International Civil Aviation Organization

WORKING PAPER

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English only

DANGEROUS GOODS PANEL (DGP)

TWENTY-FOURTH MEETING

Montréal, 28 October to 8 November 2013

Agenda Item 2: Development of recommendations for amendments to the *Technical Instructions for the Safe Transport of Dangerous Goods by Air* (Doc 9284) for incorporation in the 2015-2016 Edition

REQUIREMENTS FOR MEDICAL DEVICES OR EQUIPMENT

(Presented by the Dangerous Goods Advisory Council (DGAC))

SUMMARY

This proposal would address previous concerns the DGP has identified concerning multimodal requirements applicable to medical devices and equipment in the *UN Model Regulations* paragraph 2.6.3.2.3.7.

Action by the DGP: The DGP is invited to consider amending Part 2;6.3.2.3.7 of the Technical Instructions as shown in the appendix to this working paper.

1. INTRODUCTION

1.1 Following the introduction of new provisions for medical equipment potentially contaminated with or containing infectious substances in the 17th edition of the *UN Model Regulations*, the panel raised certain issues with respect to the new UN text. In particular, the panel (see paragraph 2.3.5 of the DGP/23 report) was concerned with the following:

— The UN text did not preclude medical equipment that had the potential for puncturing the packaging; and

— The UN text requires the packaging to be capable of withstanding a 1.2 meter drop test and this could be interpreted as meaning drop tests involving expensive equipment was required to satisfy this requirement.

1.2 To maintain harmony with the *UN Model Regulations*, DGAC recommends that the UN wording remain unchanged in the next edition of the Technical Instructions. DGAC recommends that resolution of the DGP's concerns be resolved in a two step process:

a) To account for the concerns of the panel, it is DGAC's recommendation that additional measures be included in the Technical Instructions to specifically address the DGP's concerns. This would be consistent with the corresponding UN text which states in 2.6.3.2.3.7, "For air transport, additional requirements may apply." This could provide a satisfactory solution in an interim period until such time as the UN text is revised to further address the DGP's concerns.

b) After completing work on the amendments to the 2015-2016 Edition of the Technical Instruction, the DGP could ask the UN Subcommittee to make additional changes (e.g. applying additional packaging requirements to such used medical equipment in place of the 1.2 meter drop requirement).

1.3 **Equipment with a potential for puncture.** To address the concerns for this type of equipment, DGAC recommends adding text as follows:

"For medical devices or equipment capable of cutting or penetrating skin or packaging material, the primary container must be capable of retaining the product without puncture of the packaging under normal conditions of transport."

This requirement is already in the DOT regulations.

1.4 **The 1.2 meter drop test capability requirement.** DGAC understands from UN Subcommittee discussions that the Subcommittee did not intend for consignors to drop test medical equipment (e.g. blood analysers for the Red Cross and dialysis equipment) with values in excess of $2M dollars to demonstrate compliance with this requirement. However, given the requirement, enforcement personnel are likely to ask how the consignor knows the requirement is met and corporate attorneys of the consignor are likely to insist on a legally valid approach to ensure compliance. To address these concerns DGAC recommends strengthening the packaging requirements such that the packaging may be deemed as being capable of meeting the 1.2 meter drop test. Additional packaging requirements would include:

a) medical devices or equipment must be drained of free liquid to the extent practicable and placed in a watertight primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation;

b) each primary container must be placed inside a watertight secondary container; and

c) the secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging.

DGAC considers that these additional requirements would result in a robust packaging for medical equipment. On the basis that the outer packaging is rigid and meets the construction requirements of Part 6;3, it is DGAC's opinion that such a package could be deemed as meeting the 1.2 meter drop requirement. This could be clarified with the inclusion of a new note following the 1.2 meter drop requirement stating:

"Note. - A completed packaging that includes a rigid outer packaging is deemed as being capable of meeting this requirement without the need for further evaluation."

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APPENDIX

PROPOSED AMENDMENT TO PART 2 OF THE TECHNICAL INSTRUCTIONS

Part 2

CLASSIFICATION OF DANGEROUS GOODS

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Chapter 6

CLASS 6 — TOXIC AND INFECTIOUS SUBSTANCES

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6.3 DIVISION 6.2 — INFECTIOUS SUBSTANCES

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6.3.2 Classification of infectious substances

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6.3.2.3.7 Except for:

a) medical waste (UN 3291);

b) medical devices or equipment contaminated with or containing infectious substances in Category A (UN 2814 or UN 2900); and

c) medical devices or equipment contaminated with or containing other dangerous goods that meet the definition of another hazard class,

medical devices or equipment potentially contaminated with or containing infectious substances which are being transported for disinfection, cleaning, sterilization, repair, or equipment evaluation are not subject to the provisions of these Instructions if packed in packagings designed and constructed in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents. Packagings must be designed to meet the construction requirements listed in 6;3.

6.3.2.3.7.1 Medical devices or equipment must be drained of free liquid to the extent practicable and placed in a watertight primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. For medical devices or equipment capable of cutting or penetrating skin or packaging material, the primary container must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be placed inside a watertight secondary container. The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. These packagings must meet the general packing requirements of 4;1.1.1, 4;1.1.3.1 and 4;1.1.4 (with the exception of 4;1.1.4.1). If the outer packaging is not liquid tight and the medical devices or equipment are contaminated with or contain liquid infectious substances, a means of containing the liquid in the event of leakage must be provided in the form of a leakproof liner, plastic bag or other equally effective means of containment. These packagings must be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m.

Note.— A completed packaging that includes a rigid outer packaging is deemed as being capable of meeting this requirement without the need for further evaluation.

6.3.2.3.7.2 Packages must be marked “Used medical device” or “Used medical equipment”. When an overpack is used, it must be marked with the words “Used medical device” or “Used medical equipment” unless the markings are visible.

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