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.

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

This standard is issued under the fixed designation F2995; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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.

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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.

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carried into the cabin of the plane. The package must display the following marks and labels:

(1) The sender's name and address,

(2) The recipient's name and address,

(3) An infectious substance hazard label,

(4) The proper shipping name,

(5) The UN number, and

(6) The net quantity of infectious substance (only required if other dangerous goods are in the same package).

The proper shipping names and UN identification numbers are "Infectious Substances, Affecting Humans" (UN 2814) and "Infectious Substances, Affecting Animals" (UN 2900), accordingly. The name and telephone number of the person responsible for shipment must also appear on the label of the outer packaging, as well as a "Cargo Aircraft Only" label if the quantity for shipping is greater than 50 mL or 50 g. Also, if packaged with dry ice, a Class 9 label, including UN 1845 and dry ice (or carbon dioxide, solid), must be attached, including the net weight of the dry ice.

4.3.1.2 Category B includes substances that are infectious but do not meet requirements for Category A. For shipping, the package requires the identification of the proper shipping name and the UN 3373 with the following.

(1) Biological Substance, Category B. As with the Category A substances, triple packaging is required, meeting IATA Packing Instructions 650 specifications. The maximum quantity for the primary container is 1 mL or 4 kg and the outer packaging must not contain more than 4 L or 4 kg. Labels must be displayed on the outer packaging and must include the sender's name and address, the recipient's name and address, the proper shipping name, and the UN 3373 diamond marking. For shipments with dry ice, a Class 9 label including UN 1845 and the proper shipping name dry ice (or carbon dioxide, solid) and the net weight of the dry ice. If the substance is a diagnostic specimen or a biological product and the source patient has or is suspected of being infected with a Category A infectious substance, these substances must be shipped as Category A materials with the UN number of UN 2814 or UN 2900, as appropriate.

4.3.1.3 If there is doubt as to whether or not a substance meets the requirements of Category B, then it shall be listed as Category A.

4.3.2 Biological products, in addition to those items specified earlier (3.1.1), include materials manufactured and distributed in accordance with various CFR sections of the DOT. These sections cover licenses for biological products; experimental products, distribution, and evaluation of biological products prior to licensing; permits for biological products; investigational new drug application; applications for FDA approval to market a new drug; and biologics. If the material contains pathogens in Risk Group 2, 3, or 4, it must be described as an infectious substance and assigned to UN 2814, UN 2900, or UN 3373, as appropriate, unless otherwise excepted.

4.3.3 A patient specimen, as defined previously (3.1.3), is classified as a Category B infectious substance unless the suspected pathogen meets the requirements of a Category A infectious substance. In this case, the material should be classified as a Category A infectious substance and assigned to UN 2814 or UN 2900, as appropriate.

4.3.4 Regulated medical waste containing a Category A infectious substance must be classified as a Category A infectious substance, and assigned the appropriate UN identification number.

4.3.5 The following exceptions are not subject to the requirements of Division 6.2:

4.3.5.1 A biological or diagnostic product containing pathogens where the pathogen has been neutralized or inactivated so it cannot cause disease when exposure occurs. This also applies to biological products, including an experimental product or component of a product, subject to federal approval, permit or licensing requirements, such as those required by the Food and Drug Administration, the Department of Health and Human Services, or the U.S. Department of Agriculture.

4.3.5.2 Blood collected for transfusion or preparation of blood products; blood products, tissues, or organs for transplant; human cells, tissues, and cellular and tissue-based products regulated under the Public Health Service Act and/or the Food, Drug and Cosmetic Act, unless suspected of containing a pathogen.

4.3.5.3 Corpses, remains, and anatomical parts intended for interment, cremation, or medical research.

4.3.5.4 A non-Category A patient specimen transported in a private or contracted vehicle used exclusively for that purpose.

4.3.5.5 Laundry or medical equipment conforming to regulations 29 CFR part 1910.1030. This includes equipment that will be cleaned, refurbished, and used, but not medical equipment disposal.

4.3.5.6 Material, including waste, that has been sterilized or disinfected, by steam, chemicals, or other appropriate measures, so it no longer meets requirements for infectious substance.

4.3.5.7 Any waste or recyclable, other than regulated medical waste, including garbage or trash from domestic residences; sanitary waste and sewage; sewage sludge or compost; animal waste generated from husbandry or food production; and medical waste generated in a household and transported in accordance with the regulations.

4.3.5.8 Forensic material known or suspected of containing an infectious substance must be shipped according to DOT regulations.

4.3.5.9 Environmental microbial specimens, dust, or mold, and agricultural products and food.

4.3.6 Exceptions for regulated medical waste are listed below:

4.3.6.1 Waste culture or stock containing non-Category A infectious substances must be properly packaged in a rigid non-bulk packaging and transported in a private or contract carrier dedicated to the transport of regulated medical waste. Medical or clinical equipment and laboratory products can also be transported in the same vehicle, if properly packaged and secured against contamination and possible exposure.

5. Packaging Requirements

5.1 It is the responsibility of the shipper to ensure that the materials in all packages are properly identified and classified,

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