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DANGEROUS GOODS PANEL (DGP)

MEETING OF THE WORKING GROUP OF THE WHOLE

Montreal, 18 to 22 April 2005

Agenda Item 2: Development of recommendations for amendments to the *Technical Instructions* for incorporation in the 2007/2008 edition
2.6: Part 6 — Packaging Nomenclature, Marking, Requirements and Tests

DRAFT AMENDMENTS TO THE TECHNICAL INSTRUCTIONS TO ALIGN TO THE UN RECOMMENDATIONS — PART 6

(Presented by the Secretary)

SUMMARY

Below are the draft amendments to Part 6 Chapters 4, 5 and 7 to reflect the decisions taken by the UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals at the second session (Geneva, 10 December 2004).

Chapter 4

PACKAGING PERFORMANCE TESTS

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4.1 PERFORMANCE AND FREQUENCY OF TESTS

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4.1.6 Reserved~~Where an outer packaging of a combination packaging has been successfully tested with different types of inner packagings, a variety of such different inner packagings may also be assembled in this outer packaging. In addition, provided an equivalent level of performance is maintained, the following variations in inner packagings are allowed without further testing of the package:~~

~~a) Inner packagings of equivalent or smaller size may be used provided:~~

~~1) the inner packagings are of similar design to the tested inner packagings (e.g. shape — round, rectangular, etc.);~~

~~2) the material of construction of the inner packagings (glass, plastics, metal, etc.) offers resistance to impact and stacking forces equal to or greater than that of the originally tested inner packaging;~~

~~3) the inner packagings have the same or smaller openings and the closure is of similar design (e.g. screw cap, friction lid, etc.);~~

~~4) sufficient additional cushioning material is used to take up void spaces and to prevent significant movement of the inner packagings; and~~

~~5) inner packagings are oriented within the outer packaging in the same manner as in the tested package.~~

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

Note.— For the conditions for assembling different inner packagings in an outer packaging and permissible variations in inner packagings, see 4.

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Chapter 5

REQUIREMENTS FOR THE CONSTRUCTION AND TESTING OF CYLINDERS, AEROSOL DISPENSERS AND SMALL RECEPTACLES CONTAINING GAS (GAS CARTRIDGES)

5.1 GENERAL REQUIREMENTS

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5.1.5 Periodic inspection and testing

5.1.5.1 Refillable cylinders must be subjected to periodic inspections and tests by a body authorized by the appropriate national authority, in accordance with the following:

a) Check of the external conditions of the cylinder and verification of the equipment and the external markings;

b) Check of the internal conditions of the cylinder (e.g. internal inspection, verification of minimum wall thickness);

c) Checking of the threads if there is evidence of corrosion or if the fittings are removed;

d) A hydraulic pressure test and, if necessary, verification of the characteristics of the material by suitable tests.

Note 1.— With the agreement of the appropriate national authority, the hydraulic pressure test may be replaced by a test using a gas, where such an operation does not entail any danger.

Note 2.— With the agreement of the appropriate national authority, the hydraulic pressure test of cylinders may be replaced by an equivalent method based on acoustic emission ~~or~~ testing, ultrasonic examination or a combination of acoustic emission testing and ultrasound examination.

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5.2 REQUIREMENTS FOR UN CYLINDERS

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5.2.1 Design, construction and initial inspection and testing

5.2.1.1 The following standards apply for the design, construction, and initial inspection and test of UN cylinders, except that inspection requirements related to the conformity assessment system and approval must be in accordance with 5.2.5:

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ISO 11119-3:2002	Gas cylinders of composite construction - Specification and test methods - Part 3: Fully wrapped fibre reinforced composite gas cylinders with non-load-sharing metallic or non-metallic liners.

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5.2.1.3 The following standards apply for the design, construction and initial inspection and test of UN acetylene cylinders except that inspection requirements related to the conformity assessment system and approval must be in accordance with 5.2.5.

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~~ISO 7866:1999 Gas cylinders — Refillable seamless aluminium alloy gas cylinders — Design, construction and testing.~~

~~*Note.— The note concerning the F factor in section 7.2 of this standard must not be applied for UN cylinders. Aluminium alloy 6351A — T6 or equivalent must not be authorized.*~~

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5.2.1.4 The following standard applies for the design, construction and initial inspection and test of UN cryogenic receptacles, except that inspection requirements related to the conformity assessment system and approval must be in accordance with 5.2.2.5:

ISO 21029-1:2004	Cryogenic vessels - Transportable vacuum insulated vessels of not more than 1000 l volume - Part 1: Design, fabrication, inspection and tests

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5.2.5 Conformity assessment system and approval for manufacture of cylinders

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5.2.5.3 *Manufacturer's quality system*

5.2.5.3.1 The quality system must contain all the elements, requirements, and provisions adopted by the manufacturer. It must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

The contents must in particular include adequate descriptions of:

a) the organizational structure~~,~~ and responsibilities~~, and power of the management~~ of personnel with regard to design and product quality;

b) the design control and design verification techniques, processes~~,~~ and ~~systematic actions~~ procedures that will be used when designing the cylinders;

c) the relevant cylinder manufacturing, quality control, quality assurance~~,~~ and process operation instructions that will be used;

d) quality records, such as inspection reports, test data~~,~~ and calibration data;

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5.2.5.4.10 *Modifications to approved design types*

The manufacturer must either:

a) inform the issuing appropriate national authority of modifications to the approved design type, where such modifications do not constitute a new design, as specified in the cylinder standard~~.~~; or

b) request ~~A~~ a subsequent design type approval ~~must be requested~~ where such modifications constitute a new design according to the relevant cylinder standard. This additional approval must be given in the form of an amendment to the original Design Type Approval Certificate.

5.2.5.4.11 Upon request, the appropriate national authority must communicate to any other appropriate national authority, information concerning design type approval, modifications of approvals, and withdrawn approvals.

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5.2.7 Marking of UN refillable cylinders

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5.2.7.2 The following operational marks must be applied:

f) The test pressure in bar, preceded by the letters "PH" and followed by the letters "BAR";

g) The mass of the empty cylinder including all permanently attached integral parts (e.g. neck ring, foot ring, etc.) in kilograms, followed by the letters "KG". This mass must not include the mass of valve, valve cap or valve guard, any coating, or porous mass for acetylene. The mass must be expressed to three significant figures rounded up to the last digit. For cylinders of less than 1 kg, the mass must be expressed to two significant figures rounded up to the last digit. In the case of pressure receptacles for UN 1001 acetylene, dissolved and UN 3374 acetylene, solvent free, at least one decimal must be shown after the decimal point and two digits for pressure receptacles of less than 1 kg;

h) The minimum guaranteed wall thickness of the cylinder in millimetres followed by the letters "MM". This mark is not required for cylinders with a water capacity less than or equal to 1 litre or for composite cylinders or for closed cryogenic receptacles;

i) In the case of cylinders for compressed gases, UN 1001 **Acetylene, dissolved**, and UN 3374 **Acetylene, solvent free**, the working pressure in bar, preceded by the letters "PW". In the case of closed cryogenic receptacles, the maximum allowable working pressure preceded by the letters "MAWP";

j) In the case of cylinders for liquefied gases and refrigerated liquefied gases, the water capacity in litres expressed to three significant figures rounded down to the last digit, followed by the letter "L". If the value of the minimum or nominal water capacity is an integer, the digits after the decimal point may be neglected;

k) In the case of cylinders for UN 1001 **Acetylene, dissolved**, the total of the mass of the empty receptacle, the fittings and accessories not removed during filling, any coating, the porous mass, the solvent and the saturation gas expressed to ~~two~~ three significant figures rounded down to the last digit followed by the letters "KG". At least one decimal shall be shown after the decimal point. For pressure receptacles of less than 1 kg, the mass shall be expressed to two significant figures rounded down to the last digit;

l) In the case of cylinders for UN 3374 **Acetylene, solvent free**, the total of the mass of the empty receptacle, the fittings and accessories not removed during filling, any coating, and the porous mass expressed to ~~two~~ three significant figures rounded down to the last digit followed by the letters "KG". At least one decimal shall be shown after the decimal point. For pressure receptacles of less than 1 kg, the mass shall be expressed to two significant figures rounded down to the last digit

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5.2.7.8 For acetylene cylinders, with the agreement of the appropriate authority, the date of the most recent periodic inspection and the stamp of the body performing the periodic inspection and test may be engraved on a ring held on the cylinder by the valve. The ring must be configured so that it can only be removed by disconnecting the valve from the cylinder.

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5.4 REQUIREMENTS FOR AEROSOL DISPENSERS AND SMALL RECEPTACLES CONTAINING GAS (GAS CARTRIDGES)

5.4.1 Small receptacles containing gas (gas cartridges)

5.4.1.1 Each receptacle must be subjected to a test performed in a hot water bath; the temperature of the bath and the duration of the test must be such that the internal pressure reaches that which would be reached at 55°C (50°C if the liquid phase does not exceed 95 per cent of the capacity of the receptacle at 50°C). If the contents are sensitive to heat or if the receptacles are made of plastics material which softens at this test temperature, the temperature of the bath must be set at between 20°C and 30°C but, in addition, one receptacle in 2 000 must be tested at the higher temperature.

5.4.1.2 No leakage or permanent deformation of a receptacle may occur, except that a plastic receptacle may be deformed through softening provided it does not leak.

5.4.2 Aerosol dispensers

Each filled aerosol dispenser must be subjected to a test performed in a hot water bath or an approved water bath alternative.

5.4.2.1 *Hot water bath test*

5.4.2.1.1 The temperature of the water bath and the duration of the test must be such that the internal pressure reaches that which would be reached at 55 °C (50 °C if the liquid phase does not exceed 95% of the capacity of the aerosol dispenser at 50 °C). If the contents are sensitive to heat or if the aerosol dispensers are made of plastics material which softens at this test temperature, the temperature of the bath must be set at between 20 °C and 30 °C but, in addition, one aerosol dispenser in 2000 must be tested at the higher temperature.

5.4.2.1.2 No leakage or permanent deformation of an aerosol dispenser may occur, except that a plastic aerosol dispenser may be deformed through softening provided that it does not leak.

5.4.2.2 *Alternative methods*

With the approval of the appropriate national authority alternative methods which provide an equivalent level of safety may be used provided that the requirements of 5.4.2.2.1, 5.4.2.2.2 and 5.4.2.2.3 are met.

5.4.2.2.1 *Quality system*

Aerosol dispenser fillers and component manufacturers must have a quality system. The quality system must implement procedures to ensure that all aerosol dispensers that leak or that are deformed are rejected and not offered for transport.

The quality system must include:

a) a description of the organizational structure and responsibilities;

b) the relevant inspection and test, quality control, quality assurance, and process operation instructions that will be used;

c) quality records, such as inspection reports, test data, calibration data and certificates;

d) management reviews to ensure the effective operation of the quality system;

e) a process for control of documents and their revision;

f) a means for control of non-conforming aerosol dispensers;

g) training programmes and qualification procedures for relevant personnel; and

h) procedures to ensure that there is no damage to the final product.

An initial audit and periodic audits must be conducted to the satisfaction of the competent authority. These audits must ensure the approved system is and remains adequate and efficient. Any proposed changes to the approved system must be notified to the competent authority in advance.

5.4.2.2.2 *Pressure and leak testing of aerosol dispensers before filling*

Every empty aerosol dispenser must be subjected to a pressure equal to or in excess of the maximum expected in the filled aerosol dispensers at 55 °C (50 °C if the liquid phase does not exceed 95% of the capacity of the receptacle at 50 °C). This must be at least two-thirds of the design pressure of the aerosol dispenser. If any aerosol dispenser shows evidence of leakage at a rate equal to or greater than 3.3×10^{-2} mbar.l.s^{-1} at the test pressure, distortion or other defect, it must be rejected.

5.4.2.2.3 *Testing of the aerosol dispensers after filling*

Prior to filling the filler must ensure that the crimping equipment is set appropriately and the specified propellant is used.

Each filled aerosol dispenser must be weighed and leak tested. The leak detection equipment must be sufficiently sensitive to detect at least a leak rate of 2.0×10^{-3} mbar.l.s^{-1} at 20 °C.

Any filled aerosol dispenser which shows evidence of leakage, deformation or excessive weight must be rejected.

5.4.3 With the approval of the appropriate national authority, aerosols and receptacles, small, containing pharmaceutical products and non flammable gases which are required to be sterile, but may be adversely affected by water bath testing, are not subject to 5.4.1 and 5.4.2 if:

a) They are manufactured under the authority of a national health administration and, if required by the competent authority, follow the principles of Good Manufacturing Practice (GMP) established by the World Health Organization (WHO)*; and

b) An equivalent level of safety is achieved by the manufacturer's use of alternative methods for leak detection and pressure resistance, such as helium detection and water bathing a statistical sample of at least 1 in 2000 from each production batch.

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Chapter 7

REQUIREMENTS FOR THE CONSTRUCTION, TESTING AND APPROVAL OF PACKAGES AND MATERIAL OF CLASS 7

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7.4 REQUIREMENTS FOR INDUSTRIAL PACKAGES

7.4.1 Industrial packages Types 1, 2 and 3 (Types IP-1, IP-2 and IP-3) must meet the requirements specified in 7.1, 7.2 and 7.6.2.

7.4.2 A Type IP-2 package must, if it were subjected to the tests specified in 7.14.4 and 7.14.5, prevent:

a) loss or dispersal of the radioactive contents; and
b) ~~loss of shielding integrity which would result in~~ more than a 20 per cent increase in the maximum radiation level at any external surface of the package.

7.4.3 A Type IP-3 package must meet all the requirements specified in 7.6.2 to 7.6.15.

7.4.4 Alternative requirements for Industrial packages Types 2 and 3 (Types IP-2 and IP-3)

7.4.4.1 Packages may be used as a Type IP-2 package, provided that:

a) they satisfy the requirements of 7.4.1;

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* WHO Publication: *Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Volume 2: Good manufacturing practices and inspection*.

b) they are designed to conform to the standards prescribed in Part 6, Chapter 3 or other requirements at least equivalent to those standards; and

c) when subjected to the tests required for Packing Group I or II in Part 6, Chapter 4, they would prevent:

i) loss or dispersal of the radioactive contents; and

ii) ~~loss of shielding integrity which would result in~~ more than a 20 per cent increase in the maximum radiation level at any external surface of the package.

7.4.4.2 Freight containers may also be used as Industrial package Types 2 or 3 (Types IP-2 or IP-3), provided that:

a) the radioactive contents are restricted to solid materials;

b) they satisfy the requirements of 7.4.1; and

c) they are designed to conform to ISO 1496-1:1990: "Series 1 Freight Containers — Specifications and Testing — Part 1: General Cargo Containers" excluding dimensions and ratings. They must be designed so that, if subjected to the tests prescribed in that document and to the accelerations occurring during routine conditions of transport, they would prevent:

i) loss or dispersal of the radioactive contents; and

ii) ~~loss of shielding integrity which would result in~~ more than a 20 per cent increase in the maximum radiation level at any external surface of the freight containers.

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7.6 REQUIREMENTS FOR TYPE A PACKAGES

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7.6.14 A package must be designed so that if it were subjected to the tests specified in 7.14, it would prevent:

a) loss or dispersal of the radioactive contents; and

b) ~~loss of shielding integrity which would result in~~ more than a 20 per cent increase in the maximum radiation level at any external surface of the package.

7.6.15 The design of a package intended for liquid radioactive material must make provision for ullage to accommodate variations in the temperature of the contents, dynamic effects and filling dynamics.

7.6.16 Type A packages to contain liquids

A Type A package designed to contain ~~liquids~~ liquid radioactive material must, in addition:

a) be adequate to meet the conditions specified in 7.6.14 a) if the package is subjected to the tests specified in 7.15; and

b) either

i) be provided with sufficient absorbent material to absorb twice the volume of the liquid contents. Such absorbent material must be suitably positioned so as to contact the liquid in the event of leakage; or

ii) be provided with a containment system composed of primary inner and secondary outer containment components, designed to ensure retention of the liquid contents within the secondary outer con-tainment components, even if the primary inner components leak.

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7.7 REQUIREMENTS FOR TYPE B(U) PACKAGES

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7.7.3 [To be developed.]

Editorial Note.— The following new 7.7.4 was originally 7.7.13.

7.7.4 In order to meet the requirements of 6.4.3.1, account may be taken of barriers or screens intended to give protection to persons without the need for the barriers or screens being subject to any test.

Editorial Note.— *Renumber* subsequent paragraphs accordingly.

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~~7.7.13 In order to meet the requirements of 6.4.3.1, account may be taken of barriers or screens intended to give protection to persons without the need for the barriers or screens being subject to any test.~~

7.7.14 A package containing low dispersible radioactive material must be designed so that any features added to the low dispersible radioactive material that are not part of it, or any internal components of the packaging must not adversely affect the performance of the low dispersible radioactive material.

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7.10 REQUIREMENTS FOR PACKAGES CONTAINING FISSILE MATERIAL

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7.10.2 Fissile material meeting one of the provisions in a) to d) below is excepted from the requirement to be transported in packages that comply with 7.10.3 to 7.10.12, as well as the other requirements of these Instructions that apply to fissile material. Only one type of exception is allowed per consignment:

a) A mass limit per consignment such that:

$$\frac{\text{mass of uranium\&235(g)}}{X} \% \frac{\text{mass of other fissile material (g)}}{Y} < 1$$

where X and Y are the mass limits defined in Table 6-5, provided that the smallest external dimension of each package is not less than 10 cm and that either:

i) each individual package contains not more than 15 g of fissile material;

ii) the fissile material is a homogeneous hydrogenous solution or mixture where the ratio of fissile nuclides to hydrogen is less than 5 per cent by mass; or

iii) there ~~is~~are not more than 5 g of fissile material in any 10 L volume of material.

[Neither beryllium nor deuterium in hydrogeneous material enriched in deuterium must be present in quantities exceeding 1 per cent of the applicable consignment mass limits provided in Table 6-5.]

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7.10.7 For a package in isolation, it must be assumed that water can leak into or out of all void spaces of the package, including those within the containment system. However, if the design incorporates special features to prevent such leakage of water into or out of certain void spaces, even as a result of error, absence of leakage may be assumed in respect of those void spaces. Special features must include the following:

a) multiple high standard water barriers, each of which would remain watertight if the package were subject to the tests prescribed in 7.10.12 b), a high degree of quality control in the manufacture, maintenance and repair of packagings and tests to demonstrate the closure of each package before each shipment; or

Table 6-5. Consignment mass limits for exceptions from the requirements for packages containing fissile material

Fissile material	*Fissile material mass (g) mixed with substances having an average hydrogen density less than or equal to water*	*Fissile material mass (g) mixed with substances having an average hydrogen density greater than water*
Uranium !235 (X) Other fissile material (Y)	400250	290180

b) for packages containing uranium hexafluoride only, with maximum enrichment of 5 mass per cent uranium-235:

i) packages where, following the tests prescribed in 7.10.12 b), there is no physical contact between the valve and any other component of the packaging other than at its original point of attachment and where, in addition, following the test prescribed in 7.16.3, the valves remain leaktight; and

ii) a high degree of quality control in the manufacture, maintenance and repair of packagings coupled with tests to demonstrate closure of each package before each shipment.

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7.21 APPROVALS OF PACKAGE DESIGNS AND MATERIALS

7.21.1 The approval of designs for packages containing 0.1 kg or more of uranium hexafluoride requires that:

a) ~~after 31 December 2000,~~ each design that meets the requirements of 7.5.4 must require multilateral approval;

b) ~~after 31 December 2003,~~ each design that meets the requirements of 7.5.1 to 7.5.3 must require unilateral approval by the competent authority of the State of Origin of the design , unless multilateral approval is otherwise required by these Instructions.

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