



**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-second session**

Geneva, 3 – 11 December 2012

Item 2 (d) of the provisional agenda

**Recommendations made by the Sub-Committee on its thirty-ninth,
fortieth and forty-first sessions and pending issues:****miscellaneous proposals for amendments to the Model Regulations on the Transport of Dangerous Goods****Used medical devices****Transmitted by the Council on Safe Transportation of Hazardous
Articles (COSTHA)¹****Introduction**

1. At its thirty-eight session, the Sub-Committee adopted provisions to allow for equipment which is surface-contaminated with potentially infectious pathogens and devices containing small amounts of free liquid which may contain potentially infectious pathogens to be exempted from many provisions of the Model Regulations. These changes were published in the 17th Revised Edition of the Recommendations on the Transport of Dangerous Goods, Model Regulations in 2.6.3.2.3.7.

2. The basis for much of the language in 2.6.3.2.3.7 was recently agreed language from the Joint Meeting (ADR/RID) regarding equipment which is surface-contaminated with potentially infectious pathogens such as scalpels, sharps, etc. which needed to be transported for decontamination or disposal.

3. Since adoption, a number of issues have been raised by delegations concerning the language. Specifically, the International Civil Aviation Organization (ICAO) noted concern in ST/SG/AC.10/C.3/2012/24 with the provisions in 2.6.3.2.3.7, as did COSTHA in ST/SG/AC.10/C.3/2012/2012/31. Both of these documents raise issues of how devices

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)

containing free liquid which may contain potentially infectious pathogens are appropriately packaged and hazards communicated during transportation.

Separation of surface-contaminated and containing free liquid

4. Whether a device or piece of equipment is surface-contaminated with an infectious pathogen can have a significant impact on how a material needs to be packaged. If no liquids are present, then packaging need only contain the equipment while it is in transport. However, if liquids are present, the packaging must ensure the liquid cannot leak outside the packaging.
5. The current language in 2.6.3.2.3.7 addresses concerns of surface-contaminated equipment. However, conditions such as “water tight” or “leak tight” are not appropriately emphasized. Packaging must be designed in such a way that under normal conditions of transport, the packaging cannot break, be punctured, or leak their contents. We believe additional clarity is necessary.
6. As pointed out in 2012/31, the concept of dropping a 500 kg, \$1.2 Million device 1.2 meters to determine if the packaging will survive is not realistic. But even if an exception were provided for larger devices, the concern is whether the vials and tubes within the device will fail. Thus, a packaging drop test capability is irrelevant.
7. COSTHA believes the conditions in 2.6.3.2.3.7 are appropriate for surface-contaminated equipment. However, separate conditions should be provided for used medical equipment containing free liquid which may contain potentially infectious pathogens. These devices present an extremely low risk to transport workers, but preventing any free liquid from being released even if the device were damaged is important. Further, COSTHA continues to believe hazard communication within the package is valuable to transportation workers who may encounter an opened or damaged package.

Justification

8. Due the differing natures of surface-contaminated materials versus free liquid contained within a medical device, packaging should be addressed separately.
9. Packaging for Used Medical Devices containing free liquid should consist of both inner and outer packaging. Essentially this system results in 3 layers of protection: 1) the device itself, 2) inner packaging, and 3) outer packaging. The inner packaging should consist of a water-tight or leak proof packaging which will capture all free liquids if the device should break or leak any free liquid. Further, the inner packaging must be designed not to break, be punctured, or leak their contents into the outer packaging. This requirement would limit the ability for sharps to be placed directly into the inner packaging.
10. The inner packaging should be contained within an outer packaging. The inner should be surrounded by cushioning material to prevent damage to inner packagings or the contained device. Inner and outer packagings should be constructed to meet construction standards listed in 6.1.4 and 6.6.4.
11. To communicate possible hazards to transportation workers who may come in contact with open or damaged packaging, COSTHA recommends including language on the inside of the package. The words “USED MEDICAL DEVICE, USE APPROPRIATE PRECAUTIONS” would adequately communicate to handlers possible hazards associated

with the devices contained within. Such an inner packaging marking is not without precedent in the Model Regulations. Radioactive Material in Excepted Packages includes a marking which is to be visible upon opening the package. The word "RADIOACTIVE" is not intended to communicate a hazard during transport, but instead provides handlers of damaged or opened packages the knowledge that radioactive materials are contained within.

12. COSTHA also believes a packing list indicating the potential hazards represented by the free liquid contained within the device should be included within the outer packaging. In the event that the outer packaging is damaged, handlers can use such a packing list to determine appropriate response and repackaging procedures.

Proposals

13. Given the concerns voiced by ICAO and the need for additional clarity, COSTHA believes several proposals are warranted.

Proposal 1

14. Add the following definition to 2.6.3.1:

Used health care device or equipment means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers. A health care product is "used" when it has been removed from its original packaging. It can be contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transport. Health care devices or equipment contaminated with or suspected of contamination with a Category A infectious substance shall not be transported as a used health care device or equipment.

Proposal 2

15. Modify the existing 2.6.3.2.3.7 to address equipment surface-contaminated with a potentially infectious pathogen.

2.6.3.2.3.7

Except for:

- Medical waste (UN3291),
- Medical devices or equipment contaminated with or containing infectious substances in Category A (UN2814 or UN2900), or
- Medical devices or equipment contaminated with or containing other dangerous goods that meet the definition of another hazard class.

(a) Used in Medical devices or equipment potentially surface-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~~ release their contents. Packagings shall be designed to meet the construction requirements listed in 6.1.4 or 6.6.45.

(b) 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.

(c) The packagings shall be marked “USED MEDICAL DEVICE” or “USED MEDICAL EQUIPMENT”. When using overpacks, they shall be marked in the same way, except when inscription remains visible

~~(d) *NOTE: Medical equipment which has been drained of free liquid is deemed to meet the requirements of this paragraph and is not subject to these Regulations.*~~

Proposal 3

16. Add a new sub-paragraph, 2.6.3.2.3.8 for Used Medical Devices or Equipment containing free liquid potentially contaminated with infectious pathogens:

2.6.3.2.3.8

Except for:

- Medical waste (UN3291),
- Medical devices or equipment contaminated with or containing infectious substances in Category A (UN2814 or UN2900), or
- Medical devices or equipment contaminated with or containing other dangerous goods that meet the definition of another hazard class.
- Used Medical Devices or Equipment containing free liquid potentially contaminated with infectious pathogens are not subject to these regulations provided:

(a) Each used health care device or equipment is drained of free liquid to the extent practicable. The device or equipment must be packed in a leakproof inner packaging. The packaging must be designed and constructed in such a way that, under normal conditions of transport, the inner packaging cannot break, be punctured, or leak their contents. Sharps or other protrusions which may puncture the inner packaging must be protected before packing in inner packagings;

(b) Inner packagings shall be packed in outer packagings meeting the design and construction criteria of 6.1.4 and 6.6.4. Packages must be packed in conformance with the general packing provision of 4.1.1.1 and 4.1.1.2;

(c) Each outer packaging must contain a list of the devices or equipment and any potentially infectious pathogens contained within. In addition, the marking “USED MEDICAL DEVICE, USE APPROPRIATE PRECAUTIONS” or “USED MEDICAL EQUIPMENT, USE APPROPRIATE PRECAUTIONS” must be visible in a conspicuous location upon opening the package;

(d) Each person who offers a used health care device or equipment under the provisions of this paragraph must receive adequate instruction on these Regulations commensurate with their responsibilities; and

(e) Used health care products intended for disposal as waste are not permitted to be transported under this paragraph.

NOTE: Medical equipment which has been completely drained of free liquid is not subject to these Regulations.