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 **6 December 2012**

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)

Proposals

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

Proposal 1

2. Add the following definitions 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.
>
> *Contaminated sharps* means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Proposal 2

3. 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.

Used medical devices or equipment potentially surface-contaminated with infectious pathogens and contaminated sharps which are being transported for disinfection, cleaning, sterilization, repair or equipment evaluation are not subject to these Regulations provided:

(a) ~~Used m~~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~~ Each medical device, equipment and contaminated sharp is 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 6.6.4~~5~~.

(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, and sharps 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.

~~***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

4. 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),
- medical devices or equipment known to be contaminated with Category B (UN3373), 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 and shall be sealed to prevent leakage. The sealed 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. Absorbent material shall be placed between the sealed device or equipment and the inner packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the sealed device.

(b) Inner packagings shall be packed in rigid 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, 4.1.1.2, and 4.1.1.5.

(c) Each outer packaging must contain a list of the devices or equipment and any potentially infectious pathogens contained within. In addition, the package shall bear the marking "USED MEDICAL DEVICE, USE APPROPRIATE PRECAUTIONS" or "USED MEDICAL EQUIPMENT, USE APPROPRIATE PRECAUTIONS" on an internal surface in such a manner that a warning of a potentially infectious substance is visible on of 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.

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

Annex

Infectious Substance Flowmap

Q1. Is the material and environmental sample (including food or water) which is not considered to pose a significant risk? (2.6.3.2.3.4)

Yes Go to Q6

No Go to Q2

Q2. Does the material meet the classification of CAT A Infectious Substances?

Yes **Ship as UN2814 or UN2900**

No Go to Q3

Q3. Does the material contain or potentially contain CAT B Infectious Substances?

Yes Go to Q4

No Go to Q6

Q4. Are the materials dried blood spots, faecal occult blood screening tests, blood or blood components which have been collected for the purpose of transfusion or for the preparation of blood products to be used for transfusion or transplantation or any tissues or organs intended for use in transplantation? (2.6.3.2.3.5)

Yes Go to Q6

No Go to Q5

Q5 Does the material contain pathogens which could cause disease in humans or animals? (2.6.3.2.3.1)

Yes Go to Q7

No Go to Q6

Q6. Does the material meet the classification of any other hazard class?

Yes **Classed as another hazard class**

No **Not Subject to these Regulations**

Q7. Does the material contain micro-organisms which are non-pathogenic? (2.6.3.2.3.2)

Yes Go to Q6

No Go to Q8

Q8. Is the material in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk? (2.6.3.2.3.3)

NOTE: Medical equipment which has been drained of free liquid and meets the requirements of this paragraph is not subject to these Regulations.

Yes Go to Q6

No Go to Q9

Q9. Are the material human or animal specimens for which there is minimal likelihood that pathogens are present and packed in accordance with 2.6.3.2.3.6?

Yes **Handled as Exempt Human Specimens or Exempt Animal Specimens (2.6.3.2.3.6)**

No Go to Q10

Q10. Is the material contained on or within a medical device or equipment? (2.6.3.2.3.7)

Yes Go to Q11

No **Ship as UN3373**

Q11. Are the materials medical waste? (2.6.3.2.3.7(a))

Yes **Ship as UN3191**

No Go to Q12

Q12. Is the medical device or equipment contaminated with or contain dangerous goods that meet the definition of another hazard class? (2.6.3.2.3.7(c))

Yes Go to Q6

No Go to Q13

Q13. Is the medical device or equipment packed in accordance with 2.6.3.2.3.7?

Yes **Ship as Used Medical Equipment (2.6.3.2.3.7)**

No **Ship as UN3373**

Proposed changes to Flowmap:

Q10. Is the material contained on the surface of a medical device, equipment, or sharp? (2.6.3.2.3.7)

Yes Go to Q11

No Go to Q14

Q11. Are the materials medical waste? (2.6.3.2.3.7(a))

Yes **Ship as UN3191**

No Go to Q12

Q12. Is the medical device or equipment contaminated with or contain dangerous goods that meet the definition of another hazard class? (2.6.3.2.3.7(c))

Yes Go to Q6

No Go to Q13

Q13. Is the medical device or equipment packed in accordance with 2.6.3.2.3.7?

Yes **Ship as surface contaminated Used Medical Equipment (2.6.3.2.3.7)**

No **Ship as UN3373**

Q14. Is the material a free liquid contained within a medical device or equipment?

Yes Go to Q15

No **Ship as UN3373**

Q15. Are the materials medical waste? (2.6.3.2.3.8(a))

Yes **Ship as UN3191**

No Go to Q16

Q16. Is the medical device or equipment contaminated with or contain dangerous goods that meet the definition of another hazard class? (2.6.3.2.3.8(c))

Yes Go to Q6

No Go to Q17

Q17. Is the medical device or equipment packed in accordance with 2.6.3.2.3.8?

Yes **Ship as Used Medical Equipment containing free liquid (2.6.3.2.3.8)**

No **Ship as UN3373**