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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Transport of Dangerous Goods

Forty-fourth session
Geneva, 25 November – 4 December 2013
Item 5 (c) of the provisional agenda
Miscellaneous proposals for amendments to the Model Regulations on the Transport of Dangerous Goods: used medical devices

Used medical devices or equipment

Transmitted by the Council on Safe Transportation of Hazardous Articles (COSTHA)[1]

Introduction

1. At its thirty-eight session, the Sub-Committee agreed to a transport exception for used medical devices and equipment potentially contaminated with or containing infections substances being transported for disinfection, cleaning, sterilization, repair or equipment evaluation. The adopted conditions, including the packaging requirements, are included in the 18th revised edition of the Recommendations on the Transport of Dangerous Goods Model Regulations, in 2.6.3.2.3.9.

2. As a condition of this exception from the Model Regulations, 2.6.3.2.3.9 requires the medical devices or equipment to be packed in packagings designed to meet the construction requirements of 6.1.4 or 6.6.5. Additionally, the packagings must meet the general packing requirements of 4.1.1.1 and 4.1.1.2 and be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m.

3. Since the adoption of this text, there have been numerous discussions in previous meetings on issues raised concerning the following elements:

4. The Model Regulations requires packaging used to be capable of withstanding a 1.2 meter drop test which has been interpreted by COSTHA members and the medical device

[1] In accordance with the programme of work of the Sub-Committee for 2013–2014 approved by the Committee at its sixth session (see ST/SG/AC.10/C.3/84, para. 86 and ST/SG/AC.10/40, para. 14).

and equipment community as meaning that expensive devices and equipment are required to be used to meet this requirement during the drop performance tests. In addition, requiring medical devices and equipment to be used in an actual drop test could damage delicate components within the instruments which may not be detected and/or affect patient safety.

5. ICAO has voiced concerns that medical devices and equipment capable of puncturing the packaging is not adequately addressed in the current provisions.

6. To address these issues, COSTHA suggests three possible options.

Proposal

7. **Option 1**: Insert a clarifying note explaining the device or equipment may be substituted with an alternate medium during the drop test.

2.6.3.2.3.9 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 Regulations 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 shall be designed to meet the construction requirements listed in 6.1.4 or 6.6.5.

These packagings shall meet the general packing requirements of 4.1.1.1 and 4.1.1.2 and be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m. For air transport, additional requirements may apply. (Note: Actual medical devices or equipment are not required to be used when conducting the drop test, if an article of equivalent mass and weight is used in its place for the testing.)

The packagings shall be marked "USED MEDICAL DEVICE" or "USED MEDICAL EQUIPMENT". When using overpacks, these shall be marked in the same way, except when the inscription remains visible.

8. **Option 2:** Enhance packaging requirements to require a more robust packaging system for medical devices and equipment and eliminate the 1.2 meter drop test. This would address ICAO's concern regarding medical devices and equipment capable of puncturing the packaging. The text proposed is based on the language contained within the current Packing Instruction 650, which would be the applicable packing instruction if the devices and equipment were not eligible for the exception.

2.6.3.2.3.9 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 Regulations if packed in packagings ~~designed and~~ constructed and closed in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents.

Medical devices and equipment containing liquids shall be drained of free liquid to the extent practicable and placed into a packaging consisting of at least three components:

(a) A leakproof primary receptacle. For medical devices and equipment capable of cutting or penetrating skin or packaging material, the primary receptacle shall be capable of retaining the device or equipment without puncture of the receptacle under normal conditions of transport.

(b) A leakproof secondary packaging.

(c) An outer packaging.

(d) Secondary packaging shall be secured with suitable cushioning material.

(e) Absorbent material shall be placed between the primary receptacle and the secondary packaging or between the secondary receptacle and the outer packaging. The absorbent material shall be in quantity sufficient to absorb the remaining free liquid contained within the medical device or equipment.

Packagings shall be designed to meet the construction requirements listed in 6.1.4 or 6.6.5.

These packagings shall meet the general packing requirements of 4.1.1.1 and 4.1.1.2. ~~and be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m~~. For air transport, additional requirements may apply.

The outer packagings shall be marked "USED MEDICAL DEVICE" or "USED MEDICAL EQUIPMENT". ~~When using overpacks, these shall be marked in the same way, except when the inscription remains visible.~~ When packages are placed in an overpack, the package markings shall be either clearly visible or be reproduced on the outside of the overpack.

9. **Option 3**: Remove the drop test from the used medical and equipment packaging requirements. This option does not address the concerns voiced by ICAO. Instead it simply removes the 1.2 m drop test requirement.

2.6.3.2.3.9 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 Regulations 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 shall be designed to meet the construction requirements listed in 6.1.4 or 6.6.5.

These packagings shall meet the general packing requirements of 4.1.1.1 and 4.1.1.2 ~~and be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m~~. For air transport, additional requirements may apply.

10. The packagings shall be marked “USED MEDICAL DEVICE” or “USED MEDICAL EQUIPMENT”. When using overpacks, these shall be marked in the same way, except when the inscription remains visible.