Designation: F2995 – 16

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 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 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

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.

Current edition approved Nov. 15, 2016. Published January 2017. Originally approved in 2013. Last previous edition approved in 2013 as F2995 – 13. DOI: 10.1520/F2995-16.

[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 *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 micro-organism (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.

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 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 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 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 US 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, 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 172.700) 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; no metallic objects like nails or staples which could protrude into the package, possibly causing damage to the inner packaging, should be included in the 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 should be positive means of ensuring a leak-proof seal, such as a skirted stopper, a heat seal, or metal crimp seal (Category A primary receptacles containing liquids at ambient temperatures must have their closures secured by secondary means). 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.

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. 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. For Category B outer packages the minimum dimensions only need to be 100 mm on two dimensions.

5.2.4 The outside surface of the outer packaging should be marked with the proper shipping name of the material, the technical name (Category A only) and the corresponding UN number, although for Category B the UN 3373 diamond marking qualifies as the UN number. Also marked on the package is the address of the shipper and the consignee, the name and telephone number of a person responsible (for Category B this may be on the package or the waybill) and when dry ice is used the net weight of the dry ice within the package. Other labels required on the outer packaging include a diamond-shaped Class 6, Division 6.2 “Infectious Substance” hazard label for Category A packages and the UN 3373 diamond marking for Category B packages. Package orientation labels with “this way up” indicated with an arrow should be shown on two opposite sides of the package. For Category A shipment the Shipper’s Declaration of Dangerous Goods document should be attached. Packaging Instructions 620 and 650 allow for small amounts of Dangerous Goods in Classes 3, 8, or 9 to be packed with the specimens if these substances are necessary to maintain the viability, stabilize, prevent degradation or neutralize the hazards of the infectious substances. The amounts allowed for these other Dangerous Goods is 30 mL or less per primary receptacle. If the package contains dry ice and is being shipped by air, a Class 9 “Miscellaneous Dangerous Goods” hazard label is required and if liquid nitrogen is being used two labels are required: a Division 2.2 “Non-flammable, non-toxic gas” hazard label and the “Cryogenic Liquid” handling label as well as the text “Keep upright and Do not drop-handle with care.” If the package contains more than 50 mL or 50 g of a Category A infectious substance, a “Cargo Aircraft Only” label must also be attached to the outside of the packaging.

5.2.5 Additional requirements for the packaging are based on the state of the material and other characteristics:

5.2.5.1 For lyophilized materials, acceptable primary receptacles are flame-sealed glass ampoules or rubber-stopped vials with metal seals.

5.2.5.2 Liquid or solid infectious substances, at ambient temperature or higher, should be transported in primary receptacles made of glass, metal, or plastic. For liquid Category A Infectious Substances at ambient temperatures, there must be a positive measure of a leak-proof seal, such as a heat seal, a skirted stopper, or a metal crimp seal. Screw caps must be secured in position with adhesive tape.

5.2.5.3 Ice or dry ice must be packed outside the secondary packaging or in an over-pack with one or more complete packages marked appropriately. Interior supports are required within the outer packaging to ensure that the inner packaging does not shift when the ice melts or dry ice dissipates. The outside package must be leak-proof if ice is used and allow for the release of the carbon dioxide if dry ice is used. The primary receptacle and secondary packaging must be able to withstand temperatures and pressures at both the cooled and atmospheric conditions.

5.2.5.4 If the material is transported with liquid nitrogen, the primary receptacle must be able to withstand the low temperatures. The secondary packaging will also have to withstand the low temperatures, and it may be necessary to have a secondary package for each primary receptacle to prevent breakage. It must maintain integrity at refrigerated and atmospheric air transport conditions. Other than dry shippers,

liquid nitrogen refrigerated packages must be metal vacuum-insulated vessels or flasks vented to atmosphere to prevent pressure build-up. Except for Closed Cryogenic receptacles, the use of safety relief valves, check valves, frangible disks, or similar devices in vent lines is prohibited. The filling and discharge openings must be protected against entry of materials that may increase the internal pressure. The packaging must be designed to prevent the discharge of nitrogen gas no matter the orientation of the package and must be appropriately labeled.

5.3 There are several performance tests that completed packages must pass in order to be approved for shipping material. These tests are done according to the inner and outer packaging material (performance tests outlined in DOT 49 CFR 178.609). To prevent exposure during the testing, the infectious substance is replaced with water and the primary receptacle is filled to 98 % capacity. Outer packing material is described as fiberboard, materials that lose integrity when exposed to moisture, plastic, materials which embrittle at low temperatures, or a material other than these two classifications. Inner packaging, including the primary receptacle and secondary packaging, is described as either plastic or a material other than plastic. For an inner packaging where the primary receptacle and secondary packaging are of different materials, the primary receptacle determines the appropriate test.

5.3.1 For packages where the inner packaging is made of a material other than plastic, and the outer packaging is made from a material other than plastic or fiberboard, the package is subjected to a series of free-fall drops onto a non-resilient, flat, rigid, horizontal surface from a height of 1.2 m for Category B packages and 9 m for Category A packages. If the package is in the shape of a box, the drops are made onto five different orientations: the base of the box, the top surface, the long side, the short side, and a corner. For packages shaped like drums, the drops are made on three different orientations; diagonally on the top chime, diagonally on the bottom chime, and on the side. The packages should be released from the height in the proper orientation, but if the landing is on a site other than the desired surface, the test is still considered complete. A pass for the package is no leakage from any primary receptacle after each drop.

5.3.2 For packages with an inner package of plastic and an outer package material of fiberboard, or an inner packaging other than plastic with an outer packaging of fiberboard, the package is subjected to a water spray simulating rainfall exposure of approximately 50 mm/h for at least 1 h. The package is then subjected to the free-fall drop test, summarized in 5.3.1.

5.3.3 For packages with an inner packaging of plastic and an outer packaging of fiberboard, an inner packaging of plastic with an outer packaging of plastic, an inner packaging other than plastic with an outer packaging of plastic, or an inner packaging of plastic with outer packaging other than plastic or fiberboard, the package is conditioned at to an atmosphere of –18ºC or less for a period of at least 24 h and within 15 min of removal from that atmosphere be subjected to the free-fall drop test from the appropriate height, summarized in 5.3.1.

5.3.4 For packages that contain dry ice, the package is stored until all the dry ice has dissipated. It is then subjected to the free-fall drop test from the appropriate height as given in 5.3.1.

5.3.5 Category A packages with a gross mass of 7 kg or less are subjected to the following test. The package is placed on a hard level surface. A cylindrical steel rod with a mass of at least 7 kg, a diameter not exceeding 38 mm, and a radius at the impact end edges of less than 6 mm is used. The rod is dropped from a vertical height of 1 m, measured from the end of the rod to the top of the package, onto the package as close to the primary receptacle as possible. This test is done for two orientations of the package, once with the package on its base and again with it on a surface perpendicular to the base. A pass for the test is no leakage from any of the primary receptacles in the package.

5.3.6 Category A packages with a gross mass of greater than 7 kg are subjected to a similar test. In this case the package is dropped onto the end of a cylindrical steel rod from a height of 1 m. The rod, with a diameter of 38 mm and a radius not exceeding 6 mm at the impact end, is set vertically into a hard level surface. The rod must protrude from the ground at least a height equal to the distance between the outer surface of the outer packaging and the primary receptacle, with a minimum of 20 mm. Two orientations for the package are tested from the same height, with the surfaces tested being perpendicular to each other, such that the primary receptacle will be impacted. A pass for the test is no leakage from any primary receptacle.

6. Sterilization

6.1 Substances that contain pathogens that have been neutralized, through sterilization, or otherwise inactivated such that there is no longer a health risk are not subject to these regulations of Division 6.2 “Infectious Substance.” However, if other dangerous goods are present, the substance must be classified according to those groups.

6.2 Common methods of sterilization are outlined in ISO 11607–1 and 11607–2.

6.3 Regardless of the sterilization approach used, the sterilization process must not adversely affect the chemical and mechanical properties, and appearance of the device.

6.3.1 Autoclaving is known to adversely impact the properties of some plastics.

6.3.2 The formic acid in formalin can degrade polyurethane components.

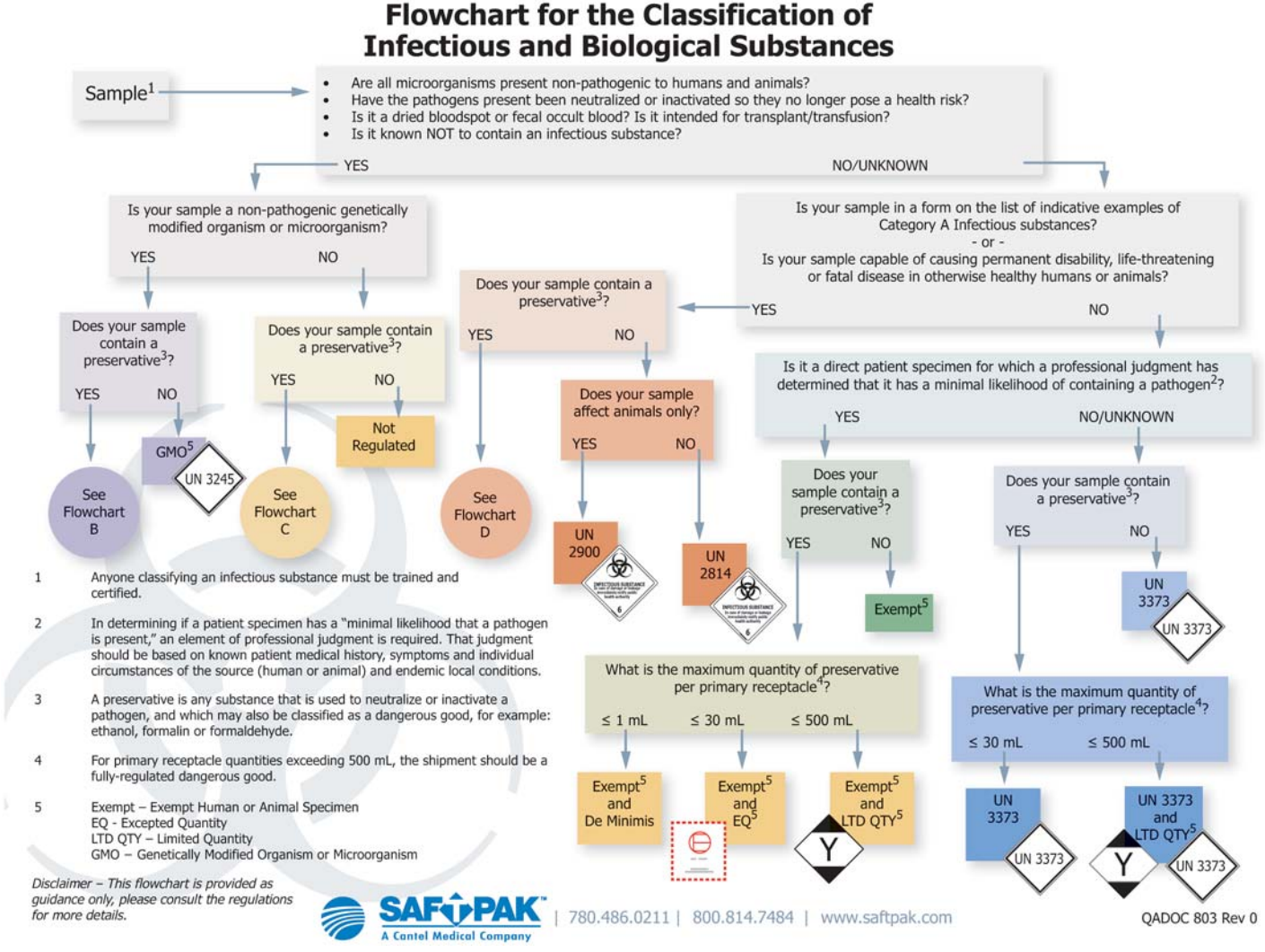
7. Classification Flow Chart

7.1 The flow chart in Fig. 1 and Fig. 2 can be used to determine the proper classification the medical component falls under. If it is unknown if the part contains pathogens, assume that it does.

8. Chain of Custody Reporting

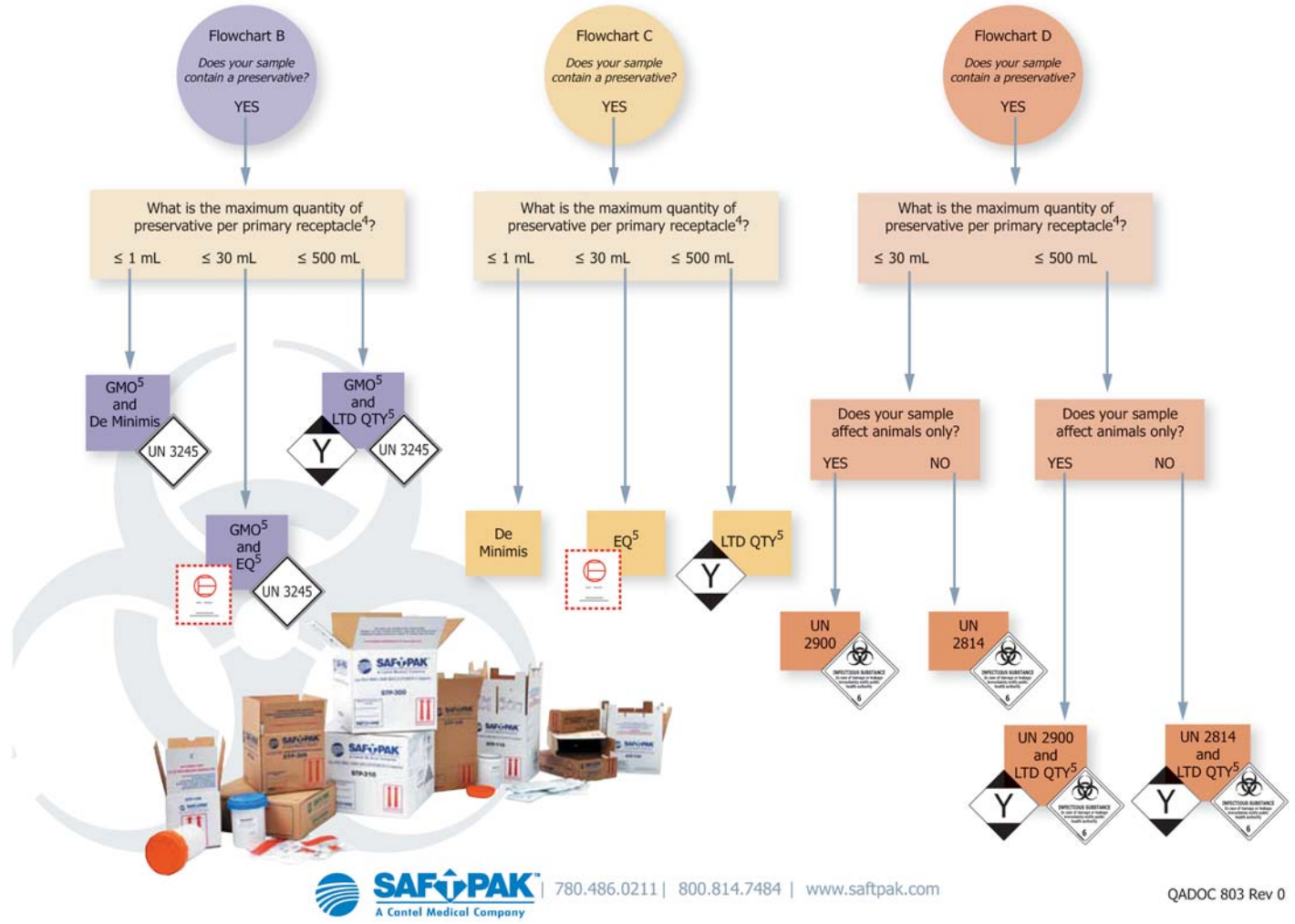
8.1 Guide D4840 may be followed.

8.2 It is recommended that a Chain of Custody Form accompany a shipped medical component. The Chain of Custody Form should include the following information:



NOTE 1—Flow chart provided by Saf-T-Pak, Inc., http://www.saftpak.com/

FIG. 1 Decision Flow Chart for Component Classification



NOTE 1—Flow chart provided by Saf-T-Pak, Inc., http://www.saftpak.com/

FIG. 2 Decision Flow Chart for Component Classification (*continued*)

8.2.1 Device shipper, including the name of company/organization, individual, and signature of the shipper;

8.2.2 Date of shipment;

8.2.3 Device recipient, including the name of company/organization, individual, and signature of the individual;

8.2.4 Date of receipt;

8.2.5 Indication if any testing was performed;

8.2.6 Indication of a confirmation of receipt was sent to the last shipper; and

8.2.7 Any general notes on the appearance of the package or device, and if any unusual storage conditions were used.

8.3 The form should have spaces for multiple shipment locations. An example is shown in Fig. 3.

8.4 Each recipient of the medical component should keep a copy of the Chain of Custody Form for their own records.

9. Keywords

9.1 DOT; explant; IATA; infectious; shipping; tissues

Explant Chain of Custody

Component List

Component Description	Part#/Lot# if visible
Acetabular Shell	XXXX-XX-XXX/XXXXXXX
Polyethylene liner	32 × 57 mm/XXXXXX
Screws	NA
Femoral ball	
Tissue	NA

Shipped by	Received by	Pictures taken?	Tested	Confirm Receipt Sent	Notes
Tom Smith ABC Hospital signature	Greg Thomas XYZ Laboratories signature	Y	N	Y	Stored in freezer to preserve tissue.
Date: 12/13/04	Date: 12/14/04				
Shipped by	**Received by**	**Pictures taken?**	**Tested**	**Confirm Receipt Sent**	**Notes**
Greg Thomas XYZ Laboratories signature	Michelle White 123 Pathology Labs signature	Y	Y	Y	Tissue blocks removed per request of client.
12/28/04	12/29/04				
Shipped by	**Received by**	**Pictures taken?**	**Tested**	**Confirm Receipt Sent**	**Notes**
Date:	Date:				

FIG. 3 Example of a Chain of Custody Form

RELATED MATERIAL

ISO 12891–1 Retrieval and Analysis of Implantable Medical Devices—Part 1: Standard Practice for Retrieval and Handling