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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-first session
Geneva, 25 June – 4 July 2012
Item 3 (b) of the provisional agenda
Listing, classification and packing: miscellaneous

Used health care devices or equipment

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

Introduction

1. At its 38th session, the Sub-Committee agreed to transport exceptions for used medical devices potentially contaminated with or containing infectious substances being transported for disinfection, cleaning, sterilization, repair or equipment evaluation. The adopted conditions, including packing requirements are included in the 17th revised edition of the Recommendations on the Transport of Dangerous Goods, Model Regulations, in 2.6.3.2.3.7.

2. As a condition of exception from the Model Regulations, 2.6.3.2.3.7 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.

Drop requirement

3. COSTHA members have voiced concern over the 1.2 m drop requirement for larger medical devices and equipment. These devices can have a mass exceeding 50 kg or larger

[1] In accordance with the programme of work of the Sub-Committee for 2011-2012 approved by the Committee at its fifth session (refer to ST/SG/AC.10/C.3/76, para. 116 and ST/SG/AC.10/38, para. 16).

and are extremely expensive in most cases. Performing a drop test using such equipment would likely irreparably damage the device and render it useless.

4. Although the requirement in 2.6.3.2.3.7 does not specifically state the drop test must be performed, without testing there is little proof that packaging would be capable of containing the equipment. COSTHA members are concerned that without performing the drop test with subject equipment or devices in possible packaging, regulatory agencies will deem the packaging non-compliant.

5. The Model Regulations provide limited exceptions for the packing of larger devices and pieces of equipment. For example, in Packing Instruction P903 applicable to large format batteries, the following exception is provided:

> *(2) In addition for cells or batteries with a gross mass of 12 kg or more employing a strong, impact resistant outer casing, and assemblies of such cells or batteries:*
>
> *(a) Strong outer packaging, in protective enclosures (e.g., in fully enclosed or wooden slatted crates); or*
>
> *(b) Pallets or other handling devices.*

6. Similar language is also found in Packing instruction P801 for Batteries, wet, spillable.

7. Given these devices or equipment can be quite large, are often extremely expensive, and are sensitive equipment, COSTHA believes an exception from the 1.2 m drop should be given to “large” pieces of equipment enclosed within impact resistant outer casings and packed in strong outer packagings, protective enclosures, pallets, or other handling devices.

Proposal

8. COSTHA proposes the addition of the following paragraph in 2.6.3.2.3.7:

> [existing text]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.
>
> [new text] For used medical devices or equipment having a gross mass greater than 12 kg, the 1.2 m drop requirement is not required provide the used medical device or equipment employ impact resistant outer casings, and are packed using:
>
> (a) Strong outer packaging, in protective enclosures (e.g., in fully enclosed or wooden slatted crates); or
>
> (b) Pallets or other handling devices.