



**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****Forty ninth session**

Geneva, 27 June – 6 July 2016

Item 4 (d) of the provisional agenda

Electric storage systems: miscellaneous**New entries for lithium batteries used for medical devices****Transmitted by the Rechargeable Battery Association (PRBA)¹****Introduction**

1. Medical devices powered by lithium batteries are critical to the improvement of public health outcomes in all areas of the world. Given the urgent nature of medical care, it is vital that life-saving medical devices and their lithium batteries be transported to patients in a timely manner, making medical device manufacturers and patients heavily dependent upon air transport. PRBA, after consultation of manufacturers of such medical devices believes that recent actions on lithium batteries taken by the International Civil Aviation Organization (ICAO) have highlighted the need for new entries in the Model Regulations for lithium batteries that are uniquely designed and manufactured to power medical devices.

2. Transportation of lithium batteries has become increasingly complex and difficult as a result of recent restrictions imposed by ICAO. The most stringent limitations have been imposed upon the transport of lithium batteries by air. Among the recent significant restrictions affecting medical device supply chains are limits on the battery's state of charge (SOC), limits on the number of packages per consignment, and a prohibition from transporting standalone lithium batteries as cargo aboard passenger aircraft. These restrictions were implemented to address the vast range of lithium battery designs, chemistries and manufacturing methods. Because of the unique design and manufacturing standards that certain medical device lithium batteries may meet, there is a need to develop additional entries in the Model Regulations to take this into account.

¹ In accordance with the programme of work of the Sub-Committee for 2015–2016 approved by the Committee at its seventh session (see ST/SG/AC.10/C.3/92, paragraph 95 and ST/SG/AC.10/42, para. 15).

3. Currently, all lithium batteries are grouped together, with the only differentiation being the split between lithium ion and metal batteries. The batteries used to power medical devices are often subject to additional safety standards and oversight from multiple non-transport related governmental agencies (*e.g.*, Federal Drug Administration (FDA in the United States of America, TÜV Rheinland in Germany).

4. Lithium batteries used to power portable and implantable medical devices are designed, manufactured, and tested to certain standards that exceed the current dangerous goods regulatory requirements. To account for these additional safety measures and standards, our proposal requires that medical device lithium batteries be subject to the requirements of ISO 13485: 2015, EN ISO 14971:2012 and 11607- 1:2006/A1:2014. These standards are described in the appendix of the paper.

5. Additionally, these lithium batteries are shipped according to specific packaging, testing and quality assurance provisions that are not generally applicable for batteries used for other purposes.

6. In this proposal, it is requested that lithium batteries manufactured and tested in accordance with the standards listed above are provided four new UN Numbers and Proper Shipping Names, a Special Provision to be used as guidance for properly classifying lithium batteries for medical devices and a new packing instruction. These batteries would be shipped as fully regulated Class 9 shipments. Exceptions under SP 188 would not be authorized for air transport except when the batteries are contained in or packed with equipment.

Proposal 1

7. In the Dangerous Goods List in Chapter 3.2, add the following entries:

UN No.	Name and Description	Class or division	Subsidiary risk	UN packing group	Special provisions	Limited and excepted quantities		Packagings and IBCs		Portable tanks and bulk containers	
						(7a)	(7b)	Packing instruction	Special packing instructions	Instructions	Special provisions
(1)	(2)	(3)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9)	(10)	(11)
UN 35XX	LITHIUM ION BATTERIES FOR MEDICAL DEVICES	9			XXX			P9xx			
					230		P908				
					310		P909				
					348		P910				
					376		P911				
					377						
35XY	LITHIUM ION BATTERIES FOR MEDICAL DEVICES contained in or packed with equipment	9			XXX	0	E0	P9xx			
					YYY		P908				
					230		P909				
					310		P910				
					348			P911			

UN No.	Name and Description	Class or division	Subsidiary risk	UN packing group	Special provisions	Limited and excepted quantities	Packagings and IBCs		Portable tanks and bulk containers	
							Packing instruction	Special packing instructions	Instructions	Special provisions
					376					
					377					
35YY	LITHIUM METAL BATTERIES FOR MEDICAL DEVICES	9			XXX	0 E0	P9xx			
					230		P908			
					310		P909			
					348		P910			
					376		P911			
					377					
35YZ	LITHIUM METAL BATTERIES FOR MEDICAL DEVICES contained in or packed with equipment	9			XXX		P9xxx			
					YYY		P908			
					230		P909			
					310		P910			
					348		P911			
					376					
					377					

8. In Chapter 3.3, insert the following as Special Provision XXX as follows:

XXX This entry may only be used for lithium batteries used in medical devices and medical devices that have met the following criteria:

- (a) The lithium batteries are manufactured to be used in a medical device. The manufacturer of the batteries and devices adheres to the requirements of ISO 13485: 2015, EN ISO 14971:2012 and 11607- 1:2006/A1:2014;
- (b) The manufacturing process is reviewed and audited by an agency designated by the competent authority to monitor, assess and oversee the safe manufacture of the medical devices and batteries used to power them;
- (c) For the purposes of these Regulations, the definition of medical device is as follows:

“Medical device means any instrument, apparatus, implement, machine, appliance, implant, material or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,

- Supporting or sustaining life,
- Orthopedic appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability;
- Aids for disabled/handicapped people,
- Accessories for medical devices (accessories intended specifically by manufacturers to be used together with a “parent” medical device to enable that medical device to achieve its intended purpose).”

9. In Chapter 3.3, insert the following as Special Provision YYY as follows:

“YYY Medical lithium cells and batteries shipped by road, rail or sea and those contained in or packed with equipment are not subject to other provisions of these Regulations if they meet the following:

- (a) For a lithium metal or lithium alloy cell, the lithium content is not more than 1 g, and for a lithium ion cell, the Watt-hour rating is not more than 20 Wh;
- (b) For a lithium metal or lithium alloy battery the aggregate lithium content is not more than 2 g, and for a lithium ion battery, the Watt-hour rating is not more than 100 Wh. Lithium ion batteries subject to this provision shall be marked with the Watt-hour rating on the outside case.
- (c) Each cell or battery meets the provisions of 2.9.4 (a) and (e);
- (d) Cells and batteries when installed in equipment is protected from damage and short circuit, and the equipment is equipped with an effective means of preventing accidental activation. When batteries are installed in equipment, the equipment is packed in strong outer packagings constructed of suitable material of adequate strength and design in relation to the packaging’s capacity and its intended use unless the battery is afforded equivalent protection by the equipment in which it is contained;
- (e) Each package is marked with the appropriate medical lithium battery mark, as illustrated at 5.X.X.X; and
- (f) Each package is capable of withstanding a 1.2 m drop test in any orientation without damage to the medical cells or batteries contained therein, without shifting of the contents so as to allow battery to battery (or cell to cell) contact and without release of contents.

As used above and elsewhere in these Regulations, “lithium content” means the mass of lithium in the anode of a lithium metal or lithium alloy cell.

A single cell battery as defined in Part III, sub-section 38.3.2.3 of the Manual of Tests and Criteria is considered a “cell” and shall be transported according to the requirements for “cells” for the purpose of this special provision.

10. In 4.1.4.1 add the following new packing instructions:

P9XX	PACKING INSTRUCTION	P9XX
	This instruction applies to UN Nos. 35AA, 35BB, 35CC and 35DD	
	<p>The following packagings are authorized for lithium ion and metal cells and batteries used in medical devices including those contained in equipment, provided the general provisions of 4.1.1 and 4.1.3 are met:</p> <p>For cells and batteries and equipment containing cells and batteries:</p> <p style="padding-left: 40px;">Drums (1A2, 1B2, 1N2, 1H2, 1D, 1G);</p> <p style="padding-left: 40px;">Boxes (4A, 4B, 4N, 4C1, 4C2, 4D, 4F, 4G, 4H1, 4H2);</p> <p style="padding-left: 40px;">Jerricans (3A2, 3B2, 3H2).</p> <p>Each cell, battery or equipment shall be individually packed in an inner packaging or encapsulating tray inside an outer packaging.</p> <p>Packagings shall conform to the packing group II performance level. In addition the inner packaging shall be capable of withstanding a 1.2 m drop test in any orientation without:</p> <ul style="list-style-type: none"> • Damage to cells or batteries contained therein; • Shifting of the contents so as to allow battery to battery or cell to cell contact; and • Release of the cells or batteries from the inner packaging. <p>Cells and batteries shall be protected so as to prevent fire propagation in the event that a single cell or battery would experience a thermal event. This shall be achieved using trays, dividers, appropriate separation distances or by limiting the quantity of cells or batteries within a packaging.</p> <p>Appropriate measures shall be taken to prevent excessive movement of the cells or batteries within the packaging that may lead to venting or rupture of the cells or batteries during transport.</p> <p>The packaging shall meet the requirements of ISO 11607 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.</p> <p>Each package shall marked with the medical lithium battery mark, as illustrated at 5.2.6.</p>	

11. Insert a new paragraph 5.2.1.10:

5.2.1.10 Medical device lithium battery mark

5.2.1.10.1 Packages containing medical device cells or batteries that meet special provision XXX shall be marked as shown in 5.2.6.

5.2.1.10.2 The mark shall indicate the UN number, preceded by the letters “UN”, i.e. “UN 35XX” for lithium metal cells or batteries or “UN 35XX” for lithium ion cells or batteries. Where the lithium cells or batteries are contained in, or packed with, equipment, the UN number, preceded by the letters “UN”, i.e. “UN 3091” or “UN 3481” as appropriate shall be indicated. Where a package contains lithium cells or batteries assigned to different UN numbers, all applicable UN numbers shall be indicated on one or more marks.

Figure 5.2.6



Lithium battery mark

* Place for UN number(s)

** Place for telephone number for additional information

The mark shall be in the form of a rectangle with a red or black line at the edges that is at least 2mm. The dimensions shall be a minimum of 120 mm wide x 110 mm high. The symbol shall be black on a contrasting background. If the size of the package so requires, the dimensions/line thickness may be reduced to not less than 105 mm wide x 74 mm high. Where dimensions are not specified, all features shall be in approximate proportion to those shown.”

Summary of ISO Standards referenced in this paper:

ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes. This standard is harmonized with the European Medical Devices Directive 93/42/EEC. The standard is a stand-alone document that establishes a certification system for medical device manufacturers to follow. ISO 13485 requires that the certified organization demonstrate that their quality system is effectively implemented and maintained.

Other requirements include:

- The promotion and awareness of regulatory requirements as a management responsibility. Examples of market-specific regulatory requirements include 21 CFR 820, the Quality System Regulation for medical devices sold in the United States, enforced by the U.S. [Food and Drug Administration](#) (FDA), or the [Medical Devices Directive](#) 93/42/EEC, required for doing business in the European Union. The standard promotes safe battery design on the basis of:
 - Controls in the work environment to ensure product safety
 - Focus on [risk management](#) activities and [design control](#) activities during product development
 - Specific requirements for inspection and traceability for implantable devices
 - Specific requirements for documentation and validation of processes for sterile medical devices
 - Specific requirements for verification of the effectiveness of [corrective and preventive actions](#)
- The conformity of Medical Devices and In-vitro Diagnostic Medical Device according to [European Union Directives](#) 93/42/EEC, 90/385/EEC and 98/79/EEC must be assessed before sale is permitted. The preferred method to prove conformity is the certification of the Quality Management System according ISO 9001 and/or ISO 13485 and [ISO 14971](#) by a [Notified Body](#). The result of a positive assessment is the certificate of conformity allowing the [CE mark](#) and the permission to sell the medical device in the European Union.

EN ISO 14971:2012 Medical devices — Application of risk management to medical devices is a risk management standard for medical devices. This version is harmonized with respect to the three European Directives associated with medical devices Medical Devices Directive 93/42/EEC. Its purpose is to specify how manufacturers establish a medical device risk management process that they can use to identify hazards, to estimate and evaluate risks, and to develop, implement, and monitor the effectiveness of risk control measures. The standard established requirements for how to:

- Document an organization's medical device risk management process;
- Apply risk management processes to an organization's medical devices;
- Maintain risk management processes for every medical device throughout its entire life-cycle; and
- Validate whether the risk management process complies with the standard by inspecting the appropriate documents.

See also: <https://www.iso.org/obp/ui/#iso:std:iso:14971:ed-2:v2:en>

ISO 11607-1:2006/A1:2014 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems is the principal guidance document for validating sterilized medical device packaging systems. Packaging must comply with ISO 11607 in order to satisfy European regulations and obtain a CE Mark. ISO 11607 is also an FDA Recognized Consensus Standard. Fulfilling the requirements within ISO 11607 ensures that a medical device packaging system provides physical protection of the product contained.

ISO 11607 consists of four key areas:

- Stability Testing (accelerated aging and real time aging)
- Performance/Dynamics Testing
- Package Strength Testing
- Package Integrity Testing

This ISO standard also addresses packaging materials by presenting requirements for their physical properties and material performance.
