Disclaimer

Only Mayo Medical Laboratories clients and couriers should use this training. Others are encouraged to use one of the many commercial vendors specializing in IATA and DOT training. This training is not endorsed or certified by any association or agency.

Regulatory Agencies and Associations
• ICAO – International Civil Aviation Organization
• IATA – International Air Transport Association
• DOT – Department of Transportation
• CFR – Code of Federal Regulations
(Links for each agency/association can be found in the resources at the end of this training)
Part 1

Overview
Dangerous Goods or Hazardous Materials (also known as 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 IATA regulations, or in the HazMat table for 49CFR.

Although we strive to ensure that the information is current and accurate we remind you that it is the employers responsibility to train and test their employees on these regulations. Anyone who is involved with shipping Dangerous Goods must follow them. The US Government can assess substantial penalties for violations of these regulations. The IATA Dangerous Goods guidelines and the 49CFR regulations can help you prepare a specimen for shipment.

Keep in mind, 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 we must follow in addition to the legal regulations. They are related to specimen classification, packaging, labeling, documentation, and the proper training of staff. This presentation covers each of these topics in detail.
Part 2

Proper Classification of Specimens
Hazard Classes

Class 1: Explosives
- 1.3 Explosives
- 1.4 Explosives

Class 2: Gases
- 2.1 flammable gas
- 2.2 Non-Flammable, Non-Toxic gas
- 2.3 Toxic (poison) gas

Class 3: Flammable Liquids

Class 4: Flammable Solids
- 4.1 Flammable solid
- 4.2 Spontaneously combustible
- 4.3 Dangerous when wet

Class 5: Oxidizers and Organic Peroxides
- 5.1 Oxidizers
- 5.2 Organic Peroxides

Class 6: Toxic (poisonous) and Infectious Substances
- 6.1 Toxic Substances
- 6.2 Infectious Substances

Class 7: Radioactive

Class 8: Corrosive

Class 9: Miscellaneous Dangerous Goods

Dangerous goods must be classified into the correct hazard class. There are 9 hazard classes. If a hazard class is wide in scope, it may be divided into additional divisions. For training purposes, you should know all 9 hazard classes exist, but generally, you will only use 2 of these hazard classes when shipping medical specimens.
Infectious substances fall under Class 6, Division 6.2.

Dry ice falls under Class 9, Miscellaneous.

When preparing a specimen for shipping you must know the hazard class to complete the packaging and documentation correctly.
In addition to the 9 hazard classes most hazardous substances are further assigned to a packing group.

The 3 packing groups indicate the degree of hazard the substance presents.

For training purposes, you should know the packing groups exist, however when shipping medical specimens you will not need to refer to a packing group, as neither 6.2 Category A or B are assigned to a packing group.

• You must specify a packing group if you ship an acid, corrosive, or flammable substance.
Infectious Substances

Infectious substances (Class 6, Division 6.2) are divided into two categories:

- Category A, Infectious Substance Affecting Humans
- Category B, Biological Substance

Rules for packaging and shipping are determined by whether a substance is Category A or Category B.

Infectious substances are known or are reasonably expected to contain pathogens. Infectious substances are classified in Division 6.2.

Class 6, Division 6.2 Infectious substances are divided into two categories:

- Category A, Infectious
- Category B, Biological Substance

Rules for packaging and shipping are determined by how an infectious substance is categorized.
Category A Infectious Substances

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

Identified as:
- UN2814, Infectious Substance, Affecting Humans in both 49 CFR and in IATA
- IATA Packing Instruction 620 (table 3.6.2.2.2.1)
- Paragraphs 173.134 and 173.196 in 49CFR

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

- 49 CFR and IATA require a Hazard Class 6 label
- IATA packing instruction 620
- The proper shipping name is “Infectious substance Affecting Humans”
Category B Biological Substances

Category B is an infectious substance, referred to as a biological substance, that does not meet the criteria for Category A.

Identified as:
- UN3373
- IATA Packing Instruction 650 (paragraph 3.6.2.2.2.2)
- Paragraphs 173.134 and 173.199 in 49CFR
- Biological substance, Category B

Category B is an infectious substance, referred to as a biological substance, that does not meet the criteria for Category A.
- 49 CFR and IATA require a UN3373 marking
- IATA packing instruction 650
- The proper shipping name is “Biological substance, Category B”
## Category A & Category B Examples

<table>
<thead>
<tr>
<th>Category A, Infectious</th>
<th>Category B, Biological</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Brucella abortus (cultures only)</td>
<td>• HIV (blood products)</td>
</tr>
<tr>
<td>• Hepatitis B virus (cultures only)</td>
<td>• Hepatitis (blood products)</td>
</tr>
<tr>
<td>• West Nile (cultures only)</td>
<td>• West Nile (blood products, CSF, and urine)</td>
</tr>
<tr>
<td>• Mycobacteria tuberculosis (cultures only)</td>
<td>• SARS</td>
</tr>
</tbody>
</table>

How do you know if a substance is Category A, Infectious or Category B, Biological?
• It is the responsibility of the laboratory staff to classify the specimen.
• This slide lists some examples of Category A, Infectious or Category B, Biological substances.
The proper shipping name for Category A is “Infectious Substance, affecting humans.” When the infectious substances to be transported are unknown but suspected of meeting the criteria for inclusion in Category A, the technical name is “Suspected Category A Infectious Substance.” Per IATA regulations, if there is doubt as to whether or not a substance meets the criteria, it must be included in Category A.

This slide lists Category A, Infectious examples from IATA regulations.

<table>
<thead>
<tr>
<th>Category A, Infectious Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacillus anthracis (cultures only)</td>
</tr>
<tr>
<td>Brucella abortus (cultures only)</td>
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<tr>
<td>Brucella melitensis (cultures only)</td>
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<tr>
<td>Brucella suis (cultures only)</td>
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<tr>
<td>Burkholderia mallei - Pseudomonas mallei - Glanders (cultures only)</td>
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<tr>
<td>Burkholderia pseudomallei - Pseudomonas pseudomallei (cultures only)</td>
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<tr>
<td>Chlamydia psittaci - avian strains (cultures only)</td>
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<tr>
<td>Clostridium botulinum (cultures only)</td>
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<tr>
<td>Coccidioides immitis (cultures only)</td>
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<tr>
<td>Coxiella burnetii (cultures only)</td>
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<tr>
<td>Crimean-Congo hemorrhagic fever virus (cultures only)</td>
</tr>
<tr>
<td>Dengue virus (cultures only)</td>
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<tr>
<td>Eastern equine encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>Escherichia coli, verotoxigenic (cultures only)</td>
</tr>
<tr>
<td>Ebola virus</td>
</tr>
<tr>
<td>Flexal virus</td>
</tr>
<tr>
<td>Francisella tularensis (cultures only)</td>
</tr>
<tr>
<td>Guanarito virus</td>
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<tr>
<td>Hantaan virus</td>
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<tr>
<td>Hantaviruses causing hemorrhagic fever with renal syndrome</td>
</tr>
<tr>
<td>Hendra virus</td>
</tr>
<tr>
<td>Hepatitis B virus (cultures only)</td>
</tr>
<tr>
<td>Herpes B (cultures only)</td>
</tr>
<tr>
<td>Human immunodeficiency virus (cultures only)</td>
</tr>
<tr>
<td>Highly pathogenic avian influenza virus (cultures only)</td>
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<tr>
<td>Japanese Encephalitis virus (cultures only)</td>
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<tr>
<td>Junin virus</td>
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<tr>
<td>Kysanur Forest disease virus</td>
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<tr>
<td>Lassa virus</td>
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<tr>
<td>Machuoo virus</td>
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<tr>
<td>Marburg virus</td>
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<tr>
<td>Monkeypox virus</td>
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<tr>
<td>Mycobacterium tuberculosis (cultures only)</td>
</tr>
<tr>
<td>Nipah virus</td>
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<tr>
<td>Omek hemorrhagic fever virus</td>
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<tr>
<td>Poliovirus (cultures only)</td>
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<tr>
<td>Rabies virus (cultures only)</td>
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<tr>
<td>Rickettsia prowazekii (cultures only)</td>
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<tr>
<td>Rickettsia rickettsi (cultures only)</td>
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<tr>
<td>Rift Valley fever virus (cultures only)</td>
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<tr>
<td>Russian spring-summer encephalitis virus (cultures only)</td>
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<tr>
<td>Sabia virus</td>
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<tr>
<td>Shigella dysenteriae type 1 (cultures only)</td>
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<tr>
<td>Tick-borne encephalitis virus (cultures only)</td>
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<tr>
<td>Varekia virus</td>
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<tr>
<td>Venezuelan equine encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>West Nile virus (cultures only)</td>
</tr>
<tr>
<td>Yellow fever virus (cultures only)</td>
</tr>
<tr>
<td>Yersinia pestis (cultures only)</td>
</tr>
</tbody>
</table>
Select Agents

The United States Health and Human Services (HHS) Secretary has determined that some biological agents and toxins have the potential to post a severe threat to public health and safety.

Examples of these Select Agents:
- Ebola viruses
- Francisella tularensis
- Marburg virus
- Monkeypox virus
- Variola major virus (Smallpox virus)
- Yersinia pestis

A complete listing of Select Agents can be found at www.selectagents.gov

Using or transferring Select Agents from, to, or within the United States are found in 42CFR, Parts 73.0 through 73.21. Most diagnostic testing laboratories would not be involved with these agents and toxins. Thus, it is beyond the scope of this presentation to cover this material. Please refer to the Centers for Disease Control website: www.cdc.gov for more information.
Exempt Human Specimens

These are specimens that do not contain infectious substances, substances containing micro-organisms that are non-pathogenic to humans, and substances in a form that any present pathogens have been neutralized or inactivated.

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

The classification of “Exempt Human Specimen” applies only to shipments by aircraft. The US Department of Transportation considers these samples to be outside of their regulations and thus does not assign them a classification at all.

IATA classifies patient specimens for which there is minimal likelihood that pathogens are present as “Exempt Human Specimens.” 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

The classification of “Exempt Human Specimen” applies only to shipments by aircraft. The US Department of Transportation considers these samples to be outside of their regulations and thus does not assign them a classification at all.
Cultures

Cultures are the result of a process by which pathogens are intentionally propagated to enable identification of the organism. As such, the risk of infection is increased if exposure occurs to the growing pathogen.

Cultures can be classified:
- Category A, Infectious
- Category B, Biological Substance

Cultures are the result of a process by which pathogens are intentionally propagated to enable identification of the organism. As such, the risk of infection is increased if exposure occurs to the growing pathogen.

Cultures can be classified as Category A, Infectious or Category B, Biological Substance:
- Any culture intended for the intentional generation of pathogens as well as any culture shipped for identification purposes must be shipped as Category A, Infectious.
- Cultures can be shipped as Category B, Biological if they are not intended for the intentional generation of pathogens and are not found in the Category A list in the IATA regulations.
Part 3
Proper Packaging and Labeling of Specimens
Category A – Infectious Substance Affecting Humans – AIR – IATA packing instruction 620

Packing category A requires a UN certified packaging:

- The triple packaging consists in a leak-proof primary and secondary packaging and a rigid outer packaging of adequate strength for its capacity
- Ambient temperature samples must ship in a primary container made of glass, metal or plastic and must have positive means of closure such as a heat seal, metal crimp seal, tape, depending on what type of tube it is
- The primary or secondary must withstand 95kPa of pressure and temperatures between -40°F and +130°F
- You cannot consolidate Category A with any other specimen types

It is a combination packaging consisting of inner and outer containers that have passed a series of tests required, including puncture, drop and stacking test, by IATA and DOT. They are tested as a combination package so it is illegal to ship them individually. You must always use the appropriate combination of containers to ensure UN-certification.
How to properly pack a Category A sample:

- The sample must be packed in a leak-proof primary container, place the tube in the bubble wrap bag and inside the plastic can. You can fit up to 2 samples per plastic can.
- The secondary packaging is our color coded bag. It must contain enough absorbent material between primary and secondary to soak up the entire contents of the bag. You may also include an itemized list of what is being shipped. The list will have to be between the secondary and the outer packaging.
- You must use a box big enough to accommodate all the proper markings and labels for the contents of the box. They cannot overlap, be obscured or folded over a corner. If there are previous labels or markings on the box, they must be completely removed or blacked out before reuse.
- Properly seal the box with tape in a way that it won’t open in transit. It is important that the samples arrive in good condition without presenting a hazard to the public.

The necessary markings on the box are:

- Proper shipping name – Infectious Substance Affecting Humans – UN2814
- Infectious Substance class 6 label
- Show markings of UN certified box
- Name and address of shipper and recipient
- A person responsible for the shipment must be indicated in the box with permanent marker
- Shippers Declaration
- If the specimen is liquid, orientation arrows are required on opposite sides of the box
- If you are shipping over 50 ml or grams of Category A, the box must also be marked with a cargo-only aircraft label
When packing microbiology cultures both Category A, Infectious and Category B, Biological should be sent in a MML supplied secondary container. Doing so ensures the safety of lab personnel.

The process of packing the samples is the same as showed before on Category A, with the addition of the blue “C” label sticker (one on the bag, one on the styro lid, and one on the outside of the box). If you have a courier pick up, they will take care of labeling the styro and box.

You can combine Category B Cultures with other Category B samples types, same for category A, but you cannot combine Category A with Category B. Each Category has their own UN number and different markings and requirements.
Packing Category B does not require a UN certified box.
• Samples must be triple packaged, with a leak-proof primary receptacle containing no more than 1 liter in the vial and a leak-proof secondary container;
• Primary and secondary must withstand 95Kpa of pressure and temperatures between -40 F and +130 F without leakage;
• Include an itemized list of contents between the secondary and outer package;
• Rigid outer packaging with no more than 4L, excluding dry ice;
• The package must pass a drop test, as described in IATA 6.5.4.4, from the height of 4 feet/1.2 meters.
How to properly pack a Category B sample:

The package for Category B must have 3 components:
1. Primary receptacle
2. Secondary packaging
3. Rigid outer packaging

- Place the tubes inside the color-coded bag with enough absorbent material.
- Add an itemized list of contents inside the pouch, and place the bag inside the berry box.
- Properly seal the box with tape in a way that it won’t open in transit for the safety of all personnel handling the box.
- You must use a diamond shape UN3373 label with the following description: Biological Substance Category B
- Name and address of shipper and recipient.
- A personal responsible for the shipment must be indicated on the box with permanent marker.
- If your specimen needs to be shipped on dry ice, use a dry ice label.
  - The label must include weight of dry ice marked in kilograms.
- If the specimen is liquid, orientation arrows are required on opposite sides of the box.
  - Since most of our shipments contain liquids, our boxes are preprinted with these arrows.
Part 4

Methods of Transportation and Documentation of Specimen Shipments
If you send your specimens by US Mail, follow the Post Office’s Dangerous Goods regulation. They closely follow the DOT regulations in 49 CFR, but may include additional restrictions. If you send your specimens by air, follow the IATA/ICAO Dangerous goods regulations. When shipping by ground, follow the DOT regulations in 49 CFR.
Private Couriers & Contract Carriers

Private courier systems and dedicated contract carriers:

- Follow DOT regulations for Category A, Infectious substances
- Exempt from DOT regulations for Category B, Biological substances as long as the motor vehicle is used exclusively to transport such materials
- Must follow OSHA requirements

If you operate your own private courier system or contract with a dedicated contract courier:

- Follow the DOT regulations for all Category A, Infectious substances.
- For Category B, Biological substances by ground, you are exempt from DOT regulations as long as the motor vehicle is used exclusively to transport such materials.
- Substances exempt from DOT regulations must still follow OSHA requirements, as stated in 29 CFR. This includes placing biohazard labels on at least one of the containers.
Proper Shipping Names & Technical Names

Use the proper shipping and technical names when shipping:

- **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** is a recognized chemical name—currently used in scientific and technical handbooks, texts, journals—which must accompany the proper shipping name when indicated in the IATA or DOT regulations.

To ship legally and safely, it is important to identify correctly on your package and paperwork the substance you are shipping.

- You must use the proper shipping name when shipping. The 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.

- In the case of an infectious substance, you must know the technical name of the substance as well. The technical name is a recognized chemical name—currently used in scientific and technical handbooks, texts, or journals—which must accompany the proper shipping name when indicated in the IATA or DOT regulations.
Dangerous Goods regulations in both 49 CFR and IATA indicate when a substance requires a technical name:

- In IATA, substances followed by a bold star (*) need a technical name included in the documentation.
- In 49 CFR, substances marked by the letter “G” in column 1 need a technical name.
When shipping Category A, Infectious substances, a Shipper’s Declaration for Dangerous Goods is required:

- The Shipper’s Declaration describes the contents of the consignment. By signing the shippers 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.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Infectious substances</td>
</tr>
</tbody>
</table>

**Important Notice:**

- Keep copies of this document for two years.
- Always notify the airline of any changes in the consignment.
- Ensure all documentation is accurate and up-to-date.
- Failure to comply with regulations may result in compliance fines or legal penalties.

**Additional Information:**

- For more information on dangerous goods and shipping regulations, consult the latest international and national guidelines.
- Ensure all packaging and labeling meet the required standards.
- Keep records of all shipments for at least two years as per regulatory requirements.
Complete an airway bill for every shipment:

• An airway bill is the only requirement for Category B, Biological substances
• Each airline has its own airway bill
Part 5

Proper Training of Employees
Training-General

- HazMat employer is responsible for training
- Initial training is required within 90 days of employment for all employees who pack and ship dangerous goods
- Training must include general familiarization, function-specific information, safety training, and security awareness training
- Training must occur every two years if you ship by air

Employee training is an important element when shipping dangerous goods
- It is the duty of each Hazmat employer to provide training and ensure each Hazmat employee is tested on the training subjects covered
- If you are audited by the FAA, your training records are typically evaluated first.
- Training requirements state that an employee may only be certified in areas in which they can successfully perform their duties.
- Training is required within 90 days of employment for all laboratory employees who ship dangerous goods. Earlier training is recommended.
- Self-training is acceptable as long as it meets the requirements of Security Awareness Training, as described in the next few slides.
- Training must include general familiarization, function-specific information, safety training, and security awareness training.
- Training must be repeated every 2 years per IATA, every 3 years per 49 CFR
Training-General (cont.)

• It is the duty of each HazMat employer to provide training (in house or outside source) and ensure each HazMat employee is tested on the training subjects covered.

• Retain complete records of Dangerous Goods Training, including:
  • Employee Name
  • Training Date
  • Description, copy, or reference materials used
  • Name and address of company providing training
  • Copy of completed test certification

Accurate training records must be retained in the event of an audit:

• In general, these records must include: the employee’s name, the most recent training completion date, and a description or copy of the training materials used, such as a copy of this presentation.

• A test that ensures the employee can perform the assigned duties in compliance with the regulations is required. No specific format must be used, however. Training and testing may be accomplished in a variety of ways—performance, written, verbal, or a combination. Once the test is completed, a copy of the certification issued must be retained.
Training-Security Awareness

- Security Awareness Training fulfills the requirements of 49 CFR 172.704(a)(4)
- Security Awareness Training is required for all laboratory employees who ship dangerous goods:
  - Required within 90 days of employment
  - Recommended as soon as possible
Training-Security Awareness (cont.)

- Security Awareness Training must include:
  - Risks of transporting dangerous goods
  - Methods of enhancing transport security
  - Ways to recognize security risks
  - Steps for responding to security threats

http://www.phmsa.dot.gov/staticfiles/PHMSA/Hazmat/digipak/

Security Awareness Training must include:
- Risks of transporting dangerous goods.
- Methods of enhancing transport security.
- Ways to recognize security risks.
- Steps for responding to security threats.

The US Department of Transportation has training materials available to satisfy these requirements. Use the link provided to access the Security Awareness Training website.
Emergency Response Information

- Emergency response information is required per 49CFR (subpart G of 172)
- Emergency response information includes:
  - Proper shipping name, “Infectious Substance Affecting Humans”
  - Technical Name
  - Telephone number for a responsible person in the event of an emergency
  - Shipper’s Declaration for Dangerous Goods (air) or Shipping paper (ground)
    - Store in vehicle when transporting by ground
    - Keep one copy for two years

Per 49 CFR, employees must be knowledgeable in emergency response information for all infectious substances. This includes:
- Proper shipping name of the substance, “Infectious Substance Affecting Humans.”
- Technical name of the substance.
- Telephone number for use in the event of an accident or other emergency.
- Ensure the Shipper’s Declaration for Dangerous Goods or the shipping paper is stored in the vehicle when transporting by ground carrier. Three copies of the Shipper’s Declaration for Dangerous Goods must be included when transporting by air.
Employees can protect themselves when shipping dangerous goods by:

- Participating in training--including the employer’s lab safety training, OSHA training, and Employee Right to Know (ERTKA)
- Always wearing gloves
- Treat all spills as if they were infectious

Emergency Measures

- Take measures to protect yourself and your employees who ship dangerous goods by
  - Participating in training including the employer’s lab safety training, OSHA, and Employee Right to Know (ERTKA)
  - Always wearing gloves
  - Treat all spills as if they were infectious
Contact Us

• If you have questions, contact the Mayo Medical Laboratories Transportation Department:
  • Phone: (507) 266-5295
  • Email: mmltrans@mayo.edu

If you have questions about transporting your specimen, contact the Mayo Medical Laboratories Transportation Department by phone or email.
Resources

49 CFR

• Chapter 49 of CFR is a document published by the US Government with regulations regarding transporting hazardous materials focusing monthly on ground transportation. However, it also contains information regarding transporting hazmat by air, rail, and boat. 49 CFR is the law in the United States. The CFR is modified periodically and the changes are written in the Federal Register. We subscribe to a service that reads the Federal Register for us and lets us know when any changes may pertain to us.

http://www.ecfr.gov/cgi-bin/text-idx?SID=10d5701abc3c1dbebb0a02bbeeaa8707c&mc=true&tpl=ecfrbrows\e/Title49/49tab_02.tpl
Resources

Department of Transportation (DOT)

https://www.transportation.gov
Resources

IATA

- IATA is an association of airlines. IATA is not the law although you must follow their regulations if you want the airline to take your shipment. IATA closely follows ICAO’s regulations. IATA publishes dangerous goods regulations every year. These regulations are the easiest to read and follow.

http://www.iata.org/pages/default.aspx
Resources

ICAO

• ICAO is a specialized agency of the United Nations that develops and maintains principles and arrangements to ensure the safety of international civil aviation. ICAO is the law.

http://www.icao.int/pages/default.aspx
Resources
A complete listing of select agents can be found at: www.selectagents.gov