United Nations ECE/TRANS/WP.15/AC.1/2010/57

Economic and Social Council

Distr.: General
19 July 2010
English
Original: French

Economic Commission for Europe

Inland Transport Committee

Working Party on the Transport of Dangerous Goods

Joint Meeting of the RID Committee of Experts and the Working Party on the Transport of Dangerous Goods

Geneva, 13–17 September 2010
Item 5 (a) of the provisional agenda
Miscellaneous proposals for amendments to RID/ADR/ADN – Pending issues

Insertion of a provision simplifying the carriage of contaminated medical devices

Transmitted by the Government of Germany[1, 2, 3]

Summary

Executive summary:	Simplification of the carriage of contaminated medical devices for purposes of disinfection, cleaning or sterilization, to facilitate their reuse.
Action to be taken:	Include an additional subsection in section 2.2.62.
Related documents:	Document ECE/TRANS/WP.15/AC.1/2010/33 (OTIF/RID/RC/2010/33) as well as the report of the most recent Joint Meeting, ECE/TRANS/WP.15/AC.1/118 (OTIF/RID/RC/2010-A), paragraph 38.

[1] The present document was returned to the ECE Transport Division by the Documents Management Section because it contained editorial errors. It has therefore been resubmitted.

[2] In accordance with the programme of work of the Inland Transport Committee for 2006–2010 (ECE/TRANS/166/Add.1, programme activity 02.7 (c)).

[3] Circulated by the Intergovernmental Organisation for International Carriage by Rail (OTIF) under the symbol OTIF/RID/RC/2010/57.

Introduction

1. At the most recent Joint Meeting (Bern, 22–26 March 2010), Germany proposed the insertion of a provision simplifying the carriage of contaminated medical devices [see document ECE/TRANS/WP.15/AC.1/2010/33 (OTIF/RID/RC/2010/33) as well as the report of the most recent Joint Meeting, ECE/TRANS/WP.15/AC.1/118 (OTIF/RID/RC/2010-A), paragraph 38].

2. Germany's proposal for the insertion of a new 2.2.62.1.5.7 was the subject of comments by a number of delegations. Delegations were asked to transmit further comments to the representative of Germany, if necessary after the Joint Meeting as well, so that a draft multilateral agreement could be prepared. Germany also announced that it would submit a fresh proposal to the Joint Meeting.

3. The comments have been incorporated to a great extent in the reworked proposal.

Background

4. There is an increasing tendency among medical practices and hospitals not to carry out the disinfection, cleaning or sterilization of their used medical instruments/medical devices themselves, but to assign these tasks to external service providers. As a result, a number of questions arise as to how the resulting transport operations can be carried out in a safe but at the same time feasible manner and with reasonable effort.

5. Such used and contaminated instruments are placed into metal sieves after use and are carried in tightly closed metal receptacles.

6. With regard to the risk of infection, which cannot be ruled out entirely, such contaminated medical devices are comparable to wastes assigned to waste code 18 01 04 (according to the European Waste Catalogue – EWC) and do not require a stricter classification. They can therefore be exempted from the provisions of RID/ADR if certain conditions are met.

7. If there is any potential danger, it consists in the possibility of cutting injuries from sharp instruments. Therefore such instruments require carriage in rigid, puncture-resistant receptacles protected against any unauthorized opening.

Proposal

8. Include a new subsection 2.2.62.1.5.7, as follows:

[*Note*: The amendments made to the original proposal, ECE/TRANS/ WP.15/AC.1/2010/33 (OTIF/RID/RC/2010/33), are indicated with underlining or strikethrough text.]

> "**2.2.62.1.5.7** Contaminated medical devices (such as surgical instruments) which are carried for purposes of disinfection, cleaning or sterilization and ~~for~~ before their subsequent reuse following their use ~~in medical facilities~~ are not subject to the provisions of RID/ADR if packed in rigid, puncture-resistant packagings of metal or plastic, which must be designed to meet the construction requirements listed in 6.1.4 and to be protected against any unauthorized opening. The packagings shall bear a written description of the contents ("contaminated medical devices"). In the event that overpacks are used, they shall be marked in the same way, unless the marking remains visible. The packagings shall satisfy the general packing provisions of 4.1.1.1 and 4.1.1.2, ~~4.1.1.4 and 4.1.1.8 and of 4.1.3~~ and shall be capable of successfully passing the drop test as described in 6.3.5.3 as specified in 6.3.5.2 at a

drop height of 1.20 m. Following the appropriate drop sequence, no item shall have punctured the wall from within the packagings, and there shall be no leakage of liquid. The packagings shall be able to be cleaned and disinfected. The provisions of Chapters 1.1, 1.2, 1.3, 1.4, 1.5, 1.6 and 1.8, Part 2, and sections 7.5.1 (apart from subsection 7.5.1.4), 7.5.7 and 7.5.8 shall remain applicable.

This exemption shall not apply to contaminated medical devices containing infectious substances in Category A. These devices shall be assigned to UN No. 2814 or 2900.

Note: This provision shall not apply to medical devices contaminated or filled with other dangerous goods that meet the definition of another class."

Justification

6. The proposed subsection would ensure that contaminated medical devices are carried in puncture-resistant, tightly closed receptacles. In the event of an accident, the risk of injury to human beings or animals is thus reduced. The risk of infection can be considered extremely low and is comparable to the risk associated with wastes assigned to waste code 18 01 04 according to EWC; therefore the packing provisions provided for such wastes are sufficient in this respect also.

7. Since the term "medical device" can refer to a wide range of different medical devices and accessories, which may be contaminated or filled with other dangerous goods (such as corrosive, toxic or flammable liquids, solids or gases) in individual cases, the note clarifies that the simplified new provision of 2.2.62.1.5.7 shall not apply to such cases.

8. Hence adverse effects on safety are not to be expected.