding UN 2900 number), refers to the Infectious Substances that affect animals and is **only allowed** if the Infectious Substance is an animal pathogen and can in no way pose a threat to humans.
- The PSN, **Infectious Substances, affecting humans** (along with the preceding UN 2814 number), is used if the Infectious Substance can pose a threat to humans as well as animals.



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

Technical Name

The Technical Name is the substance's Genus and Species. This must be added to the end of the Proper Shipping Name on the Shipper's Declaration when shipping Infectious Substances, Category A.

It should be written or typed in parentheses. For example, an isolate of West Nile Virus cultured from a mouse **has** the ability to affect a human. Therefore, the Shipping Document for this sample would show:

UN 2814 Infectious Substance, affecting humans (West Nile Virus)

Remember, the Technical Name goes on the Shipper's Declaration – **not** the package!

Packaging System

Selecting the Proper Packaging

Packaging components for Infectious Substances, Category A must pass testing requirements as a system, so mixing and matching packaging components from different manufacturer's is **not allowed**. When choosing the correct packing materials, only use packaging in the tested and certified configuration. For example, you **cannot** ship Infectious Substances, Category A in an EXAKT-PAK™ secondary container and in a SAF-T-PAK™ outer container (fiberboard box) since the containers have not been tested and certified together.

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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.

Never use boxes except those that conform to **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 OH&S at (205) 934-2487.



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Inside Packaging

Kilopascal (kPa) is a unit of pressure measurement like Pounds per Square Inch (PSI). Either the primary or secondary container must be able to withstand internal pressure of 95 kPa in a temperature of -40 degrees Centigrade (-40°C) to 55 degrees Centigrade (55°C).



All packaging components for Infectious Substances, Category A **must** be assembled per the manufacturer's packing instructions specific to the packing system purchased.

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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

Infectious Substances, Category A

Infectious Substances, Category A shipments **require** the labels described below:

- An Infectious Substance, Category A black & white Diamond-on-Point Label
 - In case of damage or leakage, **immediately** notify a UAB OH&S at (205) 934-2487
- Proper Shipping Names and Number
 - UN 2900 Infectious Substances, affecting animals
 - UN 2814 Infectious Substances, affecting humans
- 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.
- Orientation Marks or the words “**this side up**” on packages containing liquids. Two orientation marks or the words “**this side up**” should be on two opposite sides of the box. However, they must match. Both sides must be orientation marks or both sides must be marked “THIS SIDE UP”.



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Documentation

Shipper's Declaration

A Shipper's Declaration for Dangerous Goods is a legal document and is required for each shipment of Infectious Substances, Category A. It is also one of the main reasons packages get rejected – because they are incorrectly prepared.

To keep your Shipper's Declaration from being rejected, here are some things that you must do:

1. Prepare three copies – one for the shipper and two for the carrier. However, some carriers may require more. Check with your courier before submitting.
2. Keep your copies for two years – in case there are questions later.
3. If you have made prior arrangements with the courier, submit your Shipper's Declaration information electronically.
4. Fill out each line or space correctly.

Permits

Additional documentation (i.e., permits or certificates) may be required when shipping any biological substance, particularly those designated Infectious Substances, Category A. 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 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.

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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
- is good for one year and is 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.

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.

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**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](#). 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.

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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.

Security



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

ICAO and IATA require that any company or institution that handles or transports dangerous goods provide associated security training for any staff who come in contact with the dangerous goods. This training should encompass the nature of the risks, recognition of risks, practices used to reduce risks, and procedures for a security breach.

The following security guidelines are applicable to Category A Shipments at UAB:

- Make arrangements with courier for to receive package directly. Do not leave dangerous goods packages in non-secure areas for pickup.
 - 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.
- Ensure package tracking is available through the courier

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- Restrict dangerous goods access to properly trained and qualified staff
 - 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.
- Inventory dangerous goods stocks to track theft or loss
- Report all suspicious activity/persons to UAB Police at (205) 934-3535
- Exposure/Incident Response Plans are in place to define procedures in the event of a release or exposure.
- Select Agents transfer requires additional CDC/APHIS approval through coordination with UAB's Responsible Official



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

Example

Appendix A at the end of this document contains pictures showing the correct shipping label requirements for a package containing Infectious Substances, Category A.

Operator (or Carrier) Responsibilities

Not all couriers/carriers will transport all Infectious Substances, Category A, **and** not all foreign countries or states within the U.S. will accept Infectious Substances, Category A.

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.

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Commercial Courier

The airline industry is very strict about transporting infectious 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.

Quantity Limits

If the package contains ≤ 50 milliliters or ≤ 50 grams Cat A substance per package, then it can be shipped in the cargo hold of a passenger airplane. Packages exceeding 50 milliliters/grams Cat A material, or ≥ 200 kilograms Dry Ice must be shipped by cargo aircraft. Packages exceeding 4 L/Kg of Cat A material must be shipped by ground transportation or divided to remain under the limit. The quantities for all UN numbers must be marked on the outside of the package.

Receiver (or Consignee) Responsibilities

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

- Obtain the appropriate permits and send a copy to the shipper
- Obtain IBC approval prior to receiving Infectious Substance, Category A material
- Inspect the documents
- Inspect the package
- Report any damages **immediately** to the shipper and UAB Biosafety at (205) 934-2487
- Notify the sender that the package has arrived
- Keep all shipping documents for a minimum of two years

Conclusion

This concludes the **Shipping Infectious Substances, Category A (OHS_BIO202)** training course. This course has the following parts:

1. Shipping Dangerous Goods Module
2. Shipping Dangerous Goods Attestation
3. Shipping Infectious Substances, Category A Course Material
4. Reality Check: This Reality Check presents challenges and scenarios from real life examples related Infectious Substances, Category A. 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.

Want to Learn More?

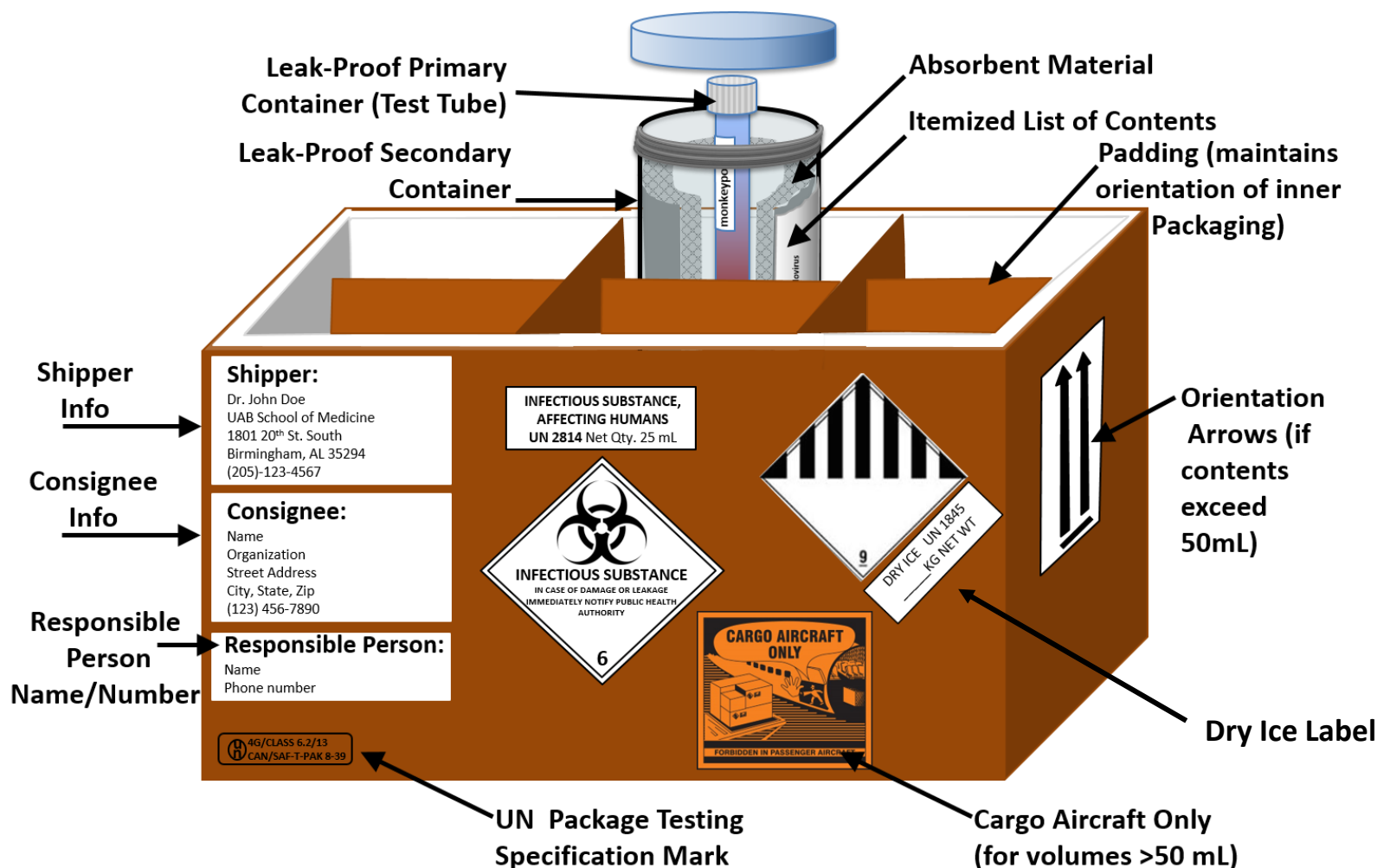
OH&S has many training courses available to all UAB active employees and students. This includes topics such as in depth radiation training, biosafety, bloodborne pathogens, chemical safety, Controlled Substances, building life safety, hazardous and medical waste, universal waste, PPE, Hazard Communication,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

Appendix A: Shipping Label Requirements

Shipping Category A, Infectious Substances on Dry Ice Follow Commercial System Instructions; IATA Packaging Instructions 620 & 954



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UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and type of packing	Packing Inst.	Authorization
UN2814	Infectious Substance, Affecting Humans, (Monkeypox Virus)	6.2		1 x 5 ml tube	620	
UN1845	Dry Ice	9		5 kg All packed in one fiberboard box	954	