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 July 2017**

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Listing, classification and packing

Revision of ST/SG/AC.10/C.3/2017/25 - Classification and packaging for infectious waste of Category A

Transmitted by the experts from Canada and the United Kingdom

Introduction

1. As a result of discussions held by the Sub-Committee, this document proposes revisions to ST/SG/AC.10/C.3/2017/25. In this paper we are proposing new Category A waste packaging requirements that are practical and safe. By advocating the use of the readily available Chapter 6.1 and 6.6 packagings, hospitals and epidemic-prone areas will be able to respond quickly and safely in the future.

2. An informal teleconferencing working group on the classification and packaging for infectious waste of Category A was created after the last Sub-Committee session in December 2016. The working group involved experts from Belgium, Canada, Germany, the Netherlands, Norway, Sweden, Switzerland, United Kingdom and the United States of America, as well as representatives of the World Health Organization, the Food and Agriculture Organization and industry.

3. The working group held teleconferences on 10 February 2017, 3 March 2017, 17 March 2017 and 31 March 2017, under the chairmanship of Canada, with minutes available on request from Canada. The proposals found in this document are based on the outcomes of these discussions.

4. Outbreaks of these pathogens are rare, but when they occur they pose a significant risk to the health and well-being of humans and animals. Response to these outbreaks is not limited to sophisticated health facilities, and is often required in remote field operations of a basic nature. In all cases, the response and control of outbreaks by public health authorities need to be swift and efficient. It should not be unnecessarily hindered by onerous or technically complex collection and transport requirements.

5. It is the view of the experts from Canada and the United Kingdom that the Committee of Experts recommendations shall assist the public health authorities in charge of the response in setting the safe conditions for transport and making recommendations that will not hinder other phases of the timely collection, packaging, preparation for transport, transport and disposal of Category A waste. The Committee's expertise in that regard is in setting out minimum requirements for packaging to ensure the safe transport of these dangerous goods.

6. The bulk of Category A waste generated at medical facilities consists of disposable personal protective equipment (gloves, masks, face-shields, booties, aprons, coveralls and other pieces of clothing), absorbent materials of all kinds including mats, pads, gauze strips

and pads, wipes and the like, bedding material such as bed sheets and liners, disposable towels and wipes, articles of clothing for patients, and medical articles such as swabs and finally the packaging material of most former items that is open in the contaminated zone.

7. This document's limited scope (i.e. solid Category A waste) does not address packaging requirements for large quantities of liquid infectious substances. Liquids are to be treated locally in a separate process stream.

Classification

8. The experts from Canada and the United Kingdom propose to create a new entry in the dangerous goods list for solid infectious waste of Category A.

9. This new UN number shall not be used for waste from bio research or other laboratory settings or when transporting liquids. Liquids are to be treated in a separate process stream. This new entry shall include only solid waste generated from the medical treatment of affected humans or veterinary care of affected animals. Any residual liquid will be absorbed before transport.

Packing instructions

10. The experts from Canada and the United Kingdom propose two new packing instructions for Category A waste; one for the use of packagings (P6XX) and one for the use of large packagings (LP6XX).

11. Both new packing instructions will require the use of a triple packaging system that meets the testing, marking and certification requirements found in Chapters 6.1 or 6.6.

12. These packing instructions may also apply to small quantities of dangerous goods that are to be included in classes or divisions other than division 6.2 and that have been used as cleaning agents or disinfectants during treatment or clean-up and are mixed in with the waste. Any small quantities of incidental liquid dangerous goods will be absorbed or solidified before transport.

13. The packagings currently authorized in packing instruction P620 are suitable for transporting small volumes of infectious substances of Category A, such as cultures and specimens as well as small quantities of waste generated in laboratory activities. However, these packagings are not adequate for transporting large volumes of Category A waste, such as the size and quantity generated during the 2014 Ebola outbreak. Packagings selected in accordance with packing instruction P620 must also comply with the provisions of Chapter 6.3. The experts from Canada and the United Kingdom emphasize the importance of triple packaging; however, not all testing requirements referred to in Chapter 6.3 may be applicable or achievable when transporting large volumes of Category A solid waste.

Pressure differential and leakproofness tests

14. As mentioned earlier, the proposed options are not to be used to cover the case of transporting large quantities of liquids, and if any liquid is present it must be absorbed before transport. Thus, the capability of inner and intermediate packagings to withstand a pressure differential of not less than 95 kPa when the infectious waste is transported by road is considered too stringent and unnecessary. A pressure differential of that magnitude would not be considered as a normal condition of surface transport.

15. On the same thought, the experts from Canada and the United Kingdom are of the opinion that the capability of the inner or the intermediate packaging to withstand a

leakproofness test in accordance with Chapter 6.1 for single packagings is unnecessary. This test is prescribed for single packagings intended to contain liquids. Which is again, not the case here. The capability to retain liquids of both the inner and intermediate packaging shall suffice for solids and a minimal amount of absorbed or solidified liquid.

Drop and puncture tests

16. Currently, the 9 m drop test required in 6.3.5.3 is only prescribed for packagings intended for Category A infectious substances and some high-integrity packagings (Type B and Type A for liquids and gases of Class 7) of Chapter 6.4 as prescribed by the IAEA Regulations for the Safe Transport of Radioactive Material. It is apparent that the IAEA Safety Standard was used in the development of the testing regime for Category A infectious substance packaging required by Packing Instruction 620.

17. Additional packaging requirements that include triple packaging and an obligation that limits the transport for disposal purposes only will reduce the likelihood of exposure in normal conditions of transport. It is unlikely that these packagings will be exposed to the risk of a 9 m drop in the expected conditions of transport. Instead of establishing new drop height requirements, the experts from Canada and the United Kingdom recommend a 1.8 m drop height, which is the minimum required drop height for solid dangerous goods of packing group I of any other class. This information is easily verified in the UN marking of the outer packaging. Also, once the waste arrives and has been unloaded at the incinerator plant, these packagings are no longer considered to be in transport. Thus, once the packages are inside the plant the height these packagings may be handled at should not have a direct effect on the minimum requirements applicable to transport.

18. The experts from Canada and the United Kingdom propose to not include the puncture test required in Chapter 6.3 for Category A waste packagings. This test is only prescribed for packagings intended for Category A infectious substances and some high-integrity packagings of Chapter 6.4 as prescribed by the IAEA Regulations for the Safe Transport of Radioactive Materials. For Category A solid waste, the risk from exposure to a solid if a triple package of waste is punctured is perceived as less than that expected when a package of radio-active substances in liquid or gaseous phase or a package containing cultures of Category A infectious substances is punctured. Also, if we compare the packaging requirements (P601 and P602) for dangerous goods that are classified as toxic by inhalation we notice that these packagings are not required to pass the puncture test even when combination packagings using a fibreboard outer packaging are permitted.

19. Category A waste is not expected to be shipped in the regular commercial logistic chain. It is expected that the handling and transport of packages of Category A waste for disposal purposes only will be carried out in a dedicated transport unit by a knowledgeable firm that specializes in this type of transport, or by trained personnel under the supervision of the local public health authority.

Flexible inner and intermediate packagings

20. In many jurisdictions, plastic bags are used for the primary collection of low density non-rigid disposable items.

21. A large volume of low-density packages is generated when a facility is set out for the medical treatment of humans or animals affected by Category A infectious substances. In the case of the 2014 Ebola outbreak, the United States' Nebraska Biocontainment Unit generated a total of 13.15 cubic metres (weighing 1,011 lbs) of solid waste in caring for a

single patient[*]. The normal protocol in many jurisdictions, such as Canada and the United States, is to use sturdy plastic bags as the inner packaging for biomedical waste.

22. During the 2014 Ebola outbreak, competent authorities in Canada and the United States issued equivalency certificates [†] and special permits [‡], respectively, which conditionally allowed the use of inner and intermediate flexible packagings (i.e. bags) in the transportation of certain Ebola contaminated waste for disposal. ADR multilateral agreement M281 made flexible packaging the intermediate component of the triple-packaging system.

23. In December 2014, the United States' Centers for Disease Control and Prevention (CDC) created *Procedures for Safe Handling and Management of Ebola-Associated Waste*[§]. For non-sharps solid waste, the CDC procedures specify the use of plastic bags for the inner and intermediate packaging.

24. The experts from Canada and the United Kingdom propose to allow the use of such sturdy plastic bags as they are readily available, their use is understood by practitioners and are in line with existing protocols.

25. The Secretariat suggested to the authors of this document to add the P207 packing instruction to the note to Section 4.1.1 they are proposing to modify for their own purpose. This suggestion in this document.

Proposal

Create a new UN Number

Amend the text of table 1.4.1 of 1.4.3.1.2 related to infectious substances to read as follows (new text underlined):

"Division 6.2 Infectious substances of Category A (UN Nos. 2814 and 2900) and medical waste of Category A (UN No. 35XX)"

Amend 2.6.3.1.6 to read as follows (new text underlined):

2.6.3.1.6 Medical or clinical wastes are wastes derived from the veterinary treatment of animals, the medical treatment of humans or from bio-research.

Amend 2.6.3.2.1 to read as follows (new text underlined):

"2.6.3.2.1 Infectious substances shall be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291, UN 3373 or UN 35XX, as appropriate."

Amend sub-paragraph (a) of 2.6.3.2.3.9 as follows (new text underlined):

"2.6.3.2.3.9 (a) Medical waste (UN3291 and UN 35XX)"

Amend 2.6.3.5.1 to read as follows (new text underlined):

2.6.3.5.1 Medical or clinical waste containing:

[*] *https://doh.sd.gov/documents/diseases/nebraskabiounit.pdf*

[†] Canada's Equivalency Certificate 11521 (http://wwwapps.tc.gc.ca/saf-sec-sur/3/tdgcert-tmdcert/certificate.aspx/11521)

[‡] United States' Special Permit 16279 Cat A Waste USA Special Permits – Packaging Requirements Summary

[§] https://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/handling-waste.html

(a) Category A infectious substances shall be assigned to UN 2814, UN 2900 or UN 35XX as appropriate. Solid medical waste containing Category A infectious substances generated from the medical treatment of humans or veterinary treatment of animals may be assigned to UN 35XX. The UN 35XX entry shall not be used for waste from bio-research or liquid waste.

(b) Category B shall be assigned to UN 3291.

Amend Table A of Chapter 3.2 to create a new entry with two new packing instructions:

								Packagings and IBCs		*Portable tanks and bulk containers*	
UN No.	*Name and description*	*Class or division*	*Subsidiary hazard*	*UN packing group*	*Special provisions*	*Limited and excepted quantities*		*Packing instruction*	*Special packing provisions*	*Instructions*	*Special provisions*
(1)	(2)	(3)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9)	(10)	(11)
-	3.1.2	2.0	2.0	2.0.1.3	3.3	3.4	3.5	4.1.4	4.1.4	4.2.5/ 4.3.2	4.2.5
35XX	MEDICAL WASTE, CATEGORY A, AFFECTING HUMANS, solid or MEDICAL WASTE, CATEGORY A, AFFECTING ANIMALS only, solid	6.2		-	318	0	E0	P6XX LP6XX			

Amend Appendix A (List of generic and N.O.S. proper shipping names)

Class or Division	*Subsidiary hazard*	*UN No*	*Proper Shipping Name*
			DIVISION 6.2
			Specific entries
6.2		35XX	MEDICAL WASTE, CATEGORY A, AFFECTING HUMANS, solid or MEDICAL WASTE, CATEGORY A, AFFECTING ANIMALS only, solid

Amend the Alphabetical index of substances and articles

Name and description	*Class*	*UN No.*
MEDICAL WASTE, CATEGORY A, AFFECTING HUMANS, solid	**6.2**	**35XX**
MEDICAL WASTE, CATEGORY A, AFFECTING ANIMALS only, solid	**6.2**	**35XX**

Amend the note in 4.1.1 to read as follows (new text underlined):

Note: For the packing of goods of Class 2, Division 6.2 and Class 7, the general provisions of this section only apply as indicated in 4.1.8.2 (Division 6.2, UN Nos 2814 and 2900),

4.1.9.1.5 (Class 7) and in the applicable packaging instructions of 4.1.4 (P201, P207 and LP02 for Class 2 and P620, P621, P6XX, IBC620, LP621 and LP6XX for Division 6.2).

Amend Chapter 6.1

6.1.1.1 The requirements of this chapter do not apply to : …

e. Packagings for Division 6.2 Infectious Substances of Category A, "except for UN35XX".

Amend the title of Chapter 6.3 to read as follows

"Chapter 6.3

Requirements for the construction and testing of packagings for Division 6.2 infectious substances of Category A (UN 2814 and UN 2900)"

6.3.1.1 The requirements of this Chapter apply to packagings intended for the transport of infectious substances of Category A, "UN2814 and UN2900"

Packing Instructions

The packing instruction for the packagings would be:

P6XX	**PACKING INSTRUCTION**	**P6XX**
This instruction applies to solid medical or clinical waste assigned to UN No.35XX transported for disposal.		
The following packagings are authorized provided the general provisions of **4.1.1** and **4.1.3** are met:		
Inner packagings	**Intermediate packagings**	**Outer packagings**
metal plastics	metal plastics	**Boxes** steel (4A) aluminium (4B) plywood (4D) fibreboard (4G) other metal (4N) plastics, solid (4H2) **Drums** steel (1A2) aluminium (1B2) plywood (1D) fibre (1G) other metal (1N2) plastics (1H2) **Jerricans** steel (3A2) aluminium (3B2) plastics (3H2)
The packaging shall conform to the packing group I performance level for solids.		

Additional requirement:

1. Fragile articles shall be contained in either a rigid inner packaging or rigid intermediate packagings.
2. Inner packagings containing sharps objects such as broken glass and needles shall be rigid and resistant to puncture].
3. The inner packaging and the intermediate packaging shall be capable of retaining liquids.
5. The inner packaging and/or ~~the~~ intermediate packaging may be flexible. When flexible packagings are used, they shall be capable of passing the tests for tear and impact resistance according to ISO 7765-1:1988 "Plastics film and sheeting – Determination of impact resistance by the free-falling dart method – Part 1: Staircase methods" and ISO 6383-2:1983 "Plastics – Film and sheeting – Determination of tear resistance – Part 2: Elmendorf method". Each bag shall have an impact resistance of at least 165g and a tear resistance of at least 480g in both parallel and perpendicular planes with respect to the length of the bag. The maximum net mass of each plastic bag shall be 30kg.
6. Each flexible intermediate packaging shall contain only one inner packaging.
7. Option #1 - [Inner packagings containing a small amount of free liquid may be included in intermediate packaging provided that there is sufficient absorbent or solidifying material in the inner or intermediate packaging to absorb or solidify all the liquid content present. Suitable absorbent material which may withstand the temperatures and vibrations liable to occur under normal conditions of transport shall be used.]

8. When outer packagings are not capable of retaining liquids either the inner packaging or the intermediate packaging shall be rigid.

9. Where the solid material is saturated and there is the possibility of liquid being released during transport only outer packagings capable of retaining liquids shall be used.

The packing instruction for the large packagings would be:

LP6XX	**PACKING INSTRUCTION**	**LP 6XX**
This instruction applies to solid medical or clinical waste assigned to UN No.35XX transported for disposal.		
The following packagings are authorized provided the general provisions of **4.1.1** and **4.1.3** are met:		
Inner packagings	**Intermediate packagings**	**Outer packagings**
metal plastics	metal plastics	steel (50A) aluminium (50B) plywood (50D) fibreboard (50G) other metal (50N) plastics (50H)
The packaging shall conform to the packing group I performance level for solids.		

Additional requirement:

1. Fragile articles shall be contained in either a rigid inner packaging or a rigid intermediate packagings.
2. Inner packagings containing sharps objects such as broken glass and needles shall be rigid and resistant to puncture.
3. The inner packaging and the intermediate packaging shall be capable of retaining liquids.
5. The inner packaging and/or ~~the~~ intermediate packaging may be flexible. When flexible packagings are used, they shall be capable of passing the tests for tear and impact resistance according to ISO 7765-1:1988 "Plastics film and sheeting – Determination of impact resistance by the free-falling dart method – Part 1: Staircase methods" and ISO 6383-2:1983 "Plastics – Film and sheeting – Determination of tear resistance – Part 2: Elmendorf method". Each bag shall have an impact resistance of at least 165g and a tear resistance of at least 480g in both parallel and perpendicular planes with respect to the length of the bag. The maximum net mass of each plastic bag shall be 30kg.
6. Each flexible intermediate packaging shall contain only one inner packaging.
7. Inner packagings containing a small amount of free liquid may be included in intermediate packaging provided that there is sufficient absorbent or solidifying material in the inner or intermediate packaging to absorb or solidify all the liquid content present. Suitable absorbent material which may withstand the temperatures and vibrations liable to occur under normal conditions of transport shall be used.

8. When outer packagings are not capable of retaining liquids either the inner packaging or the intermediate packaging shall be

rigid.

9. Where the solid material is saturated and there is the possibility of liquid being released during transport only outer packagings capable of retaining liquids shall be used.

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