



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

OCT 20 2017

Beth Schelle
Site Management Coordinator
Morton Plant Mease Health Care Inc.
455 Pinellas Street, Suite 212B
Clearwater, FL 33756

Reference No. 17-0063

Dear Ms. Schelle:

This letter is in response to your June 8, 2017, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to Category B infectious substances. You ask if interpretation letter (Reference No. 09-0011) and the training requirements it describes for transporting Category B infectious substances in accordance with § 173.199 remain valid.

The answer is yes, interpretation letter (Reference No. 09-0011) remains valid. Further, based on a cursory review of the training module you provided, it is the opinion of this Office that the content sufficiently covers the provisions in § 173.199. Employees who are trained in and familiar with the requirements of § 173.199 are excepted from all other training requirements of the HMR when Category B infectious substances are offered for transportation or transported in commerce under the provisions of § 173.199. Please note, this letter does not act as certification of your training module nor does this Office certify training required by § 173.199(e).

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

Dirk Der Kenderen
Chief, Standards Development Branch
Standards and Rulemaking Division

Dodd, Alice (PHMSA)

Andrews
\$173.199
Packaging Specs
17-0063

From: INFOCNTR (PHMSA)
Sent: Thursday, June 08, 2017 12:57 PM
To: Hazmat Interps
Subject: FW: Request for Formal Written Response
Attachments: Request to DOT.pdf; DOT Response.pdf; training packet & exam for coordinators.pdf

Hi Shante/Alice,

Please submit this as a letter of interpretation. Ms. Schelle spoke with Eamonn.

Please let me know if you have any questions.

Thanks,
Jordan

From: Schelle, Beth E. [mailto:Beth.Schelle@baycare.org]
Sent: Thursday, June 08, 2017 10:55 AM
To: INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>
Cc: Schelle, Beth E. <Beth.Schelle@baycare.org>
Subject: Request for Formal Written Response

TO: U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration -

Please review attached items that include prior communications between DOT PHMSA and ACRP.

Afterwards, please confirm that the response from DOT still remains current and applicable for the training requirements required for Category B infectious substances transportation.

Thank you!

Beth

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U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

1200 New Jersey Ave., SE
Washington, DC 20590

JUL 08 2009

Mr. David Vulcano
Chair, ACRP Board of Trustees
Association of Clinical Research Professionals
500 Montgomery Street, Suite 800
Alexandria, VA 22314

Reference No. 09-0011

Dear Mr. Vulcano:

This is in response to your January 7, 2009 letter concerning the training requirements for hazmat employees who prepare and package only Category B infectious substances (Division 6.2) in conformance with § 173.199 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You ask if the HMR excepts these employees from all other training requirements under the HMR if they are trained to carry out the provisions of this section.

The answer is yes. Employees trained to know and carry out the requirements prescribed in § 173.199 for Category B infectious substances are excepted from all other training requirements under the HMR when preparing and offering these materials for transportation in commerce. See § 173.199(a) and (e).

You also ask if the learning objectives and methods your association is considering (i.e., a paper-based self-training module, a post test, recurring 3-year training, and a record keeping system) to satisfy the training requirements in § 173.199 are sufficient and/or correct. It is the opinion of this Office that the training scenario you present is sufficient as long as all of the provisions of § 173.199 are covered. Section 173.199 stipulates that persons who offer and transport these packages in commerce must be knowledgeable about the requirements of this section. See § 173.199(e).

I hope this information satisfies your request.

Sincerely,

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Packaging “Biological Specimens, Category B”

Training Module Pertaining To The Requirements Set Forth In
49CFR173.199 and 49CFR173.217

Version: July 24, 2009

NOTE: THIS MODULE IS NOT CERTIFICATION TO PACKAGE *CATEGORY A Infectious Substances*. If you desire such certification, please contact your HazMat Officer.

Introduction and Learning Objectives

The purpose of this module is to provide function-specific training to individuals who package Biological Substances, Category B for shipment. Although the proper packaging of Category B specimens is important to transportation couriers and the general public by preventing the spread of infection through leakage, it is also important for research purposes for at least two reasons in that 1) samples that have had their integrity compromised may not be easily detected as such and thus provide faulty data to the study; and 2) samples that are rendered unusable due to improper packaging and transportation may result in the need for resampling, thus inconveniencing human subjects and putting them at additional, unnecessary risk because of this likely preventable failure.

Through the normal course of transportation, packages are likely subject to extreme temperature shifts, changes in humidity and pressure, shocks and vibrations from loading, unloading and accidental drops. Any of these can compromise the integrity of the package and/or the safety of those around it if the package is breached. The completed package must be designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. The regulations are clear that it is the shipper's responsibility, not the courier's or the recipient's, to assure that the contents are properly packaged to meet this objective.

The learning objectives of this module are to teach you...

- 1) You will be able to define the common terminology used surrounding the practice of packaging and shipping biological specimens.
- 2) You be able to differentiate between Category A and Category B Infectious Substances.
- 3) You will demonstrate knowledge that the training received in this module is only adequate for the packaging and shipping of Category B Infectious Substances and that should you desire to pack or ship Category A Infectious Substances, you require additional training outside the scope of the module.
- 4) You will recall the non-bulk packaging requirements for Category B Infectious Substances (as detailed in 49CFR199(a)-(d) or IATA Packing Instructions #650)
- 5) You will recall the requirements of non-bulk packaging of dry ice (as detailed in 49CFR173.217 or IATA Packing Instructions #904).

Common Terminology

Although we follow OSHA's Universal Precautions and assume all bodily fluids are infectious, for shipping purposes, the classification of an "Infectious Substance" takes on a whole different meaning. An "Infectious Substance" classification in the transportation world means that the substance has crossed the line from unregulated or minimally regulated materials into Hazardous Materials (or "HazMat" for short) when shipped over the US highways or airways.

When most people think of HazMat, they think of explosives, flammable, radioactive items and the like. Nearly everybody has seen trucks on the highway with the red and white HazMat diamond having "1203" written in the middle (UN1203 is the international identifier for gasoline). The DOT regulations have a list of all items that are considered Hazardous Materials called the "HazMat Table".

DOT has two classifications for blood and other human bodily fluids. The above mentioned "*Infectious Substance*" which is classified in the HazMat Table as "*UN2814 Infectious Substances, Affecting Humans*" (a.k.a. "Category A"). The other classification is "*UN3373 Biological Specimens, Category B*" (a.k.a "Category B"). Unlike Category A, a Category B specimen is exempted from many HazMat packaging and documentation regulations. Although the regulations for Category B are less strict, they still need to be followed to protect your safety and the safety of the general public while the specimen is in transit. They also provide a mechanism for avoiding delays in shipment as well as help the sample arrive at the destination lab intact and undamaged so that tests can be run promptly giving good diagnostic information without the need to redraw the sample.

The following are definitions of the commonly used terminology in this discipline:

Biological Substance, Category B: The official categorization title of Category B Infectious Substances. This term replaces "Clinical Specimen" and "Diagnostic Specimen" on the HazMat table effective January 1, 2007. The UN identifier for this classification on the HazMat table is UN3373. [DOT 49CFR172.101]

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. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. A Category A infectious substance must be assigned to identification number UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 must be 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. [DOT 49CFR173.134(a)(1)(i), 72 FR 55692, Oct. 1, 2007]

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. This includes Category B infectious substances transported for diagnostic or investigational purposes. A Category B infectious substance must be described as "Biological substance, Category B" and assigned identification number UN 3373. This does not include regulated medical waste, which must be assigned identification number UN 3291. [DOT 49CFR173.134(a)(1)(ii), 72 FR 55692, Oct. 1, 2007]

Clinical Specimen: Effective January 1, 2007, this term is no longer recognized by DOT and has been replaced with Biological Substance, Category B.

Diagnostic Specimen: Effective January 1, 2007, this term is no longer recognized by DOT and has been replaced with Biological Substance, Category B.

DOT: United States Department of Transportation

FAA: The Federal Aviation Administration. The element of the U.S. DOT with primary responsibility for the safety of civil aviation.

Hazardous Materials. Materials that the Secretary of Transportation has determined to be hazardous.

HazMat: Shorthand for “Hazardous Materials”

HazMat Table: The alphabetical list of hazardous materials located at 49CFR172.101 indicating their proper shipping name, United Nations identification number, classifications, packaging instructions, labeling instructions and other information required to ship. This table harmonizes with the ICAO table.

IATA: International Air Transport Association. IATA is the trade association of the world's international airline industry. Originally founded in 1919, it now groups together nearly 270 airlines, including the world's largest. These airlines fly over 95 percent of all international scheduled air traffic.

ICAO: The International Civil Aviation Organization. A specialized agency of the United Nations designed to bring safe, secure and sustainable development of civil aviation through cooperation amongst its member States. Most countries are part of ICAO and have harmonized regulations with ICAO standards.

Infectious Substance: (a.k.a. Class 6.2 Infectious Substance) means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals. An infectious substance must be assigned the identification number UN 2814, UN 2900, UN 3373, or UN 3291 as appropriate.

Specimen (or Patient Specimen): Human or animal material collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimen includes excreta, secretions, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g., transwabs, culture media, and blood culture bottles). (DOT 49CFR 173.134(a)(4)).

Differentiation Between Category A and Category B Infectious Substances

Differentiation between the two categories lies in the definitions stated above. You should always consult with the DOT if you are unsure if a substance is classified as a Category A or a Category B. Their Hazardous Materials Information Center can be reached at 1-800-HMR-4922 (1-800-467-4922). The DOT does publish the Transporting Infectious Substances Safely which identifies examples of Category A Infectious Substances. The following table is taken from the most recent version of this document at the time of this module:

Table 1: Examples of Category A (i.e. UN2814 Infectious Substance Affecting Humans)

Bacillus anthracis (cultures only)	Junin virus
Brucella abortus (cultures only)	Kyasanur forest disease virus
Brucella melitensis (cultures only)	Lassa virus
Brucella suis (cultures only)	Machupo virus
Burkholderia mallei—Pseudomonas mallei— Glanders (cultures only)	Marburg virus
Burkholderia pseudomallei—Pseudomonas pseudomallei (cultures only)	Monkeypox virus
Chlamydia psittaci—avian strains (cultures only)	Mycobacterium tuberculosis (cultures only)
Clostridium botulinum (cultures only)	Nipah virus
Coccidioides immitis (cultures only)	Omsk hemorrhagic fever virus
Coxiella burnetii (cultures only)	Poliovirus (cultures only)
Crimean-Congo hemorrhagic fever virus	Rabies and other lyssaviruses (cultures only)
Dengue virus (cultures only)	Rickettsia prowazekii (cultures only)
Eastern equine encephalitis virus (cultures only)	Rickettsia rickettsia (cultures only)
Escherichia coli, verotoxigenic (cultures only)	Rift Valley fever virus (cultures only)
Ebola virus	Russian spring-summer encephalitis virus (cultures only)
Flexal virus	Sabia virus
Francisella tularensis (cultures only)	Shigella dysenteriae type I (cultures only)
Guanarito virus	
Hantaan virus	Tick-borne encephalitis virus (cultures only)
Hantaviruses causing hemorrhagic fever with renal syndrome	Variola virus
Hendra virus	Venezuelan equine encephalitis virus (cultures only)
Herpes B virus (cultures only)	Vesicular stomatitis virus (cultures only)
Human immunodeficiency virus (cultures only)	West Nile virus (cultures only)
Highly pathogenic avian influenza virus	Yellow fever virus (cultures only)

(cultures only)	
Japanese Encephalitis virus (cultures only)	Yersinia pestis (cultures only)

*To package Category A specimens, the DOT regulations require special training and certification that is beyond the scope of this module. **THIS MODULE IS NOT CERTIFICATION TO PACKAGE CATEGORY A SPECIMENS.** If you desire such certification, please contact your HazMat Officer or contact the DOT for resources. Otherwise, you are not authorized under law to package a Category A specimens for shipment. To package Category B specimens requires the person who offers or transports a Category B infectious substance to “know about” the requirements of the regulations under 49CFR173.199, all of which are contained in this module.*

General Packaging Instructions for Biological Specimens, Category B (i.e. UN 3373)

All Category B infectious substance must be packaged in a “Triple Packaging” consisting of a primary receptacle, a secondary packaging, and a rigid outer packaging (a.k.a. the tertiary container). These packaging requirements are set forth in the DOT regulations (49CFR173.199) which harmonize with the IATA Standards (Packing Instructions #650). The requirements are:

1. **Primary receptacles** (sealed test-tubes being the most common) must be leakproof if shipping liquids (i.e. blood) or siftproof if shipping solids (i.e. swab). You should always assure that any seals (i.e. rubber stoppers) are secure and if using a screwtop, the screwtop should be reinforced with tape.
2. Primary receptacles must be packed in **secondary packaging** (sealed plastic bags being the most common) in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. Note that the secondary packaging must also be leakproof if shipping liquids (i.e. blood) or siftproof if shipping solids (i.e. swab).
 - a. When packaging liquids, absorbent material must be placed between the primary receptacle and secondary packaging. The absorbent material must be of sufficient quantity to absorb the entire contents of all of the primary receptacles and not compromise the integrity of the cushioning material or the outer packaging.
 - b. If several fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them. The wrapping or separation mechanism may also be the absorbent material required for liquids if it is capable of absorbing the entire contents of all of the primary receptacles as indicated above.
 - c. If residual liquid may be present in the primary receptacle during transportation OR if the solid material may become liquid during transportation (i.e. frozen specimens), the solid must be packaged as if it were a liquid.
3. Secondary packaging must be secured in **rigid outer packaging** (fiberboard boxes being the most common) with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging.

4. The following mark must be displayed on the outer packaging on a background of contrasting color. The label may be on its point or askew.



Figure 1: UN3373 Label

The width of the line must be at least 2 mm (0.08 inches) and the letters and numbers must be at least 6 mm (0.24 inches) high. The size of the mark must be such that no side of the diamond is less than 50 mm (1.97 inches) in length. The proper shipping name "Biological substances, Category B" must be marked on the outer packaging adjacent to the diamond-shaped mark in letters that are at least 6 mm (0.24 inches) high.

5. When packages are placed in an overpack (such as in placing a package into a fourth container or combining several packages into one box), all package markings required must be either clearly visible (i.e. through a clear plastic window) or reproduced on the outside of the overpack.
6. The name and telephone number of a person who is either knowledgeable about the material being shipped and has comprehensive emergency response and incident mitigation information for the material, or has immediate access to a person who possesses such knowledge and information, must be included on a written document (such as an air waybill or bill of lading) or on the outer packaging.
7. A packaging containing inner packagings of Category B infectious substances may not contain other hazardous materials except:
- Refrigerants, such as dry ice or liquid nitrogen, as authorized under paragraph (d) of this section;
 - Anticoagulants used to stabilize blood or plasma; or
 - Small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II and III (as classified on the HazMat table) used to stabilize or prevent degradation of the sample (such as preservatives), provided the quantity of such materials does not exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging.
8. For shipments by aircraft, there are some size and weight limitations
- For liquids, the maximum quantity contained in each primary receptacle, including any material used to stabilize or prevent degradation of the sample, may not exceed 1 L (34 ounces), and the maximum quantity contained in each outer packaging, including any material used to stabilize or prevent degradation of the samples, may not exceed 4 L (1 gallon). The outer packaging limitation does not include ice, dry ice, or liquid nitrogen when used to maintain the integrity of the material.
 - For solids, except for packages containing body parts, organs, or whole bodies, for shipment by aircraft, the outer packaging may not contain more than 4 kg (8.8 pounds), including any material used to stabilize or prevent degradation of the

samples. The outer packaging limitation does not include ice, dry ice, or liquid nitrogen when used to maintain the integrity of the material.

9. Packagings must be filled and closed in accordance with the information provided by the packaging manufacturer or subsequent distributor.

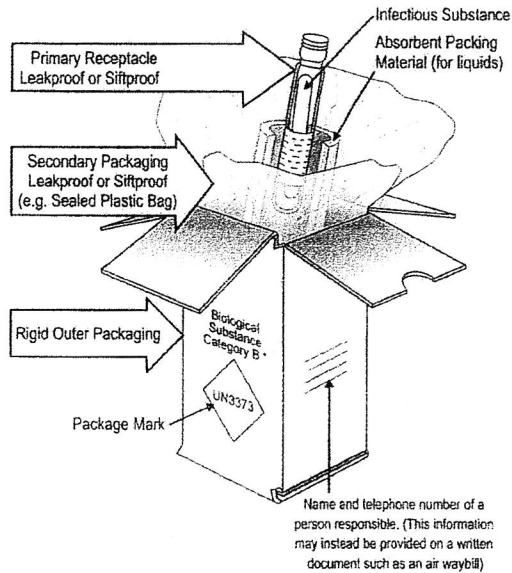


Figure 2: A properly packaged package

While most organizations who ship do not manufacture the materials used to ship, it is important to note that you cannot use just any materials. Manufacturers must pass certain quality control parameters in their products as defined in 49CFR178.609 entitled “Test requirements for packagings for infectious substances”. This section requires exposing the packaging to things such as extremes in temperature, “drop tests” by dropping the boxes from heights at least 1.2 meters and pressure tests producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) to assure that the primary receptacles remain intact and not separated from the absorbent material. Additionally, there are certain size restrictions (such as at least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm or 3.9 inches). While most individuals rely on the quality control of the manufacturer to assure their materials meet these specifications, it is important to note that if your packaging materials seem damaged in any way, this may have compromised the system so that it will not meet the specifications. As the shipper, not the manufacturer, is ultimately responsible to assure the integrity of the system, you should not use any packaging materials that seem damaged or compromised in any way.

General Packaging Instructions for Carbon Dioxide, Solid (i.e. UN 1845)

As samples often need to be shipped frozen, “dry ice” is commonly used as a refrigerant and also contained in the packaging. Due to the risks of dry ice (formally known as “Carbon Dioxide, Solid” or UN1845 in the HazMat table) its packaging and shipment is also regulated and has certain packaging and labeling requirements. These requirements are set forth in the DOT regulations (49CFR173.217) which harmonize with the IATA Standards (Packing Instructions #904). The requirements for shippers are:

1. Carbon dioxide, solid (dry ice), when offered for transportation or transported by aircraft or water, must be packed in packagings designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packaging. Fiberboard boxes and styrofoam chests suffice for this provided they are not subsequently sealed “airtight”.
 - a. Dry ice is placed between the secondary receptacle and the rigid outer packaging. It is not placed within the primary container or the secondary receptacle as the dissipation of the dry ice will build pressure in these sealed containers potentially causing rupture in these leakproof or siftproof protective containers.
2. When offered or transported by aircraft, in quantities not exceeding 2.3 kg (5 pounds) per package and used as a refrigerant for the contents of the package, the package must be marked “Carbon dioxide, solid” or “Dry ice”, marked with the name of the contents being cooled (such as your UN3373 label) and marked with the net weight of the dry ice or an indication the net weight is 2.3 kg (5 pounds) or less.
3. For each shipment by air exceeding 2.3 kg (5 lbs) per package, advance arrangements must be made between the shipper and each carrier.

From time to time, you will be presented with outer packages that have the “Class 9” HazMat diamond shaped label preprinted on as in the figure below.

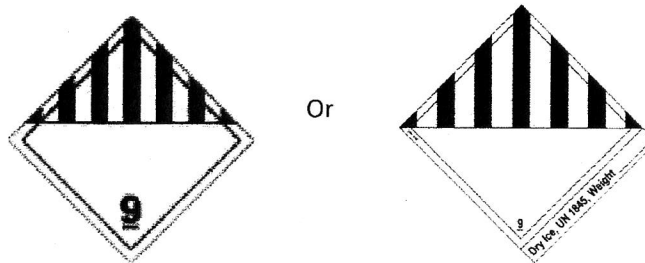


Figure 3: Two examples of Class 9 HazMat labels. The official label (left) and one with additional dry ice weight information (right). Note, HazMat labels themselves cannot be altered, only minimally added to as in the fashion on the right.

While UN1845 Carbon Dioxide, Solid is classified as a Class 9 Hazmat (Class 9 is “Miscellaneous Hazardous Materials”), the HazMat Table indicates that dry ice does not need the diamond label that is usually required of other Class 9 material because of its low degree of

risk and the sufficiency of the markings on the box as indicated in the regulations above (i.e. “Dry Ice” and the weight or indication that it is under 2.3 kg). Although the package will not be out of compliance if the Class 9 diamond label is present, it may cause confusion in the shipping process and unnecessarily delay shipment.

General Safety

The risks of blood borne pathogens are well known to healthcare workers. Healthcare workers follow “Universal Precautions” which assumes that all bodily fluids are treated as if they were infectious and that precautions should be taken when handling bodily fluids for any reason (processing, drawing, cleaning spills etc). For more information on Universal Precautions, see an Infection Control specialist. As an example of some of the few items a good Universal Precautions plan should have, the United States Centers for Disease Control advocate things like:

1. All health-care workers should routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when contact with blood or other body fluids of any patient is anticipated. Gloves should be worn for touching blood and body fluids, mucous membranes, or non-intact skin of all patients, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose, and eyes. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids.
2. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed.
3. All health-care workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needlestick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal; the puncture-resistant containers should be located as close as practical to the use area. Large-bore reusable needles should be placed in a puncture-resistant container for transport to the reprocessing area.

Dry ice is also potentially harmful in two ways. The most common injury associated with dry ice is frost bite which can occur within seconds of direct contact (dry ice is less than -78 degrees Centigrade). Only handle dry ice with heavy insulated gloves. Eye protection is also recommended when handling dry ice. Never play with dry ice or use it to cool or freeze food. Should you have direct contact with dry ice, seek medical attention. Accidental eye

contact or ingestion should seek immediate medical attention. Should medical attention not be immediately available for skin contact, keep the site in warm (but not hot) water until sensation returns and wrap the affected area using clean cloth until you receive medical attention. Never rub or massage the affected area.

The second potential harm of dry ice is CO₂ poisoning due to inhalation. Symptoms of CO₂ poisoning are hyperventilation, headaches, dyspnea and perspiration which may lead to visual disturbances and unconsciousness at higher concentrations. Should any of the warning signs appear, you should immediately move to a well ventilated area and breathe normally until symptoms subside, then move the dry ice to a better ventilated area.

Never store dry ice in airtight containers. Breathable styrofoam chests in secure areas are ideal, especially when labeled with cautionary labels such as "Caution: Dry Ice" or "Dry Ice: Do Not Touch". When transporting dry ice in your personal vehicle, place it in the trunk or trunk bed and not in the car cabin. Obtain dry ice in the size that you will need- never try to saw dry ice or break it with a hammer. Follow all regulations when disposing of dry ice (such as not dumping in public areas or disposing of it in toilets or sinks). Also, never store dry ice in poorly ventilated areas. You should keep a Material Safety Data Sheet (MSDS) for dry ice in an appropriate and easily accessible location. You may obtain an MSDS for dry ice online or from your dry ice vendor.

Final Notes And Additional Resources

It is the shipper's responsibility to assure that a package containing Category B infectious Substances and/or dry ice is properly packaged, marked and labeled for delivery. The US Department of Transportation can assign civil penalties up to \$50,000 for violations pertaining to inadequate training or packaging of hazardous materials.

While a "HazMat Shipper's Declaration" you would learn about in a certification course is not required for Category B Infectious Substances or dry ice, private couriers may require their own paperwork. Be sure you are aware of your courier's requirements of shipping Category B Infectious Substances and dry ice to better assure that they can deliver your specimens with the most care and in the timeliest manner.

Should you desire more information or to obtain full HazMat certification for Category A Infectious Substances or other hazardous materials, please contact the national DOT office or your local DOT office.

The following resources may be of interest to those who want to learn more about shipping Infectious Substances (both Category A and Category B) as well as dry ice.

- DOT Hazardous Materials Information Center 1-800-HMR-4922 (1-800-467-4922)
- U.S. Code of Federal Regulations 49CFR173.199 “Non-Bulk Packaging for Hazardous Materials Other Than Class 1 and Class 7: Category B Infectious Substances)
- U.S. Code of Federal Regulations 49CFR173.217 “Non-Bulk Packaging for Hazardous Materials Other Than Class 1 and Class 7: Carbon Dioxide, Solid (Dry Ice)
- U.S. Code of Federal Regulations 49CFR172.704 “Training Requirements”
- US Department of Transportation “Transporting Infectious Substances Safely” (https://hazmatonline.phmsa.dot.gov/services/publication_documents/Transporting%20Infectious%20Substances%20Safely.pdf)
- IATA Guidance Document “Infectious Substances” (http://www.iata.org/nr/rdonlyres/9c7e382b-2536-47ce-84b4-9a883ecfa040/0/guidance_doc62dgr_50.pdf)
- IATA Infectious Substances & Shipping Guidelines (<http://www.iata.org/ps/publications/infectious-substances.htm>)
- Emergency Response Guidebook: Guide 120- Inert Gasses (<http://www.phmsa.dot.gov/hazmat/library/erg>)
- Emergency Response Guidebook: Guide 158- Infectious Substances (<http://www.phmsa.dot.gov/hazmat/library/erg>)

What To Do With This Module

According to U.S. DOT regulation, a person must be knowledgeable of the requirements of the regulations, specifically the regulations of 49CFR173.199. Having employees read the module and take the sample Post-Test below is one mechanism you can do to assure they have the knowledge. It is recommended that you keep a copy of this module and their Post Test in their personnel file. Additionally, as regulations change, it is recommended that you review the regulations at least annually and update training as appropriate. Due to knowledge drift, it is also recommended that a person review this module every three years even in the absence of change of regulations.

The DOT confirmed through a Request For Guidance or Interpretation (a formal process of the DOT) that the objectives in this module are sufficient to meet their requirements. A copy of the request and DOT’s response is available in the ACRP Resource Library.

About The Author

David Vulcano, LCSW, MBA, CIP, RAC is the AVP of Clinical Research at Hospital Corporation of America (HCA). Among other leadership roles, he is also the current Chair of the Board of Trustees for the Association of Clinical Research Professionals (ACRP). Mr. Vulcano is a frequent speaker and publisher of information pertaining to the clinical research industry. David is a trainer for packaging Category B Infectious Substances as well as able to certify individuals for packaging Category A Infectious Substances.

Packaging "Biological Specimens, Category B"

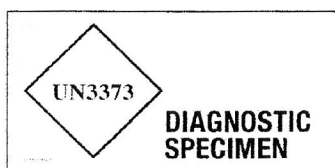
Post-Test

Printed Name: _____

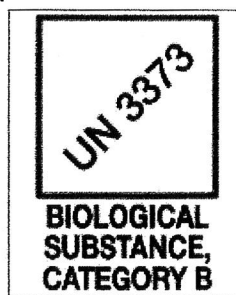
Date: _____

- 1) Based on this module alone, I will be able to package the following:
 - a. Category A Infectious Substances
 - b. Category B Infectious Substances
 - c. Dry Ice
 - d. All of the above
 - e. B and C Only
- 2) Fill In the blank: The _____ is responsible for assuring the integrity of the packaging of Category B Infectious Substances.
 - a. shipper
 - b. packaging manufacturer
 - c. courier
 - d. recipient
 - e. All of the above
- 3) Which of the following is not listed as a Category A Infectious Substance?
 - a. Ebola virus
 - b. Hepatitis C
 - c. Marburg virus
 - d. Human immunodeficiency virus (cultures only)
 - e. Rabies and other lyssaviruses (cultures only)
- 4) Which of the following is NOT true about packing liquids?
 - a. Both the primary receptacles AND the secondary packaging need to be leakproof.
 - b. Enough absorbent material is needed to absorb the entire contents of all primary receptacles should be placed between the primary receptacle and secondary packaging
 - c. More than one primary receptacle can be placed in a secondary packaging provided they are individually wrapped or otherwise padded to prevent contact.
 - d. The system of having a primary receptacle inside a secondary package which is inside a rigid outer package is commonly referred to as the "Triple Packing" system.
 - e. There is no need to double-check the containers or tightly seal caps as the absorbent material will absorb any spill from leaking caps.
- 5) Which if the following is true when shipping dry ice?
 - a. Liquid specimens that are shipped frozen on dry ice do not need absorbent material as they will be in solid form (i.e. frozen) throughout the shipment.

- b. When shipping frozen liquids, dry ice is placed between the primary receptacle and the secondary packaging.
 - c. Any box can serve as an outer package.
 - d. The package must be marked "Carbon dioxide, solid" or "Dry ice", marked with the name of the contents being cooled and marked with the net weight of the dry ice or an indication the net weight is 2.3 kg (5 pounds) or less.
 - e. It is safe to chip dry ice with a hammer and chisel when needing to conform to smaller packaging if you are wearing insulated gloves.
- 6) Which of the following is NOT true about your safety?
- a. You should follow "Universal Precautions" when handling bodily fluid.
 - b. Dry ice can cause frost bite within seconds of contacting skin.
 - c. Barrier precautions (such as rubber gloves and protective eyewear) are important safety gear.
 - d. Proper hand washing is an essential part of preventing the spread of infection.
 - e. Frostbite can be treated by running the affected area under hot water and keeping it warm by rubbing it afterwards.
- 7) You are shipping blood specimens at ambient temperature to a central lab to perform routine diagnostic tests to see if an individual qualifies for a clinical trial. You have no reasonable belief that the blood contains any Category A pathogens. Which of the following would be an appropriate label and markings?



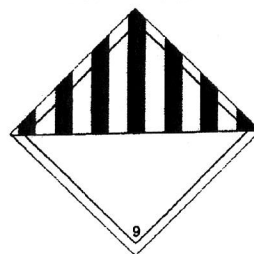
a.



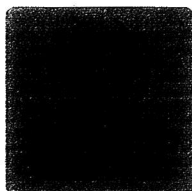
d.



b.



e.



c.