Designation: F2995 – 13

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.

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

1.3 It is recommended that individuals 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 172.323 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 173.2 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 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 602 Packing Instructions—Class 6—Toxic and Infectious Substances—Infectious Substance

Packing Instructions 650 Packing Instructions—Class 6—Toxic and Infectious Substances—Diagnostic Specimen

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 (Risk Group 2)

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.

Current edition approved March 1, 2013. Published August 2013. DOI: 10.1520/F2995-13.

[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.

2.6 *United States Postal Service (USPS).*

3. Terminology

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

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 *cultures and stocks*—materials prepared and maintained for the growth and storage of pathogens, and contain a Risk Group 2, 3, or 4 infectious substance (see 4.3.2).

3.1.3 *diagnostic specimen*—any human or animal material, including excreta, secreta, blood and its components, tissues, and tissue fluids, being transported for diagnostic or investigational purposes, excluding live infected humans or animals.

3.1.4 *infectious substance*—a material known or suspected to contain a pathogen.

3.1.4.1 *Discussion*—In older regulations and at the USPS, infectious substances are often referred to as etiologic agents.

3.1.5 *pathogen*—a virus or micro-organism (including its viruses, plasmids, or genetic elements) with the potential to cause disease to humans or animals.

3.1.6 *regulated medical waste*—a waste or reusable material known or suspected to contain an infectious substance in Risk Group 2 or 3, generated in the diagnosis, treatment, or immunization of humans or animals, or production or testing of biological products.

3.1.7 *risk group*—assigned by World Health Organization (WHO) based on 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.

3.1.8 *sharps*—any object contaminated with a pathogen or may be contaminated and also 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.

3.1.9 *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 173.2):*

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 141ºF.

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 Packing Instructions 650, the categories for classification of biological materials are infectious substances, in either Category A or Category B, diagnostic specimens, and biological products. Component classification can be assigned through the use of the flow chart in 7.1. As of January 1, 2007, diagnostic specimen and biological specimen are no longer acceptable shipping names.

4.3.1.1 Infectious substances in Category A are capable of causing permanent disability, life threatening or fatal disease to humans or animals when exposure occurs. They are classified for shipping by their effect to humans or animals. In accordance with IATA Packing Instructions 650, 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 substance may be carried into the cabin of the plane. The package must display a label on two opposite sides. This label must include:

(1) The sender's name and address,

(2) The recipient's name and address,

(3) An infectious substance label,

(4) The proper shipping name,

(5) The UN number, and

(6) The net quantity of infectious substance.

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 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 larger 50 mL or 50 g. Also, if packaged with dry ice, a Class 9 label, including UN 1845, 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 number UN 3373 with the following proper shipping names (note that the names should be in all capital letters:

(1) “BIOLOGICAL SUBSTANCE, CATEGORY B”; As of January 1, 2007, shipping names “Diagnostic Specimen” and “Clinical Specimen” will no longer be permitted. As with the Category A substances, triple packaging is required, meeting IATA Packing Instructions 650 specifications. The maximum quantity for the primary container is 500 mL or 500 g and the outer packaging must not contain more than 4 L or 4 kg. Labels must be displayed on two opposite sides of the outer packaging and must include the sender’s name and address, the recipient’s name and address, the proper shipping name and UN number, and a Class 9 label, including UN 1845 and net weight, if packaged in dry ice. A Class 9 label is not needed when using IATA Packaging Instructions 602 and 650. If the substance is a diagnostic specimen or a biological product and the source patient has or is suspected of having a serious disease that can be passed from one individual to another, and for which there are no effective preventative measures or treatments, these substances must be shipped as Category A materials with an identification number of UN 2814 or UN 2900, as appropriate.

4.3.1.3 If there is doubt if a substance meets the requirements of Category B, then it shall be listed as Category A.

4.3.2 Classification according to the DOT requires that the pathogen be assigned to a Risk Group (see Note 1) based on the known medical history and condition of the source patient or animal, the endemic local conditions, the symptoms of the source patient or animal, or by professional judgment. The Risk Group is assigned by the 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 the individual and the community, and the reversibility of the disease through the availability of known and effective preventative agents and treatments. There are four Risk Group categories:

NOTE 1—DOT no longer uses Risk Group classification.

4.3.3 Risk Group 4 includes pathogens that usually cause serious disease in humans or animals. The diseases can be readily transmitted from one individual to another, directly or indirectly, and effective treatments and preventative measures are not usually available. There is a high risk to both the individual and the community.

4.3.4 Risk Group 3 involves pathogens that can cause serious human or animal disease but do not ordinarily spread from one infected individual to another, and for which effective treatment and preventative measures are available. In this case, there is a high risk to the individual but not to the community.

4.3.5 Risk Group 2 pathogens can cause human or animal disease but are unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventative measures available and the risk of spreading the infection is limited. The risk to the individual in this case is moderate and the risk to the community is low.

4.3.5.1 Risk Group 1 includes microorganisms that are unlikely to cause human or animal disease. Materials containing only such microorganisms are not subject to the shipping requirements for infectious materials, since there is no or very low risk to the individual and the community.

4.3.6 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 or UN 2900 as appropriate, unless otherwise excepted.

4.3.7 A diagnostic specimen, as defined previously (3.1.3), is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a pathogen of Risk Group 4. In this case, the material should be classified under Division 6.2 infectious substances and assigned to UN 2814 or UN 2900, as appropriate.

4.3.8 Regulated medical waste containing an infectious material of Risk Group 4 must be classified in Division 6.2 as an infectious substance, and assigned the appropriate UN identification number.

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

4.3.10 A biological or diagnostic product containing pathogens from Risk Group 1 or no pathogens, or 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 or the Department of Health and Human Services or the US Department of Agriculture.

4.3.11 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.

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

4.3.11.2 A diagnostic specimen or biological product transported in a private or contracted vehicle used exclusively for that purpose. These materials must still be properly packaged and labeled.

4.3.11.3 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.

4.3.11.4 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.

4.3.11.5 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.

4.3.11.6 Forensic material known or suspected of containing Risk Group 2 or 3 infectious substances must be shipped according to DOT regulations. That containing or suspected to contain Risk Group 4 must be triple packaged with appropriate labels, with a biohazard symbol on the secondary packaging.

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

4.3.12 Exceptions for regulated medical waste are listed below:

4.3.12.1 If the material is transported by a private or contract carrier, no "Infectious Substance" label is required if there is a biohazard label on outer packaging. If the material is packaged in a rigid non-bulk packaging, and is not waste culture or stock, it does not need to follow the packing requirements.

4.3.12.2 Waste culture or stock containing Risk Group 2 or 3 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, as well as ensuring that the packaging can withstand the pressure and temperature variations, shocks, and possible leakages that can occur during transport. The steps that need to be followed for shipping hazardous biological materials include classification, packaging, labeling and documentation. All personnel involved in any of the above activities must be trained and certified according to the DOT (DOT 49 CFR 178) and IATA regulations.

5.2 The general package design specified by all regulations requires that the materials be transported in triple packaging that will prevent damage to the material during shipment and exposure to others. Care must be taken to avoid permeability, corrosion, softening, premature aging, and embrittlement caused by incompatibility between the packaging and the contents. All inner closures should be upright; friction should be minimized; the inner package should be cushioned and secured in the outer package to prevent breakage or leaking; and no metallic objects should be included in the packaging, like nails or staples, which could protrude into the package possibly causing damage to the inner packaging. Triple packaging, including the primary receptacle, secondary packaging, and the outer packaging, must pass set performance tests, as described in greater detail in 5.3.

5.2.1 The primary (inner) receptacle is a watertight container that holds the infectious material. The receptacle can be made of glass, metal, or plastic, including screw-cap tubes fastened with adhesive tape or shrink seals, flame-sealed glass ampoules, or rubber-stopped glass vials fitted with metal seals. There must be positive means of ensuring a leak-proof seal, such as a skirted stopper, a heat seal, or metal crimp seal. Multiple primary receptacles of the same or compatible material may be contained within a single secondary packaging.

5.2.2 The secondary packaging must also be watertight to prevent leakage. If there are multiple fragile primary receptacles placed in a secondary packaging, each must be wrapped individually to avoid breakage. Either the primary receptacle or secondary packaging must be able to withstand an internal pressure differential of 95 kPa and a temperature range of –40 to +55ºC as described by the DOT packing specifications and performance tests, also outlined by the United Nations. There must be enough absorbent material in the secondary packaging to completely absorb the entire contents of all the primary receptacles in case of leakage or damage. The smallest dimension of any external surface of the secondary packaging must be larger than 100 mm to hold any labels or shipping documents.

5.2.3 The outer packaging is a rigid container that must be of adequate strength for its capacity, mass and intended use, and meet all performance tests (as specified in DOT 49 CFR 178.602). It must not contain more than 4 L or 4 kg. If the material is transported with ice or dry ice, these must be placed outside of the secondary packaging or in an over-pack surrounding the triple package. The packaging must be leak-proof if using ice. The packaging for dry ice must allow for the escape of carbon dioxide gas and not allow a build-up of pressure that could rupture the packaging. An itemized list of the contents must be enclosed between the secondary and outer packaging, placed in a sealed plastic bag to protect from moisture. The package must be large enough to accommodate all labels placed on a single surface, with no overlapping, a minimum of 100 mm on all sides.

5.2.4 The outside surface of the outer packaging should be marked with the proper shipping name of the material, the technical name and the corresponding UN number. Also marked on the outside of the package should be a 24-h emergency response number in case of a spill or an accident, the name, address, and telephone number of the shipper and the consignee, and the net weight of the dry ice within the package if used. Other labels required on the outer packaging include a diamond-shaped Class 6, Division 6.2 "Infectious Substance" label. Package orientation labels with "this way up" indicated with an arrow should be shown on two opposite sides of the