

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

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Listing, classification and packing

Infectious substances containing lithium batteries

Transmitted by the Medical Device Transport Council (MDTC)

I. Introduction

1. As described by COSTHA in document ST/SG/AC.10.C.3/2024/51, there is currently a gap in the exemption under 2.6.3.2.3.9 to ship lithium battery powered medical devices under the used medical device exception. A similar gap exists for infectious substances assigned to UN Nos. 2814, 2900, and 3373 where a medical device exposed to such infectious substances also contains or is packed with a lithium battery.
2. The provisions associated to UN Nos. 2814, 2900, and 3373 do not allow for lithium batteries. Therefore, under the current regulations, the pathway to ship such devices for mandatory forensic analysis and reporting is unclear. This document proposes to amend several provisions to clarify that the relevant provisions for both infectious substances and lithium batteries are to be applied to ship such devices.

II. Background

3. Medical device manufacturers have obligations under national health regulations to perform forensic analysis on certain devices that they manufacture to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. Many of these devices are powered by lithium cells and batteries. The medical device industry has identified a need to clarify how to ship lithium battery powered devices when they are exposed to infectious substances.
4. Classification for infectious substances provides for UN Nos. 2814 or 2900 for Category A infectious substances, and UN No. 3373 for Category B infectious substances.
5. Entries for UN Nos. 2814 and 2900 refer to packing instruction P620, and the entry for UN 3373 refers to packing instruction P650. The additional requirements for these packing instructions include the following text¹:

“Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. These small quantities of dangerous goods of Classes 3, 8 or 9 are not subject to any additional requirements of these Regulations when packed in accordance with this packing instruction.”

6. The language in the current additional requirement described above does not clearly permit the inclusion of lithium batteries. If it were interpreted to allow lithium batteries, then it would also be interpreted that the lithium batteries contain or packed with medical devices

¹ Additional requirement number 4 in packing instruction P620, and number 13 in P650.

“are not subject to any additional requirements of these Regulations ...”. However, this would produce an unreasonable result as several provisions related to lithium batteries would then not be considered, such as testing to UN 38.3 or assessing used batteries to determine if they are damaged or defective.

7. UN No. 3373 refers to special provision 319 which provides that “[s]ubstances packed and marked in accordance with packing instruction P650 are not subject to any other requirements in these Regulations.” For a lithium battery powered medical device this would produce the same unreasonable result as described in paragraph 6.

III. Proposal

8. MDTC proposes the following changes to the *Model Regulations* to clarify that medical devices exposed to infectious substances that contain or are packed with lithium batteries shall comply with the applicable provisions of both infectious substances and lithium batteries. New text in square brackets is underlined.

“2.6.3.2.1 Infectious substances shall be classified in Division 6.2 and assigned to UN Nos. 2814, 2900, 3291, 3373 or 3549, as appropriate. [Medical devices that contain or are packed with lithium cells or batteries as described in 2.6.3.2.9(c) that are exposed to infectious substances shall also be assigned to UN Nos. 3481 or 3091, as appropriate.]”

Packing instruction P620

“[Except for lithium cells or batteries described in 2.6.3.2.1, o]Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substance. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. These small quantities of dangerous goods of Classes 3,8 or 9 are not subject to any additional requirements of these Regulations when packed in accordance with this packing instruction.”

Packing instruction P650

“[Except for lithium cells or batteries described in 2.6.3.2.1, o]Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substance. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. These small quantities of dangerous goods of Classes 3,8 or 9 are not subject to any additional requirements of these Regulations when packed in accordance with this packing instruction.”

Special provision 319

“[Except for lithium cells or batteries described in 2.6.3.2.1, s]Substances packed and marked in accordance with packing instruction P650 are not subject to any other requirements in these Regulations.”
