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Item 5 (a) of the provisional agenda
Proposals for amendments to RID/ADR/ADN
Pending issues

Proposal to amend RID/ADR/ADN to include a simplified provision for the carriage of contaminated medical devices

Transmitted by the Government of Germany[1, 2]

Summary

Executive summary:	Simplification of the carriage of contaminated medical devices for purposes of disinfection, cleaning or sterilization, to facilitate their reuse.
Decision to be taken:	Include an additional subsection in section 2.2.62.
Related documents:	Replaces document ECE/TRANS/WP.15/AC.1/2009/11-OTIF/RID/RC/2009/11.

[1] 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)).

[2] Circulated by the Intergovernmental Organisation for International Carriage by Rail (OTIF) under the symbol OTIF/RID/RC/2010/33.

Introduction

1. 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.

Background

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

3. 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.

4. 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

5. Include a new subsection 2.2.62.1.5.7, as follows:

> "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 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. 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, 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.
>
> **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.