

PACKAGING, LABELING AND SHIPPING OF INFECTIOUS SUBSTANCES

INFECTIOUS SUBSTANCES

Federal and international regulations classify substances known or reasonably expected to cause infectious disease in humans or animals, and the materials or vectors that contain them, as "infectious substances" or "etiologic agents." The international term "infectious substances" has replaced "etiologic agent" in Department of Transportation (DOT) regulations. However, "etiologic agent" is still used in some older regulations such as Public Health Service (PHS) 42 CFR Part 71.

REGULATIONS

Federal and international regulations applicable to the shipment of infectious substances are listed in Appendix 1. In the US, the Department of Transportation (DOT) is responsible for the regulations and enforcement of all hazardous materials as described and published in the Code of Federal Regulations, 49 CFR, Parts 171-180. Specific for national and international air transportation, the International Civil Aviation Organization (ICAO) has issued Technical Instructions for the Safe Transport of Dangerous Goods by air based on recommendations of the United Nations (UN). Because most shipments of infectious substances involve a commercial air carrier, the DOT has incorporated into law the use of the ICAO Technical Instructions for the air transportation of hazardous materials in the US. These instructions are updated and published annually by the International Air Transport Association (IATA) as the Dangerous Goods Regulations (DGR) and are requirements for all commercial airlines.

PHS 42 CFR Part 72 and United States Postal Service (USPS) apply to interstate transportation of infectious substances and transportation of infectious substances via the U.S. mail. For shipping infectious substances overseas, an export license may be required from the U.S. Department of Commerce, Bureau of Export Administration.

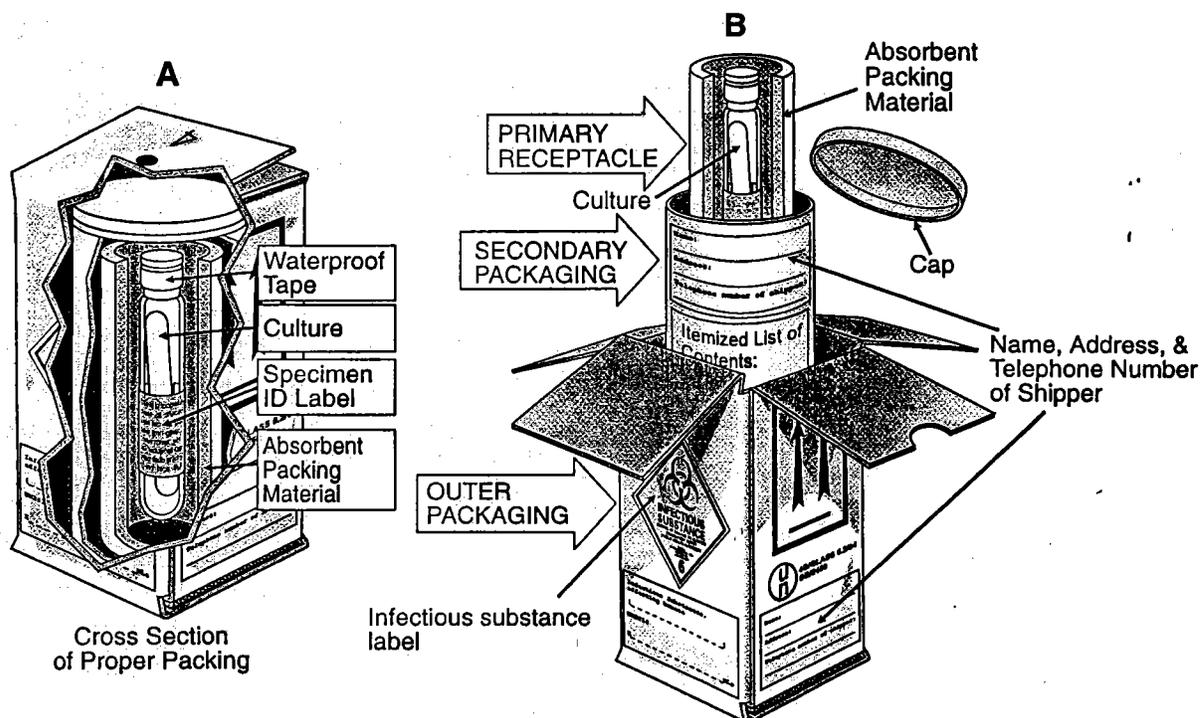
It is the responsibility of the shipper to ensure correct identification, classification, packaging, labeling, marking and documentation for all shipments of infectious substances. In addition, the shipper must make advance arrangements with the recipient (consignee) and carrier, including acquisition of any permits for the importation of infectious substances from foreign countries. Failure to comply with federal and international regulations can result in refusal of the shipment by the airline, penalties of fines, jail, or both. Hand carriage of infectious substances by air is strictly prohibited by law.

PACKAGING

1. General

Proper packaging includes the classification, identification, packing, marking, labeling, and documentation of materials for shipment. Infectious substances must be packed

according to specific instructions and specifications and the packaging material must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and



Packing and Labeling of Infectious Substances

IATA regulations. As stated in the PHS regulation 42 CFR Part 72, such material must be "packaged to withstand leakage of contents, shocks, pressure changes and other conditions incident to ordinary handling in transportation." Figure 1 depicts the principle of triple packaging (primary receptacle, water tight secondary packaging, durable outer packaging) upon which all regulations are built.

Figure 1. Packing and Labeling of Infectious Substances

1.1 Primary Receptacle. The primary receptacle contains the infectious substance and must be watertight to prevent leakage. Primary receptacles include those of glass, metal, or plastic and include screw-cap tubes, flame-sealed glass ampules, or rubber-stopped glass vials fitted with metal seals. Positive means of ensuring a leakproof seal, such as a heat seal, skirted stopper, or metal crimp seal must be provided. Screw caps may be fastened with tape, shrink seals, or other comparable material. Although glass is allowed, it is preferable to use plastic primary receptacles if

possible.

1.2 Secondary Packaging. One or more primary receptacles are placed in a watertight secondary packaging. The primary receptacle or the secondary packaging must withstand, without leakage, an internal pressure differential and temperature range as described in the United Nations (UN) packaging specifications and performance tests. The secondary packaging should also bear a label with the name, address, and telephone number of both the shipper and recipient.

1.3 Absorbent Material. Absorbent material must be placed between the primary receptacle and secondary packaging. Multiple primary receptacles must be individually wrapped to prevent contact between them. The absorbent material must be sufficient to absorb the entire contents of the primary container(s).

1.4 Itemized List. IATA, DOT and PHS require that an itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

1.5 Outer Packaging. An outer packaging must be of adequate strength for its capacity, mass, and intended use, and must be capable of meeting specific UN performance tests. Packaging that is certified to meet the test standards must bear UN specification markings.

2. Classification

All hazardous materials are classified into 9 classes of Dangerous Goods. Infectious Substances belong to Class 6, Division 6.2. Dry ice is a Dangerous Good and it must be declared as Class 9.

3. Identification

Infectious substances are assigned a "proper shipping name" and a unique 4-digit UN number to identify the substance being shipped. This information, along with the total volume of infectious substance being shipped, is included on the Shipper's Declaration for Dangerous Goods and the outer package. For infectious substances, UN 2814 is used for "Infectious substance, affecting humans", and UN 2900 refers to "Infectious substance, affecting animals." The technical name of the infectious substance must also be included if known.

3.1 Quantity Limitations. When transported by passenger airline, DOT and IATA limit the quantity per outer package to 50 ml or 50 g. When transported by cargo airline, IATA limits the quantity per outer package to 4 liters or 4 kg. The US Postal Service (USPS) limits all infectious substance packages to 50 mls.

4. Certified Packaging and Packing Instructions

If the infectious substance is transported by air, IATA regulations require a UN specification mark on the outer shipping packaging. The mark includes the United Nations packaging symbol, the type of packaging, the hazard class (6.2), the year of manufacture of the packaging, the authorizing agency and the manufacturer. Each package must be capable of passing the rigorous performance tests specified in IATA Dangerous Goods Regulations for Class 6.2 and DOT 49 CFR Part 178.609. Because performance testing is normally beyond the scope of shippers, it is strongly

recommended that certified containers purchased from commercial suppliers be used, regardless of the mode of transportation.

Instructions for packing infectious substances are designated in UN Packing Instruction 602 listed in the IATA Dangerous Goods Regulations and DOT 49 CFR Part 173.196. These packing instructions also specify other requirements and limitations.

4.1 Size. Packages consigned as freight must be at least 100 mm (4 in) in the smallest overall external dimension. Thus, the outer packaging must be of sufficient size to bear the required markings and labels.

4.2 Ice and Dry Ice. Wet ice or dry ice must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary packaging in the original position after the wet ice or dry ice has dissipated. If wet ice is used, the packaging must be leakproof. If dry ice is used, the outer packaging must permit the release of carbon dioxide gas. Dry ice is packed according to UN Packing Instruction 904 listed in the IATA Dangerous Goods Regulations.

4.3 Liquid Nitrogen. Special arrangements must be made with the carrier in advance to ensure the safe transport of liquid nitrogen. Plastic primary receptacles and secondary packaging capable of withstanding very low temperatures must be used, and special labels are required on the outer container (see Labeling below).

4.4 Overpacks. Overpacks are used to combine several UN certified triple packages into one outer unit. Each triple package inside the overpack must be properly labeled and marked and the outside of the overpack must be marked with the statement "Inner Packages Comply with Prescribed Specifications."

5. Marking and Labeling

Each package of infectious substances must be marked on the outside of the shipping container with the following:

- a) The proper shipping name, technical name, total volume of infectious substance and corresponding UN Number.
- b) 24-Hour Emergency Response Number. Both DOT and IATA require that this number appear on the outer shipping package and the shipping document and to be used whenever there is a spill or accident involving the shipment of an infectious substance. This number must be that of a person who is knowledgeable of the material being shipped and has emergency response and incident mitigation information. This number should not be confused with the CDC number for reporting damaged or leaking packages.
- c) The full name, address and phone number of the shipper and the recipient.
- d) For dry ice, the net weight of the dry ice within the package.

The outer packaging must be of sufficient size to accommodate all labels placed on a single surface. Labels must not overlap. Labels required on the outside of the shipping container include:

- a) Class 6, Division 6.2 "Infectious Substance" label. This diamond-shaped label should contain the telephone number of the CDC in Atlanta to which damaged or

leaking packages should be reported.

- b) Class 9 "Miscellaneous Dangerous Goods" label if dry ice is used
- c) "Package Orientation (This Way Up)" labels. Two package orientation labels are affixed on opposite sides of the package.
- d) If liquid nitrogen is used, 2 labels are required: Division 2.2 "Non-flammable, non-toxic gas" and the "Cryogenic Liquid" handling label.
- e) For USPS shipments only, an "Etiologic Agents/Biomedical Material" label incorporating the universal biohazard symbol is required.
- f) The completed and signed Shipper's Declaration for Dangerous Goods document secured to the outside of the outer packaging.
- g) A current U.S. Public Health Service import permit label for infectious substances imported from outside the United States.
- h) "Cargo Aircraft Only" label for shipments that exceed the maximum quantity specified for passenger aircraft.

6. Documentation

Packages containing infectious substances that are transported by air must contain a "Shipper's Declaration for Dangerous Goods" form. This legal document must be fully and accurately completed by the shipper. Incomplete, ineligible or inaccurate documents will result in refusal of the package by the carrier.

6.1 Confirmation of Receipt. According to 42 CFR part 72.3(f), certain agents may only be transferred via registered mail or an equivalent system, which requires notification of receipt to the sender immediately upon delivery. If the package is not received within 5 days, the shipper should notify the CDC.

6.2 Air Waybill. The shipper may or may not be required to fill out the air waybill for shipments by air.

7. Training

IATA and DOT require specific training of everyone directly involved in the shipping of dangerous goods. It is the responsibility of the employer to ensure that employees and supervisors shipping dangerous goods are trained. IATA requires training and recertification every 2 years, or DOT requires training and recertification every 3 years.

OTHER CONSIDERATIONS

Importation of Etiologic Agents of Human Disease

42 CFR Part 71 Foreign Quarantine. Part 71.54 Etiologic Agents, Hosts and Vectors.

This regulation requires an import permit from the Centers for Disease Control and Prevention for importing etiologic agents of human disease and any materials, including live animals or insects, that may contain them. An application and information on importation permits may be obtained by calling 1-888-CDC-FAXX and enter document number 101000 or on the Internet at:

<http://www.cdc.gov/od/ohs/biosfty/impptper.htm>

Importation of Etiologic Agents of Livestock, Poultry and Other Animal Diseases
9 CFR Parts 92, 94, 95 96, 122 and 130. These regulations requires an import permit from the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services to import or domestically transfer etiologic agents of livestock, poultry, other animals, and any materials that might contain these etiologic agents. Information may be obtained at (301) 734-3277, or from the Internet at:

<http://aphisweb.aphis.usda.gov/>

Importation and Exportation of Endangered Species of Animals and Plants

The U.S. Department of the Interior, U.S. Fish and Wildlife Service, Convention on International Trade in Endangered Species (CITES) protects many species of animals and plants to ensure that commercial demand does not threaten their survival in the wild. The Office of Management Authority administers CITES in the U.S. and processes applications for permits. Live animal shipments must meet the IATA Live Animal Regulations or the CITES guidelines for transport. In addition, the import of live mammals and birds must meet the humane shipment regulations in 50 CFR Part 14. For more information, contact Office of Management Authority, United States Fish and Wildlife Service at 1-800-358-2104 or on the internet at:

<http://www.fws.gov/r9dia/>

Transfer of Select Biological Agents of Human Disease

42 CFR Part 72.6 Additional Requirements for Facilities Transferring or Receiving Select Agents. Facilities transferring or receiving select agents must be registered with the CDC and each transfer of a select agent must be documented. Information may be obtained by calling 404-639-4418 or through the Internet at:

<http://www.cdc.gov/od/ohs/lrsat.htm>

Export of Etiologic Agents of Humans, Animals, Plants and Related Materials

Department of Commerce. 15 CFR Parts 730 to 799. This regulation requires that exporters of a wide variety of etiologic agents of human, plant and animal diseases, including genetic material will require an export license. Information may be obtained by calling the DOC Bureau of Export Administration at 202-482-4811 or through the Internet at:

<http://bxa.fedworld.gov>, or <http://www.bxa.doc.gov>

Damaged or Leaking Packages

If damage or leakage to a package containing infectious substances is discovered, avoid further handling of the package or keep handling to a minimum, and notify the shipper, recipient and the CDC (800-232-0124).

Information sources

These resources are for guidance purposes only. Information sources on regulations applying to the interstate and international transportation of infectious substances are shown in Appendix 1. Appendix 2 contains a partial list of manufacturers and suppliers of shipping materials and Appendix 3 lists some suppliers of Dangerous Goods Shipper's Declaration forms and labels.

Appendix 1. INFORMATION SOURCES FOR REGULATIONS ON THE TRANSPORTATION OF INFECTIOUS SUBSTANCES

Public Health Service 42 CFR Part 72. Interstate Transportation of Etiologic Agents. This regulation is in revision to harmonize it with the other U.S. and international regulations. A copy of the current regulation may be obtained from the Internet at:

<http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>

Department of Transportation. 49 CFR Parts 171-180. Hazardous Materials Regulations.

Applies to the shipment of both biological agents and clinical specimens. Information may be obtained from the Internet at:

<http://hazmat.dot.gov/rules.htm>

United States Postal Service. 39 CFR Part 111. Mailability of Etiologic Agents.

Codified in the Domestic Mail Manual 124.38: Etiologic Agent Preparations. A copy of the Domestic Mail Manual may be obtained from the Government Printing Office by calling 1-202-512-1800 or from the Internet at:

<http://www.access.gpo.gov>

Occupational Health and Safety Administration (OSHA). 29 CFR Part 1910.1030.

Occupational Exposure to Bloodborne Pathogens. Provides minimal packaging and labeling requirements for transport of blood and body fluids within the laboratory and outside of it. Information may be obtained from your local OSHA office or from the Internet:

<http://www.osha.gov>

Dangerous Goods Regulations (DGR). International Air Transport Association (IATA). These regulations provide packaging and labeling requirements for infectious substances and materials, as well as clinical specimens that have a low probability of containing an infectious substance. These are the regulations followed by the airlines. These regulations are derived from the Committee of Experts on the Transport of Dangerous Goods, United Nations Secretariat, and the Technical Instructions for the Transport of Dangerous Goods by air which is provided by the International Civil Aviation Organization (ICAO). For assistance with the requirements of the regulation, call the IATA DG hotline at 514-390-6770. A copy of the DGR may be obtained by calling 1-800-716-6326 or through the Internet at:

<http://www.iata.org/cargo/dg/>

Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens. World Health Organization, 1997.

<http://www.who.int/emc/biosafety.html>

**Appendix 2. MANUFACTURERS OF UNITED NATIONS CERTIFIED SHIPPING
CONTAINERS FOR 6.2 INFECTIOUS SUBSTANCES**

Action Pak, Inc.
2550 Pearl Buck Road
Bristol, PA 19007
Phone: 800-755-9764
FAX: 215-788-1760
Web: www.actionpakinc.com

Air Sea Atlanta
1234 Logan Circle
Atlanta, GA 30318
Phone: 404-351-8600
FAX: 404-364-4005
Web: <http://www.airseatlanta.com>

Air Sea Containers, Inc.
2749 NW. 82nd Avenue
Miami, FL 33122
Phone: 888-272-9883
FAX: 305-599-1668
Web: <http://www.airseacontainers.com>

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA 15017-2854
Phone: 800-245-2283
FAX: 412-257-3001
Web: <http://www.allpakinc.com>

Casing Corporation
P.O. Box 820369
Dallas, TX 75382-0369
Phone: 800-358-6866
FAX: 214-320-1682
Web: <http://www.casingcorp.com>

Cin-Made Corporation
1780 Dreman Avenue
Cincinnati, OH 45223
Phone: 513-681-3600
Web: www.cin-made.com

The Compliance Center, Inc.
2150 Liberty Drive
Niagara Falls, NY 14304
Phone: 800-767-7231

Cargo Pak Corporation
306-A White Street South
Wake Forest, NC 27587
Phone: 800-266-0652
FAX: 919-554-9055
Web: <http://www.cargopak.com>

DG Supplies, Inc.
28 C Industrial Drive
Hamilton, NJ 08619
Phone: 800-347-7879
FAX: 609-860-0285
Web: www.dgsupplies.com

Environmental Packaging Systems, Ltd
1 Research Drive
Dartmouth, N.S., Canada B2y 4M9
Phone: 800-277-8675
FAX: 902-466-6889

EXAKT Technologies, Inc.
7416 North Broadway Extension, Suite E
Oklahoma City, OK 73116
Phone: 800-866-7172
FAX: 405-848-7701
Web: www.exaktpak.com

Federal Industries Corp.
2550 Niagara Lane
Plymouth, MN 55447
Phone: 800-523-9033
FAX: 612-476-8155
Web: www.chem-tran.com

HAZMATPAC, INC.
5301 Polk Avenue, Bldg 18
Houston, TX 77023
Phone: 800-923-9123
FAX: 713-923-1111
Web: <http://www.hazmatpac.com>

Inmark, Inc.
220 Fisk Drive, S.W.
Atlanta, GA 30336
Phone: 404-267-2020; 800-646-6275 (OUTSIDE GEORGIA)
FAX: 404-349-5249
Web: <http://www.inmarkinc.com>

Nalge Nunc International
75 Panorama Creek Drive
P.O. Box 20365
Rochester, NY 14625
Phone: 716-586-8800
FAX: 716-586-8987
Web: www.nalgenunc.com

O'Berk International, Inc.
3 Milltown Court
P.O. BOX 1690
Union, NJ 07083
Phone: 800-577-7624
FAX: 908-687-5157
Web: <http://www.aluminiumbottles.com>

Polyfoam Packers Corporation
2320 Foster Avenue
Wheeling, IL 60090-6572
Phone: 800-323-7442
FAX: 847-398-0653
Web: <http://www.polyfoam.com>

SAF-T-PAK, Inc.
101, 17872 - 106 Avenue
Edmonton, Alberta, Canada T5S 1V4
Phone: 800-841-7484
FAX: 403-486-0235
Web: <http://www.saftpak.com>

Sage Products, Inc.
815 Tek Drive
P.O. Box 9693
Crystal Lake, IL 60039-9693
Phone: 815-455-4700
FAX: 815-455-3310
Web: <http://www.sageproducts.com>

Source Packaging Of New England, Inc.
405 F Kilvert Street
Warwick, RI 02866
Phone: 800-200-0366
FAX: 401-738-7762
Web: <http://www.sourcepak.com>

**Appendix 3. MANUFACTURERS OF LABELS FOR
SHIPPING OF INFECTIOUS SUBSTANCES**

Label Master
5724 North Pulaski
Chicago, IL 660646
Phone: (800) 621-5808
FAX: (800) 723-4357

Shamrock, Inc.
34 Davis Drive
Bellwood, IL 60104
Phone: (800) 323-0249
FAX: (800) 248-1907

United Ad Label Company, Inc.
P.O. Box 2216
Brea, CA 92622-2216
Phone: (800)423-4643
FAX: (800) 962-0658