

## “CHAPTER 6.3

**REQUIREMENTS FOR THE CONSTRUCTION AND TESTING OF PACKAGINGS FOR  
DIVISION 6.2 INFECTIOUS SUBSTANCES OF CATEGORY A****6.3.1 General**

6.3.1.1 The requirements of this chapter apply to packagings intended for the transport of infectious substances of Category A.

**6.3.2 Requirements for packagings**

6.3.2.1 The requirements for packagings in this section are based on packagings, as specified in 6.1.4, currently in use. In order to take into account progress in science and technology, there is no objection to the use of packagings having specifications different from ~~those in Chapter 6.1~~ this chapter provided that they are equally effective, acceptable to the competent authority and able successfully to withstand the tests described in 6.3.5. Methods of testing other than those described in these Regulations are acceptable, provided they are equivalent.

~~6.3.2.2 Packagings used for infectious substances of Category A shall comprise the following elements:~~

- ~~———— (a) a rigid outer packaging of a type defined in 6.1.4 and shall have no external dimension less than 100mm;~~
- ~~———— (b) a leakproof secondary packaging(s);~~
- ~~———— (c) one or more primary receptacles.~~

~~6.3.2.3. Primary receptacle means a receptacle intended for the immediate containment of the sample, specimen or substance to be transported. It may be manufactured from rigid plastics, glass or metal or from paper, metal film or plastics film for solids only.~~

~~6.3.2.4. Where the packaging is intended to contain liquids the primary or secondary receptacle shall be capable of withstanding without leakage an internal pressure differential of 95 kPa.~~

6.3.2.52 Packagings shall be manufactured, and tested under a quality assurance programme which satisfies the competent authority in order to ensure that each packaging meets the requirements of this Chapter.

6.3.2.63 Manufacturers and subsequent distributors of packagings shall provide information regarding procedures to be followed and a description of the types and dimensions of closures (including required gaskets) and any other components needed to ensure that packages as presented for transport are capable of passing the applicable performance tests of this Chapter.

**6.3.3 Code for designating types of packagings**

6.3.3.1 The codes for designating types of packagings are set out in 6.1.2.7.

6.3.3.2 The letters “U” or “W” may follow the packaging code. The letter “U” signifies a special packaging conforming to the requirements of 6.3.5.1.7. The letter “W” signifies that the packaging, although, of the same type indicated by the code is manufactured to a specification different from that in 6.1.4 and is considered equivalent under the requirements of 6.3. 2.1.

#### 6.3.4 Marking

**NOTE 1:** *The marking indicates that the packaging which bears it corresponds to a successfully tested design type and that it complies with the requirements of this Chapter which are related to the manufacture, but not to the use, of the packaging.*

**NOTE 2:** *The marking is intended to be of assistance to packaging manufacturers, ~~reconditioners,~~ packaging users, carriers and regulatory authorities. ~~In relation to the use of a new packaging, the original marking is a means for its manufacturer(s) to identify the type and to indicate those performance test regulations that have been met.~~*

**NOTE 3:** *The marking does not always provide full details of the test levels, etc., and these may need to be taken further into account, e.g. by reference to a test certificate, to test reports or to a register of successfully tested packagings.*

6.3.4.1 Each packaging intended for use according to these Regulations shall bear markings which are durable, legible and placed in a location and of such a size relative to the packaging as to be readily visible. For packages with a gross mass of more than 30 kg, the markings or a duplicate thereof shall appear on the top or on a side of the packaging. Letters, numerals and symbols shall be at least 12 mm high, except for packagings of 30 litres or 30 kg capacity or less, when they shall be at least 6 mm in height and for packagings of 5 litres or 5 kg or less when they shall be of an appropriate size.

6.3.4.2 A packaging that meets the requirements of this section and of 6.3.5 shall be marked with:

- (a) the United Nations packaging symbol;



~~This shall not be used for any purpose other than certifying that a packaging complies with the relevant regulations in this Chapter.~~

- (b) the code designating the type of packaging according to the requirements of 6.1.2;
- (c) the text “CLASS 6.2”;
- (d) the last two digits of the year of manufacture of the packaging;
- (e) the state authorizing the allocation of the mark, indicated by the distinguishing sign for motor vehicles in international traffic;
- (f) the name of the manufacturer or other identification of the packaging specified by the competent authority.
- (g) For packagings meeting the requirements of 6.3.5.1.7, the letter “U”, inserted immediately following the marking required in (b) above.

6.3.4.3 Marking shall be applied in the sequence shown in 6.3.4.2 (a) to (g); each element of the marking required in these sub-paragraphs shall be clearly separated, e.g. by a slash or space, so as to be easily identifiable. For examples, see 6.3.4.4. ~~Any additional markings authorized by a competent authority shall still enable the parts of the mark to be correctly identified with reference to 6.3.4.1.~~

6.3.4.4 *Example of marking*



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as in 6.3.4.2 (a), (b), (c), (d), (e) and (f)

**6.3.5 Test requirements for packagings**

**6.3.5.1 Performance and frequency of tests**

6.3.5.1.1 The design type of each packaging shall be tested as provided in this section in accordance with procedures established by the competent authority.

6.3.5.1.2 ~~Tests shall be successfully performed on each packaging design type before such packaging is used. Each packaging design type shall successfully pass the tests prescribed in this Chapter before being used.~~ A packaging design type is defined by the design, size, material and thickness, manner of construction and packing, but may include various surface treatments. It also includes packagings which differ from the design type only in their lesser design height.

*(Consequential changes to 6.1 and 6.5 required)*

6.3.5.1.3 Tests shall be repeated on production samples at intervals established by the competent authority.

6.3.5.1.4 Tests shall also be repeated after each modification which alters the design, material or manner of construction of a packaging.

6.3.5.1.5 The competent authority may permit the selective testing of packagings that differ only in minor respects from a tested type, e.g. smaller sizes or lower net mass of primary receptacles ; and packagings such as drums, and boxes which are produced with small reductions in external dimension(s).

~~6.3.5.1.6 Provided an equivalent level of performance is maintained, the following variations in the primary receptacles placed within a secondary packaging are allowed without further testing of the completed package:~~

~~(a) Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:~~

~~(i) The primary receptacles are of similar design to the test 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 stacking forces 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 take up void spaces and to prevent significant movement of the primary receptacles;~~

~~(v) Primary receptacles are oriented within the secondary packaging in the same manner as in the tested package; and~~

~~(b) A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in (a) above, may be used provided sufficient cushioning is added to fill the void spaces(s) and to prevent significant movement of the primary receptacles.~~

6.3.5.1.7 Primary receptacles of any type may be assembled within a secondary packaging and transported without testing in the outer packaging under the following conditions:

- (a) The ~~secondary/outer~~ packaging ~~combination~~ shall have been successfully tested in accordance with 6.3.5.2.2 with fragile (e.g., glass) primary receptacles;
- (b) The total combined gross mass of primary receptacles shall not exceed one half of the gross mass of the ~~secondary/outer packaging combination~~ primary receptacles used for the drop test in (a) above;
- (c) The thickness of cushioning between primary receptacles and between primary receptacles and the outside of the secondary packaging shall not be reduced below the corresponding thicknesses in the originally tested packaging; and if a single primary receptacle was used in the original test, the thickness of cushioning between primary receptacles shall not be less than the thickness of cushioning between the outside of the secondary packaging and than the thickness of cushioning between the outside of the secondary packaging and the primary receptacle in the original test. When either fewer or smaller primary receptacles are used (as compared to the primary receptacles used in the drop test), sufficient additional cushioning material shall be used to take up the void spaces;
- (d) The outer packaging shall have successfully passed the stacking test in 6.1.5.6 while empty. The total mass of identical packages shall be based on the combined mass of the ~~secondary/outer packaging combination~~ packaging used in the drop test in (a) above;
- (e) For primary receptacles containing liquids, an adequate quantity of absorbent material to absorb the entire liquid content of the primary receptacles shall be present;
- (f) If the outer packaging is intended to contain primary receptacles for liquids and is not leakproof, or is intended to contain primary/secondary receptacles for solids and is not siftproof, a means of containing any liquid or solid contents in the event of leakage shall be provided in the form of a leakproof liner, plastics bag or other equally effective means of containment;
- (g) In addition to the markings prescribed in 6.3.4.2 (a) to (f), packagings shall be marked in accordance with 6.3.4.2 (g).

6.3.5.1.8 The competent authority may at any time require proof, by tests in accordance with this section, that serially-produced packagings meet the requirements of the design type tests.

6.3.5.1.9 Provided the validity of the test results is not affected and with the approval of the competent authority, several tests may be made on one sample.

**6.3.5.2 Preparation of packagings for testing**

6.3.5.2.1 Samples of each packaging shall be prepared as for transport except that a liquid or solid infectious substance shall be replaced by water or, where conditioning at -18 °C is specified, by water/antifreeze. Each primary receptacle shall be filled to not less than 98% of its capacity.

**NOTE:** The term water includes water/antifreeze solution with a minimum specific gravity of 0.95 for testing at -18 °C.

**6.3.5.2.2 Tests and number of samples required**

**Tests required for packaging types**

Type of packaging			Tests required					
Outer packaging	Primary receptacle		Water spray 6.3.5.3.5.1	Cold conditioning 6.3.5.3.5.2	Drop 6.3.5.3	Additional drop 6.3.5.3.5.3	Puncture 6.3.5.4	Stack 6.1.5.6
	Plastics <sup>c</sup>	Other <sup>d</sup>	No. of samples	No. of samples	No. of samples	No. of samples	No. of samples	
(A) <sup>a</sup>	(B) <sup>a</sup>	(C) <sup>a</sup>	(D)	(E)	(F)	(G)	(H)	(I)
Fibreboard box <sup>b</sup>	Yes		5	5	10	Required on one sample when the packaging is intended to contain dry ice.	2	Required on three samples when testing a “U”-marked packaging as defined in 6.3.5.1.7 for specific provisions
		Yes	5	0	5		2	
Fibreboard drum <sup>b</sup>	Yes		3	3	6		2	
		Yes	3	0	3		2	
Plastics box <sup>c</sup>	Yes		0	5	5		2	
		Yes	0	5	5		2	
Plastics drum/jerricans <sup>c</sup>	Yes		0	3	3		2	
		Yes	0	3	3		2	
Boxes of other material <sup>d</sup>	Yes		0	5	5		2	
		Yes	0	0	5		2	
Drums/jerricans of other material <sup>d</sup>	Yes		0	3	3	2		
		Yes	0	0	3	2		

- a. Columns A, B and C categorize packagings for test purposes according to their material characteristics and shape.
- b. The term “fibreboard” shall include similar materials whose performance may be rapidly affected by moisture.
- c. The term “plastics” relates to materials which may embrittle at low temperature.
- d. The term “other” relates to other materials such as metal whose performance is not affected by moisture or temperature.

**NOTE 1:** ~~If a primary receptacle and secondary packaging are made of different materials, the material of the primary receptacle determines the appropriate test.~~

**NOTE 2:** In instances where a primary receptacle is made of two or more materials, the material most liable to damage determines the appropriate test.

**NOTE 3:** The material of the secondary packagings are not taken into consideration when selecting the test or conditioning for the test

*Explanation for use of the table:*

If the package to be tested consists of a fibreboard outer box with a plastics primary receptacle, five samples must undergo the water spray test ( see 6.3.5.3.5.1) prior to dropping and another five must be conditioned to  $-18^{\circ}\text{C}$  (see 6.3.5.3.5.2) prior to dropping. If the package is to contain dry ice then one further single sample shall be dropped five times after conditioning in accordance with 6.3.5.3.5.3.

Packagings prepared as for transport shall be subjected to the tests in 6.3.5.3 and 6.3.5.4, which - for test purposes - categorizes packagings according to their material characteristics. For outer packagings, the headings in the table relate to fibreboard or similar materials whose performance may be rapidly affected by moisture; plastics which may embrittle at low temperature; and other materials such as metal whose performance is not affected by moisture or temperature.

**6.3.5.3 Drop test**

6.3.5.3.1 Samples shall be subjected to free-fall drops on to a rigid, non-resilient, flat, horizontal surface from a height of 9 m. Where the samples are in the shape of a box; five shall be dropped one each on the following attitude:

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

6.3.5.3.2 Where the samples are in the shape of a drum, three shall be dropped one in each of the following attitudes:

- (vi) diagonally on the top chime, with the centre of gravity directly above the point of impact;
- (vii) diagonally on the base chime;
- (viii) flat on the side.

6.3.5.3.3 The sample shall be released in the orientation, which for packagings in Chapter 6.1.3.5.1 would normally result in an impact on the specified point. It is accepted that over a free fall of 9 m the impact may not take place in that orientation.

6.3.5.3.4 Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by cushioning/absorbent material in the secondary packaging;

**6.3.5.3.5 Special preparation of test sample for the drop test**

*6.3.5.3.5.1 Fibreboard - The water spray test*

Fibreboard outer packagings: The sample shall be subjected to a water spray that simulates exposure to rainfall of approximately 5 cm per hour for at least one hour. It shall then be subjected to the test described in 6.3.5.3.1;

*6.3.5.3.5.2 Plastics material – Cold Conditioning*

Plastics primary receptacle or outer packagings: ~~The sample shall be conditioned in an atmosphere of -18 °C or less for a period of at least 24 hours. The temperature of the test sample and its contents shall be reduced to -18°C or lower~~ and within 15 minutes of removal from that atmosphere be subjected to the test described in 6.3.5.3.1. Where the sample contains dry ice, the conditioning period ~~may~~ shall be reduced to 4 hours;

6.3.5.3.5.3 *All packages containing dry ice*

Where the packaging is intended to contain dry ice, a test additional to that specified in 6.3.5.3.1 or 6.3.5.3.5.1 or 6.3.5.3.5.2) shall be carried out. One sample shall be stored so that all the dry ice dissipates and then that sample shall be dropped in one of the attitudes described in 6.3.5.3.1 which shall be that most likely to result in failure of the packaging.

**6.3.5.4** *Puncture test*

6.3.5.4.1 Packagings with a gross mass of 7 kg or less

Samples shall be placed on a level hard surface. A cylindrical steel rod with a mass of at least 7 kg, a diameter ~~not exceeding~~ 38 mm and the impact end edges a radius not exceeding 6 mm. The rod shall be dropped in a vertical free fall from a height of 1 m, measured from the impact end to the impact surface of the sample. One sample shall be placed on its base. A second sample shall be placed in an orientation perpendicular to that used for the first. In each instance the steel rod shall be aimed to impact the primary receptacle. Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s);

6.3.5.4.2 Packagings with a gross mass exceeding 7 kg

Samples shall be dropped on to the end of a cylindrical steel rod. The rod shall be set vertically in a level hard surface. It shall have a diameter ~~not exceeding~~ 38 mm and the edges of the upper end a radius not exceeding 6 mm. The rod shall protrude from the surface a distance at least equal to that between the centre of the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm. One sample shall be dropped with its top face lowermost in a vertical free fall from a height of 1 m, measured from the top of the steel rod. A second sample shall be dropped from the same height in an orientation perpendicular to that used for the first. In each instance the packaging shall be so orientated that the steel rod would be capable of penetrating the primary receptacle(s). Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s);

**6.3.5.5** *Test report*

6.3.5.5.1 A written test report containing at least the following particulars shall be drawn up and shall be available to the users of the packaging:

1. Name and address of the test facility;
2. Name and address of applicant (where appropriate);
3. A unique test report identification;
4. Date of the test and the report;
5. Manufacturer of the packaging;

6. Description of the packaging design type (e.g. dimensions, materials, closures, thickness, etc.), including method of manufacture (e.g. blow moulding) and which may include drawing(s) and/or photograph(s);
7. Maximum capacity;
8. The test contents;
9. Test descriptions and results;
10. The test report shall be signed with the name and status of the signatory.

6.3.5.5.2 The test report shall contain statements that the packaging prepared as for transport was tested in accordance with the appropriate requirements of this Chapter and that the use of other packaging methods or components may render it invalid. A copy of the test report shall be available to the competent authority.”

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### **Consequential amendments**

A number of amendments to 4.1.8 and 4.1.4.1 (P620 and P650) become necessary.

#### ***Amendments to 4.1.8***

4.1.8.1 This is a fundamental requirement of ALL packages. It could either be repeated, deleted or amended and added as a new sentence in 4.1.1.1.

4.1.8.2 The first sentence is a repeat of the note at the beginning of 4.1.1 and makes a small qualification. The second sentence is covered in Chapter 6.3 and IBCs are not permitted for UN 2814 and UN 2900.

#### **Suggested redraft of 4.1.8**

Assuming no significant changes, the following amendments to the current text of section 4.1.8 are proposed (new text is underlined):

- “**4.1.8 Special packing provisions for infectious substances of Category A (Division 6.2, UN 2814 and UN 2900)**
- 4.1.8.1 Consignors of infectious substances shall ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport.
- 4.1.8.2 The definitions in 1.2.1 and the general packing provisions of 4.1.1.1 to 4.1.1.14, except 4.1.1.10 to 4.1.1.12, apply to infectious substances packages. However, liquids shall only be filled into packagings, ~~including IBCs~~, which have an appropriate resistance to the internal pressure that may develop under normal conditions of transport.
- 4.1.8.3 For UN 2814 and UN 2900, an itemized list of contents shall be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown, but are suspected of meeting the criteria for inclusion in



Category A and assignment to UN 2814 or UN 2900, the words "suspected category A infectious substance" shall be shown, in parentheses, following the proper shipping name on the document inside the outer packaging.

- 4.1.8.4 Before an empty packaging is returned to the consignor, or sent elsewhere, it shall be ~~thoroughly~~ disinfected or sterilized ~~to nullify any hazard~~ to nullify any hazard and any label or marking indicating that it had contained an infectious substance shall be removed or obliterated.”.

4.1.8.5 Provided an equivalent level of performance is maintained, the following variations in the primary receptacles placed within a secondary packaging are allowed without further testing of the completed package:

(a) Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:

(i) The primary receptacles are of similar design to the test 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 stacking forces 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 take up void spaces and to prevent significant movement of the primary receptacles; and

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

(b) A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in (a) above, may be used provided sufficient cushioning is added to fill the void spaces(s) and to prevent significant movement of the primary receptacles.

**Amendments to 4.1.4.1, P620:**

**Amendments to 4.1.4.1:**

**P620** - In (a) (i) and (ii): Replace "watertight" with ["leaktight" or leakproof].

- Delete (b). Current (c) becomes new (b).

Under the heading “Additional requirements”:

- Para. 2(b): Replace “6.3.1.1” with “6.3.3” in the second sentence.

~~Para. 3 : Delete "and temperatures in the range -40 °C to +55 °C."~~

~~(This is the subject of a proposal from the expert from the United States (see ST/SG/AC.10/C.3/2005/33)).~~

~~Add a new paragraph 4 to read as follows:~~

~~"4. The primary receptacle and the secondary packaging used for infectious substances must be capable of withstanding without leakage temperatures in the range of -40°C to +55°C."~~

**P650 Proposal 1:**

Amend the first sentence of paragraph (6) as follows:

"The completed package shall be capable of successfully passing the drop test in ~~6.3.2.5~~ 6.3.5.3 as specified in ~~6.3.2.2 to 6.3.2.4~~ 6.3.5.2 of these Regulations at a height of 1.2 m.

~~**Proposal 2:**~~

~~Amend paragraph (6) to read as follows:~~

~~"The completed package shall be capable of successfully passing a drop test onto a rigid non resilient flat horizontal surface from a height of 1.2 metres. Where the package is in the shape of a box it shall be dropped five times (flat on the base, flat on the top, flat on longest side, flat on shortest side and onto a corner). Where the package is in the shape of drum three must be dropped diagonally onto the top chime, diagonally on to the bottom edge and flat on to a side. In either case where the outer is constructed of plastics material the sample must be conditioned to -18 °C or less for a period of at least twenty four hours before being dropped. The test shall be completed within 15 minutes of removal of the sample from the conditioning atmosphere."~~