



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

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Item 3 of the provisional agenda

Listing, classification and packing

Used medical devices containing lithium batteries

Transmitted by the Council on the Safe Transportation of Hazardous Articles (COSTHA)*

I. Introduction

1. At the sixty-third session of the Sub-Committee, delegations met to discuss challenges currently associated with infectious substances. One of the topics of this discussion was that COSTHA and the Dangerous Goods Trainers Association (DGTA) would propose revisions to the used medical device exemption in 2.6.3.2.3.9 of the *Model Regulations*.

2. The used medical device exemption in 2.6.3.2.3.9 does not include provisions for lithium batteries. Therefore, when a used medical device containing lithium batteries is being shipped for disinfection, repair, etc., the material must be shipped as UN 3373 (BIOLOGICAL SUBSTANCE, CATEGORY B). This document proposes amendments to 2.6.3.2.9.

II. Background

3. Industry partners have recorded various complications when transporting used medical devices containing lithium batteries when they are being shipped for disinfection, cleaning, sterilization, repair, or equipment evaluation due to the lack of provisions for lithium batteries within the provisions of 2.6.3.2.9.

4. The used medical device exemption in 2.6.3.2.3.9 currently states:

“2.6.3.2.3.9 Except for:

- (a) Medical waste (UN Nos. 3291 and 3549);
- (b) Medical devices or equipment contaminated with or containing infectious substances in Category A (UN Nos. 2814 or 2900); and

* A/78/6 (Sect. 20), table 20.5.



- (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.

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."

5. As the text is currently written, lithium ion batteries and lithium metal batteries installed in medical devices that are being transported for disinfection, cleaning, sterilization, repair, or equipment evaluation disqualify the devices from the exception as lithium batteries installed in equipment is not listed in the introduction to the exception. Therefore the devices are consequently assigned to UN 3373 (BIOLOGICAL SUBSTANCE, CATEGORY B) in accordance with the requirements of 2.6.3.2.2.2.

III. Discussion

6. Lack of provisions for used medical devices containing lithium batteries leads to the misclassification of materials by the shipper. These lithium batteries are tested in accordance with section 38.3 of the *Manual of Tests and Criteria*. Due to these testing requirements, provisions for used medical devices containing lithium batteries when they are being shipped for disinfection, cleaning, sterilization, repair, or equipment evaluation should be included within 2.6.3.2.3.9 to allow the materials to be assigned to UN 3481 (LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT or LITHIUM ION BATTERIES PACKED WITH EQUIPMENT) or UN 3091 (LITHIUM METAL BATTERIES CONTAINED IN EQUIPMENT or LITHIUM METAL BATTERIES PACKED WITH EQUIPMENT), as applicable.

IV. Proposal

7. COSTHA proposes the addition of the following new text at the end of 2.6.3.2.3.9, to include provisions for lithium batteries intended for use within medical devices which are being transported for disinfection, cleaning, sterilization, repair, or equipment evaluation:

“Lithium ion batteries and lithium metal batteries intended for use within medical devices which are being transported for disinfection, cleaning, sterilization, repair, or equipment evaluation shall be assigned to UN 3481 or UN 3091.

NOTE 1: *The proper shipping name for UN 3481 is LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT or LITHIUM ION BATTERIES PACKED WITH EQUIPMENT. The proper shipping name for UN 3091 is LITHIUM METAL BATTERIES CONTAINED IN EQUIPMENT or LITHIUM METAL BATTERIES PACKED WITH EQUIPMENT.*

NOTE 2: *Lithium ion batteries and lithium metal batteries intended for use within medical devices which are being transported for disinfection, cleaning, sterilization, repair, or equipment evaluation must be tested in accordance with section 38.3 of the "Manual of Tests and Criteria".*”