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Standard Guide for Shipping Possibly Infectious Materials, Tissues, and Fluids[1]

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1. Scope

1.1 This guide provides a general guide to transportation, including packaging and shipping, of possibly infectious materials, tissues, and fluids that have been removed from patients during revision surgery, at postmortem, or as part of animal studies, including packaging and shipping.

1.2 This guide does not address any materials, tissues, or fluids that may contain prions.

1.3 Individuals must be properly trained prior to shipping possibly infectious materials.

1.4 This guide is a compilation of national and international regulations and guidelines that apply to the packaging and shipment of possibly infectious materials.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D4840 Guide for Sample Chain-of-Custody Procedures

2.2 *Federal Standards and Regulatory Bodies:*[3]

DOT 49 CFR 172.700 Purpose and Scope

DOT 49 CFR 172.101–172.800 Transportation—Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans—Infectious Substances

DOT 49 CFR 173.134 Transportation—Shippers—General Requirements for Shipments and Packagings—Class 6, Division 6.2—Definitions and Exceptions

DOT 49 CFR 173.3 Transportation—Shippers—General Requirements for Shipments and Packagings—Hazardous Materials Classes and Index to Hazard Class Definitions

DOT 49 CFR 178 Transportation—Other Regulations Relating to Transportation—Specifications for Packagings

DOT 49 CFR 178.602 Preparation of Packagings and Packages for Testing

DOT 49 CFR 178.609 Transportation—Testing of Non-Bulk Packagings and Packages—Preparation of Packagings and Packages for Testing

29 CFR Part 1910.1030 Occupational Safety and Health Standards—Bloodborne Pathogens

2.3 *International Air Transport Association (IATA) uses Dangerous Goods Regulations (DGR). These are currently the strictest regulations:*[4]

Packing Instructions 620 Packing Instructions—Division 6.2—Category A Infectious Substances

Packing Instructions 650 Packing Instructions—Division 6.2—Category B Infectious Substances

2.4 *ISO Standards:*[5]

ISO 11607-1 Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

ISO 11607-2 Packaging for Terminally Sterilized Medical Devices—Part 2: Validation Requirements for Forming, Sealing and Assembly Processes

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[4] Available from International Air Transport Association (IATA), http://www.iata.org.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

2.5 *UN Dangerous Transport Standards:*[6]
UN 1845 Carbon dioxide, solid, also called dry ice
UN 2814 Infectious substance, affecting humans
UN 2900 Infectious substance, affecting animals
UN 3373 Biological substance, Category B
2.6 *United States Postal Service (USPS)*

3. Terminology

3.1 *Regulatory Definitions (from DOT 49 CFR 173.134 unless otherwise indicated):*

3.1.1 *biological product*—a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, tissue, allergenic product, or analogous product used for diagnosis, treatment, or cure of diseases in human or animals.

3.1.2 *culture*—an infectious substance containing a pathogen that is intentionally propagated; culture does not include a human or animal patient specimen.

3.1.3 *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, secreta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (for example, transwabs, culture media, and blood culture bottles).

3.1.4 *pathogen*—a virus or microorganism (including its viruses, plasmids, or genetic elements) with the potential to cause disease to humans or animals, or both.

3.1.5 *regulated medical waste*—a waste or reusable material known or suspected to contain an infectious substance (except Category A infectious substances), generated in the diagnosis, treatment, or immunization of humans or animals or both or production or testing of biological products.

3.1.6 *risk group*—term assigned by World Health Organization (WHO) based on the severity of the disease caused by the organisms, the mode and relative ease of transmission, the degree of risk to both an individual and the community, and the reversibility of the disease through availability of known and effective preventative agents and treatments.[7]

3.1.7 *sharps*—any object contaminated or potentially contaminated with a pathogen and capable of cutting and capable of cutting or penetrating skin or packaging material; this includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental and suture wire.

3.1.8 *used health care product*—a medical, diagnostic, or research device, piece of equipment or implant, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the requirements of a diagnostic specimen, biological product, or regulated medical waste; this product is contaminated with potentially infectious bodily fluids or materials and has not been decontaminated to remove or mitigate the infectious hazard prior to transportation.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *implant*—any permanent or temporary device implanted into a human.

3.2.2 *materials*—any portion of an artificial implant.

4. Classification of Dangerous Substances

4.1 There are a number of different regulatory agencies, each of whom has their own classifications. A summary is included in 4.2.

4.2 *General Classification Codes (outlined in DOT 49 CFR 173.3):*

4.2.1 *Class 1: Explosives:*
4.2.1.1 *Division 1.1*—Mass explosive hazard.
4.2.1.2 *Division 1.2*—Projection hazard.
4.2.1.3 *Division 1.3*—Mass fire hazard.
4.2.1.4 *Division 1.4*—Minor explosion hazard.
4.2.1.5 *Division 1.5*—Very insensitive explosives.
4.2.1.6 *Division 1.6*—Extremely insensitive explosives.
4.2.2 *Class 2: Gases:*
4.2.2.1 *Division 2.1*—Flammable gases.
4.2.2.2 *Division 2.2*—Non-flammable gases.
4.2.2.3 *Division 2.3*—Poisonous or toxic.
4.2.2.4 Includes compressed, dissolved under pressure, or pressurized cryogenic liquids and liquefied gases.
4.2.3 *Class 3: Flammable Liquid*—material whose flash point is not more than 141 °F.
4.2.4 *Class 4: Flammable Solids:*
4.2.4.1 *Division 4.1*—Flammable solid.
4.2.4.2 *Division 4.2*—Spontaneously combustible material.
4.2.4.3 *Division 4.3*—Dangerous when wet.
4.2.5 *Class 5: Oxidizing Substances; Organic Peroxides:*
4.2.5.1 *Division 5.1*—Oxidizer.
4.2.5.2 *Division 5.2*—Organic peroxide.
4.2.6 *Class 6: Poisonous (Toxic) and Infectious Substances:*
4.2.6.1 *Division 6.1*—Poisonous (toxic) material.
4.2.6.2 *Division 6.2*—Infectious substance.
4.2.7 *Class 7: Radioactive Material.*
4.2.8 *Class 8: Corrosives.*
4.2.9 *Class 9: Miscellaneous Dangerous Goods.*
4.2.9.1 Includes environmentally hazardous substances, elevated temperature materials, hazardous wastes, and marine pollutants.

4.3 *Infectious Substance Classifications:*

4.3.1 According to IATA 3.6.2.2, the categories for classification of biological materials are infectious substances, in either Category A or Category B, exempting patient specimens, and biological products. Component classification can be assigned through the use of the flow charts in 7.1.

4.3.1.1 Infectious substances in Category A are in a form capable of causing permanent disability, life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. They are classified for shipping by their effect on humans or animals. In accordance with IATA Packing Instructions 620, these substances must be in triple packaging. The maximum quantity that can be shipped by air is 4 L or 4 kg in one package. On a passenger carrier, the amount is decreased to 50 mL or 50 g. No infectious substance may be

[6] Available from United Nations Economic Commission for Europe (UNECE), Palais des Nations, CH-1211 Geneva 10, Switzerland, http://www.unece.org.
[7] Available from the WHO Laboratory Biosafety Manual, http://who.int.