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DANGEROUS GOODS PANEL (DGP)

TWENTY-NINTH MEETING

Montréal, 13 to 17 November 2023

Agenda Item 3: Facilitating safe transport of dangerous goods by air *(Ref: REC-A-DGS-2025)*

CLARIFICATION OF THE EXCEPTIONS FOR CARRIAGE OF MEDICAL DEVICES AND BATTERIES FOR PERSONAL USE IN TABLE 8-1

(Presented by the Dangerous Goods Advisory Council (DGAC))

SUMMARY

This information invites the DGP to consider amending the passenger provisions relating to portable electronic medical devices and spare batteries for such devices in Table 8-1 to clarify that the exceptions therein for personal use extend to, for example, employees of medical device manufacturers, doctors and authorized agents carrying portable medical devices and spare batteries for the urgent treatment of patients for life saving or preserving purposes.

1. INTRODUCTION

1.1 A medical device manufacturer recently reached out to an operator seeking authorization for an employee of a medical device manufacturer to carry a medical device aboard a flight in carry-on baggage. The device was an implantable pacemaker specially modified for pediatric use in an infant. The device was authorized by the applicable health authority under an emergency use provision and was transported for a surgical procedure on an infant. The device was not yet in commercial production and had been developed to support an emergency case. The battery used to power the device was UN38.3 tested and therefore not considered a prototype. Due to time constraints in development of the device, the device was placed in internal packaging that complied with the applicable requirements of Packing Instruction 970 but the packaging was not designed or validated to protect delicate internal components of the emergency medical device from forces that may occur during the normal conditions of commercial transport. As a result, the medical device company and health authority agreed that the medical device must be hand carried, rather than shipped as cargo. After review of battery specifications, the airline indicated that the employee could transport the device in their carry-on baggage since they considered it to meet the intent of personal use.

1.2 There are also medical device batteries exceeding 100 Wh but not more than 160 Wh that could be carried by employees of medical device manufacturers, doctors, medical professionals and authorized agents. An example are the batteries that are used to power a ventricular assist device (VAD) that helps the heart pump and increases the amount of blood that flows through the body in patients with advanced heart failure. VADs are designed to help patients with end-stage heart failure when one of the heart's natural pumps (a ventricle) does not perform well. Without treatment, these patients have a very low survival rate. In 2017, the U.S. Food and Drug Administration (FDA) approved a VAD system for patients with advanced heart failure who are not candidates for heart transplants (commonly referred to as "destination therapy"). The system is also available as a bridge to heart transplant in eligible patients. The batteries needed to power the VAD systems made by various companies range from 70 to 145 Wh. Unfortunately, medical device companies have experienced first-hand the challenges of moving emergency replacement batteries to remote locations. In fact, this situation played out where a company needed to supply an emergency replacement battery to a patient on an island in the Caribbean Sea, only to have the shipment unnecessarily delayed due to a lack of daily cargo aircraft service. While many populated places around the world have routine access to cargo aircraft delivery, this is not the case in many remote locations. Allowing medical devices and spare batteries to be carried as proposed in this paper would serve a public health interest.

1.3 The "personal use" restriction for lithium batteries has over time been interpreted in different ways by regulators and operators alike. In this recent situation, the airline fortunately agreed the device could be carried in the interest of the patient's needs and the surgery on the infant was a success. While this matter was resolved in a positive manner there are concerns that not all operators will similarly interpret the "personal use" provisions and that the operator, while seeking to serve a humanitarian need, could be subject to penalties if a State inspector takes issue with this interpretation. To address this critical need, the proposal in this paper is intended to ensure that, in the future when such urgent matters arise, portable electronic medical devices and spare lithium batteries for such devices can be carried in carry-on baggage by, for example, employees of medical device manufacturers, doctors, medical professionals and authorised agents according to Table 8-1.

2. PROPSAL

2.1 The DGP is invited to consider amending Table 8-1 by inserting the following note under entry 1: "Lithium batteries (including portable electronic devices)":

> *Note.— When required for imminent patient care, portable electronic medical devices, such as devices intended for implant in patients and ventricular assist devices, containing lithium metal or lithium-ion cells or batteries, and spare lithium metal or lithium-ion cells and batteries for such devices, when conforming to the applicable requirements of this entry 1) of Table 8-1 may be carried in carry-on baggage by, for example, employees of medical device manufacturers, doctors, medical professionals, or authorized agents.*

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