

§ 178.609 Test requirements for packagings for infectious substances.

(a) Samples of each packaging must be prepared for testing as described in paragraph (b) of this section and then subjected to the tests in paragraphs (d) through (i) of this section.

(b) Samples of each packaging must be prepared as for transport except that a liquid or solid infectious substance should be replaced by water or, where conditioning at $-18\text{ }^{\circ}\text{C}$ ($0\text{ }^{\circ}\text{F}$) is specified, by water/antifreeze. Each primary receptacle must be filled to 98 percent capacity. Packagings for live animals should be tested with the live animal being replaced by an appropriate dummy of similar mass.

(c) Packagings prepared as for transport must be subjected to the tests in Table I of this paragraph (c), which, for test purposes, categorizes packagings according to their material characteristics. For outer packagings, the headings in Table I relate to fiberboard or similar materials whose performance may be rapidly affected by moisture; plastics that may embrittle at low temperature; and other materials, such as metal, for which performance is not significantly affected by moisture or temperature. Where a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of more than one material, the material most likely to be damaged determines the appropriate test.

Table I—Tests Required

Material of					Tests required				
Outer packaging			Inner packaging		Refer to para. (d)				Refer to para. (h)
Fiberboard	Plastics	Other	Plastics	Other	(d)	(e)	(f)	(g)	
X			X			X	X	When dry ice is used	X
X				X		X			X
	X		X				X		X
	X			X			X		X
		X	X				X		X
		X		X	X				X

(d) Samples must be subjected to free-fall drops onto a rigid, nonresilient, flat, horizontal surface from a height of 9 m (30 feet).

The drops must be performed as follows:

(1) Where the samples are in the shape of a box, five samples must be dropped, one in each of the following orientation:

- (i) Flat on the base;
- (ii) Flat on the top;
- (iii) Flat on the longest side;
- (iv) Flat on the shortest side; and
- (v) On a corner.

(2) Where the samples are in the shape of a drum, three samples must be dropped, one in each of the following orientations:

- (i) Diagonally on the top chime, with the center of gravity directly above the point of impact;

(ii) Diagonally on the base chime; and

(iii) Flat on the side.

(3) While the sample should be released in the required orientation, it is accepted that for aerodynamic reasons the impact may not take place in that orientation.

(4) Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which should remain protected by absorbent material in the secondary packaging.

(e) The samples must be subjected to a water spray to simulate exposure to rainfall of approximately 50 mm (2 inches) per hour for at least one hour. They must then be subjected to the test described in paragraph (d) of this section.

(f) The sample must be conditioned in an atmosphere of $-18\text{ }^{\circ}\text{C}$ ($0\text{ }^{\circ}\text{F}$) or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in paragraph (d) of this section. Where the sample contains dry ice, the conditioning period may be reduced to 4 hours.

(g) Where packaging is intended to contain dry ice, a test additional to that specified in paragraph (d) or (e) or (f) of this section must be carried out. One sample must be stored so that all the dry ice dissipates and then be subjected to the test described in paragraph (d) of this section.

(h) Packagings with a gross mass of 7 kg (15 pounds) or less should be subjected to the tests described in paragraph (h)(1) of this section and packagings with a gross mass exceeding 7 kg (15 pounds) to the tests in paragraph (h)(2) of this section.

(1) Samples must be placed on a level, hard surface. A cylindrical steel rod with a mass of at least 7 kg (15 pounds), a diameter not exceeding 38 mm (1.5 inches), and, at the impact end edges, a radius not exceeding 6 mm (0.2 inches), must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the impact end of the sample's impact surface. One sample must be placed on its base. A second sample must be placed in an orientation perpendicular to that used for the first. In each instance, the steel rod must be aimed to impact the primary receptacle(s). For a successful test, there must be no leakage from the primary receptacle(s) following each impact.

(2) Samples must be dropped onto the end of a cylindrical steel rod. The rod must be set vertically in a level, hard surface. It must have a diameter of 38 mm (1.5 inches) and a radius not exceeding 6 mm (0.2 inches) at the edges of the upper end. The rod must protrude from the surface a distance at least equal to that between the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm (7.9 inches). One sample must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the top of the steel rod. A second sample must be dropped from the same height in an orientation perpendicular to that used for the first. In each instance, the packaging must be oriented so the steel rod will impact the primary receptacle(s). For a successful test, there must be no leakage from the primary receptacle(s) following each impact.

(i) *Variations*. The following variations in the primary receptacles placed within the secondary packaging are allowed without additional testing of the completed package. An equivalent level of performance must be maintained.

(1) *Variation 1*. Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided they meet all of the following conditions:

(i) The primary receptacles are of similar design to the tested primary receptacle (e.g., shape: round, rectangular, etc.).

(ii) The material of construction of the primary receptacle (glass, plastics, metal, etc.) offers resistance to impact and a stacking force equal to or greater than that of the originally tested primary receptacle.

(iii) The primary receptacles have the same or smaller openings and the closure is of similar design (e.g., screw cap, friction lid, etc.).

(iv) Sufficient additional cushioning material is used to fill void spaces and to prevent significant movement of the primary

receptacles.

(v) Primary receptacles are oriented within the intermediate packaging in the same manner as in the tested package.

(2) *Variation 2.* A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in paragraph (i)(1) of this section, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

(3) *Variation 3.* Primary receptacles of any type may be placed within a secondary packaging and shipped without testing in the outer packaging provided all of the following conditions are met:

(i) The secondary and outer packaging combination must be successfully tested in accordance with paragraphs (a) through (h) of this section with fragile (e.g., glass) inner receptacles.

(ii) The total combined gross weight of inner receptacles may not exceed one-half the gross weight of inner receptacles used for the drop test in paragraph (d) of this section.

(iii) The thickness of cushioning material between inner receptacles and between inner receptacles and the outside of the secondary packaging may not be reduced below the corresponding thicknesses in the originally tested packaging. If a single inner receptacle was used in the original test, the thickness of cushioning between the inner receptacles must be no less than the thickness of cushioning between the outside of the secondary packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material must be used to fill the void.

(iv) The outer packaging must pass the stacking test in §178.606 while empty. The total weight of identical packages must be based on the combined mass of inner receptacles used in the drop test in paragraph (d) of this section.

(v) For inner receptacles containing liquids, an adequate quantity of absorbent material must be present to absorb the entire liquid contents of the inner receptacles.

(vi) If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not sift proof, a means of containing any liquid or solid contents in the event of leakage must be provided. This can be a leakproof liner, plastic bag, or other equally effective means of containment.

(vii) In addition, the marking required in §178.503(f) of this subchapter must be followed by the letter "U".

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