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Standard Guide for Shipping Possibly Infectious Materials, Tissues, and Fluids¹

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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 and health practices and determine the applicability of regulatory limitations prior to use. Some specific hazards statements are given in Section 7 on Hazards.*

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 Ma-

terials 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

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

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>.

⁶ Available from United Nations Economic Commission for Europe (UNECE), Palais des Nations, CH-1211 Geneva 10, Switzerland, <http://www.unece.org>.