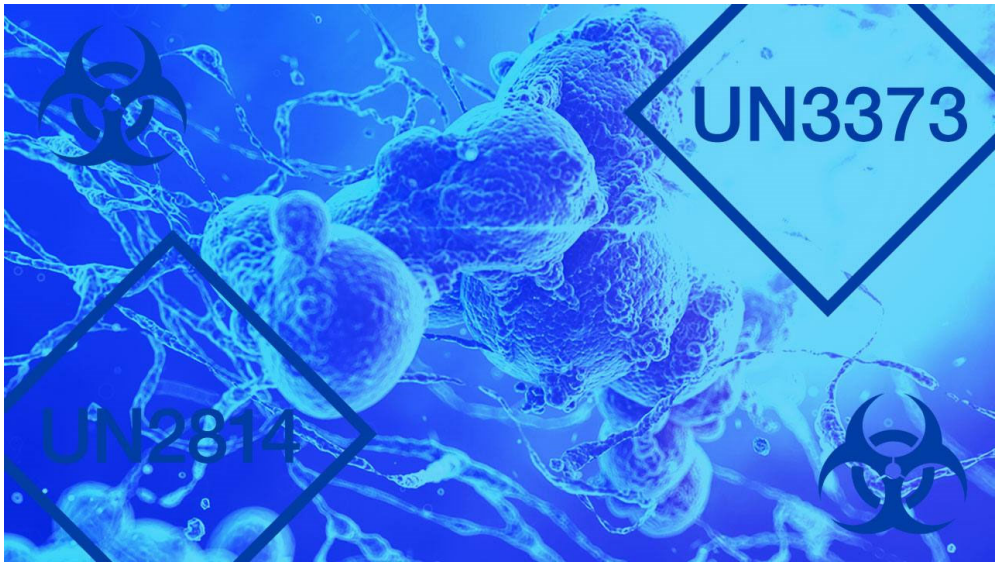
MDHHS | Bureau of Laboratories

Michigan Department of Health & Human Services

Packing & Shipping for the Clinical Laboratory



Revision Date: April, 2024

Packing and Shipping for the Clinical Laboratory

MDHHS Michigan Department of Health & Human Services
Bureau of Laboratories

Table of Contents:

Additional Information:

Resource Information for Packing & Shipping:

This section is left blank for notes.

Bureau of Laboratories Contacts:

Bioterrorism Training Coordinator:
Jason Wholehan, wholehanj@michigan.gov
Phone: 517-335-9653
Cell: 517-331-7356

Data and Specimen Handling:
Matt Bashore, BashoreM@michigan.gov
Phone: 517-335-8373

Shipping Materials Contact: MDHHSLab@michigan.gov
Bureau of Laboratories Outreach Contact: MDHHS-BOL-Outreach@michigan.gov

Introduction

This booklet is the accompanying document to a training class provided by the Michigan Department of Health and Human Services Bureau of Laboratories (MDHHS BOL). The training is directed toward staff who prepare infectious materials for transport and is called, "Packing and Shipping for the Clinical Laboratory." Use of this booklet without completing the corresponding training does not replace comprehensive training. This booklet is a tool for assisting our partners in transporting infectious substances safely.

Disclaimers

This booklet was prepared as a training aid and should NOT be used to determine compliance in the proper use of the Department of Transportation Hazardous Material Regulations (HMR) Title 49 Code of Federal Regulations (CFR) 100-185, the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) current edition, nor the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard. This guidance does NOT have the force and effect of law and is not meant to bind regulated entities in any way. Transportation regulations are constantly updated, and therefore it is impossible to guarantee total and absolute accuracy of the material contained and presented in this booklet. MDHHS BOL does not assume responsibility for possible errors or omissions. **Shippers MUST conduct their own due diligence in following the regulations for the safe transport of dangerous goods.** Each facility is responsible for assuring that appropriate packing instructions are adhered to as required by federal law and air transport association standards.

This booklet's publication and the corresponding training course are supported by the Public Health Emergency Preparedness Cooperative Agreement number 6NU90TP22062-03-02, 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, the Federal Department of Health and Human Services, the Michigan Department of Health and Human Services, nor the Bureau of Laboratories.

Products and commercial sources presented here are for example use only and do not imply recommendation or endorsement by MDHHS BOL. MDHHS does not sponsor or endorse these materials but are included as reference only. Product names, logos, brands, and other trademarks featured or referred to are property of their respective trademark holder.

All regulatory numbers, codes, and citations were accessed as of September 2023. Best efforts have been made to ensure all guidance and regulatory citations are current and up to date but there is no guarantee of accuracy.

Purpose and Scope of this Training Material

The purpose of this training booklet is to assist healthcare partners in Michigan to remain compliant with shipping regulations. Therefore, the scope and focus of this document is to assist partners in shipping infectious substances and related materials.

This training covers general awareness and familiarization for dangerous goods. Generalized discussion of safety and emergency response are included, but other sources of more in-depth training are recommended.

What are Dangerous Goods and Hazardous Materials?

When we discuss dangerous goods and hazardous materials shipping regulations, we first need to understand what it means to transport. **Transport is defined** in 49 CFR 171.1(c) as offering hazardous materials for **shipment in commerce**, or transportation between one place and another place. This includes the entire process of performing functions related to handling, packaging, storing, moving, loading, and unloading of the hazardous material, and responding to emergency situations while such materials are in transportation. Please note, movement of infectious substances within a private facility is not governed by DOT and the sections under 49 CFR HMR, but instead this movement is regulated by OSHA.

Dangerous Goods is an international term for articles or substances which are capable of posing a hazard to health, safety, property, or the environment and which are shown in the list of Dangerous Goods or classified according to regulations (IATA DGR 1.0).

Hazardous Materials is the term used in the United States to describe substances or materials that have been determined to be capable of posing unreasonable risk to health, safety, and property when transported in commerce, and has been designated as hazardous under section 5103 of Federal hazardous material transportation law. Sometimes this term is abbreviated to **hazmat** (49 CFR 171.8).

In practice these the two terms, dangerous goods and hazardous materials, are describing very similar substances. When applied to infectious substances offered for transport the definitions are essentially the same and only differ in their use by the regulator that is applying the term.

A hazmat employer is anyone who uses one or more employees to transport hazardous materials in commerce or causes hazardous materials to be transported (49 CFR Part 171.8). The hazmat employer shall ensure that each employee is trained. Issues or accidents associated with a hazardous material will cause legal issues or fines to go back to the employer, not the employee or their trainer (49 CFR Subpart H Section 172.702).

A hazmat employee is anyone who affects the transport of hazardous materials. This means that if part of your job function is to identify, classify, or prepare packages of hazardous materials for transport, you are a hazmat employee. You must be trained and proven competent by your employer to perform your hazmat function (49 CFR 171.8).

Importance of Packing and Shipping

Transporting clinical samples from one site to another is an important part of the analytical process. Often clinical samples must travel many miles from the point of collection to a laboratory for testing. Patients and their clinical teams rely on the results of these tests to provide quality healthcare. However, the transportation of possibly infectious materials introduces some inherent risk to the public, the environment, and property. These risks must be managed.

Safety is always important in any workplace, but it takes on special importance in clinical settings. Properly preparing infectious substances for transport is important because we do not want to be sending damaged or leaking items for transport. We must all guard against accidental release or exposure from infectious materials.

Legal issues may arise from improperly prepared packages. There are **fines, civil penalties, and prosecutions** that may be directed toward institutions who defy the regulations. As of September 2023, if an individual or institution is found noncompliant with the regulatory requirements, they are subject to a civil penalty, with a maximum penalty of **$96,624** for each violation (49 CFR 171.1(g)). The maximum increases to **$225,455** if the violation results in death, substantial property damage, serious illness, or severe injury to any person (49 CFR 107.329 and 107.333). The minimum civil penalty for training violations is **$582 for each violation**. For example, not training 10 employees could result in a fine of over $5,800 for cumulative training violations.

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** (49 CFR 107.333). For current violations list and common fines see 49 CFR 107, Appendix A-D.

To give an example of a common type of fine levied by DOT; in 2011, 20% of all fines issued were due to the shipper's failure to follow the manufacturer's instructions for preparing packages.

For an example of a fine directed toward a single shipper; in 2009 a shipper was fined $5,250 for offering a Category A substance in a UN package that was not authorized because the inner packaging had been altered from the tested design.

Improperly prepared packages can be the **impetus for inspections**. Regulatory agencies may use a deficient package to launch an inspection of your facility to confirm your compliance or deviation from regulatory standards.

Commercial carriers may **reject your package** if it is improperly prepared. Commercial carriers are very aware of regulatory standards and will reject any package from a shipper if it has been improperly prepared. This can lead to frustrating delays and slower testing turnaround times.

Governing Agencies and Regulatory Agencies: DOT, IATA, and More

There are many organizations that influence the regulatory landscape for the transport of dangerous goods. Depending on the mode of transportation, the carrier used, and national government of the shipper and receiver, the regulatory standards that apply might be different. Despite the numerous organizations and regulatory publications, the standards are very similar and often differences come down to wording and format. However, some regulators do set more stringent guidelines, and for compliance, you must apply the more stringent guidelines to your package.

There are international regulators that set model rules and recommendations that provide harmonization to the global supply chain. The **United Nations (UN) has a Subcommittee of Experts on the Transport of Dangerous Goods**. They establish standards and make recommendations that are published every two years in the UN Recommendations on the Transport of Dangerous Goods – Model Regulations. In addition, the UN provides harmonization to the labeling of dangerous goods by establishing a list of dangerous goods and assigning a 4-digit UN number. There are over 3,000 materials assigned a 4-digit UN number. For example, UN numbers for infectious substances are UN2814 and UN2900 for Category A and UN3373 for Category B. The letters UN must appear before the 4-digit number.

When transported by air the **International Civil Aviation Organization (ICAO)** sets rules and regulations published in the Technical Instructions for the Safe Transport of Dangerous Goods by Air. ICAO is a specialized agency of the UN. All international flights are subject to compliance with ICAO while domestic flights are subject to a country's civil aviation authority.

The **International Air Transport Association (IATA)** is a trade association of airlines that sets rules for their members to follow. Most of the world's major airlines and freight carriers are IATA members, including UPS and FedEx. Therefore, any shipment by aircraft will need to follow IATA rules, even if that flight is a domestic flight and does not leave the borders of the United States. So, even though IATA regulations are not enforceable by law, you must adhere to the rules. IATA works with its members to formulate and republish the ICAO technical instructions into what is essentially a field manual for aircraft transport safety. This document is titled the **Dangerous Goods Regulations (DGR).** The DGR is very similar to domestic regulations but has some significant differences that the shipper must be aware of. The DGR is considered the most restrictive regulatory standard, and therefore complying with the DGR will ensure safe and efficient transport of your dangerous goods package. Air transport regulations are often the most restrictive due to the inherit dangers of air travel. There is nowhere to pull over and stop to review suspicious packages at 30,000 feet.

The **Universal Postal Union (UPU)** is an international organization for mail carriers. The UPU publishes the Letter Post Manual which guides postal carriers on their rules and regulations. Domestically, the **United States Postal Service (USPS)** adopts the UPU recommendations and sets additional rules and packaging standards in **Publication 52 - Hazardous, Restricted, and Perishable Mail** also found in 39 CFR 113. USPS tends to set more stringent packing and labeling requirements which are different than DOT and IATA regulations. If your institution utilizes USPS to ship samples, please familiarize yourself with the different labeling requirements found in Publication 52.

While there are international rail and sea transportation groups laboratory samples are rarely transported by these modes. We will not discuss these regulatory bodies further in this booklet.

In the United States we must also follow the national regulations set forth by the **Department of Transportation (DOT)**. The **Pipeline and Hazardous Materials Safety Administration (PHMSA)** is a branch of DOT and derives its authority from the Hazardous Materials Transportation Uniform Safety Act (1990). DOT publishes the **Federal Hazardous Materials Regulation (HMR)** and these regulations are available in the Code of Federal Regulations Title 49 section 100-185 (49 CFR 100-185). These regulations are law. These regulations govern all shipments of hazardous materials in the United States by all modes of transport, including air, ground, rail, and sea. There are provisions in the HMR that state shippers should follow international guidance such as IATA. 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, International Maritime Dangerous Goods Codes, and Transport Canada Regulations.

The **Occupational Safety and Health Administration (OSHA)** sets regulations that apply to all workplace settings in the United States including healthcare, laboratories, and the transportation sector. Regulations for safe work practices while handling blood is published in 29 CFR Part 1910.1030 also called the **Bloodborne Pathogens Standard**. Many of the OSHA rules relate to hazard communication, labeling, and cleanup of spills. The Bloodborne Pathogens Standard apply to all human blood and body fluids transported by any mode.

Additionally, many healthcare institutions must be accredited by an accrediting agency which will have requirements for specimen tracking and transport. For example, many clinical laboratories are accredited by the **College of American Pathologists (CAP).** CAP has a few checklist tags that are related to specimen tracking and transport (GEN.40512 & GEN.40515).

In summary, the main regulators that shippers need to be aware of are DOT and IATA, with OSHA Bloodborne Pathogens Standard as a safety background. DOT regulates all shipments by all modes in the United States. And don't let the word "International" in IATA confuse you, currently all major domestic airlines are IATA members, and therefore their rules still apply in this country.

Key point: there is harmonization between all previously mentioned regulators with the goal of assuring safe handling and establishing common language.

Regulatory Compliance and Interpretation

Some of the regulations set forth by DOT and IATA can be confusing and difficult to interpret. Both DOT and IATA maintain "helpdesks" that are independent of their enforcement branches to assist in answering compliance questions. Helpdesk contacts can be found in the Recourses section of this booklet along with many other sources of shipping information. MDHHS BOL does our best to be a resource for our partners. Feel free to contact the MDHHS Bioterrorism Training Coordinator for any shipping questions.

The IATA DGR is only sold in book form, but sections can often be accessed by internet searches. The Code of Federal Regulations are all available on the website, https://www.ecfr.gov/.

DOT and IATA have very similar requirements for shipping clinical samples by air. It is required to adhere to the more stringent regulator when preparing shipments for air transport, often this is IATA. Both DOT and IATA have language in their regulations that state shippers must follow the more stringent regulatory version. In DOT's 49 CFR 171.22 it "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."

Commercial Carrier Specific Variations

When utilizing a large commercial carrier, such as **FedEx, UPS, or DHL,** please be advised that these carriers may place additional requirements for your shipment. These commercial groups often require the use of certain software while completing shipping documents or they may require certain contractual agreements before any shipments can be placed. **Please research carrier specific software requirements and contractual agreements before attempting to place a shipment with these companies.**

Training Requirements

Who needs training? Training requirements can be confusing. Requirements vary based on substance, quantity, and mode of transport. DOT establishes training requirements for packing and shipping hazardous material in the United States. However, when dangerous goods are shipped with an IATA-member airline, the Dangerous Goods Regulations (DGR) training requirements must be followed. Failure to train, and document that training, is one of the most common findings during DOT inspections. The responsibility for training, and the civil penalties associated with not training, rests with the employer.

49 CFR 172.700 describes the training that is required to be provided to employees who are preparing hazardous materials shipments. To paraphrase, a hazmat employee must have familiarity with the regulations, is able to recognize and identify hazards, and has knowledge of the specific requirements to perform their job. Generally, this means you must be trained to a level that you can identify and handle the hazards that are present at your workplace. For example, if you handle and process Category A infectious materials, you must be trained to a different level than someone who only handles Category B materials. The training requirements apply to hazmat employers and hazmat employees as defined in 49 CFR 171.8. This includes all hazmat employees and their employers with direct supervision of hazmat transportation functions. See the table below.

Training Requirements	**Air**					**Ground**				
Initial Training	Prior to performing functions					Within 90 days of hire				
Recurrent Training Frequency	Every 24-Months					Every 36-Months				
Storage requirements of training records	3 Years					3 Years				
Regulatory standards that employees should have knowledge of before preparing packages of possibly infectious material for transport.	**Hazard Classification for Transport**									
	Category A	**Category B**	**Exempt**	**Exceptions**	**Dry ice**	**Category A**	**Category B**	**Materials of Trade (MOT)**	**Exceptions**	**Dry ice**
OSHA Bloodborne Pathogens Standards 29 CFR 1910.1030	X	X	X	X		X	X	X	X	
IATA 1.5.1.2 – Objectives of Dangerous Goods Training	X				X					
49 CFR 172.704(a)(1-4) Training Requirements	X					X				
49 CFR 172.704(a)(5) In-depth security training	Confirmed Select Agents					Confirmed Select Agents				
IATA Packing Instructions 650		X								
49 CFR 173.199(e) Category B		X					X			
Knowledge of classifying and packing the hazard	X	X	X	X	X	X	X	X	X	X

- OSHA Bloodborne Pathogens Standards 29 CFR 1910.1030 covers general safety while handling blood and other possibly infectious materials.
- IATA 1.5.1.2 Objectives of Dangerous Goods Training says three important topics must be covered in a training program. (1) General familiarization with the provisions of the material they will be working with. (2) Function specific training. Personnel must be trained to perform the functions for which they are responsible. (3) Safety training. Personnel must be trained on how to recognize the hazards presented by the dangerous goods they are handling and on emergency response procedures.
- 49 CFR 172.704(a)(1-4) Training Requirements says 4 main topics must be covered for hazmat employees. (1) General awareness. Employees should be familiar and be able to recognize and identify hazardous materials. (2) Function specific training. Each employee must be provided function specific training. (3) Safety training. Employees must receive emergency response information, know measures to protect themselves from hazards and methods to avoid accidents. (4) Security awareness training. Hazmat employees must be aware of risks associated with hazardous materials.
- 49 CFR 172.704(a)(5) In-depth security training. For hazmat employees who offer select agents or toxins for transport additional in-depth security training is required.
- 49 CFR 173.199(e) Category B. Each person who offers or transports a Category B infectious substance under the provisions of this section must know about the requirements of this section.

There are three main parties involved in the transport of dangerous goods. The **shipper** prepares the hazardous material for transport. The **operator** is the party that transports the material from point A to point B. And the **receiver** accepts the package at the end of transport. Each party has different responsibilities and training requirements. MDHHS BOL's "Packing and Shipping for the Clinical Laboratory" course is focused on shipper's and receiver's responsibilities. Operators will need to seek training from another source. 49 CFR 177.800 and 177.816 have information for operators and highway transport. See the table below for a summary of responsibilities.

Hazardous Materials Transport Responsibilities		
Shipper (Consignor)	**Operator (Carrier)**	**Receiver (Consignee)**
Training	**Training**	**Inspection before opening**
Classification	**Inspection**	**Incident reporting**
Identification (of Hazard)	**Acceptance or Rejection**	**Training (Recommended, not required)**
Select Proper Packaging	**Storage**	**Verification of itemized list (Recommended, not required)**
Packing	**Transportation**	
Marking and Labeling	**Incident Reporting**	
Documentation (Shipping papers)		
Ensure package is clean from contamination		

49 CFR 172.704(a)(1-2) require hazmat employees to receive **General Awareness Training** and **Function Specific Training**. The MDHHS BOL "Packing and Shipping for the Clinical Laboratory" module should cover all aspects of general awareness for the shipment of infectious substances. Please note, function specific training can only be verified by the hazmat employer. Function specific training provided by the employer is hands on, in-house training and should cover the materials and duties encountered at their specific workplace. This training must be documented, and current training records retained.

The DOT **training requirements for dry ice** shipments by air are quantity based. Formal training is only required when shipping quantities greater than 2.5kg, (5.5lbs) (49 CFR 173.217(c)(5)). IATA does not accept these quantity-based training requirements. All shippers of dry ice by air must be trained in accordance with IATA training requirements.

Please note that **staff who only offer Category B infectious substances are exempted from the full DOT training requirements** (49 CFR 173.199 and IATA Packing Instructions 650). Staff are only responsible for identifying the hazard they ship and knowing the packing requirements of that hazard. IATA states that employees must be aware of classification, incident reporting, and inspection of damaged or leaking packages. For Category B infectious substances, it is recommended that general awareness and familiarization training is

offered. The employees must be able to follow packing instructions provided by the packaging manufacturer. This training should be documented, and current training records retained.

Training requirements for excepted infectious substances, such as Materials of Trade or those listed in 49 CFR 173.134(b) and (c), state that employees who perform pre-transport and transport tasks are required to be trained on the applicable requirements of each exception. Full DOT or IATA training is not required.

Training Timeframes

DOT regulations state that during the first 90 days of employment a hazmat employee can perform their job functions while being directly supervised. However, during that 90-day introductory period they must receive training to continue in their job functions. DOT considers the 91st day of employment without training to be noncompliant. Additional training must be offered to employees if their job functions change significantly, or if the regulations change significantly (49 CFR 172.704(c)(1)).

IATA DGR H.5.1.6.2(a) states that initial training must be provided prior to a person performing their functions related to air transport. Effectively, this means an employee must receive training on handling dangerous goods according to their function prior to starting their job or a whenever a new function or gap has been identified.

Regulations also state that there must be **continuing education** in awareness of the regulations for hazardous materials. **DOT prescribes that employees must receive training at least every 36 months** to maintain their knowledge (49 CFR 172.704(c)(2)). Recurrent training every 3 years is also a Joint Commission and College of American Pathologist (CAP) requirement (CAP tag GEN.40512 and GEN.40515). This three-year period begins on the actual date of training. Relevant training received from a previous employer or source may be used to satisfy the requirements provided a current record of training is obtained from the previous employer or other sources. And, for dangerous goods shipments by air, **employees must be trained every 24-months according to IATA** (IATA DGR H.5.1.6.2(b)). 1.5.5 of the IATA Infectious Substances Shipping Regulations states that:

> "Personnel must receive recurrent training and assessment within 24 months of previous training to ensure that the knowledge is current. However, if recurrent training and assessment is completed within the final 3 months of validity of previous training, the period of validity extends from the month on which the recurrent training and assessment, was completed until 24 months from the expiry month of that previous training."

MDHHS BOL recommends staying compliant with the IATA required 24-month recurrent training cycle. Maintaining the 24-month recurrent training schedule allows the institution to ship samples by air in case of emergency or extenuating circumstances.

Training Recordkeeping

Documents certifying that employees have been trained and tested must be retained for the preceding 3 years. If an employee is no longer employed at an institution, their records must be retained for at least 90 days following their departure (49 CFR 172.704(d) and IATA DGR 1.5.1.4).

The certificate of completion provided by MDHHS after successful training has all the requirements listed in 49 CFR 172.704(d)(1-4). However, please note that MDHHS BOL does not certify individuals in packing and

shipping dangerous goods. The training certificate has a place for the employer to certify their employees have received all additional applicable training and have been tested to institutional standards (49 CFR 172.704(d)(5)).

Despite the lower training requirements for Category B materials please be aware that some accrediting agencies, such as the College of American Pathologists (CAP), require documentation of training and record retention of those documents (CAP Tag GEN.40515).

Any facility should be able to retrieve all training documents and materials promptly in case of regulator inspection. Proof and certification of training should be kept for: **General Awareness Training, Safety Training (OSHA Bloodborne Pathogens Standard), Security Awareness Training, and Function Specific Job Task Training.** These records need not be kept in the same location, nor on the same form, but all documentation should be well organized and easily accessible.

Selection of Training Material

Training source and suitability of that material must be chosen by the employer. There are no pre-approved DOT or IATA training programs. The hazmat employer is responsible for selecting training that fulfills laboratory needs, safety goals, and HMR requirements (DOT Interpretation Response 08-0078). DOT has no procedure for reviewing training programs ahead of time. However, DOT will gladly review your training program during an inspection.

There are many training programs available from both private and public sources. Shippers can even create their own training program. MDHHS BOL believes that this module covers the general awareness requirements for Sentinel Laboratories to be compliant in shipping infectious substance and their related materials. DOT evens says that individuals may "self-certify," as long as you have documented the process and retain appropriate training records in accordance with 49 CFR 172.704.

Again, please note that **MDHHS BOL does not certify individuals in packing and shipping** dangerous goods. **Individuals can only be certified by their employers.** It is the employer's responsibility to ensure their employees are competent. Only the hazmat employer can certify that an employee has been trained and tested (IATA DGR 1.5.1.2). This program is not all inclusive of all the function specific tasks that attendees will encounter at their workplace. Therefore, additional trainings are necessary to complete a comprehensive institutional training program.

Other training materials can be used to complete hazmat employee training (49 CFR 172.704(b)). In many cases safety OSHA Bloodborne Pathogens Standard training, 29 CFR 1910.120 or 1910.1200, may meet all or part of the **Safety Training** requirements for transporting infectious materials (49 CFR 172.704(a)(3)). To work safely employees must be aware of the dangers of the hazardous materials they are handling.

Safety training must include **Emergency Response Information** as required by 49 CFR 172.704(3)(i). Emergency response information training requirements can be found in 49 CFR 172.600-606. Training must include measures to protect the employee from dangers associated with the hazards found in their workplace. Again, OSHA Bloodborne Pathogens Standard training should cover most of the requirements in this section.

Security Awareness Training is required under 49 CFR 172.704(a)(4). Each hazmat employee should be aware of the risks associated with handling hazardous materials and how to enhance security. The MDHHS BOL "Packing and Shipping for the Clinical Laboratory" training module will briefly cover this training requirement. However, based on site specific risk assessments additional security training might be advised.

Additionally, 49 CFR 172.704(a)(5) states that **In-depth Security Training is required to transport high-consequence hazardous materials such as confirmed select agents or toxins**. For a list of select agents regulated by the CDC (42 CFR Part 73) or the US Department of Agriculture (9 CFR Part 121) please visit http://www.selectagents.gov. In-depth security training is comprehensive and is not covered in this module. Security plan requirements can be found in 49 CFR 172.800 through 172.804.

To ensure employees are trained to the appropriate level it is recommended to list all employee functions and responsibilities, and then verify training requirements. Any employee who works in a shipping and receiving or material handling area or who may be involved in preparing or transporting hazardous materials is required to have training. All employees who perform work functions covered by the HMR, 49 CFR Parts 171-180, will require some level of training.

IATA has more stringent training requirements for shipment by air. IATA states that employers must have a **Competency Based Training and Assessment (CBTA) program**. In this program IATA states that employers shall confirm that their employees are competent by function specific on the job evaluations. This is to be done in conjunction with passing an awareness training course such as the training provided by MDHHS BOL.

How to get Trained

MDHHS BOL offers "Packing and Shipping for the Clinical Laboratory" in several formats. Live in-person lectures can be scheduled by contacting Jason Wholehan, wholehanj@michigan.gov. Classes can also be arranged to be held on live on Microsoft Teams. "Packing and Shipping for the Clinical Laboratory" is also available in an on-demand format by visiting Mi-Train, https://www.train.org/mi-train/home. Search course number 1094582.

The CDC offers an infectious substances on-demand class at https://www.cdc.gov/labtraining/. The Department of Transportation offers a general hazardous materials class at https://dothazmat.vividlms.com/. In addition, there are a multitude of private vendors that offer infectious materials transport training. It is up to the shipper to verify that the training source meets the requirements of the regulations and fits the needs of their specific facility.

Please note there may be additional trainings required such as OSHA safety training and security awareness training that are outside of the scope of many general awareness courses.

To finalize hazardous materials training 49 CFR 172.702 states that, "a hazmat employer shall ensure that each of its hazmat employees is **tested** by appropriate means on the training subjects covered in 49 CFR 172.704." However, DOT never clearly defines "tested," or what a test must include. Therefore, any test that is found suitable by the employer may be used to fulfil this requirement. This could be written, verbal, or performance-based testing. Just make sure this testing is documented.

Material of Trade (MOT) - Courier by Private Vehicle

Please note: the Materials of Trade exception can only be applied to Category B patient specimens. Category B cultures and all Category A materials must follow the full HMR regulations. There are no exceptions in the MOT provision for Category B cultures and all Category A materials. Category B cultures and Category A materials may be transported by private motor carrier, but the shipper must follow all DOT training, packaging, and labeling requirements in 49 CFR 173.196 & .199 (PHMSA Interpretation Response 07-0023).

Clinical samples and infectious materials may be transported by private motor carrier under 49 CFR 173.6(4), Materials of Trade Exceptions. If a company's principal business is collecting and analyzing samples and transporting those samples is in direct support of their business as defined, then the company is eligible for the **Material of Trade (MOT)** provision, provided the samples meet the requirements in 49 CFR 173(6). An MOT is a hazardous material, other than a hazardous waste, that is carried… by a private motor carrier in direct support of a principal business that is other than transportation by motor vehicle (49 CFR 171.8).

DOT regulates material that is being transported while **"in commerce**" (49 CFR 171.1). **PHMSA interprets "in commerce" to mean trade or transportation in furtherance of a commercial enterprise.** In essence, if you pay a third party to transport a hazardous material that material is now "in commerce." MOT fall somewhere outside of this definition. Think of a lawn care company transporting extra gasoline for their mowers. This is in direct support of their business, so they don't need to follow full DOT fuel transport regulations. This is similar to the laboratory transporting specimens in support of their business. For the same reasons hazardous materials transported by state, local, or federal government employees for government purposes are also not considered in commerce and thus are exempt from DOT regulations (49 CFR 171.1(d)(5)). Government contractors and contract employees are NOT able to use this regulatory loophole (PHMSA Interpretation Response 06-0225 and 10-0213).

49 CFR 173.134(b)(10) also allows for a division 6.2 Category B substance that is 1) contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or a biological product; to be 2) transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials. This exempts Category B patient specimens from the requirements of the Hazardous Materials Regulation while being transported by private motor carrier. However, if the shipment does not meet the provisions in 49 CFR 173.134(b)(10), then it may not be transported in a private vehicle.

In essence, most clinical samples can be defined as a MOT. Exceptions would include clinical samples that are expected to contain highly pathogenic viruses such as Ebola. Patient samples containing hemorrhagic viruses must be transported following Category A packing requirements.

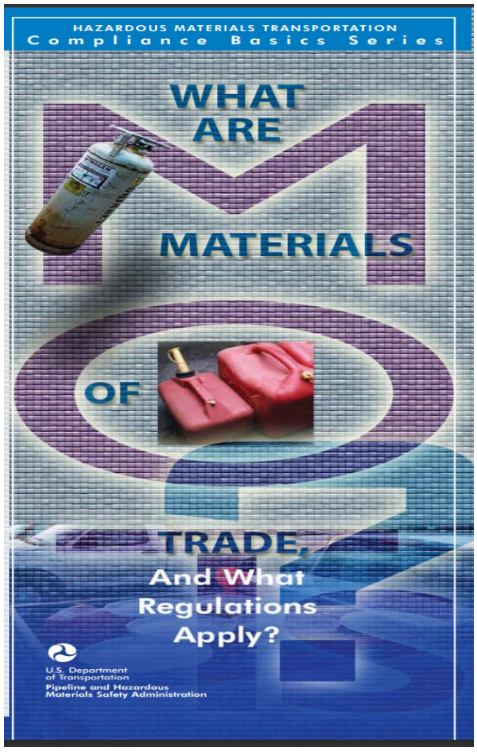
Private Vehicles used exclusively to transport medical samples/supplies means traveling from Point A to Point B with no other stops and no other purposes. Keep in mind, at other times the vehicle can be used for different purposes. To be considered "used exclusively" or in "exclusive use," a motor vehicle may not contain other goods, materials, or passengers at the same time it is used to transport the MOT. A single trip transporting only these materials from either one or multiple shippers may be considered the exclusive use of a transport vehicle under 49 CFR 173.134(b)(10). Essentially this means don't operate Uber or Lyft while applying the MOT exception to your vehicle. PHMSA Interpretation Response 20-0064 further clarifies that this vehicle does not need to be owned by company and can be an individual's personal vehicle. Please be advised that before using an

individual's personal vehicle to transport MOT the individual should consult with their personal vehicle insurance policy regarding liability and coverage.

No special driver license or endorsements are required to operate a vehicle transporting MOT. However, for the **driver's safety** they must be made aware of the presence of the hazardous material and must be informed of the requirements in the MOT provision (49 CFR 173.6(c)(4)). Drivers and their vehicles may be private citizens, medical couriers or other drivers who work directly for a laboratory or hospital.

Staff and institutions utilizing a courier to ship Category B patient samples in accordance with 49 CFR 173.134(b)(10) are not subject to the **training requirements** in 49 CFR Part 172 Subpart H (PHMSA Interpretation Response 20-0064). However, employees who perform classifying and packaging tasks for excepted infectious substances, such as MOT or those listed in 49 CFR 173.134(b)&(c), are required to be trained on the applicable requirements of each exception. Please note that staff who transport Category B cultures and Category A materials are subject to the full DOT training requirements as hazmat employees.

In preparation for an **emergency clean up** best practices would be that there should 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 a refrigerant is used during the transport, then a pair of cryogenic gloves should be available in the vehicle. The OSHA Bloodborne Pathogens Standard says spills of blood should be cleaned immediately (29 CFR 1910.1030(d)(4)(ii)(A)). Having a spill kit with proper cleaning supplies allows you to clean immediately while remaining safe. At the very least, there should be an institutional plan in place for spills and other emergency clean up during the transport of MOT. 49 CFR 171.15 lists requirements for "Immediate notice of certain hazardous materials incidents". If there is a significant incident while transporting hazardous materials, you may need to notify DOT.



Packaging requirements for specimens sent using the MOT provision are different and less stringent than the full DOT HMR regulations. 49 CFR 173.6 states that biological material must be contained in combination packaging that is leakproof, tightly capped, and secured against movement.

Packaging requirements for liquids, the inner packaging must be leakproof, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. **For solids,** the package is recommended to be shiftproof to avoid spillage.

Packaging requirements for sharps, the inner packaging (sharps container) must be constructed of a rigid material resistant to punctures and securely closed to prevent leaks or punctures, and the outer packaging must be securely closed to prevent leaks or punctures. 49 CFR 173.6(4)(ii)(A) discusses medical waste volume limits which is applicable to sharps waste, inner packaging may not contain more than 4 kg (8.8 lbs), and an outer packaging containing not more than 16 kg (35.2 lbs).

Packaging requirements for all MOT, the outer packaging must be a strong, tight packaging securely closed and secured against shifting,

including relative motion between packages within the vehicle on which it is being transported. It is recommended that the packaging must be the manufacturer's original packaging or a package of equal or greater strength and integrity.

These packaging requirements comply with the OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030(d)(2)(xiii). This section requires specimens of "blood or other potentially infectious material (OPIM) to be placed in a container which prevents leakage during collection, handling, processing storage, *transport, and/or shipping*." (Author emphasis added)

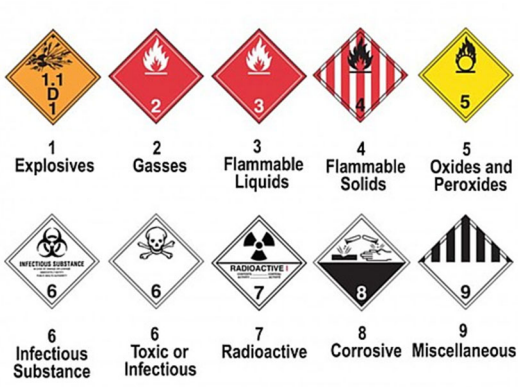
There are also 49 CFR 173.6 **volume limitations for clinical samples,** such as inner packaging may not contain more than 0.5kg (1.1lbs) and outer packages may not contain more than 4kgs (8.8lbs). In aggregate the total gross weight of all MOT transported by motor vehicle may not exceed 200kg (440lbs).

Labeling requirements for specimens sent using the MOT provision are different and less stringent than the full DOT HMR regulations. Communication about the hazards being transported must follow 49 CFR 173.6(c). The packaging must be marked with a common name or proper shipping name (such as "exempt human specimen", "diagnostic specimen", or "Dry ice"). Since they are exempt from DOT markings and labeling requirement, MOT do not require the diamond shaped hazard placards. However, OSHA Bloodborne Pathogens Standard labeling still applies and therefore for Class 6, Division 6.2, Category B materials, and materials that contain blood or is visibly contaminated with blood the OSHA standard requires a biohazard label be placed on the outer or inner packaging. More information can be found in 29 CFR 1910.1030(g)(1)(i), such as a description of lettering and biohazard symbol requirements. If individual containers of blood or OPIM are placed in a larger container during storage, transport, shipment or disposal and that larger container is either labeled with the OSHA "BIOHAZARD" label or color-coded, the individual containers are exempt from the labeling requirement 29 CFR 1910.1030(g)(1)(i)(F-I). Further investigation on OSHA labeling requirements in transport can be found in the OSHA Regulatory Intrepretations 2005-09-08 and 2002-09-17.

If **dry ice** is used as a refrigerant the package should be marked with the common or proper shipping name, i.e. "Carbon dioxide, solid" or "Dry ice," to conform with 49 CFR 173.6(c)(1) hazard communication requirements. Dry ice, when transported over the roadway, is not subject to DOT HMR 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 the package. Because dry ice can displace oxygen and act as an asphyxiant, it should be separated from all vehicle occupants, such as placing the package in the trunk. If this is not possible, roll down a window to allow fresh air to circulate to avoid buildup of CO_2 gas.

Please note that whether designated as laboratory staff members, contractor personnel, or self-employed agents, **couriers carry the risk of encountering extremely contagious pathogens.** Ensuring on-the-job safety is of utmost significance, not solely for the well-being of the courier, but also for the proper management of specimens and the protection of the broader community. It is imperative for the institution to create a comprehensive strategy and protocols for the secure storage and transportation of specimens. Adequate preparations encompassing an operational framework, essential tools, and suitable personal protective gear must be established to effectively address potential incidents such as spills or environmental breaches.

Classify Hazards



The single most important job of the shipper is to correctly classify the hazard being handled. Correctly classifying the hazard will allow the shipper to find and follow all the applicable packing instructions and regulations.

There are 9 hazard classes of dangerous goods. Some of these classes are further divided into divisions. As a hazmat employee you should be aware of all 9 classes and divisions.

Class 1: Explosives
- Division 1.1: Mass explosion hazard
- Division 1.2: Projection hazard, but not a mass explosion hazard
- Division 1.3: Fire hazard and either minor blast hazard or minor projection hazard
- Division 1.4: No significant hazard
- Division 1.5: Very insensitive substance with a mass explosion hazard
- Division 1.6: Extremely insensitive articles with no mass explosion hazard

Class 2: Gases
- Division 2.1: Flammable gas
- Division 2.2: Non-flammable, non-toxic gases
- Division 2.3 Toxic gases

Class 3: Flammable Liquids

Class 4: Flammable Solids
- Division 4.1: Flammable solids, self-reactive substances, solid desensitized explosives
- Division 4.2: Substance liable to spontaneous combustion
- Division 4.3: Water-reactive substances

Class 5: Oxidizing substances and organic peroxides
- Division 5.1: Oxidizing Substances
- Division 5.2: Organic Peroxides

Class 6: Toxic and Infectious substances
- Division 6.1: Toxic Substances
- **Division 6.2: Infectious substances**

Class 7: Radioactive material

Class 8: Corrosives

Class 9: Miscellaneous Dangerous Goods (Dry ice)

Hazard Class 6.2: Infectious Substances

To be classified as a Class 6.2 infectious substance a material must be **known or reasonably expected to contain a pathogen.** A pathogen is a micro-organism (including bacteria, viruses, rickettsia, parasites, fungi) or other agent such as proteinaceous infectious particle (prion), that can cause disease in humans or animals. Infectious substances can be shipped in 1 of 2 forms. Infectious substances can be contained in patient specimens or grown in cultures.

Cultures of infectious substances are defined in 49 CFR 173.134(a)(3) as a substance that has been "intentionally propagated." These are materials that have spent time in a laboratory where the amount of pathogen in the material has increased. Due to the increased concentration of pathogens in the sample the risk classification MAY change when pathogens are shipped as cultures. Many pathogens are still classified as Category B even in concentrated culture forms.

Patient specimens are defined in 49 CFR 173.134(a)(4) as substances "collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimens include 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)." Please note that many specimens sent to a microbiology laboratory are labeled as "culture." These "culture" specimens are defined as patient specimens until they have been processed in the lab and the pathogen has been recovered and propagated.

Biological Products can be defined as an infectious substance. For a biological product to be exempted from DOT transport regulations it must have prior approval by the FDA, HHS, or the USDA. If the product does not have prior approval, it will be assumed to contain a pathogen, or be reasonably expected to contain a pathogen, and therefore must be handled as an infectious substance. Biological products are therapeutic serum, toxins, antitoxins, vaccines, blood, or blood components or derivatives, when shipped for the prevention, treatment, or cure of a disease or condition of human beings or animals as defined in 49 CFR 173.134(a)(2), and 173.134(b)(6).

Classification of Infectious Substances

Infectious substances are classified into risk categories. These risk categories will direct the shipper to the packaging, labeling, and markings required. Please remember that there is never zero risk when shipping infectious substances, only that different risk categories are prepared differently based on the perceived risk of the substance. These risk categories are Category A, Category B, and other materials probably not infectious.

Category A Infectious Substances

Category A is defined as "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" (49 CFR 173.134 and IATA 3.6.2). This classification is based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.

There are Category A indicative lists prepared by the UN, WHO, and IATA (IATA Table 3.6.D). **A Category A Indicative List is provided in the Resources Section of this Booklet**. These lists explicitly catalog the organisms that are to be classified as the highest risk level, Category A. DOT does not print a list in

the HMR; however, DOT does provide an "example" list that matches the UN, WHO, and IATA. Please note that these lists are not exhaustive, as there might be emerging pathogens that have not yet been added to the lists. So, if you encounter an unusual organism it is recommended to check the list to verify if the material is classified as Category A. If the organism is not listed, then always refer to the definition of Category A provided in the beginning of this section and in 49 CFR 173.134 and IATA DGR 3.6.2 to properly classify your specimen.

The perceived risk of Category A infectious substances is often based on the form in which they are present. Some pathogens listed on the Category A indicative list have a caveat after their name, "(Culture only)." When an organism is listed with (Culture only) in parentheses, the material is only classified as Category A when they are in culture form. Materials that contain these organisms can therefore be transported using Category B packaging materials when they are suspected of being present in patient specimens. Again, these organisms are listed as "Organism name (Culture only)." If the organism is listed without this caveat, such as in the case of "Ebola virus", all materials suspected of containing the organism must be prepared using Category A packing materials. That is, both patient specimens and cultures must be shipped using Category A packing materials.

Organisms and samples suspected of meeting Category A requirements must be shipped as a Category A. Based on the professional judgement concerning patient or medical history of a culture or patient specimen a sample suspected of fulfilling the classification to Category A must be shipped as a Category A. Often this means you will ship a culture that is suspected of being a Category A organism for confirmation testing. In these cases, if there is a serious suspicion that the organism is a Category A agent then it must be packaged using Category A practices.

Category A infectious substances are given two UN numbers that informs handlers of the dangers present. Pathogens that can affect humans are assigned **UN2814**, and pathogens that can only affect animals are assigned **UN2900**. If the pathogen is zoonotic and can affect both humans and animals, it is assigned UN2814. UN2814 proper shipping name is "Infectious substance, affecting humans," and UN2900 proper shipping name is "Infectious substance, affecting animals."

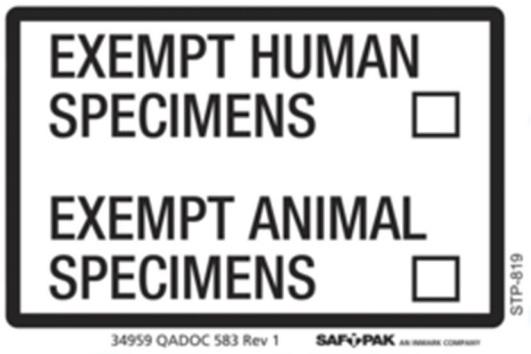
Category B Infectious Substances

Category B is a lower risk level than Category A and is defined as "an 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" (49 CFR 173.134 and IATA 3.6.2.2.2.2). Generally, **all other infectious substances NOT classified as Category A are classified as Category B**.

Unless otherwise suspected of meeting the definition of Category A, all infectious substances transported for diagnosis or investigational purposes are transported as Category B. When a material is collected and transported to a laboratory and the tests ordered are looking for the presence of a pathogen this means that that material is reasonably assumed to contain a pathogen and must be shipped at least as a Category B.

Category B is assigned the UN number **UN3373**, and proper shipping name "Biological substance, Category B."

Exempt Human Specimens



This classification is only found in IATA and USPS regulations. DOT does not recognize this classification, so please be aware of the mode of transport and carrier of your materials.

Exempt human specimens are **specimens that are not likely to contain a pathogen.** To classify a material as exempt, you MUST apply professional judgment. If no judgement has been applied, then the material must be classified as either Category A or B. Factors such as medical history, patient symptoms, and patient circumstances must be taken into consideration (IATA DGR 3.6.2.2.3.8).

The UN does not define these specimens as dangerous goods so there is no UN number assigned. Despite not being listed as a dangerous good, exempt human specimens still need to be handled safely. IATA and USPS still place strict regulations for packing and shipping of these materials.

Examples of specimens that can be classified as exempt human specimens are blood or urine collected to monitor glucose levels, or blood collected to monitor organ function such as heart, liver, or kidney function tests. Remember, before classifying these samples as exempt you must apply professional judgement based on patient history and individual circumstances. For example, if a patient has their blood collected for glucose monitoring but also has blood collected for monitoring of HIV levels you would reasonably expect to find a pathogen in that patient's blood, and therefore all samples would need to be classified as at least Category B.

Not Regulated – Exceptions to Regulations

DOT and IATA both list materials that are not subject to their infectious substance's regulations (49 CFR 173.134(b) and IATA DGR 3.6.2.2.3). In essence, these are materials or specimens that do not contain a pathogen, or that are unlikely to cause disease. These are substances that have been neutralized or sterilized and no longer pose a health risk and therefore are no longer regulated under the infectious substance's sections. There are no DOT or IATA guidelines for packing not regulated specimens. Please be aware that substances not subject to the requirements of the infectious substance's sections may meet the criteria for other dangerous goods classes so ensure that these materials are packed to the appropriate standard.

Materials known not to contain an infectious substance are not regulated under these sections. For example, dried blood spots and fecal occult cards are both listed as not regulated because the act of placing these samples on filter paper renders them noninfectious. Materials that have been neutralized or inactivated are not subject to the infectious substance's regulations. For another example, blood collected for transfusion by the Red Cross, or other transfusion services, that has been screened and tested negative for infectious materials is not subject to the regulations under these sections. Microorganisms that do not cause disease in humans or animals are not regulated as infectious substances as these do not fit the definition of a pathogen. Food and water environmental samples that are not suspected to contain an infectious substance may be classified as not regulated under these sections. **Plant pathogens are not regulated under these** sections, unless listed by USDA

as a select agent. The definition of a pathogen in the transport regulations only applies to human and animal pathogens.

Be advised, there might be additional OSHA requirements to follow when shipping materials that are exceptions to DOT and IATA rules, please review 29 CFR 1910.1030 to assure compliance. OSHA Standard Interpretation from 7/21/1999 states in part: human blood, human blood components, and products made from human blood are included in the Bloodborne Pathogens Standard, and cannot be considered "non-infectious", whether used for diagnostic purposes or other purposes, regardless of a specimen's declared purpose as a diagnostic tool and its relative safety. Samples can be classified as low risk according to IATA and DOT but remember there is never zero risk.

Materials such as **dried blood spots (DBS) for newborn screening** testing can be shipped by mail or other carrier with no reasonable expectations of occupational exposure to blood or other potentially infectious material. Use “standard precautions” when preparing dried blood spot specimens for shipment and comply with institutional policies. Even though DBS are classified as not regulated under the infectious substances sections you must properly package and label the specimens for shipping. Proper packaging and labeling notifies employees and transportation personnel of your package’s contents. If transported by U.S. Mail, USPS Packaging Instructions - 6G Nonregulated Infectious Materials guidelines must be followed. To mail dried blood spot specimens, you must use the basic triple-packaging system: 1. The primary container is the filter paper matrix that contains the absorbed and dried blood, 2. A secondary container must enclose the primary (filter paper) container. The secondary container should have a fold-over flap or an inner envelope to secure the contents, and 3. The third level of containment is an outer envelope of sturdy, high quality paper. These levels of containment provide reasonable safety from occupational exposure and maintain optimal specimen integrity. No additional content markings are required on the outer shipping container; however, you must affix or print the international biohazard symbol on the either the primary or secondary container to meet OSHA labeling requirements.

For a summary of infectious substances classification please see Table 3.

Table 3: Summary of Infectious Substances Classification

Category A	Category B	Exempt Human Specimen	Not Regulated
In a form on the indicative list of Category A infectious substances.	All pathogens not classified as Category A.	Patient specimens with a minimal likelihood of containing a pathogen.	Materials known NOT to harbor an infectious substance. Or materials rendered non-infectious.
Causes severe disease in healthy humans or animals.	Patient specimens sent for diagnosis of infectious diseases.	Professional judgment applied to patient history and likelihood of the absence of a pathogen.	Plant pathogens (not listed on the USDA select agent list).

Medical Waste

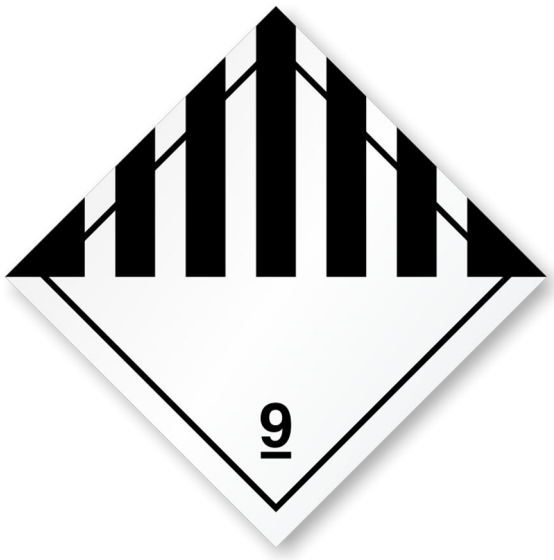
Additionally, infectious substances may be contained in waste and therefore will need to be classified as “Regulated Medical Waste.” Any waste that contains a Category A agent must be classified as such. Waste that contains Category B substances must be classified as medical waste and shipped and handled accordingly.

Hazard Class 9: Dry ice

Carbon dioxide that has been frozen solid, commonly called dry ice, is classified as a dangerous good by the UN. It is assigned the UN number **UN1845.** Dry ice is frequently used as a refrigerant in shipments containing infectious substances. The hazards of dry ice are related to the extreme temperature and the nature that dry ice will sublimate, meaning it will transfer directly from a solid to a gas.

Dry ice can be a **contact hazard**. Dry ice is made of frozen carbon dioxide gas (CO_2). The temperatures needed to freeze CO_2 gas are extreme, -79°C (-107°F). These temperatures are so cold that it can cause frostbite upon contact with unprotected skin. You should always handle dry ice with care by using the appropriate thermal protective gloves.

Dry ice can be an **explosive hazard**. Dry ice releases large volumes of CO_2 gas as it sublimates. It has an expansion ration of 1:554. This means that half a kilogram of dry ice will produce approximately 250 liters of CO_2 gas. If the solid dry ice is packed into a container that does not let this expanding gas escape the package will pressurize. If there is too much pressure built up the package may rupture or even explode possibly causing injury or property damage.



Dry ice can be an **asphyxiant hazard**. CO_2 gas is heavier than air and it will settle if left undisturbed. The accumulating CO_2 gas can displace room air and lower oxygen concentrations. Even at levels too low to cause true asphyxiation CO_2 can be toxic causing shortness of breath and headaches. Prolonged CO_2 exposure can even lead to death. It is always recommended to handle dry ice in a well-ventilated area. During transportation packages containing dry ice should be placed away from drivers or vehicle occupants, such as in a trunk. If this is not possible and dry ice must be transported in the same space as occupants, vehicle windows should be lowered slightly to allow fresh air to circulate.

Knowing the mode of transport while preparing a shipment containing dry ice is important. IATA regulates the transport of dry ice by its member airlines. DOT only regulates the transportation of dry ice when shipped by air or water modes. In practice, dry ice is almost exclusively shipped by air modes because of the urgency of the shipment. Dry ice is not regulated by DOT as a hazardous material when shipped over the roadway. However, all the same dry ice hazards exist even when dry ice is not airborne.

Pack the Material

After determining the mode of transport and the regulatory standards to be applied the shipper must select the appropriate packaging materials. See **Table 4** for modes and packing standards.

Table 4: Mode and Packing Standards		
Mode	**Regulator**	**Packing Requirements**
Air	**IATA DGR**	Category A = PI 620 Category B = PI 650 Exempt = IATA DGR 3.6.2.3.8 Dry ice = PI 954
Ground – Motor vehicle	**DOT HMR**	Category A = 49 CFR 173.196 Category B = 49 CFR 173.199 Dry ice = 49 CFR 173.217
US Mail	**USPS Publication 52**	Category A = Not mailable Category B = Pub 52 346.321, Packaging Instructions 6C Exempt = Pub 52 346.326, Packaging Instructions 6H Dry ice = Packing Instructions 9A, 49 CFR 173.217, and 175.10(a)(10)

The essence of all infectious substances packing requirements is the triple pack. All infectious substances must be prepared using triple packaging. The components of a triple pack are the primary receptacle, secondary packaging, and outer packaging. A properly prepared infectious substance should have a very minimal risk of causing an exposure while in transit. Diligence in selecting the proper packaging will safeguard your shipment and reduce your liability in case of an accident.

The **primary receptacle** is the specimen container, such as a blood tube or urine cup. The primary receptacle must be made of glass, metal, or plastic. This container should be leakproof or siftproof for solids. The opening should be sealed in a positive means, such as with tape or parafilm. Sealing with tape or parafilm will ensure the opening will not become loose in transport. The package may vibrate in transit and the closure could become loose if not sealed. This is required for Category A, and highly recommended for all others. Cultures of infectious substances may be transported on agar plates. However, this is not recommended as agar plates are difficult to secure and make leakproof. **Please call ahead to arrange transportation if an agar plate is to be used as a primary receptacle when submitted to MDHHS BOL.**

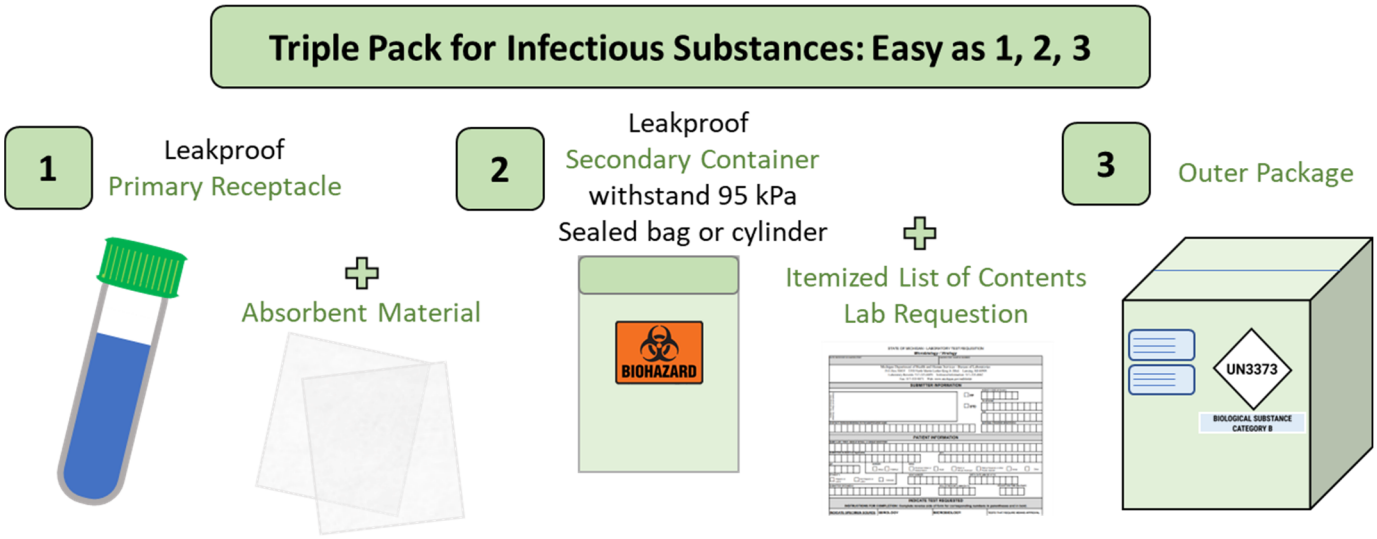
Primary receptacles must be packaged so they cannot break or leak into the **secondary packaging.** The secondary packaging is a sealed bag or cylinder. It must include cushioning around the primary receptacle to prevent damage. If multiple primary receptacles are placed in a single secondary pack, the primary receptacles must be individually wrapped to prevent contact between them. In the secondary packaging there must be **sufficient absorbent material** to absorb the entire volume of the sample if a spill or leak were to occur. The secondary packaging must also be leakproof in case the primary receptacle leaks.

When traveling by aircraft IATA packing instruction 650 and 620 (All Category A and Category B liquids) stipulates that either the primary or secondary packaging must be able to withstand an internal pressure of

95kPa. This will prevent the package from spilling or rupturing in the event of emergency plane depressurization. This rule is not applicable to exempt human specimens and Category B solids.

The outer packing must be made of a rigid material such as corrugated fiberboard, wood, metal, or rigid plastic, and must have at least one side of 4 inches. If Styrofoam is required for temperature control, it should be placed within another rigid container. Dry ice or ice packs can be placed between secondary and outer package. If dry ice, ice packs, or gel packs are used for temperature control, please ensure they will not leak or sweat outside of the outer package.

49 CFR 173.22(a)(4)(ii) states that if the manufacturer's closure instructions are not permanently embossed or printed on the package, **the shipper MUST maintain a copy of the instructions for a period of 90 days from the time the shipment was offered for transport.**



Package Testing Requirements

<u>These package test requirements are performed by the manufacturer</u>, but it is important to be aware of the regulations. Infectious substances packages are tested to withstand high levels of abuse to ensure safety. It is important to follow all manufacturer instructions to ensure that the package performs to the level it was designed while in transit. See the table below for completed package testing requirements. These requirements can be found in 49 CFR 178.609 and IATA DGR 5.1.

Completed Package Testing Requirements			
Requirement		Category A	Category B
Drop Test Conditioning	Water Spray	Yes	Yes
	-18°C	Yes	Yes
Drop Test Height		9 m	1.2 m
Puncture Test		7kg Rod	No
Stacking Test		Yes	No

Due to these testing requirements, it is recommended that shippers do NOT mix and match packaging components. Again, these packing supplies are tested together to work as a unit, all manufacturer instructions must be followed.

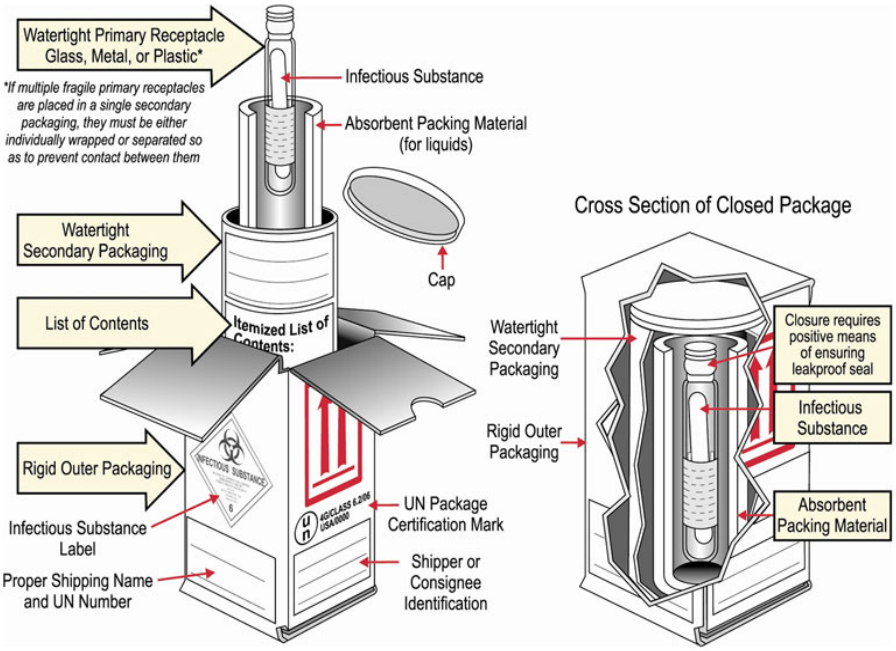
The Category A completed package testing requires are very stringent. Only packages containing radioactive materials undergo more rigorous testing. Therefore, the shipper MUST follow all manufacturer packing instructions to ensure the package will perform as expected.

Often due to the less stringent testing requirements for Category B packages the shipper may create their own Category B packages. But the shipper should take care to ensure the samples are packaged in a way that there will be no leakage from the primary receptacle, which must remain protected by the absorbent material in the secondary packaging – when required, 49 CFR 178.609(d).

Exempt human specimen packages are not required to undergo testing by the manufacturer.

Packing Category A

To prepare a package containing a Category A infectious substance follow packing instructions IATA: 620 or DOT: 49 CFR 173.196 depending on the mode of transport. The UN Number assigned is UN2814, or UN2900, and the proper shipping name is either “Infectious substance, affecting humans” or “Infectious substance, affecting animals.”



All shipments of infectious substance MUST be packed in a triple pack format. Please review the section above discussing **Triple Pack** packaging. For Category A infectious substance, the primary receptacle MUST be sealed in a positive means.

The outer package of all shipments of dangerous goods must be labeled with a **shipper (consignor)** and **receiver (consignee).** The shipper and receiver must be people’s names, not laboratories or companies (49 CFR 172.301(d)). Who sent the package, and where is it going. You should use complete names and full address. A phone number may be included but is not required.

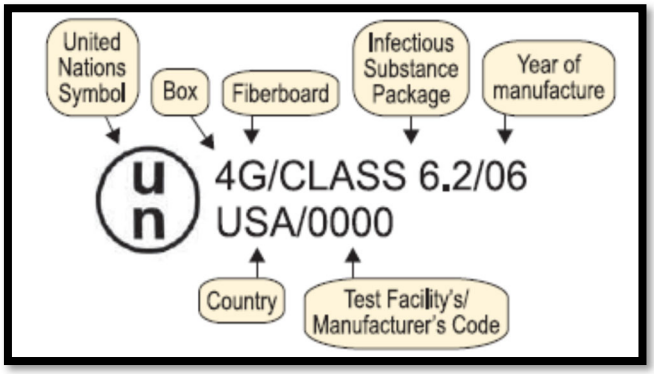
Additionally, all dangerous goods packages are required to have a **responsible person contact.** This must be a person who is aware of the package and its contents. The telephone number must be monitored during a company's administrative hours (*i.e.,* company's operational business hours). For Category A shipments the responsible person contact information is required to be on both the written documents and the outer package.

Category A shipments must have an additional **24/7 Emergency Contact** phone number included (IATA Code USG-12 and 49 CFR 172.604). This point of contact is often confused with the responsible person. While the 24/7 contact and the responsible person can be the same person the 24/7 contact must be a continuously monitored phone line for immediate emergency access information. This contact must be a live person, NOT an answering machine. A third-party contract company can be used as the 24/7 Emergency Contact. The contact must be an individual who is knowledgeable concerning the hazards and characteristic of the dangerous good being transported and has comprehensive emergency response and accident mitigation information for the dangerous good or can immediately call upon a person who possesses such knowledge and information. And please note, the 24/7 emergency contact goes on the shipping papers, not the outer package.

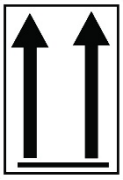
Packages containing Category A infectious substances must have the **class 6 infectious substances label** on the outer package. This is a square label that should be set on a 45° angle, or like a diamond shape. The label must contain the text: "In case of Damage or Leakage, immediately Notify Public Health Authority." The proper shipping name and UN number must appear on the outer package, "Infectious substances, affecting humans", and UN2814. Minimum dimensions of this diamond shaped label are 50x50mm for small packages and 100x100mm for all others.

Due to the stringent testing requirements of Category A packages the manufacturer will place a **UN package certification marking** (49 CFR 178.503(f)). If the package does not have this mark, you cannot use the package to ship a Category A material. The mark MUST be present. There are other dangerous goods that need to be shipped in UN certified packages, but these packages have been tested to different UN certification standards. Therefore, the UN mark for Category A infectious substances must say "CLASS 6.2" to designate that the package has been tested to the correct standards. This label is proof from the manufacturer that the package has passed all applicable Category A package tests. It can NOT be covered up by other labeling. Again, this mark is placed by the manufacturer and the shipper can NOT add this to any box to create a UN certified package. Only order Category A packing material from reputable manufacturers.

Due to the stringent package testing all packing material must be used according to manufacturer instructions. You cannot mix and match Category A packaging components, as this will be an untested modification to the certified package. The year of manufacture appears at the end of the mark code but this is not an expiration date. However, please remember to only use good quality packaging when shipping infectious substances.



If the primary receptacle contains >50 ml of liquid, then **Orientation Labels or Orientation Arrows** are required. The shipper may choose from 2 colors, the arrows may be black on white background, or red on a white background. The label must have two arrows and appear like the example pictures. Minimum dimensions for this label are 74x105 mm. The completed package must have 2 labels, and the labels must be placed on opposite sides of package. When orientation arrows are used the primary receptacle's closures must be oriented in the same direction as the arrows. Although orientation arrows are not always required it is recommended to add them to all infectious substances packages (IATA DGR 7.2.4.3).



An important thing to note while preparing a Category A package: 49 CFR 173.22(a)(4)(ii) states that if the manufacturer's closure instructions are not permanently embossed or printed on the package, the shipper MUST maintain a copy of the instructions for a period of 90 days from the time the shipment was offered for transport. So please save copies of manufacturer instructions.

IATA packing instruction 620 and DOT 49 CFR 173.196(6)(7) state that either the primary or secondary package must withstand 95 kPa of pressure and temperatures in the range -40°F to 130°F (-40°C to 55°C). **The shipper must include an itemized list of contents between the secondary and outer packaging.**

While the proper shipping name must appear on the outer package **the technical name should not appear on the outer package** (49 CFR 172.301(b)). Please see the section "Lost in the Crowd Shipping" of this booklet for more details.

The **net quantity** of fully regulated dangerous goods, such as Category A infectious substances, needs to be marked on the outer package (IATA DGR 7.1.4.1). However, there are 3 major exceptions to this regulation: 1) Consignments of only one package with dangerous goods contents, 2) Consignments of multiple packages with identical dangerous goods contents, or 3) ID 8000 and Class 7 radioactive materials. Therefore, generally a shipper preparing a package with only Category A materials need not to mark the net quantity of the material on the outer package. Please note that some commercial carriers, such as FedEx, will require the net quantity to be marked on outer packages regardless of the exceptions.

USPS will NOT accept Category A packages. Additionally, many large commercial carriers will NOT accept packages containing confirmed select agents. Please plan accordingly.

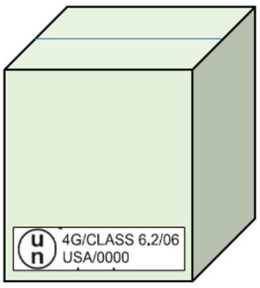
Marking and Labeling for Category A

Outer Package Requirements

Minimum surface: 4x4 inch

In good condition

UN Certified Package, Class 6.2



Marking and Labeling

Material Info:
Proper Shipping Name: "Infectious substance, affecting humans"

UN Number: UN2814

Net Quantity (if applicable): Listed in milliliters or grams

Contact Info:
Names and Addresses of Shipper and Consignee

Name and telephone number of Responsible Person

6.2 Hazard Label

Additional Information (as required)

Dry Ice

Outer Package Requirements
Package can vent CO_2 gas

Properly insulated

Outer Package is leakproof

Material Info:
Proper Shipping Name: "Dry Ice"

UN Number: UN1845

Net Quantity: Listed in kilograms

Class 9 Hazard Label

Quantity Specific

Orientation Arrows
2 labels, opposite faces of package

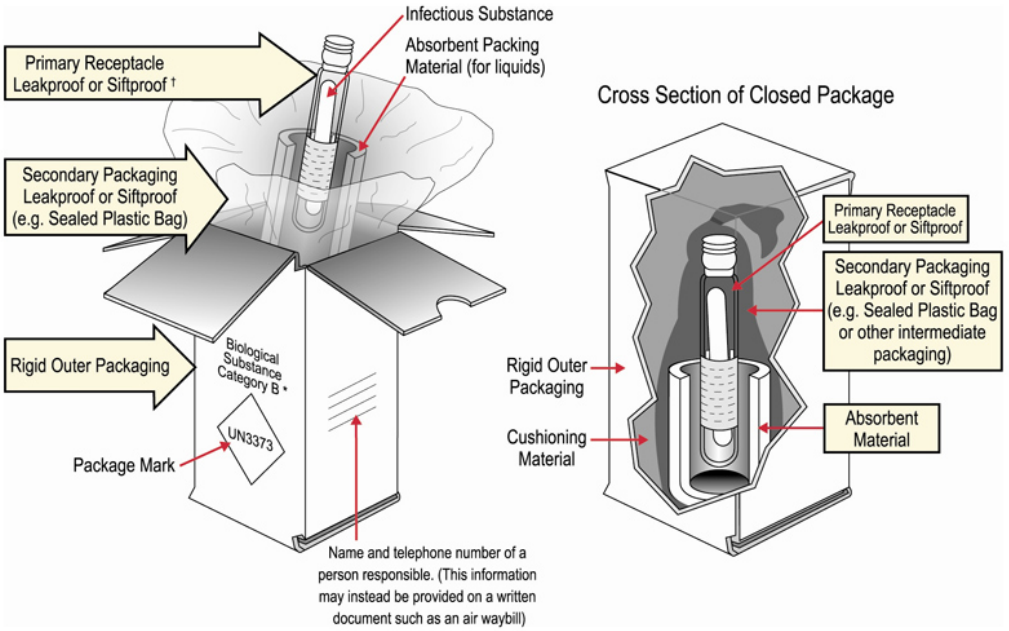
>50 mL liquid

Cargo Aircraft Only

>50 mL or >50 g

Packing Category B

To prepare a package containing a Category B infectious substance follow packing instructions IATA: 650, DOT: 49 CFR 173.199, or US Mail Pub 52 346.321 depending on the mode of transport. The UN Number assigned is UN3373, and the proper shipping name is Biological Substance, Category B.



All shipments of an infectious substances MUST be packed in a triple pack format. Please review the section above discussing **Triple Pack** packaging.

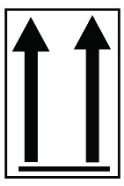
The outer package of all shipments of dangerous goods must be labeled with a **shipper (consignor)** and **receiver (consignee)**. Shipper and receiver must be people's names, not laboratories or companies (49 CFR 172.301(d)). Who sent the package, and where is it going. You should use complete names and full address. A phone number may be included but is not required.

Additionally, all dangerous goods packages are required to have a **responsible person contact.** This must be a person who is aware of the package and its contents. The telephone number must be monitored during a company's administrative hours (*i.e.,* company's operational business hours). For Category B shipments the responsible person contact information is required to be on either the written documents or the outer package (49 CFR 173.199(a)(7)).

BIOLOGICAL SUBSTANCE CATEGORY B

Packages containing Category B infectious substances must have the **biological substances label** on the outer package. This is a square label that should be set on a 45° angle, or like a diamond shape. The proper shipping name and UN number must appear on the outer package, "Biological Substance, Category B", and UN3373. Minimum dimensions of this diamond shaped label are 50x50 mm. The label can be printed in any contrasting color (49 CFR 173.199(a)(4-5)).

If the primary receptacle contains >50 ml of liquid, then **Orientation Labels or Orientation Arrows** are required. The shipper may choose from 2 colors, the arrows may be black on white background, or red on a white background. The label must have two arrows and appear like the example pictures. Minimum dimensions for this label are 74x105 mm. The completed package must have 2 labels, and the labels must be placed on opposite sides of package. When orientation arrows are used the primary receptacle's closures must be oriented in the same direction as the arrows. Although orientation arrows are not always required it is recommended to add them to all infectious substances packages (IATA DGR 7.2.4.3).



According to IATA packing instruction 650, your package must withstand 95 kPa of pressure and temperatures in the range -40°F to 130°F (-40°C to 55°C), and contain no more than 4 liters in the outer packaging, excluding ice. **Include an itemized list of contents between the secondary and outer packaging.**

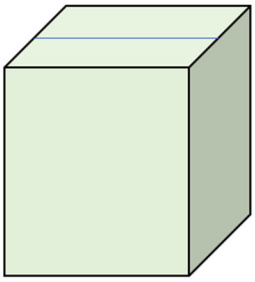
Marking and Labeling for Category B

Outer Package Requirements

Minimum surface: 4x4 inch

In good condition

Rigid - Sturdy



Marking and Labeling

Material Info:
Proper Shipping Name: "Biological substance, Category B"

UN Number: UN3373
(listed on diamond hazard label)

Contact Info:
Names and Addresses of Shipper and Consignee

Name and telephone number of Responsible Person
(Responsible person information can be on shipping paper instead)

Biological Substances Hazard Label

Additional Information (as required)

Dry Ice

Outer Package Requirements
Package can vent CO_2 gas

Properly insulated

Outer Package is leakproof

Material Info:
Proper Shipping Name: "Dry Ice"

UN Number: UN1845

Net Quantity: Listed in kilograms

Class 9 Hazard Label

What is being refrigerated: "Frozen Medical Specimen"

Quantity Specific

Orientation Arrows
2 labels, opposite faces of package

>50 mL liquid

Cargo Aircraft Only

>1 L or >1 kg

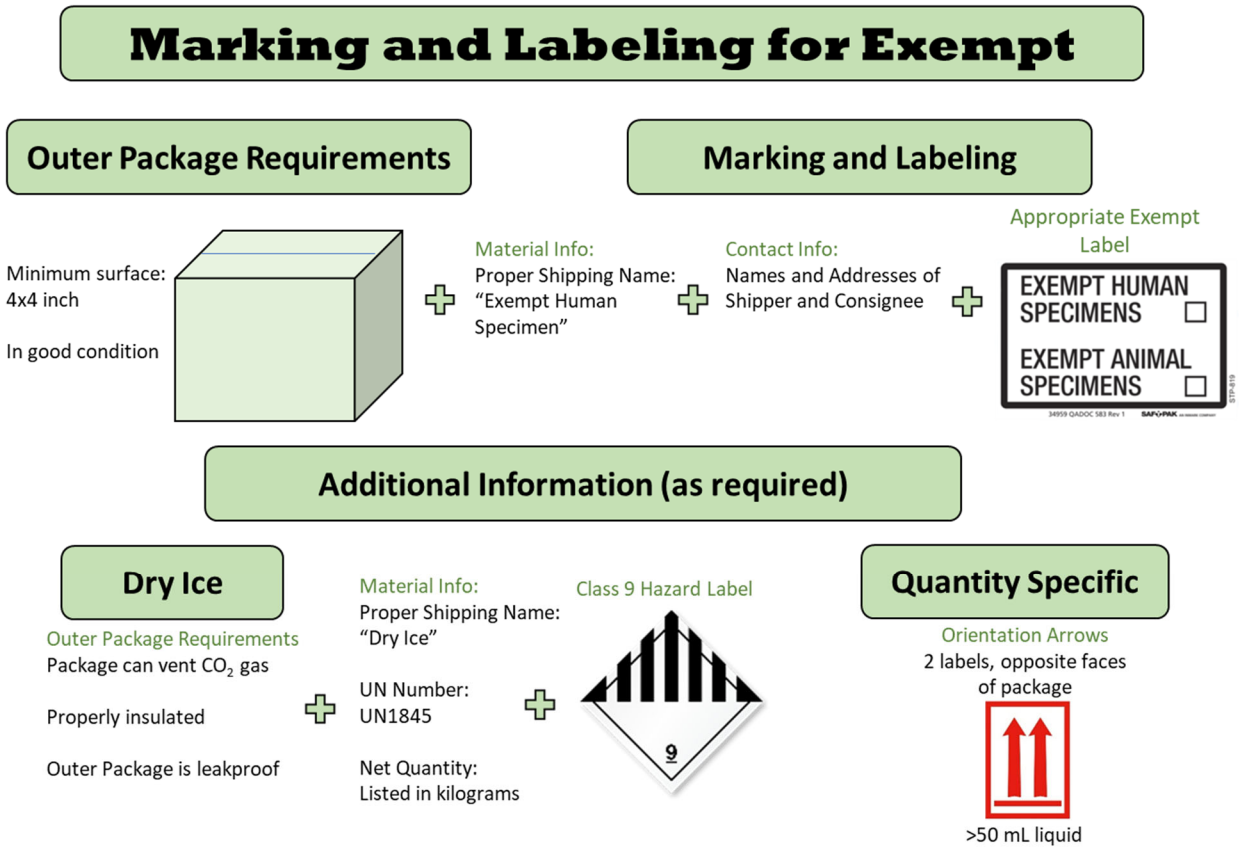
Packing Exempt Human Specimen

To prepare a package containing an exempt human specimen follow the packing instructions found in IATA DGR 3.6.2.3.8 or US Mail Pub 52 346.326 depending on the mode of transport. The packaging must consist of three parts; a leakproof primary receptacle, a leakproof secondary packaging, and an outer packaging of adequate strength for its capacity, mass, and intended use. If the sample is liquid, there must be adequate absorbent material to absorb the entire contents should a leak occur. Remember, these are specimens transported by air for routine testing NOT related to an infectious disease.

Per IATA the outer package does not need to be rigid for exempt human specimens. Any outer package that is sufficiently strong and durable may be used. However, USPS requires a rigid outer package.

Exempt human or animal specimen packages must be labeled to declare that that is what is being transported. Exempt human specimens are not assigned proper shipping names or UN numbers; however appropriate marking must appear so that if an incident occurred and the specimen leaked first responders would treat the spill appropriately.

Exempt human specimens transported by ground within the U.S. do not have packaging, marking, or labeling requirements listed in the Hazardous Material Regulations (49 CFR 173134(b)(11)). OSHA Bloodborne Pathogens Standard marking, and labeling rules still apply. Any specimen containing blood or OPIM needs to follow Universal Precautions per OSHA and should be leakproof and labeled with a biohazard symbol. (29 CFR 1910.1030).



Packing Dry ice

Dry ice is often added to packages containing infectious substances to keep them frozen during transport. To prepare a package containing dry ice follow packing instructions IATA: 954 or DOT: 49 CFR 173.217 depending on the mode of transport. The UN Number assigned is UN1845, and the proper shipping name is either "Dry ice" or "Carbon Dioxide, Solid." When shipping dry ice, the package must be sealed in a way to allow the gas to vent. Dry ice must never be placed in a sealed container. As previously discussed in another section, dry ice sublimates as it warms and the expanding gas must be allowed to escape the package, or pressure will build up cause the package to explode. Dry ice should be included between the secondary packaging and the rigid well insulated outer packaging.

Since dry ice is regulated primarily by air transport, the IATA packing instructions will be referenced heavily in these next sections (IATA Packing Instruction 954). In order to ensure proper ventilation during transport the shipper must make advanced arrangement with the operator before dry ice may be transported. Appropriate documentation of the presence of dry ice in Category A shipments will be included in the Dangerous Goods Declaration. For Category B and exempt human specimen packages sent for air transport this information should be recorded on the Air Waybill.

A dry ice package must have several pieces of information on the outer package. The diamond shaped Class 9 Miscellaneous Dangerous Goods label must be present. This is a square label that should be set on a 45° angle, or like a diamond shape. One of two proper shipping names may appear allow with the UN number, "Dry ice" or "Carbon dioxide, solid" and UN1845. Font size of dry ice labeling is regulated by volume as follows: 12 mm or larger (>30 kg), 6 mm or larger (5-30 kg), of adequate size (<5 kg). Dry ice packages must have the net weight of the dry ice listed in kilograms, not pounds.

The outer package containing dry ice must be strong enough to withstand the loading and unloading normally encountered in transport. Styrofoam is not considered durable enough to be an outer package. When Styrofoam is used for insulation, it should be placed inside another more rigid packing material such as fiberboard.

Please note that **Category B samples shipped with dry ice** for temperature control must have a label stating what is being refrigerated by the dry ice. Therefore, there must be a label indicating that the material being refrigerated is to be used for diagnostic or treatment purposes. For example, "frozen medical specimens" (49 CFR 173.199(d)(2)). This label is not standardized by 173.199, but it should be legible and printed with contrasting colors.

Please remember that packing instructions for infectious substances state that when dry ice is used as a refrigerant, the package must be designed in a manner that secures the secondary packaging in the original position once the dry ice has dissipated. Dry ice is not padding or filler for stabilizing the secondary packaging as the dry ice will sublimate and change in size. The shipper must ensure the secondary packaging will not move inside the outer package in the absence of dry ice.

Recommendations to follow while shipping dry ice. Shipments are generally recommended to contain 2.5-5 kgs (approximately 5-10 lbs.) of dry ice per 24 hours of transit time in a well-insulated cooler. Be sure to consider weekends and holidays when calculating dry ice shipment time. Refer to manufacturer instructions for dry ice quantity recommendations. Add additional filler packing material such as packing peanuts to minimize the volume of air to which the dry ice is exposed as this will slow the rate of sublimation and help stabilize the secondary packing.

A Styrofoam insulation box should not be reused if it is cut, cracked, torn, or stained. A damaged Styrofoam container will compromise temperature insulation and may cause the sample temperature to go out of recommended range. Always refer to the manufacturer's recommendations while using packaging materials.

Carrier specific variations for dry ice. USPS will not accept more than 5 lbs. (2.5 kg) of dry ice per package for air transport. For surface transport USPS will allow more than 5 lbs. of dry ice. UPS requires an additional "blue dry ice" label. FedEx has no additional requirements.

Special labels are not needed for **ice pack, gel packs, or wet ice**, but the package must be leakproof. However, the use of wet ice is strongly discouraged. Ice melts and makes a mess. If wet ice is used sufficient absorbent material must be provided to absorb all liquid, including melted ice (49 CFR 173.199(d)(1)).

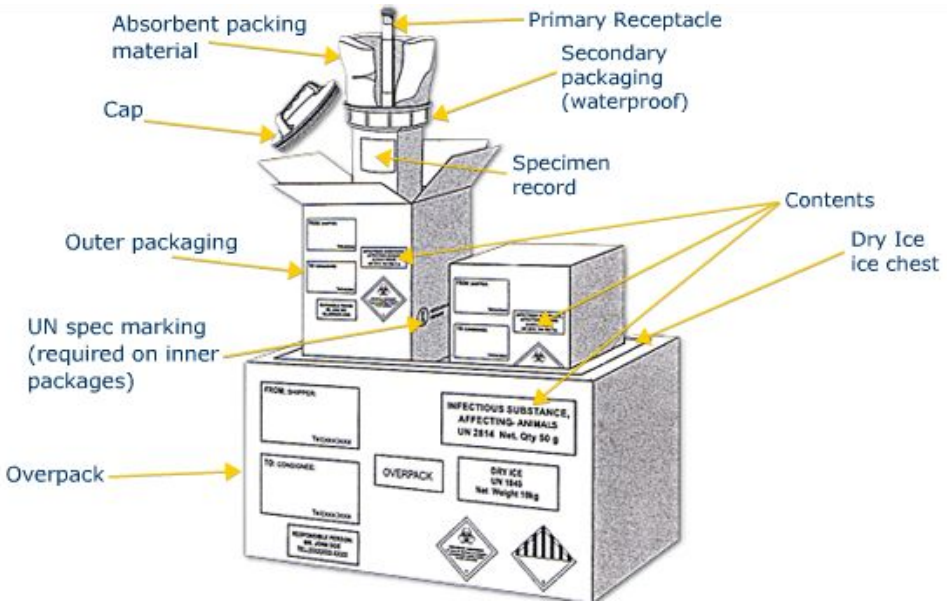
Using an Overpack

When shipping multiple containers to the same recipient it may be useful to utilize an overpack. Overpacks are considered supplemental to the required triple packaging, therefore there are no specific testing requirements listed in the regulations (49 CFR 173.25 – Authorized packaging and overpacks). Because overpacks are not considered an official package component all interior packages need to be properly handled, marked, and labeled. The overpack must have all the same markings as inner packages, plus a label displaying "Overpack" in at least 12mm letters. IATA 2.6.7.2 covers additional air marking requirements.

Overpacks are useful to ship multiple packages that need similar temperature control. Dry ice or ice packs can be placed between interior packages and the overpack container. The package used must be leakproof. And again, the use of wet ice is strongly discouraged.

OVERPACK

IATA special provision A805 states that dry ice can be placed directly into an overpack. However, the overpack must then meet the requirements of IATA packing instructions 954.



Packing Not Regulated - Exceptions

DOT and IATA have no packing requirements for materials not regulated by the infectious substance's sections.

USPS requires clinical samples that do not meet the criteria for Category A or Category B to use DOT's Category B triple packing requirements, omitting the UN3733 label and biological substances, Category B proper shipping name. Please research U.S. Mail Publication 52 346.325 for packing instructions.

Human blood, body fluids, or other potentially infectious materials (OPIM) will need to follow applicable OSHA regulations. OSHA requires a biohazard label on primary or secondary packaging containing these materials.

Reuse of Packages

49 CFR 173.28(f) outlines the provisions for reusing outer packages. Due to the robust nature of infectious substance packaging materials the shipper is permitted to reuse the packaging if it remains in good condition. The package must be clean and undamaged. "Clean and undamaged" is open to interpretation, so please use professional judgement when reusing packaging material. Only reuse a box if you can personally verify it is not contaminated or damaged. Reused packages must be prepared according to the original manufacturer instructions. If the manufacturer instructions are unavailable, you may NOT reuse the package.

Marking, Labeling, and Documentation

Marking and Labeling instructions can be found in IATA DGR 7.2.6. These regulations state that any marking or labeling found on the outside of a dangerous goods package must be securely affixed. The labels must be durable and will not come unstuck during transport. All labeling must be visible. Labels must be printed on contrasting background. Labels must be on the sides of the package, not the top or bottom. Labels must be orientated in the same direction. Any marking or labeling must be legible. Labels must not fold over the corners or edges of the package. Labels must not overlap or be obscured by any other marking. If anything is handwritten the writing must not smudge and be clearly legible. Many labels have prescribed sizes so if you create your own labels, please investigate proper label size. Hazard label and supplemental information should be placed on the same side of the package if possible.

Every package containing a dangerous good must be identified with the UN Number and Proper Shipping Name. The UN number is a four-digit number identifying dangerous goods. The letters "UN" must precede the four-digit number. For example, the UN number for dry ice is "UN1845." Proper shipping names are associated with UN numbers. There is only one acceptable proper shipping name per UN number. The proper shipping name should be spelled exactly the way it appears in the regulations. You may NOT abbreviate the proper shipping name. For example, UN3373 Category B's proper shipping name is "Biological substance, Category B." See the table below for UN numbers and proper shipping names of infectious substances and their related material.

Infectious Substances and Related Materials		
UN Number	**Proper Shipping Name**	**Hazard Class**
UN2814	Infectious substance, affecting humans	6.2
UN2900	Infectious substance, affecting animals	6.2
UN3373	Biological substance, Category B	6.2
UN1845	Dry ice (or Carbon Dioxide, solid)	9
UN3291	Regulated medical waste, n.o.s.	6.2
UN3245	Genetically modified organisms	9

Only use correct DOT labeling or acceptable exceptions listed in the regulations (UN, ICAO, IATA, GHS, 49 CFR 172.401 – **Prohibited labeling)**. If a package is reused irrelevant marking and labels must be removed or obliterated. And 49 CFR 173.28(f), Reused outer packages, states that packages must be clean and undamaged. This section can be a bit vague and open to interpretation, so use professional judgement as to what constitutes a clean undamaged package. It is best to only reuse a package if you can personally verify it is not contaminated or damaged.

OSHA requires a **biohazard symbol** on primary or secondary packaging that contains blood or is contaminated with human blood or other possible infectious substances. Please remember that OSHA says, "Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials..." (29 CFR 1910.1030). Therefore, you must place the biohazard symbol on either the primary or secondary container.

Urine is not included in the body fluids that must be labeled. However, a biohazard symbol is required if the urine is visibly contaminated with human blood (OPIM) or suspected to contain blood.

This biohazard symbol is independent of DOT and IATA hazmat classification. Therefore, do not place the biohazard symbol on outer packages unless otherwise required (29 CFR 1910.1030(g)(1)(i)(B)). OSHA's Standard Interpretation from 09/17/2002 states, "OSHA will accept the Department of Transportation's (DOT's) "INFECTIOUS SUBSTANCE" label in lieu of the "BIOHAZARD" label on packages where DOT requires its label on shipped containers, but will require the BIOHAZARD label where OSHA regulates a material but DOT does not. If DOT-required label is the only label used on the outside of the transport container, the OSHA-mandated label must be applied to any internal containers containing blood or other possibly infectious materials (OPIM)."

Documentation

An **Itemized list** of contents is required for some shipments of dangerous goods. IATA requires a list for Category A and B shipments, while DOT only requires a list for Category A shipments. It is recommended to always include an itemized list of contents. A Laboratory Requisition most often fulfills this requirement, and many laboratories require a requisition to be sent with diagnostic specimens. The itemized list should be placed between the secondary and outer package. DOT and IATA do not describe in detail the information that is required for the itemized list, nor do they provide a template.

An **Air Waybill** is required for all shipments of dangerous goods by air. This is a contract between the shipper and the carrier airline that is to be attached to the outer packaging. If the air waybill is a physical piece of paper it should be affixed within a pouch on the outer package. Currently, many carrier airlines no longer use physical paper air waybills and instead the air waybill will be included in the barcoded shipping information. Please follow all carrier ordering instructions. This information is not based on DOT or IATA regulations but is required by air carriers. Therefore, each carrier will have their own specific forms to use and proprietary software to generate shipping labels such as FedEx's Ship Manager.

In the case of dry ice and Category B shipments the completed air waybill could be your only documentation of the shipment. Therefore, you must save these documents for 2 years per DOT regulation 49 CFR 172.201(e).

Shipper's Declaration

Step by step instructions on how to complete this document are provided in the resources section of the booklet as well as examples of completed Shipper's Declarations.

The Shipper's Declaration, sometimes called the Dangerous Goods Declaration or Dangerous Goods Form, **is a requirement for packages containing Category A substances.** This document identifies the hazards contained in the package and provides specifics of the package to the carrier. Please note that if there are other

dangerous goods present in the consignment then those too need to be listed on the Shipper's Declaration. For example, if a Category A specimen is shipped with dry ice for temperature control, then the dry ice also needs to be listed on the Shipper's Declaration. If additional Category B specimens are present in this hypothetical package, then those need to be listed on the form too. Otherwise, dry ice and Category B do NOT require a Shipper's Declaration on their own.

For air transport there are two formats provided by IATA. Information can be presented in columns or an open format. Both forms can be found on IATA's website. For shipments by ground DOT does not provide a template for this document. BOL recommends using IATA's form to maintain continuity. However, an example of a possible DOT shipper's paper is provided in the resources section of this booklet.

Please note that private carriers will often require the shipper to complete this document using their proprietary software. For example, FedEx requires the use of FedEx Ship Manager software when generating a Shipper's Declaration. If other software is used it must be FX-18 compliant.

49 CFR 172.201(e) states that the shipper must retain a copy of the document for 2 years and IATA DGR 8.1.2 states that the shipper must provide the carrier with **2 signed copies.** Some carriers, such as FedEx, require 3 signed copies to be provided. Therefore, MDHHS BOL recommends shippers print and prepare **4 signed color copies** for processing, 1 copy for internal records, and 3 copies to give to the carrier for processing.

IATA's shipper's declaration must be printed in color. The document has red hash marks on the border of the form, and these must be printed in red, or the carrier will reject your package.

Even seemingly minor errors on this document can cause your package to be disqualified and returned. Do not use abbreviations while completing this document. Make sure to include the 24/7 emergency contact. Don't forget to sign and date the bottom, and the person who signs the Shipper's Declaration must be trained and certified in Category A packaging and assumes full legal responsibility for the shipment.

Currently there is NO fully electronic version of the DGD. You must provide paper copies. IATA is working on an e-DGD project for electronic transfer of DGD information as of September 2023. For more information on electronic Dangerous Goods Declarations please research at iata.org or contact your commercial carrier.

Do not use correction fluid to correct mistakes. It is recommended that if you accidently make an error while completing this document that you start over with a clean sheet. However, regulations state that the mistake may be amended by drawing a single line through the error and then signing a full signature and date next to the change.

A **technical name is required** when completing this document for Category A infectious substances. The technical name is the genus and species name of the organism placed in parentheses. For example, the anthrax bacteria's technical name is (*Bacillus anthracis*). When completing this document for shipments of organisms that are unknown, or unconfirmed but suspected of meeting criteria for Category A classification you may substitute the following technical name **(Suspected Category A infectious substance)**. This is listed as IATA Special Provision A140.

Emergency Response

DOT requires emergency response information for shipments of hazardous materials (49 CFR 172.602). The following information must be on the shipping papers or attached to it. This information would be used in case of emergency. This information must accompany Category A shipments.

The required information should include:

1. Basic description and technical name (if applicable).
2. Immediate hazards to health.
3. Risks of fire or explosives.
4. Immediate precautions to be taken in the event of an accident or incident.
5. Immediate methods of handling fires.
6. Initial methods for handling spills of leaks in the absence of fire.
7. Preliminary first aid measures.

This information must be available for use away from the package containing the hazardous material. A helpful resource for providing emergency response information for infectious substances is the **Emergency Response Guide (ERG), Guide 158.** The ERG was developed for use by emergency services personnel to assist responders in protecting themselves and the general public during the initial phase of an incident. See the resources section of the booklet for a copy of the ERG Guide 158.

Category B shipments do not require additional emergency response information. 49 CFR 173.199 states Category B infectious substances are excepted from all other requirements of the infectious substance subchapter when offered for transportation or transported in accordance with the 49 CFR 173.199 section. Category B infectious substances offered for transportation or transported under the provisions of the HMR are only subject to the incident reporting requirements in 49 CFR 171.15 and 171.16.

Additional Information:

Genetically Modified Organisms

Genetically modified organisms (GMOs) are organisms where the genetic material has been intentionally altered through genetic engineering in a manner that would not naturally occur. If the GMO fulfils the definitions of an infectious substance or a pathogen, then it should be classified as either Category A or B and packaged accordingly. Otherwise, **GMOs are assigned the UN number UN3245 and are classified as Division 9** miscellaneous dangerous goods.

The proper shipping name is "Genetically modified organism." IATA packing instructions 959 are similar to the triple pack instructions found in 620 and 650 for Category A and B. The primary receptacle must be leakproof, and if multiple primary receptacles are sent together, they must be separated to prevent contact. It is recommended to seal the primary receptacle in a positive means with tape or parafilm. The secondary container must be leakproof and sufficient absorbent material must be included to absorb the entire volume of the primary receptacle should a spill occur. The outer package must be rigid and of adequate strength for its contents.

The package must be marked with the shipper and receiver information along with the diamond shaped placard displaying the UN number UN3245.

There are no requirements for shipping GMOs by ground within the United States. DOT does not recognize non-pathogenic GMOs as a hazardous material.

Transport Quantity Limitations

Infectious Substances Quantity Limits – Aircraft

IATA limits the quantity of certain dangerous goods while traveling on an aircraft. See the table provided.

Aircraft Quantity Limits	Category A	Category B	Dry ice
Passenger Aircraft	50 mL	1 L	200 kg
Cargo Aircraft	4 L	4 L	200 kg

For the safety of passengers and staff IATA limits the amount of infectious substances and dry ice per package. Please note that special provision A81 states there are no quantity limits on body parts, organs, or whole bodies. If the shipper applies special provision A81 it must be declared on shipping papers.

These quantity limits are per package, not per consignment. If you need to ship larger volumes of a substance you may need divide it up into multiple packages. A consignment can be multiple packages consisting of fully compliant packages.

When quantity limits prohibit transit on a passenger aircraft the shipper must affix this "Cargo Aircraft Only" label to notify aircraft loading staff. Minimum dimensions of the label are 120x110mm.

DOT does not set clear quantity limits by ground carrier, or motor vehicle. However, there are Material of Trade quantity limits for ground transport. See section on MOT for more information.

Quantity Specific Regulations: Excepted and De minimis

The shipper does not need to declare <30ml of a perseverative or anticoagulant from hazard classes 3, 8, or 9 if that material is contained in the primary receptacle of an infectious substance (49 CFR 173.199 (a)(9)(iii) and IATA Packing Instructions 620 and 650).

While preparing an infectious substance for transport you should always stop and think: is there something here I am missing from the other hazard classes? Some hidden hazards that are encountered while working with clinical samples are reagents and specimen preservatives such as alcohol, ethanol, or formalin that are flammable (Flammable Liquids, Hazard Class 3). Some reagents that accompany clinical specimens may also be reactive, or corrosive, such as hypochlorite and formaldehyde (Flammable, or Corrosive, Hazard Class 3, or 8). And of course, always be mindful of properly handling dry ice (Miscellaneous, Hazard Class 9).

IATA DGR 3.10.5 states that in a mixed hazard situation, where an infectious substance also has another hazardous property, that substance must always be classified in Division 6.2 and the greatest of the additional hazard must also be identified.

However, if an infectious substance is mixed with a very small quantity of another dangerous good some quantity-based exceptions can be applied. Small or excepted quantities of dangerous goods can be shipped using

relaxed regulatory requirements. But please note, these quantity-based exceptions cannot be applied to infectious substances. **Any amount of an infectious stance must be identified, classified, and packaged appropriately.**

De Minimis =<	1 mL/g
Excepted Quantities =	1-30 mL/g

De minimis quantities regulations are outlined in 49 CFR 173.4(b). If you have a very small quantity of certain dangerous goods, less than 1 mL or 1 g, you may follow the standards set in 49 CFR 173.4(b). These regulations are very relaxed as there are no additional marking or labeling required. However, the material must be packaged securely without leakage, i.e. it must be sealed in positive means. Please ensure that the absorbent material used in the packaging will not react chemically with the de minimis hazard present and that the absorbent material will absorb the entire contents if a spill occurs. The completed package must be capable of surviving a fall of 1.8 m (5.9 feet).

Excepted quantities regulations are outlined in 49 CFR 173.4(a), and IATA Special Provision A180. These sections cover transporting 30 mL or less of common preservatives such as ethanol and isopropanol. For a full list of materials that can be transported using this exception please review 49 CFR 173.4(a)(b). The total quantity in the completed package of the excepted material must NOT exceed 1L, (30 mL distributed among several primary receptacles). And of course, everything must be securely packaged using appropriate cushioning and leakproof primary and secondary packaging. Primary receptables must be sealed in positive means. Please ensure that the absorbent material used in the packaging will not react chemically with the excepted hazard present and that the absorbent material will absorb the entire contents if a spill occurs. The completed package must be capable of surviving a fall of 1.8 m (5.9 feet).

There may be some additional **labeling for excepted quantities** packages. The outer package must be marked with: “Scientific research specimens, not restricted, Special Provision A180 applies.” For shipment by highway no shipping paper is needed. For transport by air, a shipping paper is not required, except that, if a document such as an air waybill accompanies a shipment, the document must include the statement “Dangerous Goods in Excepted Quantities” and indicate the number of packages, and the waybill must have the text, “not restricted” and A180 in the description of the substance.

Formaldehyde and Formalin

Some laboratory samples are shipped in solutions of formalin to help preserve the sample. Formalin is made from formaldehyde gas dissolved into a solution such as water or alcohol. The percentage of formaldehyde dissolved into the formalin solution will change the hazard risk of the material. Refer to the accompanying table to determine the correct classification of the formalin solution you are working with.

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

IATA Special Provision A189 allows solutions containing less than 10% formaldehyde dissolved in water to be excepted from the regulations. This special provision should cover the most common usages of formalin as 10% neutral buffered formalin only contains 3-4% formaldehyde. Please verify the composition of the formalin you are shipping, the manufacturer's MSDS should have the information. And IATA Special Provision A180 can be applied to ship <30 mL of dangerous goods such as formalin.

Verify the correct packaging instructions based on the classification of the formaldehyde solution. Please note that common formaldehyde solutions are allowed to be classified as de minims or excepted quantities if transporting small quantities of the formaldehyde solution.

Medical Waste

Medical waste that contains infectious substances is a dangerous good. It is classified as UN3291, Clinical Waste, unspecified, n.o.s.. If the waste contains an infectious substance classified as a Category A infectious substance, then it must be classified and packaged as a Category A infectious substance. The regulations for medical waste are listed in 49 CFR 173.134(b), 49 CFR 173.134(c), Exceptions for Division 6.2 Packing: Regulated Medical Waste, and 49 CFR 173.197, Regulated Medical Waste.

Please note that decontaminated medical waste is not subject to dangerous goods regulations. Also, note that transport of Medical Waste is outside the scope of this booklet and the training course. For additional resources or assistance contact MDHHS BOL Bioterrorism Training Coordinator.

If you generate Category A waste and you do not have the ability to decontaminate the waste on site, please make appropriate plans to handle the situation properly.

Air Passenger Provisions

Category A or B infectious substances are not permitted for transport in carry-on or checked baggage. Infectious substances cannot be hand carried by persons as an air passenger. Dangerous goods must be transported in accordance with IATA regulations.

Packages containing exempt human or animal specimens may be transported in carry-on or checked baggage provided they meet the applicable packaging requirements. Exempt and non-pathogenic specimens can be carried on as these are not defined as Dangerous Goods. IATA 3.3.2 Exceptions, has a list of examples of exempt and non-pathogenic materials.

Dry ice needs prior approval from the airline to be carried on or checked in luggage. 2.5kgs or less of dry ice may be approved to refrigerate perishable non-dangerous goods.

IATA DGR 2.2.4 has a list of substances that may contain Hidden Dangerous Goods. Examples of these substances that apply to infectious materials are:

- Diagnostic Specimens: May contain infectious substances.
- Frozen Embryos: May contain refrigerants.
- Laboratory/Testing Equipment.
- Samples for Testing: May contain any number of hazards, flammable or infectious (what are they testing?).
- Vaccines: May be packed on dry ice.

Specimen Handling Best Practices

Before You Go – Specimen Collection

Good laboratory practice requires that when colleting specimens from a patient the first thing you should do is verify the patient's identity. A best practice is for the collector to ask patients to spell their first and last names every time specimens are collected. The patient's name (first and last) AND a second identifier must be clearly written on the specimen container. Proper labeling of specimens will ensure that the laboratory will be able to process the specimen quickly and accurately. Improperly labeled specimens may lead to laboratory delays or outright specimen rejection.

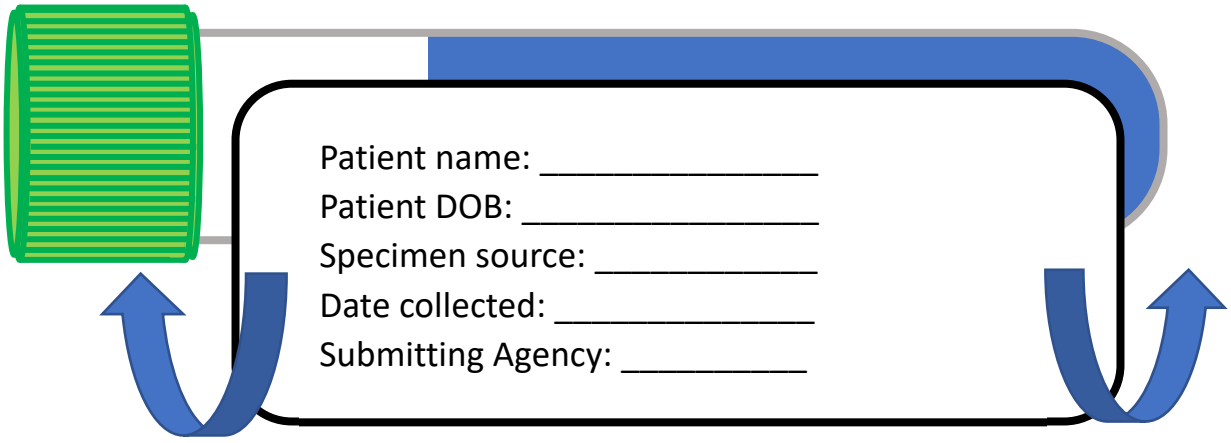
Each specimen should be labeled with 2 unique patient identifiers. The patient's name (first and last) AND a second identifier must be clearly written on the specimen container. The second identifier can be a hospital number, date of birth, or another unique identifier. Date of collection is NOT considered a unique identifier.

The appropriate test requisition, complete with the patient's name and unique identifier, must be sent with the specimen. The information on the test requisition must match the container exactly. Specimens that are unlabeled or mislabeled will not be tested.

Dress For Success - Specimen Labeling

Specimen identifiers may be handwritten, but please remember that pens or markers may smudge or smear and become illegible. The best thing you can do is use a printed sticker to label laboratory specimens. When choosing printed labels be sure to find a type that will attach securely to the specimen container and does not become unstuck during transport or cleaning activities.

If using a specimen label neatly affix the label so it lays flat on the tube. No bumps, no lumps. Ensure the label does not overlap the cap or any important specimen transport information.

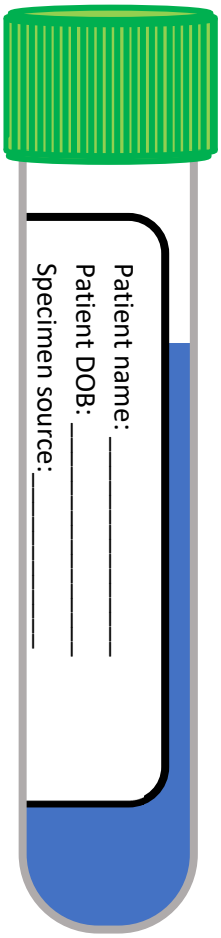


DO

Neat

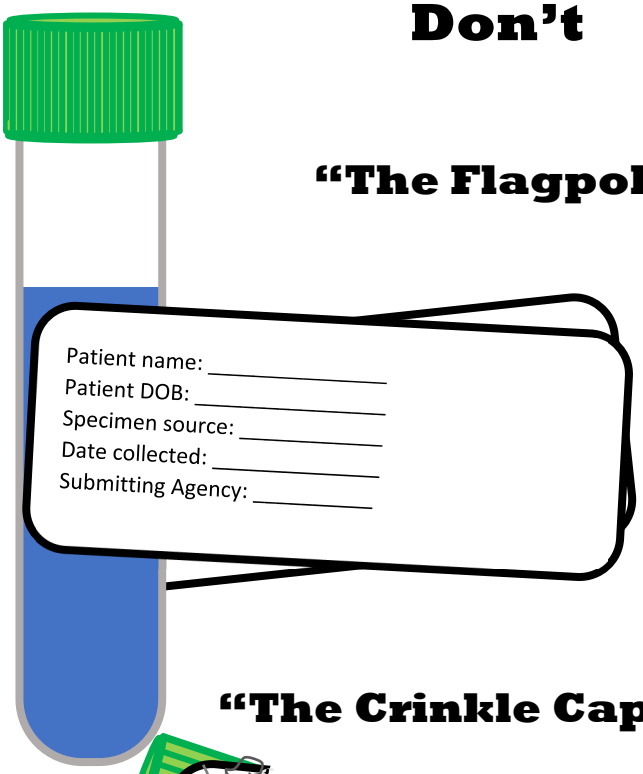
Clean &

Well Dressed

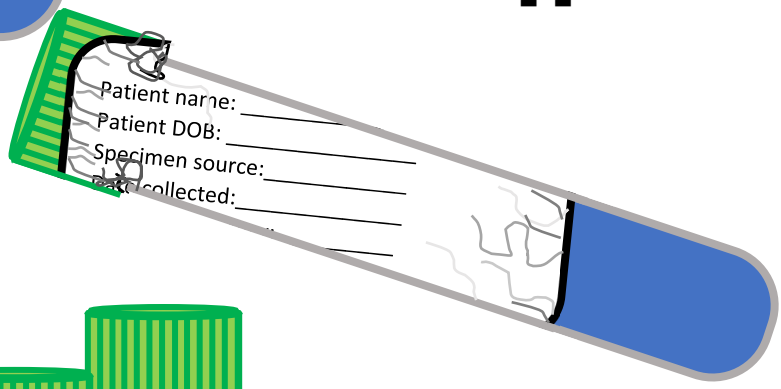


Don't

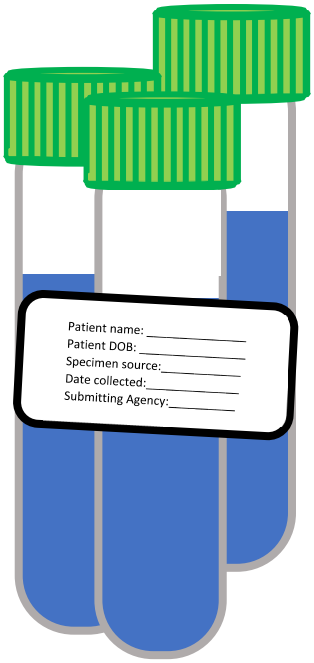
"The Flagpole"



"The Crinkle Capper"



"The Bundle"



Safe Travels – Specimen Packaging

In a properly prepared triple packed specimen package each primary specimen container must be packaged so that it will not leak into the secondary packaging. When shipping multiple primary receptacles in one package the shipper should separate and protect each specimen. **It is recommended to place each sample individually into a sealable bag with absorbent material.** Do NOT place multiple primary receptacles into a single secondary package. If one specimen spills or leaks the entire shipment will become compromised.

Packages containing infectious substances must be prepared in a way to avoid external contamination. People handling the package in transport will not, and should not, need special personal protective equipment (PPE) to handle infectious substances packages. Packages should be prepared moving from a contaminated area to clean area. Packages should be clean and free from contaminates when leaving the facility.

Safety, Security, and Emergency Preparedness

Security Awareness

Due to the sensitive nature and potential for misuse DOT has issued security training requirements for anyone handling hazardous materials. Anyone shipping Category A infectious substances should be aware of security threats and have plans to mitigate them. Personnel preparing Category B and dry ice packages are generally exempt from these requirements, however it is always a good idea to be prepared and be aware of potential security risks. Everyone should know their roles and responsibilities in safeguarding their workplace.

Highly infectious pathogens such as those listed on the Category A infectious substance list could be of interest to bad actors or anyone who wishes harm to others. Some of these pathogens could be used as agents of bioterrorism. Addressing and mitigating these threats are important to the health and safety of our fellow citizens.

Institutions and their staff should find ways to prevent and deter theft, loss, or release of potential agents of bioterrorism. Evaluate your workplace to assess vulnerabilities. Make sure unauthorized staff or the public do not have access to highly pathogenic organisms. Make sure storage areas are secure. Ensure that when highly pathogenic organisms are to be shipped to outside partners that the package is secure and only handled by qualified staff. Ensure that the package is passed to the correct and qualified courier.

While external threats may come to mind first when doing security reviews, please remember that insider threats are a real danger to an organization as well. Current or former employees know the vulnerabilities of an organization and therefore best know how to exploit them. Be aware of odd behavior, or sudden changes in behaviors of fellow employees as this may indicate malicious intentions. Insider threats do not have to be intentional as a careless employee could cause just as much harm. A careless employee allowing unauthorized access to a secure area can be a serious security risk. All threats should be taken seriously.

Security policies and procedures should be reviewed and kept up to date.

Lost in the Crowd Security

When shipping Category A infectious substances some biosecurity measures should be observed. One of these being that the Category A package should become "Lost in the Crowd." This is achieved by NOT including the technical name of the organism on the outer package. 49 CFR 172.203(k) states in part that, "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 48 CFR 171.8. **A technical name should not be marked on the outer package of a Division 6.2 material** (49 CFR 172.301(b)).

The proper shipping name for Category A infectious substances must have a technical name listed on the Shipper's Declaration. However, **the technical name should NOT appear on the outside of the package to achieve "Lost in Crowd" status** (Federal Select Agent Program's SA-Grams from 3/15/2013).

The **Technical name** is written in parentheses after the proper shipping name for Category A infectious substances. 49 CFR 171.8 states that the:

> "*Technical name:* means a recognized chemical name or microbiological name currently used in scientific and technical handbooks, journals, and texts. Generic descriptions are authorized for use as technical names provided they readily identify the general chemical group, or microbiological group. Examples of acceptable generic chemical descriptions are organic phosphate compounds, petroleum aliphatic hydrocarbons and tertiary amines. For proficiency testing only, generic microbiological descriptions such as bacteria, mycobacteria, fungus, and viral samples may be used. Except for names which appear in subpart B of part 172 of this subchapter, trade names may not be used as technical names."

To clarify, DOT Reference Letter 20-0035 states, **"if the Division 6.2 material is assigned identification number UN2814 or UN2900 and is suspected to contain an unknown Category A infectious substance, the words "suspected Category A infectious substance" must be entered in parentheses in place of the technical name as part of the proper shipping description (§ 172.203(k))."**

Emergency Preparedness

If damage occurs to a shipment, you should avoid further handling. Inspect the damaged package and adjacent packages. Look for spills or leaks. Isolate the spill area and keep unauthorized personnel away. Immediately notify the shipper or receiver depending on when or where the damage has occurred.

Use proper PPE to clean up any spills or leaks. Follow your institution's clean up protocols. Provide first aid if necessary to any affected personnel. Healthcare follow-up may be warranted. Follow your institution's policy and procedures for possible prophylaxis or fever watch depending on the specimen spill or severity of any exposure.

Incident Reporting

Any release of Category A or B infectious substances must be reported to DOT. 49 CFR 171.15 lists requirements for "Immediate notice of certain hazardous materials incidents". Within 12 hours of an incident the person in possession of the hazardous materials must notify the National Response Center (NRC) 800-424-8802. And within 30 days a written incident report must be submitted. 49 CFR 171.15 has telephone reporting requirements and 171.16 for written report requirements. Depending on the severity of the damage or leakage you may need to contact Public Health authorities or the CDC for further assistance.

Select Agent Transport

Transporting confirmed select agents can present many challenges to a shipper. Select agents are a regulated list of highly pathogenic organisms and toxins that present the highest danger of possible misuse. Many of these organisms and toxins have been studied in the past for their potential use as biological weapons. For a list of select agents regulated by the CDC and the USDA see 42 CFR Part 73 and 9 CFR Part 121 respectively. Or visit http://www.selectagents.gov for more information.

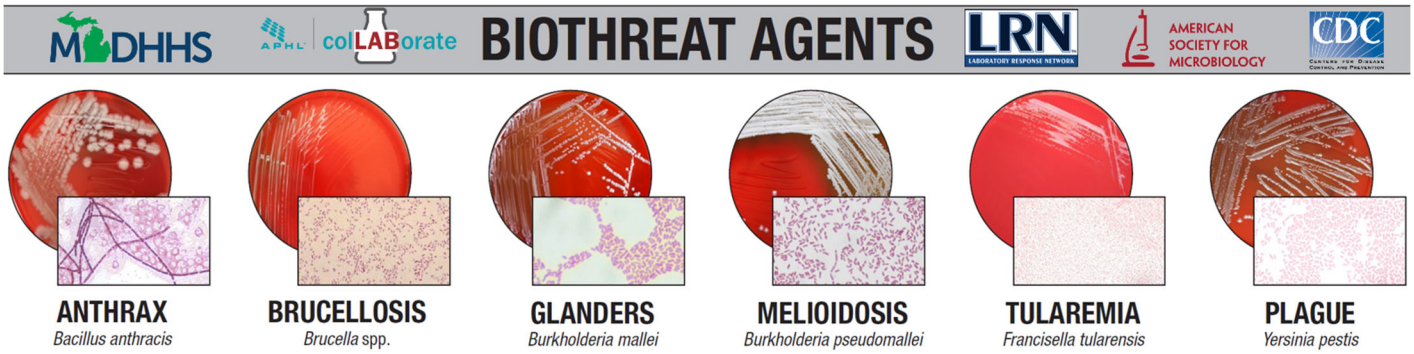
CDC USDA

FEDERAL SELECT AGENT PROGRAM

Loss, theft, or release of these materials would be of serious public health concern. Therefore, their transport or transfer is highly regulated by the Federal Select Agent Program (FSAP). FSAP stipulates that they should be notified and must give their approval whenever a select agent is offered for transport. FSAP must approve of the recipient of any select agent material. To start the transfer approval process the shipper and receiver must complete APHIS/CDC Form 2 found on FSAP's website. Select agents are packaged using normal Category A practices.

USPS along with many of the large private carriers, such as FedEx and UPS, do not accept confirmed select agents for transport. Research into smaller more specialized carriers that will accept such a package is warranted. Alternatively, the select agent package can be transported by private motor vehicle, but "the driver must be a Security Risk Assessment (SRA) approved individual" (FAQ from APHIS/CDC Form 2 Transfers).

In addition, entities that transfer select agents will need to comply with 49 CFR 172.802, Transportation Security Plan. Complete plan requirements can be found throughout 49 CFR 172.800 and 172.804. When transporting high consequence dangerous goods DOT stipulates that such an entity needs additional security planning to ensure the safe transport of the materials. Even if your facility does not transport high consequence dangerous goods being aware of potentially dangerous situations and having mitigation strategies is valuable.



Definitions and Acronyms

49 CFR: Title 49 of the Code of Federal Regulations

CDC: Centers for Disease Control and Prevention

DGR: Dangerous Goods Regulations (IATA Regulations)

DOT: Department of Transportation

ERG: Emergency Response Guide

FAA: Federal Aviation Administration

FSAP: Federal Select Agent Program

Hazmat: Hazardous Materials

HMR: Hazardous Materials Regulations (49 CFR, Parts 100-185)

IATA: International Air Transport Organization

OSHA: Occupational Safety and Health Administration

PHMSA: Pipeline and Hazardous Materials Safety Administration

UN: United Nations

USPS: United States Postal Service

WHO: World Health Organization

Definitions to common words and phrases as they relate to the transport of dangerous goods.

Biological Product: A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, applicable to the prevention, treatment, or cure of a disease. 49 CFR 173.134(a)(2)

Carrier: A person who transports passengers or property in commerce by rail car, aircraft, motor vehicle, or vessel. 49 CFR 171.8

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. 49 CFR 173.134(a)(1)(i)

Category B Infectious Substance: An 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. 49 CFR 173.134(a)(1)(ii)

Commerce: Trade or transportation in the jurisdiction of the United States within a single state; between a place in a state and a place outside of the state; that affects trade or transportation between a place in a state and place outside of the state; or on a United States-registered aircraft. 49 CFR 171.8

Consignee: (or Receiver) The person or place shown on a shipping document, package marking, or other media as the location to which a carrier is directed to transport a hazardous material. 49 CFR 171.8

Culture: An infectious substance containing a pathogen that is intentionally propagated. 49 CFR 173.134(a)(3)

Dangerous Goods: Articles or substances which are capable of posing a hazard to health, safety, property or the environment.

Exempt Human Specimen: Human or animal specimens which are not likely to contain an infectious substance. In order to classify a specimen as an exempted patient specimen professional judgement is required.

Exposure: Occurs when the infectious substance leaks to the outer packaging or contaminates the outer package. Any leaks contained within the secondary package do not constitute an exposure. An exposure occurs when the infectious substance comes into physical contact with a human or an animal.

Function Specific Training and Function Specific Job Tasks: Training that covers specifically the tasks that an employee will perform during their job functions.

General Awareness Training: Training designed to provide familiarity with the general requirements of hazmat regulations and enable employees to recognize hazards associated with their function specific tasks.

Infectious Substance: A material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, parasites, and fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals. 49 CFR 173.134(a)(1)

Material of Trade: A hazardous material, other than a hazardous waste, that is carried on a motor vehicle - (1) For the purpose of protecting the health and safety of the motor vehicle operator or passengers; (2) For the purpose of supporting the operation or maintenance of a motor vehicle (including its auxiliary equipment); or (3) By a private motor carrier (including vehicles operated by a rail carrier) in direct support of a principal business that is other than transportation by motor vehicle. 49 CFR 171.8

Overpack: An enclosure that is used by a single consignor to provide protection or convenience in handling of a package or to consolidate two or more packages. *Overpack* does not include a transport vehicle, freight container, or aircraft unit load device. Examples of overpacks are one or more packages: (1) Placed or stacked onto a load board such as a pallet and secured by strapping, shrink wrapping, stretch wrapping, or other suitable means; or (2) Placed in a protective outer packaging such as a box or crate. 49 CFR 171.8

Packing: Is the act of placing dangerous goods into appropriate packaging.

Package: A packaging plus its contents. 49 CFR 171.8

Packaging: A receptacle and any other components or materials necessary for the receptacle to perform its containment function. 49 CFR 171.8

Proper Shipping Name: The name of the hazardous material that is universally recognized for specific dangerous goods. 49 CFR 171.8

Receptacle: A containment vessel for receiving and holding materials, including any means of closing. 49 CFR 171.8

Safety Training: Training that instructs the employee of the hazards associated with dangerous goods, as well as safe handling and emergency response procedures.

Security Training: Training that addresses the security requirements associated with the dangerous goods offered for transport. The level of security training required depends on the substance being shipped.

Shipment: All of the components offered to the operator or carrier including packages and documentation.

Shipper: (or Consignor) Is the party that prepares and offers the material for shipment.

MDHHS | Bureau of Laboratories
Michigan Department of Health & Human Services

Resource Information for

Packing & Shipping

Helpful Resources Affecting Transport of Division 6.2 Infectious Substances

Department of Transportation (DOT):

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

- **DOT's Hazardous Materials Information Center:** DOT Hazardous Material Information Center exists to promote compliance and does not report to the 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 (ERG)
  - 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:

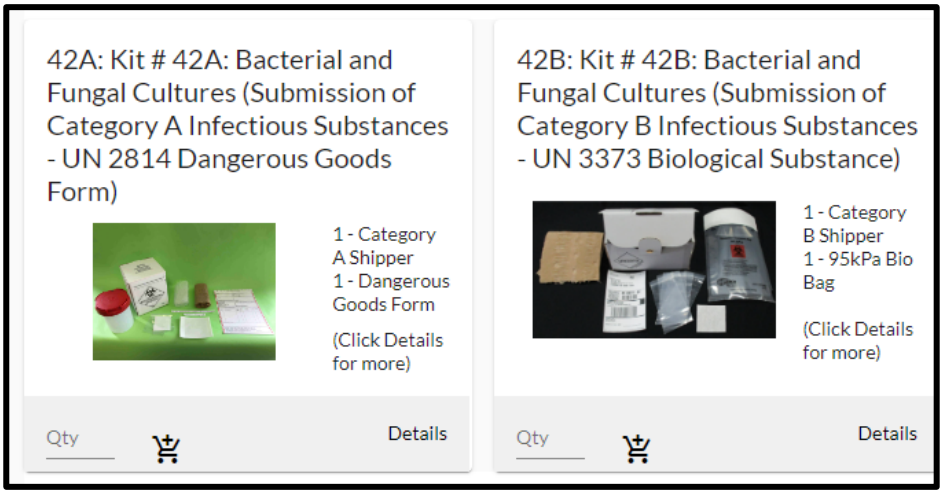
https://www.aphl.org/programs/infectious_disease/Pages/ID-Packaging-and-Shipping-Toolkit.aspx

Laboratory Kit Order Tracking System: LKOTS

How to Order Supplies

LKOTS is a web-based system for Michigan public health partners to order shipping supplies from BOL. Visit [Lab Services (michigan.gov)](). For more information about LKOTS message MDHHSLab@michigan.gov.

Search for Kit 42A for general Category A shipping material, and 42B for general Category B shipping material.



Hazardous Materials Tables

DOT: 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	
							Exceptions	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

United States Postal Service:

Packing Standards

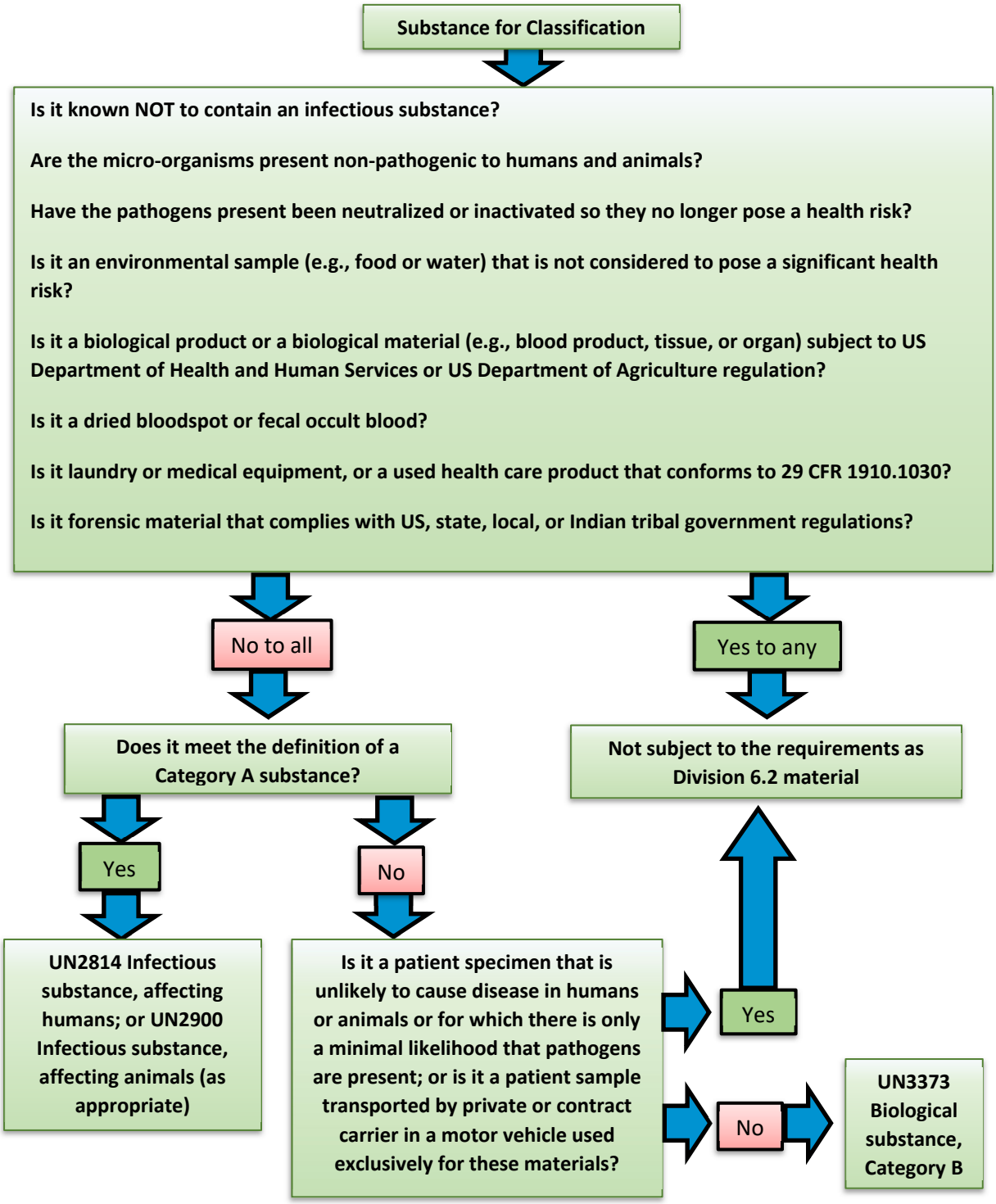
Publication 52

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

Classify the Hazard Flowchart: DOT

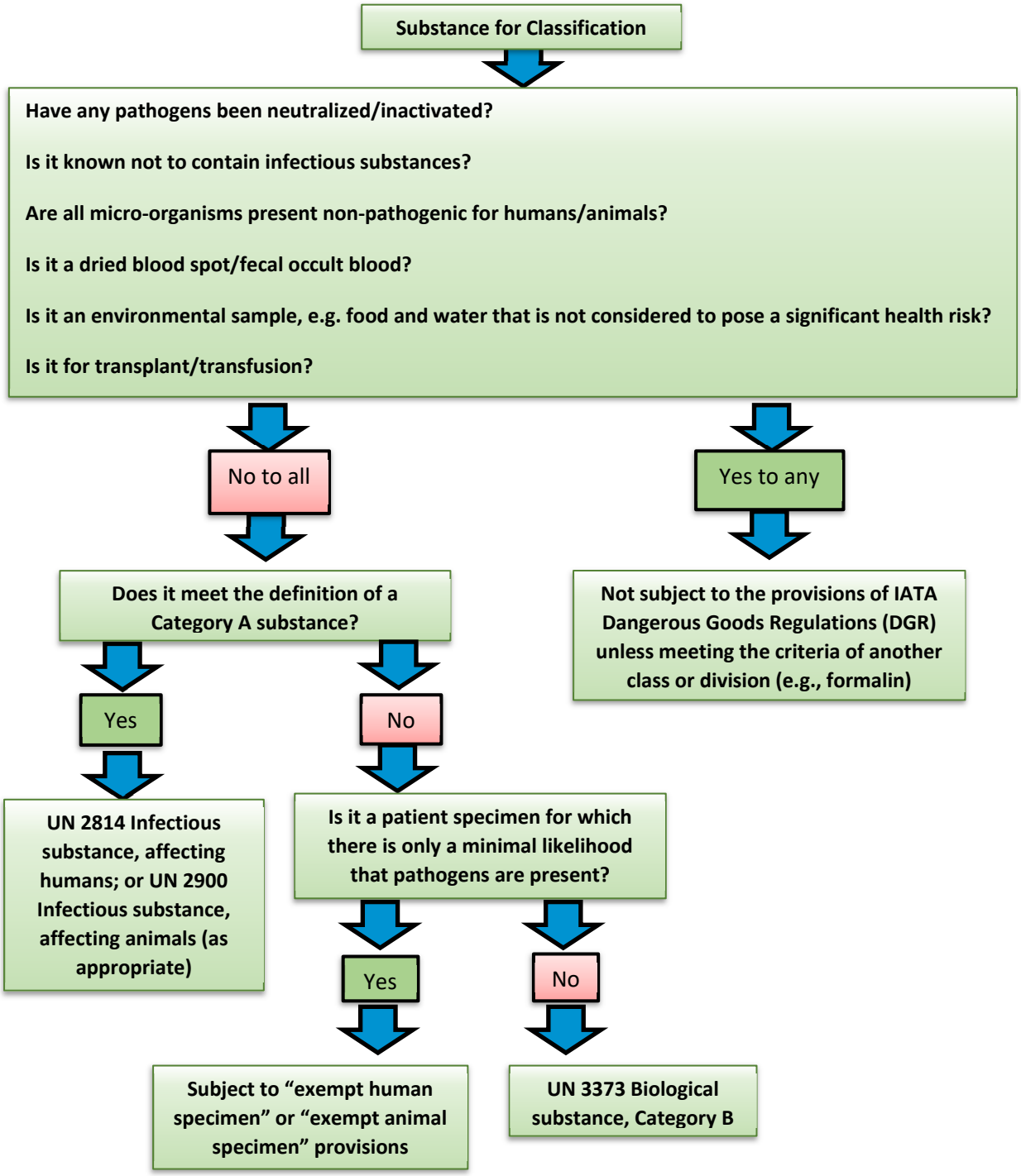
Use the decision tree below to help you classify your substance if shipping by motor vehicle courier/ground in accordance with Hazardous Materials Regulations (HMR). Use the IATA job aid for packages sent by air.



Adapted from CDC Lab Training, DOT: Job Aid – Motor Vehicle Courier Train or Cargo Ship

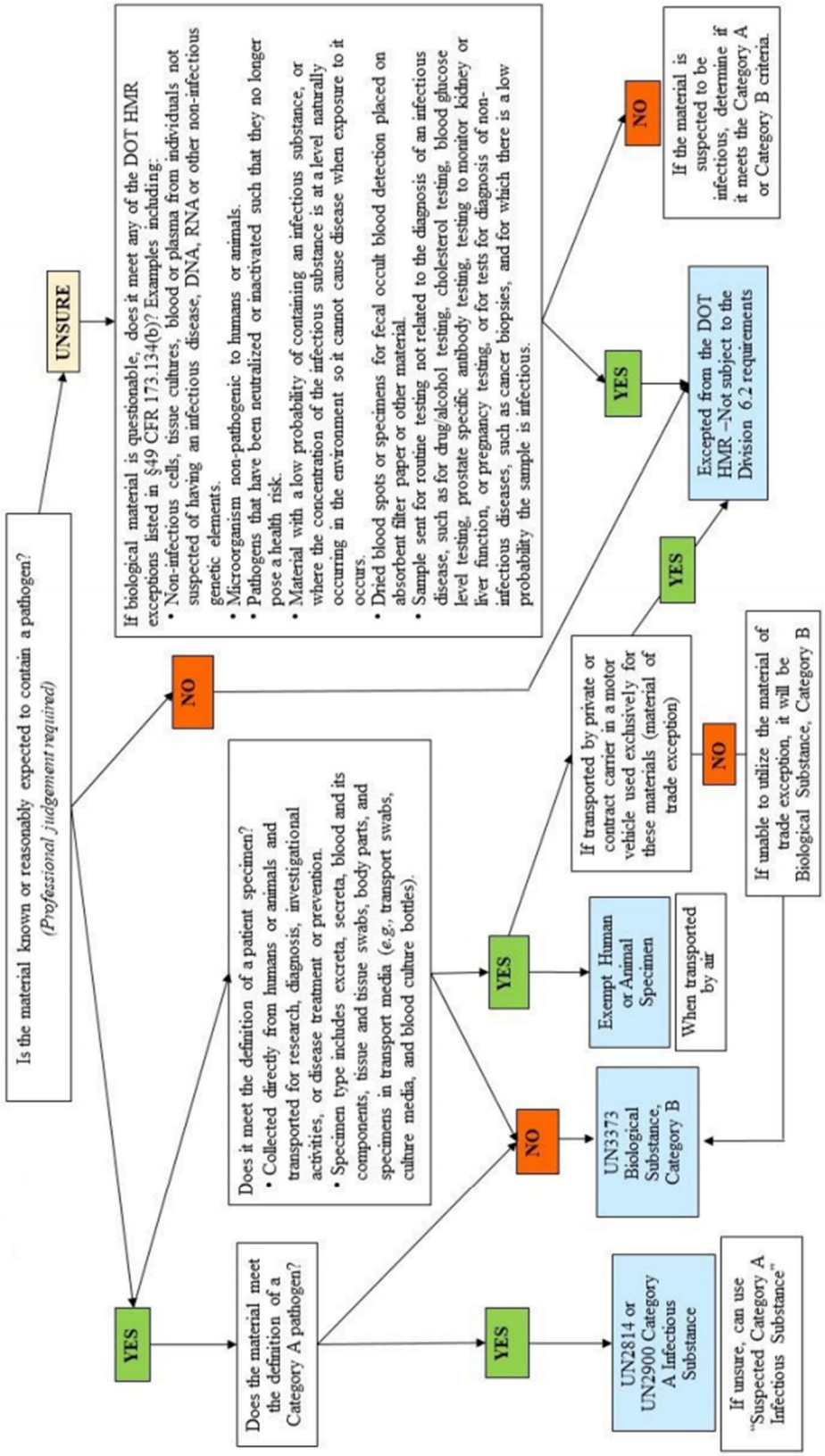
Classify the Hazard Flowchart: IATA and USPS

Use the decision tree below to help you determine the classification for your substance if shipping by air or US Mail. Use the DOT job aid for packages sent by motor vehicle courier/ground.



Adapted from CDC Lab Training, IATA Job Aid – Air or US Mail

Classify the Hazard Flowchart: Comprehensive



38

Figure 1. Classification Flowchart

Copied from ASM Sentinel Level Guideline: Packaging and Shipping Infectious Substances

IATA Indicative Category A List

DOT Example Category A List

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

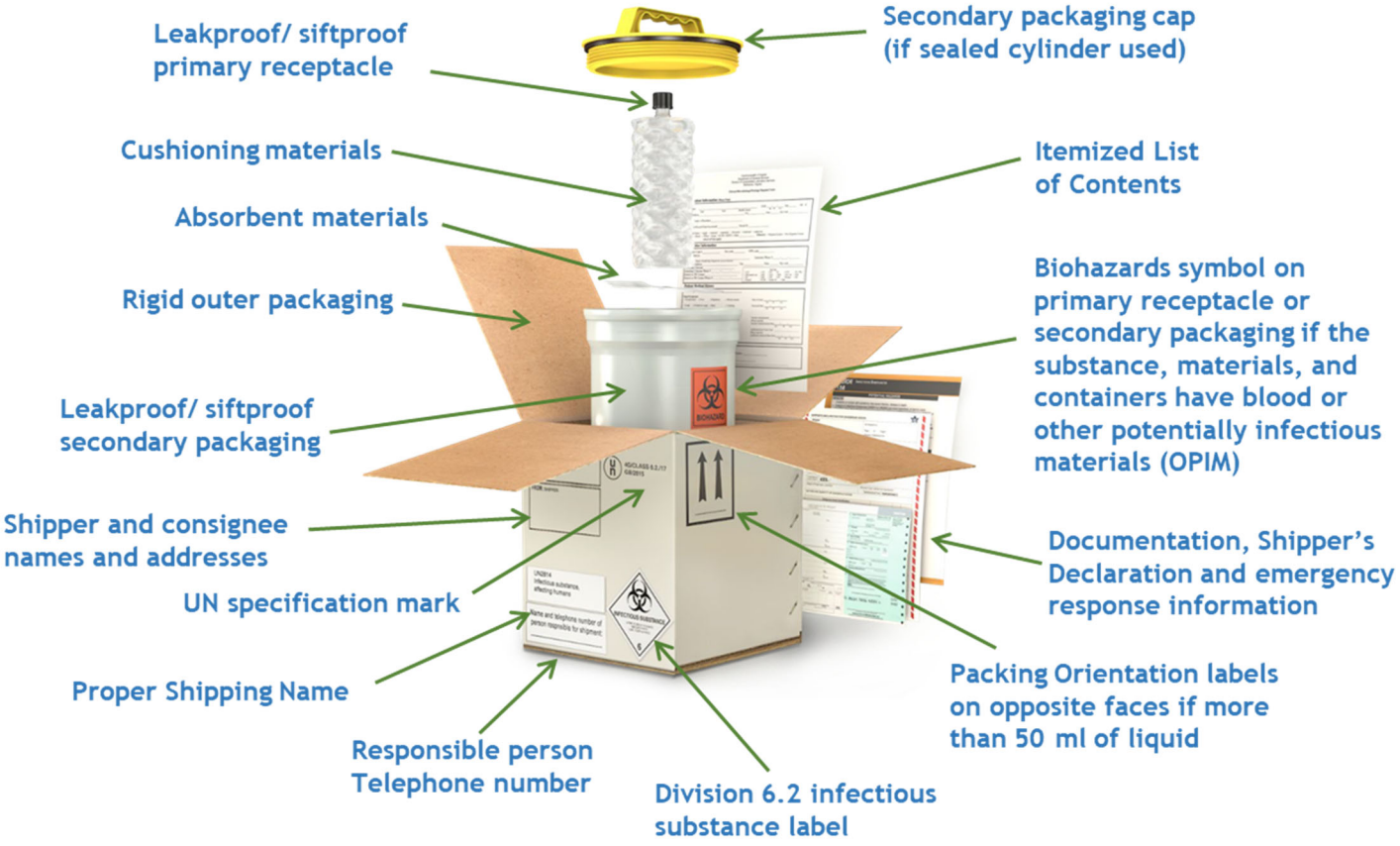
Bacillus anthracis (cultures only)
Brucella abortus, *Brucella melitensis*, *Brucella suis* (cultures only)
Burkholderia mallei, *Burkholderia pseudomallei* (cultures only)
Chlamydia psittaci avian strains (cultures only)
Clostridium botulinum (cultures only)
Coccidioides immitis (cultures only)
Coxiella burnetii (cultures only)
Crimean-Congo hemorrhagic fever virus
Dengue virus (cultures only)
Eastern equine encephalitis virus (cultures only)
Ebola virus
Escherichia coli, verotoxigenic (cultures only)
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)
Highly pathogenic avian influenza virus (cultures only)
Human immunodeficiency virus (HIV) (cultures only)
Japanese encephalitis virus (cultures only)
Junin virus
Kyasanur Forest disease virus
Lassa virus
Machupo virus
Marburg virus
Mpox or Monkeypox virus
Mycobacterium tuberculosis (cultures only)
Nipah virus
Omsk hemorrhagic fever virus
Polio virus (cultures only)
Rabies virus (cultures only)
Rickettsia prowazekii, *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)

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

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 only)

Refer to IATA Table 3.6.D for complete IATA Category A listing.
DOT does not have an official list published in the regulations. Listed as "Example" in DOT document "Transporting Infectious Substances Safely. Refer to 49 CFR 173.134(a)(1)(i) for the definition of Category A.
Category A: "An infectious substance in a form capable of causing permanent disability or life-threatening disease in otherwise healthy humans or animals when exposure occurs."
Note: This is an indicative list and not an all-inclusive list. The names of new and emerging pathogens may not always be included and published immediately on regulatory lists. 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. 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.

Category A Triple Packaging



Adapted from CDC Lab Training: Packing Category A Specimen Job Aid

Save and file a copy of the manufacturer's closure instructions for all Category A packages.

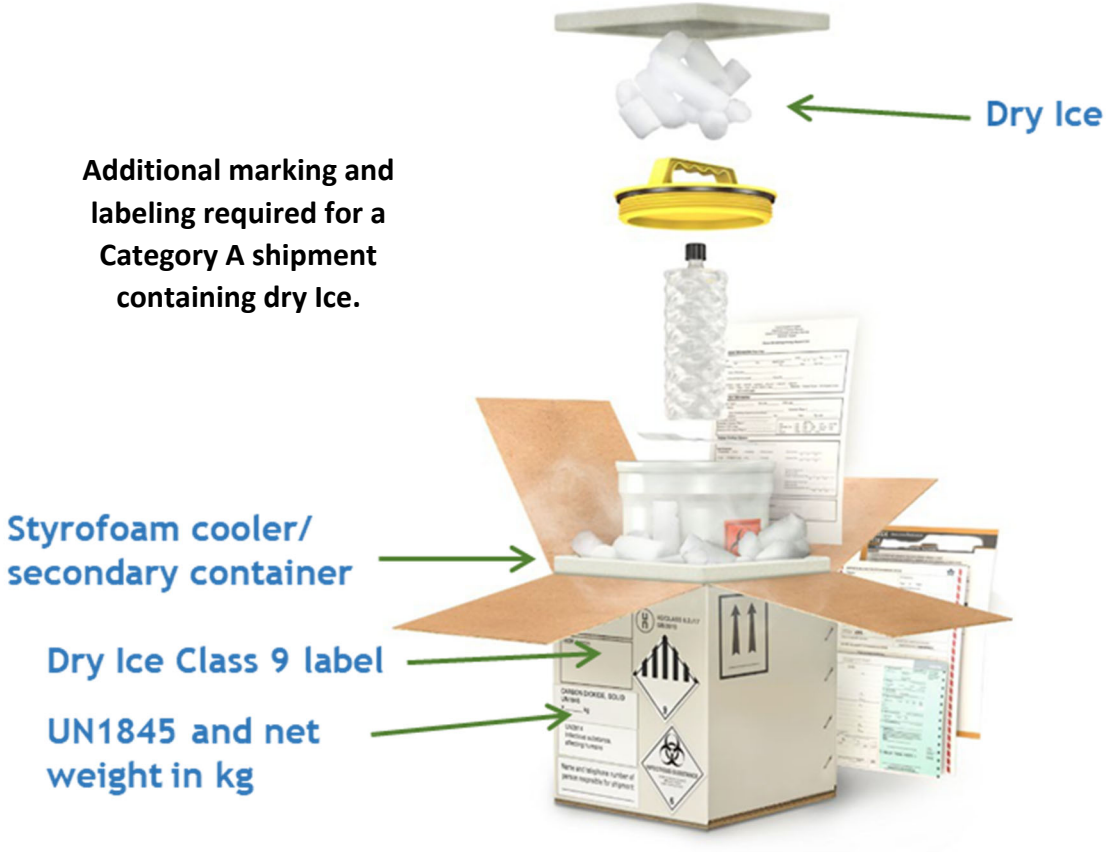
*49 CFR 173.22(a)(4)(ii) If the manufacturer's closure instructions are not permanently embossed or printed on the package, the shipper MUST maintain a copy of the instructions for a period of 90 days from the time the shipment was offered for transport.

Completed Nature and Quantity of Dangerous Goods Column Format section of IATA Shipper's Declaration for example packing scenario above, 1 room temperature sample (approx. 20 mL)

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (subsidiary hazard)	Packing Group	Quantity and Type of Packing	Packing Inst.	Authorization
UN2814	Infectious substance, affecting humans (Suspected Category A infectious substance)	6.2		1 fibreboard box x 20 mL	620	

Category A Infectious Substance With Dry ice Outer Packaging

Additional marking and labeling required for a Category A shipment containing dry Ice.



Adapted from CDC Lab Training: Packing Category A Specimen Job Aid

Completed Nature and Quantity of Dangerous Goods Column Format section of IATA Shipper's Declaration for example packing scenario above, 1 frozen sample (approx. 20 mL) packed with 3 kg of dry ice.

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (subsidiary hazard)	Packing Group	Quantity and Type of Packing	Packing Inst.	Authorization
UN2814	Infectious substance, affecting humans (Suspected Category A infectious substance)	6.2		20 mL	620	
UN1845	Dry Ice	9		3 kg All packed in one Fibreboard box.	954	

Shipping Papers:

IATA Dangerous Goods Shipper's Declaration Form

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least three copies to the airline.)

Shipper

1

Air Waybill No. 3

Page of Pages 4

Shipper's Reference Number 5

Consignee

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

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)* 6

PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY

Airport of Departure 7

Airport of Destination:

Shipment type: *(delete non-applicable)* 8

NON-RADIOACTIVE	RADIOACTIVE

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)	Packing Group			
9	10	11	12	13	14	15

Additional Handling Information

Emergency Telephone Number: 16

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.

Emergency Telephone Number

Name/Title of Signatory 17

Place and Date

Signature *(see warning above)* 18

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

Checklist Item		Complete		Item(s) in Need of Follow Up / Notes
		Yes	N/A	
* Note	Itemized list of contents included in package. Between secondary and outer package. (e.g., test request form)			
1	Completed **Shipper** info (Full name, complete address, and phone number)			
2	Completed **Recipient/Consignee** info (Full name, complete address, and phone number)			
3	**Air Waybill:** number listed on Shipper's Declaration, if used			
4	**Page of Pages:** How many pages are in Dangerous Goods Form. **Example:** Page 1 of 1			
5	**Shipper's Reference Number:** Sample/Specimen number listed (Optional)			
6	**Transport Details:** Delete either "Passenger and Cargo Aircraft" or "Cargo Aircraft Only" to indicate whether the shipment is packed to comply with quantity limitations *Passenger (Up to 50ml) vs. Cargo only selected (>50ml) Use orange cargo label on box **only** if cargo selected			
7	**Airport of Departure** and **Airport of Destination:** Enter full name of airport or city of departure and destination (Optional, 3 letter airport code is not acceptable)			
8	**Shipment Type:** Delete "Radioactive" to indicate the shipment does not contain radioactive material			
9	**UN or ID No.:** UN hazard identification(s) listed **UN2814** or UN2900 (Category A) UN1845 (if Dry ice included)			
10	**Proper Shipping Name:** Enter proper shipping and technical name **UN2814: Infectious substance, affecting humans** Or UN2900: Infectious substance, affecting animals UN1845: Dry ice (if included) **Technical Name:** Must be listed in backets () after proper shipping name **(Suspected Category A infectious substance)** – If unconfirmed isolate (Genus and species of microorganism) - If identification confirmed			
11	**Class or Division:** **6.2** for Category A **9** for Dry ice			
12	**Packing Group:** Leave blank. Infectious substances and Dry ice are not assigned a package group			
13	**Quantity and type of packaging:** Enter the number of packages, type of material of the outer package, and the net quantity in each package. When an Overpack is used the wording "Overpack Used" must appear **Example:** 1 Fibreboard box x 5mL			
14	**Packing Instruction:** Category A = **620** ; Dry ice = **954**			
15	**Authorization:** IATA Special Provisions listed here, otherwise leave blank			
16	**Additional Handling Information:** list the Responsible Person information and the 24-hour emergency contact listed (name and number include area code)			
17	**Name/Title of Signatory:** The name of the person signing the declaration			
18	**Signature and Date:** Sign and date the document – MUST be handwritten or stamped, NOT typewritten **Please note, this person must be trained in classifying and identifying the hazardous materials being prepared for transport**			

Print at least 4 copies

Save 1 copy for internal documentation (can be printed "black and white")

Provide at least 3 signed COLOR copies to the carrier (these copies must have red ribbon border)

Example IATA Shipper's Declaration documentation for a Category A sample.

One fiberboard box with approx. 20 mL sample sent via UPS.

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
HAZ+
Page 1 of 1 Page(s)
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.

TRANSPORT DETAILS

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

PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY
	XXXXX

Airport of Departure:

Airport of Destination:

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.

Shipment type: *(delete non-applicable)*

Non-Radioactive	XXXXXXXXX

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)

02111414 1/08 RRD

Shipping Papers:
Example of possible DOT Shipper's Paper

Completed Example:

# of Boxes	Basic Description UN #, Proper Shipping Name, Hazard Class	Total Quantity (i.e. gm or mL)
1	UN2814, infectious substance, affecting humans (suspected Category A infectious substance), 6.2	3 mL
24 hr. Emergency Contact Phone (include area code): 555-555-5555 **Offeror's Name or Contract # (complete only if shipper is NOT the emergency contact):**		

This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation

Shipper's Signature: John Smith _____

Date: 8/1/19 _____

Blank Example:

# of Boxes	Basic Description UN #, Proper Shipping Name, Hazard Class	Total Quantity (i.e. gm or mL)
24 hr. Emergency Contact Phone (include area code): **Offeror's Name or Contract # (complete only if shipper is NOT the emergency contact):**		

This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation

Shipper's Signature: _____

Date: _____

Job aid adapted from CDC course "Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know"

Emergency Response Information – ERG 2020 Guide 158

GUIDE 158 INFECTIOUS SUBSTANCES

POTENTIAL HAZARDS

HEALTH

- Inhalation or contact with substance may cause infection, disease or death.
- Category A Infectious Substances (UN2814, UN2900 or UN3549) are more hazardous, or are in a more hazardous form, than infectious substances shipped as Category B Biological Substances (UN3373) or clinical waste/medical waste (UN3291).
- Runoff from fire control or dilution water may cause environmental contamination.
- Damaged packages containing solid CO_2 as a refrigerant may produce water or frost from condensation of air. Do not touch this liquid as it could be contaminated by the contents of the parcel.
- Contact with solid CO_2 may cause burns, severe injury and/or frostbite.

FIRE OR EXPLOSION

- Some of these materials may burn, but none ignite readily.
- Some may be transported in flammable liquids.

PUBLIC SAFETY

- **CALL 911. Then call emergency response telephone number on shipping paper.** If shipping paper not available or no answer, refer to appropriate telephone number listed on the inside back cover.
- Keep unauthorized personnel away.
- Stay upwind, uphill and/or upstream.
- Consult the shipping paper to identify the substance involved.

PROTECTIVE CLOTHING

- Use judgement based on the amount of material present and the possible routes of exposure to select protective clothing.
- Wear appropriate respiratory protection, such as fit-tested N95 respirator (at minimum), powered air purifying respirator (PAPR), or positive pressure self-contained breathing apparatus (SCBA).
- Wear full coverage body protection (e.g., Tyvek suit), faceshield, and disposable fluid-resistant gloves (e.g., latex or nitrile).
- Wear appropriate footwear; disposable shoe covers can be worn to protect against contamination.
- Puncture- and cut-resistant gloves should be worn over fluid-resistant gloves if sharp objects (e.g., broken glass, needles) are present.
- Wear insulated gloves (e.g. cryo gloves) over fluid-resistant gloves when handling dry ice (UN1845).
- Decontaminate protective clothing and personal protective equipment after use and before cleaning or disposal with a compatible chemical disinfectant (e.g., 10% solution of bleach, equivalent to 0.5% sodium hypochlorite) or through a validated decontamination technology (e.g., autoclave) or process.
- Structural firefighters' protective clothing provides thermal protection **but only limited chemical protection**.
- For more information on decontamination, consult p. 362

EVACUATION

Immediate precautionary measure

- Isolate spill or leak area for at least 25 meters (75 feet) in all directions.

In Canada, an Emergency Response Assistance Plan (ERAP) may be required for this product. Please consult the shipping paper and/or the ERAP Program Section (page 390).

EMERGENCY RESPONSE

FIRE

Small Fire

- Dry chemical, soda ash, lime or sand.

Large Fire

- Use extinguishing agent suitable for type of surrounding fire.
- Do not scatter spilled material with high-pressure water streams.
- If it can be done safely, move undamaged containers away from the area around the fire.

SPILL OR LEAK

- Do not touch or walk through spilled material.
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- Absorb with earth, sand or other non-combustible material.
- Cover damaged package or spilled material with absorbent material such as paper towel, towel or rag to absorb any liquids, and, beginning from outside edge, pour liquid bleach or other chemical disinfectant to saturate. Keep wet with liquid bleach or other disinfectant.
- **DO NOT CLEAN-UP OR DISPOSE OF, EXCEPT UNDER SUPERVISION OF A SPECIALIST.**

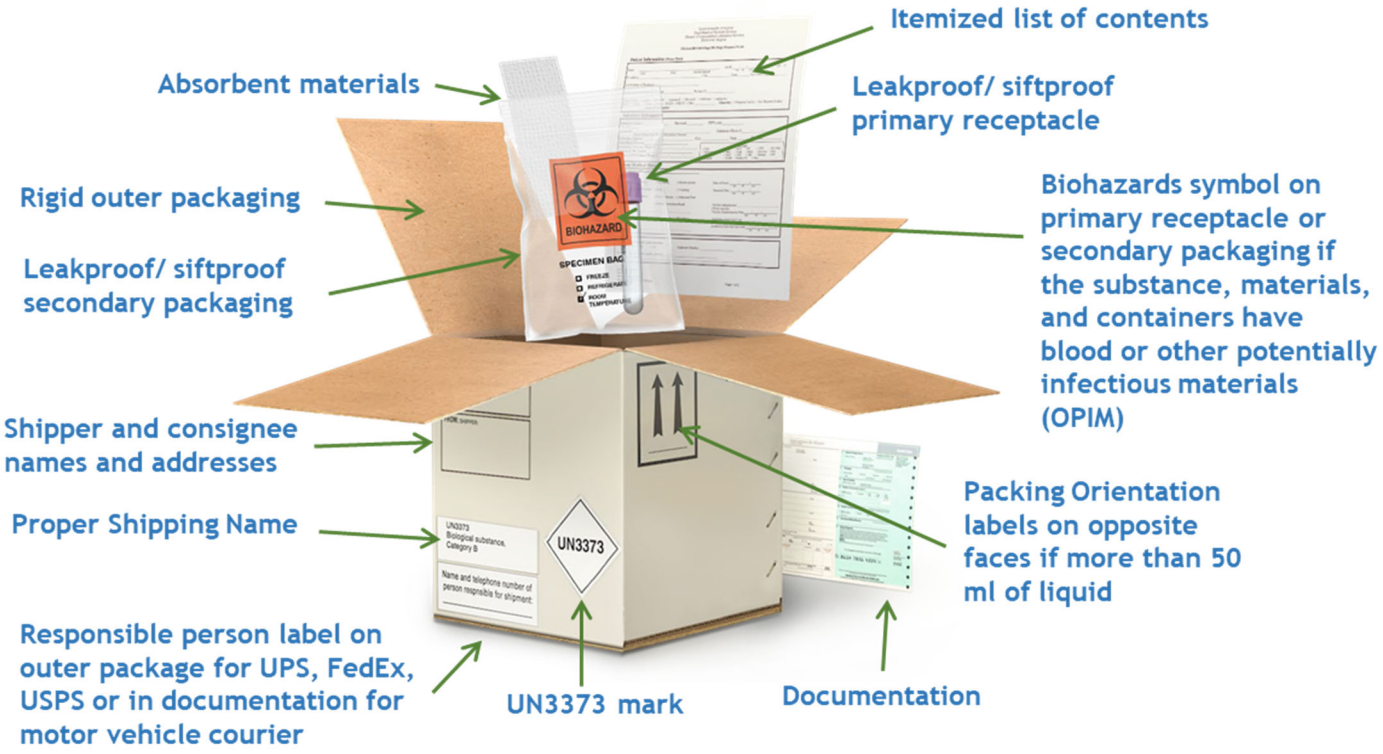
FIRST AID

- Call 911 or emergency medical service.
- Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
- Move victim to a safe isolated area if it can be done safely.

CAUTION: Victim may be a source of contamination.

- Remove and isolate contaminated clothing and shoes.
- In case of contact with substance, immediately flush eyes with running water and wash skin with soap and water for at least 20 minutes. Take caution not to break the skin.
- Effects of exposure (inhalation, ingestion, injection/inoculation or skin contact) to substance may be delayed. Victim should consult medical professional for information regarding symptoms and treatment.
- **For further assistance, contact your local Poison Control Center.**

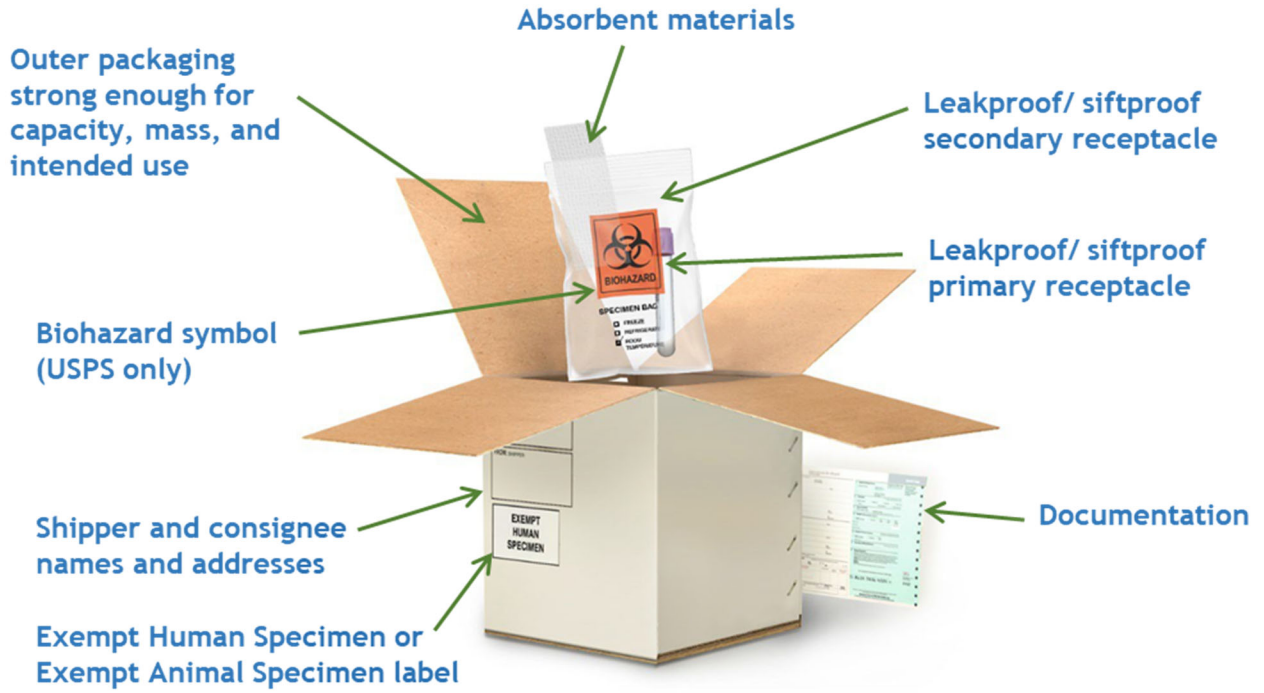
Category B Triple Pack Example

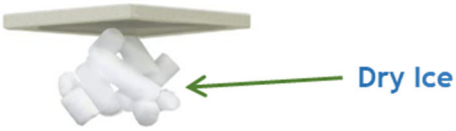


Additional marking and labeling required for a Category B shipment containing dry ice.

Adapted from CDC Lab Training: Packing Category B Specimen Job Aid

Exempt Human Specimen Triple Pack Example





Additional marking and labeling required for an exempt human specimen shipment containing dry ice.

Adapted from CDC Lab Training: Packing Exempt Human Specimen Job Aid

Final Category A Acceptance Checklist

This checklist is adapted from Appendix H – Carrier's Checklist, IATA Infectious Substances Shipping Guidelines. It is intended to assist shippers in Category A package preparation in accordance with Packing Instruction 620.

Package Preparation:

☐ Primary receptacles leakproof and sealed in positive means

☐ Multiple primary receptacles are wrapped individually, to prevent contact and damage

☐ Sufficient absorbent material is placed between primary and secondary packaging to absorb entire contents if spilled

☐ Secondary package: leakproof, 95kPa compliant, and secured as to not shift inside outer package

☐ Biohazard label on primary or secondary packaging

☐ Itemized list of contents between the secondary and outer package

☐ No other dangerous goods except dry ice (Unless <30 mL from hazard class 3, 8, 9 to maintain specimen acceptability)

☐ All manufacture packing instructions followed, and closure instructions saved for 90 days after specimen transport

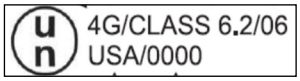
Outer Package

☐ Outer Package is rigid and free from damage and leakage

☐ Irrelevant marks and labels removed or obliterated

☐ Outer package is free from contaminates and was prepared in a safe manner

Markings – MUST be present on outer package



☐ UN certified package used. Package has "CLASS 6.2" UN package certification marking:

☐ Proper Shipping Name and UN number. "Infectious substances, affecting humans" and UN2814 are present

☐ Technical name of infectious substance is **absent** from outer package (must be on shipping papers)

☐ Net quantity of material (If applicable, carrier specific, and mixed consignments only. Recommended)

☐ Full names and addresses of shipper and consignee

☐ Name and telephone number of Responsible Person

☐ Class 6.2 diamond shaped Infectious substances hazard label:

Additional labels, only as needed on outer package

☐ Cargo aircraft only label if net quantity >50 mL (on same package surface as hazard label)

☐ Orientation arrows if >50 mL of liquid (2 labels required, placed on opposite sides of package)

☐ Overpacks: All markings of interior packages duplicated on overpack, with addition of "Overpack" label

Documentation

☐ Shipper's Declaration – All Category A shipments MUST have a Shipper's Declaration

☐ For shipment by air use the IATA Dangerous Goods Declaration (DGD)

☐ For shipment by ground any DOT compliant documentation, IATA DGD recommended

☐ 24/7 Emergency Response telephone number contact listed in documentation

☐ Additional Emergency Response information – Use ERG Guide 158, or other compliant documentation

☐ Air Waybill (for shipments by air only)

☐ Shipper/Carrier has been trained concerning risks and regulations associated with infectious substances transport

Final Category B Acceptance Checklist

This checklist is adapted from Appendix H – Carrier's Checklist, IATA Infectious Substances Shipping Guidelines. It is intended to assist shippers in Category B package preparation in accordance with Packing Instruction 650.

Package Preparation:

☐ Primary receptacles leakproof (recommended to be sealed in positive means)

☐ Multiple primary receptacles are wrapped individually, to prevent contact and damage

☐ Sufficient absorbent material is placed between primary and secondary packaging to absorb entire contents if spilled

☐ Secondary package: leakproof, 95 kPa compliant (liquids by air), and secured as to not shift inside outer package

☐ Biohazard label on primary or secondary packaging

☐ Itemized list of contents between the secondary and outer package

☐ No other dangerous goods except dry ice (Unless <30 mL from hazard class 3, 8, 9 to maintain specimen acceptability)

☐ All manufacture packing instructions were followed

Outer Package

☐ Outer Package is rigid and free from damage and leakage

☐ Irrelevant marks and labels removed or obliterated

☐ Outer package is free from contaminates and was prepared in a safe manner

Markings – MUST be present on outer package

☐ Proper Shipping Name and UN number. "Biological substance, Category B" and UN3373 are present

☐ Full names and addresses of shipper and consignee

☐ Name and telephone number of Responsible Person (on package or shipping papers)

☐ Category B diamond shaped Infectious substances hazard label:

Additional labels, only as needed on outer package

☐ Cargo aircraft only label if net quantity >1 L (on same package surface as hazard label)

☐ Orientation arrows if >50 mL of liquid (2 labels required, placed on opposite sides of package)

☐ Overpacks: All markings of interior packages duplicated on overpack, with addition of "Overpack" label

☐ If dry ice is used as refrigerant a marking stating what is being refrigerated, "Frozen Medical Samples"

Documentation

☐ Air Waybill (for shipments by air)

☐ Shipper/Carrier has been trained concerning risks and regulations associated with infectious substances transport

Final Dry ice Acceptance Checklist – Transport by Aircraft

This checklist is adapted from "2023 Acceptance Checklist for Dry ice," IATA DGR 64th Edition. It is intended to assist shippers in Dry ice package preparation in accordance with Packing Instruction 954.

Markings – MUST be present on outer package

☐ Full names and addresses of shipper and consignee

☐ Net quantity of dry ice in package (in kilograms)

☐ UN number (UN1845)

☐ Proper Shipping Name: Dry ice (or Carbon Dioxide, solid)

☐ Class 9 Miscellaneous hazard label:

Outer Package

☐ Outer Package is free from damage and leakage

☐ Irrelevant marks and labels removed or obliterated

☐ Outer package is free from contaminates and was prepared in a safe manner

☐ Package conforms to packing instructions 954 (vented to permit the release of gas)

☐ Material inside outer package is secured and will not shift once dry ice dissipates

☐ Category B only: If dry ice is used as refrigerant a marking stating what is being refrigerated, "Frozen Medical Samples"

For Overpacks

☐ Packaging marks, hazard labels, and handling labels as required must be reproduced on the outside of the overpack

☐ The word "Overpack" marked on overpack package

☐ The total net weight of dry ice contained in overpack

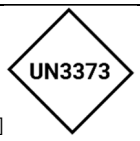
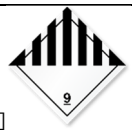
General

☐ Shipper/Carrier has been trained concerning risks and regulations associated with dry ice transport

Final Packaging Checklist

	Category A	Category B	Exempt
Manufacturer's instructions followed	☐	☐	☐
Good quality packaging	☐	☐	☐
Primary receptacle properly closed and leakproof	☐	☐	☐
Primary receptable secured with secondary means (tape, parafilm)	☐	Recommended	Recommended
Multiple fragile primary receptacles wrapped individually	☐	☐	☐
Sufficient absorbent inside each secondary packaging	☐	☐	☐
Secondary packaging properly closed and leakproof	☐	☐	☐
Primary or secondary container 95 kPa compliant (air transport)	☐	☐	N/A
Itemized list of content between secondary and outer packaging	☐	☐	N/A
Outer package displays UN specification mark	☐	N/A	N/A
Rigid outer packaging	☐	☐	N/A
Check minimum external dimensions of outer packaging	☐ All dimensions at least 100mm	☐ One surface at least 100mm x 100mm	☐ One surface at least 100mm x 100mm

Final Marking and Labeling Checklist

	Category A	Category B	Dry ice	Exempt
Address of consignor	☐	☐	☐	☐
Address of consignee	☐	☐	☐	☐
Hazard Label/ Mark affixed	☐ 	☐ 	☐ 	N/A
UN number	☐ UN2814 or UN2900	N/A (already on mark)	☐ UN1845	N/A
Proper shipping name or other designation	☐ Infectious substance affecting humans or Infectious substance affecting animals	☐ Biological substance, Category B	☐ Dry ice, or Carbon dioxide, solid	☐ Exempt human specimen or Exempt animal specimen
Technical name	☐ (Optional on package)	N/A	N/A	N/A
Quantity of dangerous good	☐	N/A	☐	N/A
Name and telephone number of responsible person	☐	☐ (Optional if on waybill or documentation)	N/A	N/A
Indicate materials for diagnostic purposes	N/A	☐ Frozen Medical Samples (Dry ice with Category B only)		N/A

Checklists adapted from Saf-T-Pak – Compliance Reference Manual – Division 6.2