



Packaging Hospital Samples and Patient Specimens for Transport

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HISTORY: Under the Hazardous Materials Transportation Act (HMTA) of 1975, the Department of Transportation (DOT) was empowered to promulgate regulations for the safe transport of hazardous materials. The Hazardous Materials Transportation Uniform Safety Act (HMTUSA) of 1990 improved upon the HMTA and resulted in more stringent regulations. Docket HM-181 issued as a final rule in December 1990, effective October 1991, resulted in a comprehensive revision of these regulations. Under Docket HM-181, new requirements were implemented for the classification, packaging, marking, labeling, and placarding of hazardous materials. Laboratory samples and specimens meeting the DOT definition of a hazardous material must conform to these new standards.

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USAPHC Training Office

The Regulations

The Code of Federal Regulations Title 49 (49 CFR) is the document that governs the transportation of hazardous materials. It contains all of the latest Department of Transportation rules for transporting hazardous materials including docket HM-181 amendments. Other regulations governing the international transport of hazardous materials include the United Nations Orangebook, the International Air Transport Association (IATA) Dangerous Goods Regulations, International Civil Air Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air, and the International Maritime Dangerous Goods Code (IMDG). Air Force Interservice Manual 24-204(I) (AFMAN 24-204(I)), also termed Army Technical Manual 38-250, details the requirements for transporting hazardous materials by military air. Specific agency regulations such as the United States Postal Service Domestic Mail Manual are also referenced when transporting hazardous material.

What Makes a Sample Hazardous

The Department of Transportation defines a hazardous material as any substance or material which has been determined by the Secretary of Transportation to pose an unreasonable risk to health, safety and property when transported in commerce. (Commerce means trade, traffic or transportation within the United States.) Items used in the laboratory which are considered hazardous materials by the DOT include most acids and bases, infectious substances, gases, flammable or combustible liquids, spontaneously combustible materials, flammable solids, materials ignitable in water, oxidizers, organic peroxides, poisonous materials, radioactive materials, and corrosive materials. To determine if your laboratory samples and specimens are considered hazardous materials by the DOT, check the Hazardous Materials Table in the Code of Federal Regulations Title 49 Section 172.101. The Hazardous Materials Table will identify the proper shipping name for your material, hazard class or division, United Nation (UN) or North American (NA) identification number, type of packaging for your material, required labels, and identify limitations for shipments by air and water. Generally, materials regulated by the Occupational Safety and Health Administration (OSHA) or the Environmental Protection Agency (EPA) are also regulated by the DOT.

Preparing your Hazardous Samples for Transport

Hazardous laboratory samples and specimens must comply with the new provisions as established by the DOT. Use the information provided in the Hazardous Materials Table of 49 CFR and these few simple steps to properly prepare your laboratory samples for transport.

- 1. Place the sample or specimen or product in a primary watertight receptacle with a leakproof seal** (i.e. a heat sealed, skirted stopper or metal crimped test tube or vial). If screw caps are used, reinforce the seal with adhesive tape.
- 2. For liquid infectious substances, wrap the watertight primary receptacle in absorbent material** (i.e. cellulose packing, thick paper towel or cotton wool). Place the absorbent material around the top, bottom and sides of the primary container.
- 3. Place the wrapped container in a secondary watertight receptacle** (i.e. a Ziplok bag or plastic container). Several primary containers may be enclosed in one secondary container provided each primary container is individually wrapped with absorbent material to prevent contact with one another.
- 4. Place the entire package in a rigid outer packaging approved by the DOT for transport of your hazardous chemical** (See the hazardous materials table in 49 CFR 172.101 and 49 CFR Part 178.500). Affix all appropriate warning labels and markings as indicated in 49 CFR Part 172.300 and 172.400.
- 5. Place an itemized list describing contents into your box between the secondary packaging and the outer packaging.** Do not seal your package. A designated certifying official who successfully completed formal training must approve your package for transport (Refer to Page 7, Certifying Hazardous Shipments). For a list of designated certifying officials, contact your Installation Transportation Office or Commander.

***For all refrigerated substances, **place ice, dry ice or pre-frozen packs between the secondary watertight receptacle and the outer packaging.** To prevent the inner packaging from shifting due to melting ice, use a watertight outer packaging with interior supports. Packagings containing dry ice must permit the release of carbon dioxide gas and meet the provisions in 49 CFR 173.217.

Special Provisions for Infectious Substances

Infectious substances are considered hazardous materials. A rule supplemental to docket HM-181 known as docket HM-142A redefined terms and packaging requirements for infectious substances. Docket HM-142A removed the 50 ml exception and for purposes of transportation, replaced the term “etiologic agents” with “**infectious substances.**” It changed the definition of an infectious substance to mean “**a viable microorganism, or its toxin, that causes or may cause disease in humans or animals, and includes those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services or any other agent that causes or may cause severe, disabling or fatal disease.**”

Shipping infectious substances requires coordinated action by the shipper, the transporter and the receiver to ensure safe transport and arrival on time. **Dispatch of infectious substances should not take place before advance arrangements are made for transport and arrival.** Prepare packages using the guidelines previously stated ensuring packages arrive at their destination in good condition presenting no hazard to persons or animals during conveyance. **The package should include a watertight inner container wrapped in absorbent material placed in a secondary watertight container.** Place both containers in a strong outer container (i.e. a sturdy box) whose dimensions are at least 100mm (3.9 inches) per side. **No single primary container shall contain more than 1,000 milliliters (1 liter) of material.** The maximum amount of infectious substance allowed in one outer packaging is 4,000 milliliters (4 liters). These requirements are detailed in 49 CFR Part 173.196 and 42 CFR 72.3 (b)(4). A certifying official must certify that your package is properly packed and ready for transport.

Federal regulations require all outer packagings of infectious substances be labeled and properly marked. Print or affix labels and markings of proper color and size to any side of the package (other than the bottom). Place all labels on the same surface of the package near the proper shipping name marking, if dimensions are adequate. If the outer packaging is too small or irregular for all labels, place labels on a securely fastened tag or print the label directly on the container. Affix the **the DOT Infectious Substance Label (49 CFR 172.407 & 172.432) and/or the CDC Biomedical Material Label (42 CFR 72.3).** The OSHA Biohazard Label is not required on the outer packaging per 29 CFR 1910.1030(g) provided the **DOT and CDC labels are used on the package. Package Orientation Markings (49 CFR 172.312)** for liquid hazardous material in non-bulk packagings must be legibly marked on two opposite vertical sides of the package. If storing or using inner packagings separate from the outer packaging, affix the OSHA Biohazard Label to the inner packaging to comply with OSHA requirements.

Proper documentation must accompany shipments of infectious substances. Place an itemized list of samples being transported between the secondary and the outer packaging. Shipping

papers stating the **Shipper's Name, Receiver's Name, Shipping Description [UN 2814, Infectious Substance, affecting humans (Technical Name), 6.2, (Total Quantity)], Emergency Response Telephone Number, and the Shipper's Certification** must be carried by the driver of the transport vehicle and must be in within immediate reach of the driver or in a holder mounted to the inside of the driver's door (49 CFR 177.816). If the substance affects **animals only**, use the following description--- **UN 2900, Infectious substance, affecting animals (Technical Name), 6.2, (Total Quantity)**.

The consignee of **all international shipments** of infectious substances must confirm with his **competent authority** that the substance can legally be imported and that the necessary licenses have been obtained. Transporting infectious substances on your person or in your personal luggage is prohibited. **Personnel caught illegally transporting infectious substances aboard commercial aircraft may be fined up to \$27,500 and/or receive 5 years in prison per 49 United States Code 1809.** Military personnel may also face disciplinary action under the Uniformed Code of Military Justice or the Federal Personnel Manual if civilian.

In the event a package labeled as an infectious substance leaks during transport, public health and veterinary authorities, the shipper and any country through which the substance was transported shall be notified. **The Director, Centers for Disease Control shall also be notified by dialing 1-800-232-0124** (49 CFR 171.15). Notification of all personnel is required to minimize contamination of humans and animals.

Patient Specimens and Biological Products

Patient specimens are defined as any human or animal materials, including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention. Specimens shipped to undergo a screening test for the purpose of initial diagnosis may be considered as general patient specimens provided such material is not known or suspected to contain infectious substances, the Hepatitis B Virus (HBV) or the Human Immunodeficiency Virus (HIV). If a patient specimen contains or is suspected to contain an infectious substance, the HBV or HIV, it is an infectious substance and must comply with the infectious substance transport requirements. **Specimens shipped to undergo confirmatory testing which are known or suspected to contain an infectious agent, including viruses, are regulated as infectious substances and must, therefore, comply with infectious substance transport requirements.** If your specimen is being shipped for initial diagnosis, follow the steps outlined in preparing your hazardous sample for transport.

Biological products are products prepared and manufactured in accordance with the provisions of 9 CFR Part 102 (Licenses for biological products), 9 CFR Part 103 (Biological products for experimental treatment of animals), 9 CFR Part 104 (Permits for biological products), 21 CFR Part 312 (Investigational new drug application), or 21 CFR Parts 600-680 (Biologics), which, in accordance with such provisions, are transported in interstate traffic. **Biological products are products containing a virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of diseases or injuries to man. Biological products are either finished biological products for human or veterinary use or finished**

biological products shipped prior to licensing for developmental or investigational purposes using humans or animals. Live animal and human vaccines are considered biological products and not infectious substances.

Shippers are responsible for understanding the regulations governing patient specimens and biological products. These regulations include 9 CFR (APHIS), 21 CFR (FDA), and 42 CFR (CDC). Poorly packaged patient specimens and biological products may break and lead to unnecessary expenses and concerns regarding the spilled materials. To be certain proper protection is provided for the containment of any undetectable pathogenic microorganisms, package patient specimens and biological products as previously stated in *Preparing your Hazardous Samples for Transport*. These guidelines comply with the IATA Dangerous Goods regulations and are required when transporting patient specimens and biological products by air. Check with the commercial carrier you select for specific air transport requirements. **When transporting patient specimens or biological products by air, ensure the “Nature and Quantity of Goods” box of the air waybill states “PATIENT SPECIMEN PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650” or “BIOLOGICAL PRODUCT PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650”, respectively.**

The 50th Edition of the IATA regulations states:

3.6.2.3 Biological Products

3.6.2.3.1: “For the purposes of these Regulations, biological products are divided into the following groups:

(a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to these Regulations.

(b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group must be assigned to UN2814, UN2900 or UN3373, as appropriate.

Note: Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

3.6.2.7 Patient Specimens

Patient specimens must be assigned to UN 2814, UN 2900, or UN 3373 as appropriate except if they comply with **3.6.2.2.3**

3.6.2.2.3: Exemptions

3.6.2.2.3.1 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.2 Substances containing micro-organisms, which are non-pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.4 Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection, are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.5 Dried blood spots, collected by applying a drop of blood onto absorbent material, or fecal occult blood screening tests and blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Regulations.

3.6.2.2.3.6 Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words "Exempt human specimen" or "Exempt animal specimen", as appropriate. The packaging must meet the following conditions:

(a) The packaging must consist of three components:

(1) a leak-proof primary receptacle(s);

(2) a leak-proof secondary packaging; and

(3) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm;

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

NOTE: In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc.).”

Additionally, each shipper internationally transporting patient specimens and biological products must confirm with his competent authority that the specimens and products being transported can legally be imported. Specific licenses may also be required. Contact the Centers for Disease Control in Atlanta and/or the Animal Plant Health Inspection Service for specific licensing requirements to import or export biological products. **No DOT labels are currently required for packages of patient specimens and biological products. However, specific labeling requirements as outlined in the Food and Drug Administration and Animal and Plant Health Inspection Service in the 9 and 21 CFRs are required for biological products.** The DOT Package Orientation Marking per 49 CFR 172.312 is, however, required for all packages containing liquid samples. In the event a package containing a patient specimen and/or a biological product leaks during transport, the shipper, his commander, and the receiver shall be notified. Refer to CDC, APHIS and OSHA regulations for special provisions.

Personnel Training Requirements

On May 15, 1992, the Research and Special Programs Administration of the Department of Transportation issued a final rule known as Docket HM-126F, Training for Safe Transportation of Hazardous Materials. This rule which is now stated in 49 CFR Subpart H, 172.700-172.704 amended the Hazardous Material Regulations and requires that any **hazardous material (hazmat) employee** involved in the transportation of hazardous materials receive **general awareness, function-specific, safety, and security awareness training**. Additionally, all drivers transporting hazardous materials must receive driver’s training. A new hazmat employee or a hazmat employee who has a change in job function must receive training **within 90 days of employment or change in job function**.

Personnel who load, unload, handle, package, mark and label, move or prepare hazardous samples and specimens for transport are classified as hazmat employees. It is the hazmat employers’ responsibility to ensure the required training is conducted and adequate/appropriate for each hazmat employee. A **record of training**, inclusive of the preceding three years, must be created and retained by each hazmat employer for as long as the hazmat employee is employed by the employer and for a period of 90 days thereafter. This record **must include the hazmat employee’s name, training completion date, description of training, copy of training**

material, location of training, the name and address of the person(s) providing training, and certification that the hazmat employee has been trained and tested.

DOD Certification Training

In addition to DOT training requirements, the Department of Defense (DOD) establishes training standards in DOD 4500.9-R, the Defense Transportation Regulation Part II Cargo Movement. They are also defined in Attachment 25 of the Air Force Interservice Manual 24-204(I) (AFMAN 24-204(I)). These training standards require specific training for personnel preparing and transporting hazardous materials by any mode of transportation. They also require all hazardous material shipments be approved by an appointed DOD certifying official who is so designated through formal DOD training. **To be designated as a DOD certifying official, a person must be designated in writing by their activity Commander and have successfully completed formal training.** For personnel certifying all classes of hazardous materials by any mode of transportation, the only DOD approved 80 hour training courses are listed below. Refresher training is required at least every two years following initial training. The following courses are available to meet the initial and refresher training requirements:

- 1) 345th Training, Transportation Training Flight
345 TRS/TTTD
1000 Femoyer
Lackland, AFB, TX 78236-5404
DSN: 473-4917, Commercial: 210 671-4917

Web address: <http://www.lackland.af.mil/37trg/345.asp>

- 2) Navy Supply Corps School
1425 Prince Avenue
Athens, GA 30606
DSN: 354-7240/7215, Commercial: 706 354-7240/7215

Web address: <https://www.npdc.navy.mil/css/nscs/>

- 3) Department of the Army
Defense Ammunition Center
Attn: SJMAC-AST
1C Tree Road
McAlester, OK 74501-9053
DSN: 956-8931, Commercial: 918 420-8931, FAX: 8944

Web address: <http://www.dac.army.mil/as>

Graduates of these courses, when designated in writing by their Commander, will thoroughly inspect hazardous shipments and verify by signature on the shipping documentation accompanying each package that it is marked, labeled, and packaged in accordance with the established regulatory requirements. If no certifying official is available in your activity, establish an agreement with a certifying official in your installation transportation office.

Transport of Biomedical Material Course

The U.S. Army Public Health Command has **developed a course specific to the needs of healthcare facility personnel who transport infectious substances, biological products, patient specimens and regulated medical waste.** The course entitled “**Transport of Biomedical Material**” was approved by the Military Traffic Management Command to certify healthcare facility personnel to package infectious substances and specimens for transport in accordance with Department of Transportation and Department of Defense regulations. The course is interactive with practical exercises used throughout. The training satisfies both the DOT and DOD training and certification requirements. Military and civilian personnel, who handle, package, mark, label, move or prepare infectious substances, patient specimens, biological products or regulated medical waste for transport should apply.

Transport of Biomedical Material Course (Initial and Refresher) offered by:

U.S. Army Public Health Command

5158 Blackhawk Road

Aberdeen Proving Ground, MD 21010-5403

DSN: 584-5228/3651, Commercial: 410 436-5228/3651, Fax: 5237 Toll
free: 800 222-9698

Web address:

<http://phc.amedd.army.mil/topics/envirohealth/hmw/Documents/Transport%20of%20Biomedical%20Materials.pdf>.

Select training conferences for specific course dates and locations. On-site training is available by request through the Web address.

A two-day Transport of Biomedical Materials Refresher and an on-line refresher course are presently offered to certified TBM personnel to meet the DOD biennial refresher training requirement.

Summary

It is necessary to comply with all of the transportation regulations. Non-compliance endangers public health and safety and results in large fines for laboratory personnel and their Commanders. The DOT guidelines establish a means to safely transport laboratory samples and specimens. Follow all regulatory requirements when packaging hazardous samples and specimens. Shippers are responsible for proper coordination and packaging. Contact your local or State Department of Transportation for additional guidance or packaging and transporting your hazardous materials. Review all regulations and ensure that only properly trained and certified personnel approve your shipment for transport.

Direct any questions or comments regarding this paper to Commander, U.S. Army Public Health Command, ATTN: MCHB-TS-EHM, Aberdeen Proving Ground, MD 21010-5403. Phone 410-436-3651.