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Lithium battery test summary (TS) document

Transmitted by the Medical Device Battery Transport Council (MDBTC)

1. The challenges with validating whether a test summary is available for battery-powered equipment led MDBTC to revisit the adopted regulatory text in the UN Model Regulations. The regulatory text adopted only applies to manufacturers and downstream distributors of cells and batteries (UN3480 and UN3090). According to 2.9.4(g) there is no requirement to make a TS available for lithium battery-powered equipment.

“2.9.4 (g) ***Manufacturers and subsequent distributors of cells and batteries*** shall make available the test summary as specified in the Manual of Tests and Criteria, Part III, sub-section 38.3, paragraph 38.3.5”

1. Guidance material that has been provided publicly suggests equipment manufacturers must make available a TS, which has led to confusion and unnecessary burden for equipment manufacturers and distributors. Non-manufacturing distribution companies with thousands of unique lithium battery-powered devices, including e-commerce companies, cannot possibly validate that the TS is available for each cell or battery contained in each battery-powered product they ship. A distributor who is not the equipment manufacturer will not know what cell or battery is contained in equipment, especially where the battery is embedded in the device and is not accessible. If individuals and companies that ship batteries and battery-powered products must verify that a TS document is available, this could be extremely burdensome if not impossible. We do not believe this was the intent of the Sub‑Committee.
2. Considering the errant guidance that has been distributed, the Sub-Committee is requested to confirm that a TS is not required to be made available by manufacturers and subsequent distributors of lithium battery-powered equipment.

Proposal

1. The MDBTC believes the text in 2.9.4(g) only mandates that product manufacturers and subsequent distributors make available test summary documents for standalone lithium cells or batteries. The text in 2.9.4(g) provides that “manufacturers and subsequent distributors of cells or batteries shall make available the test summary as specified in the Manual of Tests and Criteria, Part III, sub-section 38.3, paragraph 38.3.5.” The scope of sub-section 38.3 is limited under paragraph 38.3.2.1 to cells, batteries, and cells or batteries that are “an integral part of the equipment it is intended to power that is transported only when installed in the equipment” (e.g. cells and batteries that are tested to the 38.3 standard when contained in the device). Because of its limited scope, the requirement for a test summary under 38.3.5 only applies to cells, batteries, and those cells or batteries that are an integral equipment of the equipment that they are intended to power when tested as such.
2. It does not require manufacturers or distributors of lithium battery powered products to make available a test summary. It is our opinion that a product manufacturer can voluntarily provide a test summary but is not required by 2.9.4(g) to do so. The Sub-Committee is requested to verify MDBTC’s interpretation of 2.9.4(g). If the Sub-Committee agrees with MDBTC compliance with the new test summary requirement will be more practical and reasonable.

Proposal

1. It is proposed to revise 2.9.4 (g) to read: “Manufacturers and subsequent distributors of cells or batteries **(UN3480 and UN3090)** shall make available the test summary as specified in the Manual of Tests and Criteria, Part III, sub-section 38.3, paragraph 38.3.5.”