United Nations ST/SG/AC.10/C.3/2010/73

Secretariat

Distr.: General
14 September 2010

Original: English

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

Thirty-eighth session
Geneva, 29 November–7 December 2010
Item 4 of the provisional agenda
Listing, classification and packing

Used health care products

Transmitted by the Council on Safe Transportation of Hazardous Articles (COSTHA)[1]

Introduction

1. At the thirty-seventh session of the Sub-Committee, Switzerland submitted an informal document addressing the problems with shipments of used health care products (INF.61)[2]. Unfortunately, this paper was not addressed due to the full schedule of work. Therefore, COSTHA would like to support Switzerland's previous proposal by addressing it as a formal proposal at this session.

2. As pointed out in INF.61, medical devices are used readily by hospitals, medical facilities, or even home healthcare providers to diagnose, treat, or conduct research on a number of ailments. And while certain competent authorities have domestic requirements that address this issue, and at least one modal organization provides some exemptions that may cover this issue (example – ADR/RID 1.1.3.1(b)), the lack of reference in the Model Regulations is a gap that needs to be addressed.

3. COSTHA supports the concept identified by Switzerland to use a process similar to that identified in the United States Hazardous Materials Regulations. However, the US Regulations also reference requirements dictated by the US Occupational Health and Safety Administration (OSHA) for laboratory handling requirements. These requirements must be

[1] In accordance with the programme of work of the Sub-Committee for 2009-2010 approved by the Committee at its fourth session (refer to ST/SG/AC.10/C.3/68, para. 118 (b) and ST/SG/AC.10/36, para. 14).

[2] Note by the secretariat: Now issued as document ST/SG/AC.10/C.3/2010/61.

reconciled with the World Health Organization (WHO) requirements, less US domestic requirements dictate global policies.

US Requirements

4. The US provisions for Used Health Care Products are identified in 49 CFR 173.134 (b)(12)(ii) including paragraphs (A) through (D). These paragraphs are provided state:

> **49 CFR 173.134(b)(12)(ii)** Used health care products not conforming to the requirements of 29 CFR 1910.1030 and being returned to the manufacturer or the manufacturer's designee are excepted from the requirements of [the Hazardous Materials Regulations] when offered for transportation or transported in accordance with this paragraph (b)(12). For the purposes of this paragraph, a health care product is used when it has been removed from its original packaging. Used health care products contaminated with or suspected of contamination with a Category A infectious substance may not be transported under the provisions of this paragraph.
>
> **(A)** Each used health care product must be drained of free liquid to the extent practicable and placed in a watertight primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. For a used health care product capable of cutting or penetrating skin or packaging material, the primary container must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).
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> **(B)** Each primary container must be placed inside a watertight secondary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. The secondary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).
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> **(C)** The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. An itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outside packaging.
>
> **(D)** Each person who offers or transports a used health care product under the provisions of this paragraph must know about the requirements of this paragraph.

5. The US requirement includes three levels of packaging and further limits the materials to items not contaminated with or suspected to be contaminated with a Category A infectious substance. Additionally, a marking recognized by OSHA as the BIOHAZARD marking must be affixed to the "secondary container" which is enclosed within the outside packaging. This marking is a laboratory safety communication indicating to anyone opening the outer packaging that the materials contained within the secondary packaging may represent a biohazard.

World Health Organization

6. Requiring a marking on a primary or secondary packaging that is not visible outside the package is not a new concept but is similar to the requirements for marking of

EXCEPTED PACKAGES of radioactive material detailed in the Paragraph 2.7.2.4.1.4 of the Model Regulations.

7. The World Health Organization (WHO) recognizes the biohazard marking described in the US Regulations identified above. For example, the WHO publishes a guidance entitled "Four steps for the sound management of health-care waste in emergencies". Under Step 2, the document describes how health-care wastes should be segregated into three different categories. But all three containers should be marked with the biohazard symbol.

8. Given that the WHO recognizes and recommends use of the biohazard symbol, it is reasonable to require the marking on internal packaging surfaces that would not be visible during transport, but may be visible, and possibly required by WHO or OSHA requirements, when opened at the destination facility.

Proposals

9. COSTHA supports the original proposals offered in INF.61 as modified below.

Add the following definition to 2.6.3.1:

"*Used health care product* 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 products contaminated with or suspected of contamination with a Category A infectious substance shall not be transported as a used health care product. ".

10. Add the following paragraph to 2.6.3.2.3 Exemptions:

"2.6.3.2.3.x Used health care products are not subject to these Regulations if:

(a) Each used health care product is drained of free liquid to the extent practicable and packed in a watertight primary receptacle designed and constructed in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Each primary container shall be marked with the BIOHAZARD marking as specified in paragraph (e);

(b) Each primary receptacle shall be packed in watertight secondary packagings with suitable cushioning material to prevent any movement or damage in transport. The secondary packagings shall be marked with a BIOHAZARD marking as specified in paragraph (e);

(c) Secondary packagings shall be packed in outer packagings of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transshipment between cargo transport units and between cargo transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling;

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

(e) The BIOHAZARD marking shall be similar to the illustration shown below:

[*Size Recommendation*]

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