

Dangerous Goods Training Module

Class 6.2, UN2814/UN3373; Class 9, UN1845



Mayo Clinic Laboratories provides this training as a service to clients and couriers.

It is limited to shipping of medical specimens for diagnostic testing, including Category A Infectious Substances, Category B Biological Substances, and Class 9 Dry Ice. Although Mayo Clinic Laboratories strives to ensure that the information is current and accurate, it is the employer's responsibility to perform and verify the training of employees.

No training is endorsed or certified by International Civil Aviation Organization (ICAO), Federal Aviation Administration (FAA), Transportation Security Administration (TSA), International Air Transport Association (IATA), Department of Transportation (DOT), or any other association or agency.

Parts of this training apply only to shipments originating or ending in the United States. Only Mayo Clinic Laboratories clients and couriers should use this training. Non-Mayo Clinic Laboratories clients and couriers are encouraged to use one of the many commercial vendors specializing in IATA and DOT training.

Welcome to our Transporting Dangerous Goods training. I'm Tom Griffin, Operations Manager for Global Logistics at Mayo Clinic Laboratories. We've created this training to help you understand the regulations when shipping medical specimens for diagnostic testing, including Category A Infectious Substances, Category B Biological Substances, and Class 9 Dry Ice. Dangerous goods, or hazardous materials (hazmat), are articles or substances which are capable of posing a risk to health, safety, property, or the environment and which are shown in the list of dangerous goods in the International Air Transport Association (IATA) Dangerous Goods Regulations or in 49 Code of Federal Regulations (CFR), Hazardous Materials Table. Although we strive to ensure that the information is current and accurate, we remind you that it is the employer's responsibility to train and test employees on these regulations. Anyone who is involved with shipping dangerous goods must follow them. The U.S. government can assess substantial penalties for violations of these regulations. The IATA Dangerous Goods Regulations and the 49 CFR regulations can help you prepare a specimen for shipment. Keep in mind that there are numerous regulations that change all the time. One person cannot remember all the regulations, so don't be afraid to ask or call someone if you are unsure. Every mode of transportation has its own rules that we must follow in addition to the legal regulations. They are related to proper training of staff, specimen classification, packaging, labeling, and documentation. This presentation covers each of these topics in detail.

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General Familiarization

The purpose of dangerous goods regulations is to provide procedures by which articles and substances with hazardous properties can be safely transported. It is the shipper's responsibility to follow the rules when preparing a dangerous goods shipment.

Training is necessary for all individuals involved in the preparation or transport of dangerous goods to ensure the packages can be safely transported without exposing the contents to the individuals handling the shipment during transit.

Packaging is an essential component to safely transporting dangerous goods. The quantity of dangerous goods permitted in each form of transportation is strictly limited by regulations so as to minimize the risk should an accident or incident occur. Proper declaration is necessary to ensure that everyone in the transportation chain knows how to safely load, handle, and transport dangerous goods, as well as what to do in the event of an accident or incident.

Reporting of dangerous goods incidents and accidents is necessary to help establish a cause and put corrective measures in place.

Proper Shipping Name

Proper shipping name is a standard name used to identify the article or substance on the outside of the package and on the shipper's declaration form.

Technical name

Technical name is a recognized chemical name and must accompany the proper shipping name when indicated in the regulation.

It is required when:

- A bold star (*) is shown in IATA 4.2 list of dangerous goods (blue pages), column B
- A "G" is shown on column one of table 172.101 in 49 CFR

1.3 Training

- Training is required within 90 days of employment for all laboratory employees who pack and ship dangerous goods. It is the employer's responsibility to ensure employees are properly trained and tested.
- Training must be repeated every two years (air shipments) according to IATA and every three years (ground shipments) according to 49 CFR. Training must include general familiarization, function-specific information, safety training, and security awareness training.
- Air shipments are the exception for the 90-day grace period. Before any package is offered for air transport, the employee must be trained prior to shipment, unless the employee is working under direct supervision of another employee with valid training.







Training records must be kept by the employer for a minimum of 36 months and must be made available upon request of the appropriate national authority in case of an audit.

Training records must include:

- Employee name
- Training date
- Description, copy, or reference materials used
- Name and address of the company providing the training
- Evidence that a test has been completed satisfactorily





2. Function-Specific Training

This training was developed to fulfill the specific needs of Mayo Clinic employees, couriers, and Mayo Clinic laboratories clients.

Dangerous goods are classified into nine different classes. Class 6 Division 6.2 and Class 9 will be covered in this module.



Class 6. Infectious Substance

UN2814 – Category A – Infectious Substances, Affecting Humans

UN3373 – Category B – Biological Substances



Class 9. Miscellaneous

UN1845 - Dry Ice



 Category A is an infectious substance transported in a form that, when exposure to it occurs, is capable of causing permanent disability or life-threatening or fatal disease to humans or animals.

Note: An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

 Shippers of infectious substances must comply with regulations and must ensure packages are prepared in such a manner that they will arrive at their destination in good condition and present no hazard during transit.



IATA Packing Instructions 620 or 49 CFR 173.134 and 173.196 describe the requirements for packing infectious samples.

The packaging must include triple-layer packaging:

• **Inner packaging** with leak-proof primary receptacle.

Note: Primary or secondary containers must be capable of withstanding an internal pressure differential of not less than 95 kPA and temperature ranges of -40°C to 55°C, without leakage.



The packaging must include triple-layer packaging:

 Secondary packaging with material sufficient to absorb the entire contents placed between primary and secondary

(if multiple fragile primary receptacles are inside one secondary, they must be individually wrapped or separated to prevent contact between them)



The packaging must include triple-layer packaging:

Itemized list of contents enclosed between secondary and outer packaging

Batch 01	864301		R		。 疑瞬■
FROM: Web Portal Testi WEB PORTAL TESTING A ROCHESTER MN 55905 UNITED STATES	ng Account CCOUNT #1		Patrigenated TO: Mayo Clinic Laboratories, Attn: Tom Griffin 3050 Superior Drive NW Acchester, MN 55901 UNITED STATES +1 507 266 5700		
Order No.	Patient Name	Patient ID	Collected/Physician	Gender	DOB
WEB1M7P4V22K	Calrissian, Lando	741	12 Dec 2016 00:00 LANZA, TIFFINI	м	07/09/1975
	AAT Alpha-1-Antitr	ypsin, Serum — Serum			
WEB1M7P4V22L	Kenobi, Obi-Wan "Ben"	/8520	12 Dec 2016 00:00 LANZ, JAMES	М	06/06/1955
	HSV Herpes Simple Serum	ex Virus (HSV) Type 1- ani	d Type 2-Specific Antibodies, Serum	-	
WEB1M7P4V22M	Fett, Boba	8520	12 Dec 2016 00:00 LANZ, JAMES	М	10/31/2012
	AAT Alpha-1-Antitr	ypsin, Serum — Serum			
WEB1M7P4V22Y	Vader, Darth	963.	12 Dec 2016 00:00 LANZKOWSKY, LEOBA	М	05/14/1932
	HGH Growth Hormo	one, Serum — Serum			

The packaging must include triple-layer packaging:

• A rigid outer packaging



- When transporting UN2814, Category A samples, a UN certified package is required. It means that the packaging has been built, tested, and certified to carry liquid or solid dangerous materials. This is a unified way to ensure dangerous materials are transported safely. The markings below represent a successful test.
- Category A samples require a combination package, which is provided by Mayo Clinic Laboratories. That specific combination has been tested and certified, and therefore cannot be altered. It is important to use the complete kit following the closing instructions printed on the box and secure with tape.

The test was performed with a 3M Scotch Commercial Packaging Tape 2", with one strip across the top and one across the bottom of the box.





UN2814 Infectious Substances, Affecting Humans – Additional Requirements

- Packaging containing Category A samples cannot be consolidated with other specimen types.
- When the substances to be transported are unknown but suspected to meet the criteria for inclusion in Category A, the words "Suspected Category A Infectious Substance" must be shown in parentheses following the shipping name on the itemized list of contents inside the outer packaging.
- For substances at ambient or higher temperatures, primary receptacles must be of glass, metal, or plastic. A leak-proof seal is required, such as a heat seal, skirted stopper, or metal crimp seal. If screw caps are used, they must be secured by tape, paraffin sealing tape, or a manufactured locking closure.
- For refrigerated or frozen substances, the refrigerant must be placed around the secondary packaging. The combination packaging must maintain its integrity at the temperature of the refrigerant used.

The purpose of the markings and labels on the box is to communicate the contents of the box. The label should show:

- Dangerous goods being transported.
- The box was tested according to the specifications defined by regulatory agencies.
- Shipper name.
- Consignee name.
- Responsible person for properly packing the substance.
- Orientation arrows to indicate how the box should be placed facing up if the substance being shipped is liquid.



- When shipping Category A samples, the necessary documents are the air waybill and a Shipper's Declaration for Dangerous Goods.
- The shipper's declaration is prepared by the shipper and describes the contents of the consignment. By signing the shipper's declaration, the shipper declares the consignment is classified, packaged, marked, and labeled according to international and national government regulations. If this form is filled out incorrectly in any way, your shipment will be rejected.
- At least two copies of the declaration must be given to the airline. You must retain a copy of the Shipper's Declaration for two years.



Required fields:

- Full name and address for shipper and consignee
- Air waybill number and number of pages
- Transport details box: mark out either "passenger and cargo aircraft" or "cargo aircraft only"
- Airport or city of departure and airport or city of destination
- Shipment type: mark out "radioactive"
- The following order must be completed on the Nature and Quantity of Goods: UN2814, Infectious Substances, affecting humans (i.e., dengue virus), 6.2, 1 Fibreboard box x 30 ml, 620
- Additional handling information: include the 24-hour emergency contact number, the contract number if it is a third-party service, and the person responsible for the shipment
- Certification statement that ensures the shipment is acceptable for transport
- Name, place, and date, signature



- IATA offers a table of examples of infectious substances, which you can find a link to in the Resources section at the end of this training.
- The list may not include everything that qualifies as Category A—for example, new and emerging pathogens may not yet be on the list.



This video will demonstrate how to pack Class 6.2, Category A specimens when you are shipping to Mayo Clinic Laboratories.

Category A requires UN certified packaging. Every 2 years this packaging combination goes through a series of testing, described in the regulation. If it passes all tests without any leakage, a certification is issued which is demonstrated by this UN marking on the box.

Triple layer packaging is required, so you will need your vial (which is the primary container), a secondary container, and the outer box.

You will place your primary container inside the bag, roll it, seal it, and place it inside your secondary container. You will be able to fit 2 vials inside the secondary. Then close it and place inside the plastic bag.

Use the pouch outside the bag for the itemized list of contents you are shipping. Fold the batch with the barcode facing towards the outside so if you have a courier pick-up, they will be able to scan the shipment.

Then place the bags inside the styro along with the cool packs. Place the lid onto the styro, close the box, and tape the top to make sure the box does not open in transit. Attach the air waybill on the box, making sure you are not covering any of the required markings. Don't forget that a shipper's declaration is required with Category A shipments.

Required markings for Category A are: UN certified packaging, Class 6 label, Proper shipping name and UN #, Shipper, Recipient, Responsible person (name and phone number), Orientation arrows on opposite sides of the box

Never mix Category A with Category B shipments in the same box as the requirements are different for each category. Thank you for watching and if you have any questions, don't hesitate to contact the Global Logistics Department.



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- Category B Biological Substances are infectious substances which do not meet the standards for inclusion in Category A.
- Category B samples are classified as UN3373 with a proper shipping name of Biological Substance.
- IATA Packing Instructions 650 or 49 CFR 173.134 and 173.199 provide detailed information when shipping Category B samples.
- Category B does not require a UN-certified box. The completed package must pass a drop test, as described at IATA 6.5.4.4, from a height of 4 feet (1.2 meters). Following the drop, there must be no apparent leakage, being contained by the absorbent material and second layer of protection.
- Include an itemized list of contents between the secondary packaging and outer packaging. The batch our system generates can be used as the itemized list.



BIOLOGICAL SUBSTANCE, CATEGORY B

The packaging must be of good quality and strong enough to withstand the shocks and loadings normally encountered during transport. Packaging must be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by change in temperature, humidity, or pressure.

Samples must be triple packaged with:

 Leak-proof primary receptacle containing no more than 1 liter in the vial with enough absorbent material to soak up the entire contents of the bag

Note: Primary or secondary container must withstand a pressure differential of 95 kPa without leakage in the range of -40°F and 130°F.



Samples must be triple packaged with:

• Leak-proof secondary packaging (if your vials are fragile, you must individually wrap them to prevent breaking in transit)

		SR0008576
	N	
	BIOHAZ	ARD
AMBI This sp	ENT (ROUTI) ecimen does not r	NE) SPECIMI
	or Freezing duri	ng transit.
1) F 2) F	Place specimen in b Press reclosable zip	ag. oper to seal.
3) 1	nsert requisition in	to outside pocket.
Ma	yo Medical I	aboratories

Samples must be triple packaged with:

• Itemized list of contents should be enclosed between secondary and outer packaging

	964201				
Daton Ul	004001		Refrigerated		
FROM: Web Portal Testi WEB PORTAL TESTING A ROCHESTER MN 55905 JNITED STATES	ng Account CCOUNT #1		TO: Mayo Clinic Laboratories, Attn: Tom Griffin 3050 Superior Drive NW Rochester, MN 55901 UNITED STATES +1 507 266 5700		
Order No. WEB1M7P4V22K	Patient Name Calrissian, Lando	741	12 Dec 2016 00:00	Gender M	DOB 07/09/1975
	AAT Alpha-1-Antitry	psin, Serum — Serum	LANZA, TIFFINI		
WEB1M7P4V22L	Kenobi, Obi-Wan "Ben"	/8520	12 Dec 2016 00:00 LANZ, JAMES	М	06/06/1955
	HSV Herpes Simplex Serum	Virus (HSV) Type 1- an	d Type 2-Specific Antibodies, Serun	n – 	
WEB1M7P4V22M	Fett, Boba	8520	12 Dec 2016 00:00 LANZ, JAMES	М	10/31/2012
	AAT Alpha-1-Antitry	psin, Serum — Serum			
WEB1M7P4V22Y	Vader, Darth	963.	12 Dec 2016 00:00 LANZKOWSKY, LEORA	м	05/14/1932
	HGH Growth Hormon	ne, Serum — Serum			
			- -	III 890 00 8005-	K. (1889) - 1111

Samples must be triple packaged with:

Rigid outer packaging

Must not contain more than 4 liters of UN3373 specimens



When shipping UN3373, the following is required to be displayed on the box:

- UN3373 label on a background of contrasting color. Adjacent to the diamond-shaped mark, the proper shipping name "Biological Substance, Category B" must be displayed in letters at least 6 mm high.
- Name and address of shipper and consignee.
- Name and telephone number of a person responsible must be provided in the air waybill or on the package.
- Orientation arrows on opposite sides of the box.



This video will demonstrate how to pack Class 6.2, Category B specimens when you are shipping to Mayo Clinic Laboratories.

Triple layer packaging is required, so you will need your primary container, the plastic bag, and the outer box. As we've mentioned in the training, Category B does not require a UN certified box, it just needs to pass the drop test of 1.2 meters. The boxes MCL provides to clients fulfill all the requirements to ship dangerous goods. If you decide to use your own packaging, it is your responsibility to be in compliance with regulations.

Place your vial, or primary container, inside the bag. You can fit up to 10 vials per bag. If your primary container is glass, make sure to individually wrap each vial before placing in the bag to avoid them breaking in transit. Then place the bags inside the styro with the cool packs, put the lid on top, fold the lids of the cardboard box, and tape it shut.

For your secondary container, MCL offers color coded bags based on the shipping temperature. Absorbent material is required in case there is any release of liquid from the primary container.

Use the pouch outside the bag for the itemized list of contents you are shipping. Fold the batch with the barcode facing towards the outside so if you have a courier pick-up, they will be able to scan the shipment.

If you are shipping frozen samples, use the box with the class 9 label then mark the amount of dry ice on the box and air waybill. Add dry ice pellets in the bottom of the box, place the bags with the samples, and then cover the bags with more dry ice. Leave enough space to fit the lid securely. Do not tape the lid as the carbon dioxide must be allowed to escape. Fold the lids of the cardboard box and tape the box shut. Attach the air waybill on the box, making sure you are not covering any of the required markings.

For Category B, those are: The diamond shaped UN3373 label, Biological substance, Category B, (For frozen shipments: Class 9 label, Dry Ice UN1845, and the amount you are shipping in kilograms), Shipper, Recipient, Responsible person (name and phone number), Orientation arrows on opposite sides of the box

Thank you for watching and if you have any questions, don't hesitate to contact the Global Logistics Department.



LABORATORIE

- Instructions for using or transferring select agents from, to, or within the United States are found in 42 CFR, parts 73.0 through 73.21.
- Most diagnostic testing laboratories are not involved with these agents and toxins. Thus, this material
 is beyond the scope of this presentation. Please refer to the Centers for Disease Control website,
 <u>cdc.gov</u>, for more information.



For patient specimens that have a low likelihood of the presence of pathogens, IATA uses the classification "Exempt Human Specimens" (applies only to shipments by aircraft).

Examples include:

- Dried blood spots
- Blood or blood components that have been collected for the purpose of transfusion
- Blood or urine tests to monitor cholesterol levels, blood glucose levels, or hormone levels
- Tests conducted for insurance or employment purposes to determine the presence of drugs or alcohol
- Pregnancy tests
- Note: The US Department of Transportation considers these samples to be outside of its regulations and thus does not assign them a classification at all.

2.5 Cultures

- Cultures present an increased risk of infection if exposure occurs. Any culture intended for the intentional generation of pathogens, or any culture shipped for identification purposes, must be shipped as Category A, Infectious Substance. In all other cases, cultures can be shipped as Category B, Biological Substance.
- When packing microbiology cultures, both Category A, Infectious Substances and Category B, Biological Substances should be sent in a Mayo Clinic Laboratories-supplied secondary container.





- When packaging cultures, use the same process as for Category A, with the addition of three blue "C" label stickers: one in the bag, one on the styro lid, and one on the outside of the box. If you have a courier pickup, the courier will label the styro and the box. This ensures the safety of laboratory personnel.
- You can combine Category B cultures with other Category B sample types, and you can combine Category A cultures with other Category A. However, you cannot combine Category A with Category B. Each category has its own UN number and different markings and requirements.



IATA packing instructions 954 or 49 CFR 173.217 refer to the packing requirements when shipping dry ice:

 The package must be designed and constructed to permit the release of carbon dioxide gas and to prevent a buildup of pressure that could rupture the packaging

Box

- UN1845
- Dry ice
- Class 9 label
- Net weight in kg



IATA packing instructions 954 or 49 CFR 173.217 refer to the packing requirements when shipping dry ice:

 A shipper's declaration is not required for dry ice when used as a refrigerant (e.g., when used to keep specimens frozen)

Air Waybill

- UN1845
- Proper shipping name (carbon dioxide, solid, or dry ice)
- Class 9 label
- The number of packages
- The net weight of dry ice in each package





Take measures to protect yourself and your employees who ship dangerous goods by:

- Participating in training, including the employer's lab safety training, OSHA training, and employee right to know (ERTKA)
- Always wearing gloves
- Treating all spills as if they were infectious





Security Awareness

Security awareness training is required for all employees who ship dangerous goods in order to fulfill the requirements of 49 CFR 172.704 (a)(4). It is required within 90 days of employment, although recommended as soon as possible.

Training must include:

- Risks of transporting dangerous goods
- Methods of enhancing transport security
- Ways to recognize security risks
- Steps for responding to security threats

To complete the security awareness training portion, you can either develop your own or use the free training offered by the Department of Transportation. Use the link <u>dothazmat.vividlms.com</u> to log in, take the training, and obtain the security awareness certificate. At the end of the overall dangerous goods course, you will have a dangerous goods certificate as well. Both will need to be kept on file, according to the regulation.

Note: Mayo Clinic employees can search for the training module: MCL Operations: Hazmat Transportation – Security Awareness Training

Mayo Clinic Laboratories Global Logistics

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49CFR

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

IATA

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

Packing instructions 620 – Infectious Substances, Category A Packing instructions 650 – Biological Substances, Category B Packing instructions 954 – Dry Ice, UN2814

DOT

https://www.transportation.gov/

ICAO

https://www.icao.int/Pages/default.aspx

FAA

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

Select Agents

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

Examples of Category A Infectious Substances

https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf