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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-third session
Geneva, 24 June–28 June 2013
Item 6 (c) of the provisional agenda
Miscellaneous proposals for amendments to the Model Regulations on the Transport of Dangerous Goods: used medical devices

Used health care devices or equipment

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

Introduction

1. At its thirty-eighth 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 seventeenth revised edition of the Recommendations in 2.6.3.2.3.7 of the Model Regulations.

2. During the forty-first and the forty-second sessions practical concerns regarding implementation of conditions in the exceptions were raised by COSTHA. In particular, the 1.2 m drop requirement for packaging presented problems for the transport of large medical devices (ST/SG/AC.10/C.3/2012/31). At the forty-second session, the Sub-Committee discussed the matter in greater depth while reviewing proposals to reorganize the exceptions contained in 2.6.3.2.3.7. The Sub-Committee decided against the reorganization proposal in ST/SG/AC.10/C.3/2012/84. Yet several members of the Sub-Committee voiced interest in the addressing the 1.2 m drop test for large medical devices.

3. 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 6.6.4. Additionally, the packagings must meet the general packing

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

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

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. During the previous discussions of the issue during the forty-first and the forty-second sessions, several delegations noted that the original intent of the capability test was to ensure contaminated fluids held within the device would not be released through breakage or leakage. Thus a capability requirement was included to make sure any drop of up to 1.2 m would not lead to a breakage of internal device parts.

6. COSTHA agrees with the previous comments by the Sub-Committee that the drop test capability requirement is not to prove that the packaging will survive a drop test, but instead to prove that the internal components of the medical device will not break during such a test. The only way to positively prove this condition is to perform the test. Testing packaging that does not contain the medical devices will not prove protection of the internal components of the actual device.

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

8. 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

9. 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:
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> (a) Strong outer packaging, in protective enclosures (e.g., in fully enclosed or wooden slatted crates); or
>
> (b) Pallets or other handling devices.

10. Alternately, COSTHA proposes the 1.2 m drop test capability be eliminated for all medical devices:

> [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.