non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030, provided the material does not include a waste concentrated stock culture of an infectious substance. Sharps containers must be securely closed to prevent leaks or punctures.

(2) The following materials may be offered for transportation and transported as a regulated medical waste when packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030 and transported by a private or contract carrier in a vehicle used exclusively to transport regulated medical waste:

(i) Waste stock or culture of a Category B infectious substance;

(ii) Plant and animal waste regulated by the Animal and Plant Health Inspection Service (APHIS);

(iii) Waste pharmaceutical materials;

(iv) Laboratory and recyclable wastes;

(v) Infectious substances that have been treated to eliminate or neutralize pathogens;

(vi) Forensic materials being transported for final destruction;

(vii) Rejected or recalled health care products;

(viii) Documents intended for destruction in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements;

(ix) Medical or clinical equipment and laboratory products provided they are properly packaged and secured against exposure or contamination; or

(x) Sharps in sharp containers provided the containers are securely closed to prevent leaks or punctures; do not exceed 18 gallons capacity; registered under the Medical Device Regulations of FDA; made of puncture resistant plastic that meets ASTM Standard F2132–01, Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps; and are securely fitted into wheeled racks that hold them in an upright position. The wheeled racks must contain full rows of sharps containers secured in place by a moveable bar; and must be securely held in place on the motor vehicle by straps or load bars during transportation. No shelf in any wheeled rack may exceed the manufacturer's recommended load capacity.

(d) If an item listed in paragraph (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of this subchapter.

(e) *Transitional provisions.* The authorization for continued use of the criteria for packing group assignments in effect on December 31, 2006 ended on January 1, 2012.

[67 FR 53138, Aug. 14, 2002, as amended at 68 FR 57632, Oct. 6, 2003; 70 FR 56098, Sept. 23, 2005; 71 FR 32258, June 2, 2006; 71 FR 78631, Dec. 29, 2006; 72 FR 55692, Oct. 1, 2007; 73 FR 4718, Jan. 28, 2008; 74 FR 2257, Jan. 14, 2009; 76 FR 43530, July 20, 2011; 77 FR 60942, Oct. 5, 2012; 78 FR 15327, Mar. 11, 2013; 85 FR 27880, May 11, 2020; 85 FR 83397, Dec. 21, 2020; 87 FR 44992, July 26, 2022]

§ 173.136 Class 8—Definitions.

(a) For the purpose of this subchapter, ''corrosive material'' (Class 8) means a liquid or solid that causes irreversible damage to human skin at the site of contact within a specified period of time. A liquid, or a solid which may become liquid during transportation, that has a severe corrosion rate on steel or aluminum based on the criteria in § 173.137(c)(2) is also a corrosive material. Whenever practical, *in vitro* test methods authorized in § 173.137 of this part or historical data authorized in paragraph (c) of this section should be used to determine whether a material is corrosive.

(b) If human experience or other data indicate that the hazard of a material is greater or less than indicated by the results of the tests specified in paragraph (a) of this section, PHMSA may revise its classification or make the determination that the material is not subject to the requirements of this subchapter.

(c) Skin corrosion test data produced no later than September 30, 1995, using the procedures of part 173, appendix A, in effect on September 30, 1995 (see 49 CFR part 173, appendix A, revised as of

October 1, 1994) for appropriate exposure times may be used for classification and assignment of packing group for Class 8 materials corrosive to skin.

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended at 56 FR 66270, Dec. 20, 1991; Amdt. 173–234, 58 FR 51532, Oct. 1, 1993; Amdt. 173–241, 59 FR 67508, Dec. 29, 1994; Amdt. 173–261, 62 FR 24732, May 6, 1997; 69 FR 76155, Dec. 20, 2004; 71 FR 78631, Dec. 29, 2006; 76 FR 3372, Jan. 19, 2011; 85 FR 27880, May 11, 2020]

§ 173.137 Class 8—Assignment of packing group.

The packing group of a Class 8 material is indicated in Column 5 of the §172.101 Table. When the §172.101 Table provides more than one packing group for a Class 8 material, the packing group must be determined using data obtained from tests conducted in accordance with the OECD Guidelines for the Testing of Chemicals, Test No. 435, ''*In Vitro* Membrane Barrier Test Method for Skin Corrosion'' (IBR, *see* §171.7 of this subchapter) or Test No. 404, ''Acute Dermal Irritation/Corrosion'' (IBR, *see* §171.7 of this subchapter). A material that is determined not to be corrosive in accordance with OECD Guideline for the Testing of Chemicals, Test No. 430, ''*In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)'' (IBR, *see* §171.7 of this subchapter) or Test No. 431, ''*In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method'' (IBR, *see* §171.7 of this subchapter) may be considered not to be corrosive to human skin for the purposes of this subchapter without further testing. However, a material determined to be corrosive in accordance with Test No. 430 must be further tested using Test No. 435 or Test No. 404. If the in vitro test results indicate that the substance or mixture is corrosive, but the test method does not clearly distinguish between assignment of packing groups II and III, the material may be considered to be in packing group II without further testing. The packing group assignment using data obtained from tests conducted in accordance with OECD Guideline Test No. 404 or Test No. 435 must be as follows:

(a) *Packing Group I.* Materials that cause irreversible damage to intact skin tissue within an observation period of up to 60 minutes, starting after the exposure time of three minutes or less.

(b) *Packing Group II.* Materials, other than those meeting Packing Group I criteria, that cause irreversible damage to intact skin tissue within an observation period of up to 14 days, starting after the exposure time of more than three minutes but not more than 60 minutes.

(c) *Packing Group III.* Materials, other than those meeting Packing Group I or II criteria—

(1) That cause irreversible damage to intact skin tissue within an observation period of up to 14 days, starting after the exposure time of more than 60 minutes but not more than 4 hours; or

(2) That do not cause irreversible damage to intact skin tissue but exhibit a corrosion on either steel or aluminum surfaces exceeding 6.25 mm (0.25 inch) a year at a test temperature of 55 °C (130 °F) when tested on both materials. The corrosion may be determined in accordance with the UN Manual of Tests and Criteria (IBR, see §171.7 of this subchapter) or other equivalent test methods.

(d) *Alternative packing group assignment methods for mixtures.* For mixtures it is necessary to obtain or derive information that allows the criteria to be applied to the mixture for the purpose of classification and assignment of packing groups. The approach to classification and assignment of packing groups is tiered, and is dependent upon the amount of information available for the mixture itself, for similar mixtures and/or for its ingredients. The flow chart in Figure 1 to paragraph (d) outlines the process to be followed: