

Battery Certification For Medical Devices

Rich Byczek, 7/31/2013



- IEC 62133 adoption, transition
- Certification options for Lithium Batteries
- End product requirements and application
- Transportation requirements for Lithium Batteries

US- Based Standards:

UL-1642: Lithium Batteries

- Focus on single-cells
- Used for evaluation of Lithium-Metal (PRIMARY)
- Used for evaluation of Lithium-Ion (SECONDARY)



UL-2054: Household and Commercial Batteries

- Focus on Portable Batteries
- Typically Battery Packs
- References UL 1642 for Lithium Cells



IEC - Based Standards:

IEC-60086

- Primary Batteries (Non-rechargeable)
- Covers Performance and Safety
- IEC-60086-4 For Lithium (Primary) battery safety



IEC-62133

- Secondary Batteries (Rechargeable)
- Focus on Lithium-ion Batteries
- First Edition, October 2002
- Second Edition released: December 2012



NORTH AMERICAN NRTL CERTIFICATIONS:

- May still use UL 1642/ UL 2054 for cells and packs, as acceptable US-based component standards.
- Applies to Lithium and Lithium-ion chemistries
- Applies to Nickel Metal Hydride and Nickel Cadmium chemistries

- Verify with NRTL if they will allow usage of batteries and cells certified to IEC standards (such as IEC60086 CB Scheme)



IECEE CB SCHEME:

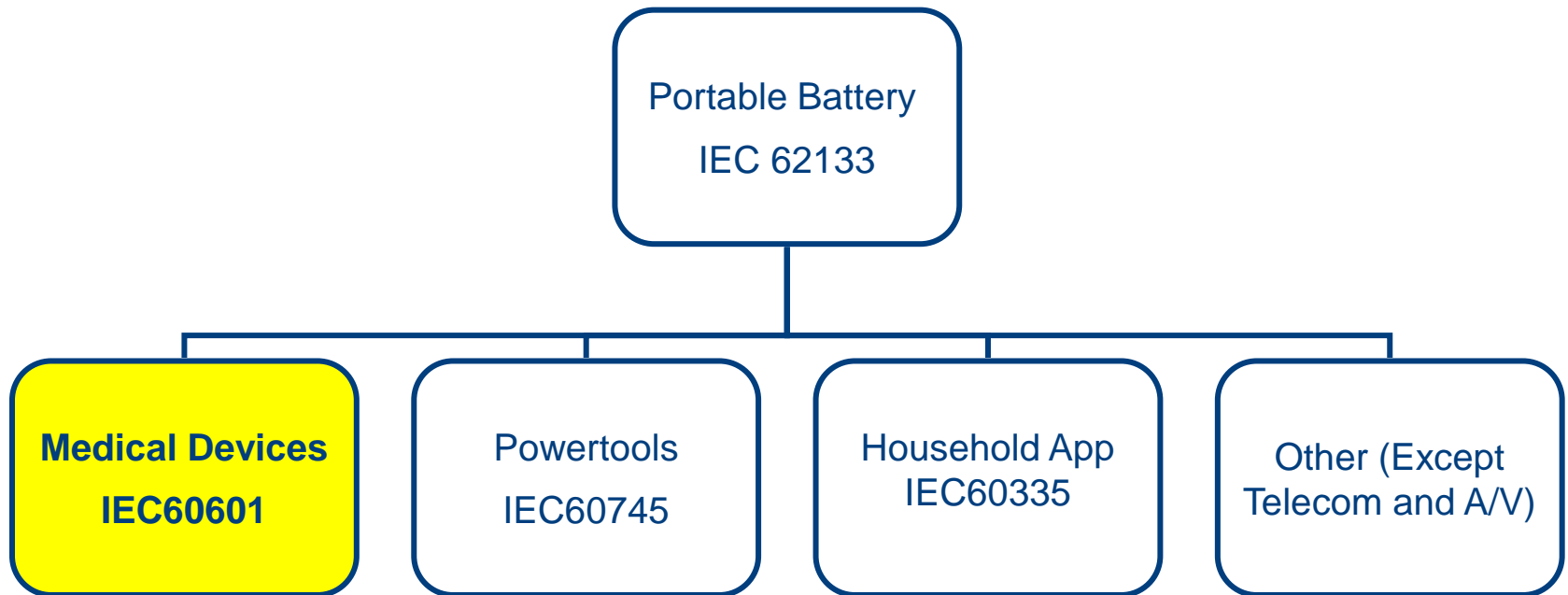
TRANSITION TESTING IS NO LONGER VALID OPTION

Since May 2012:

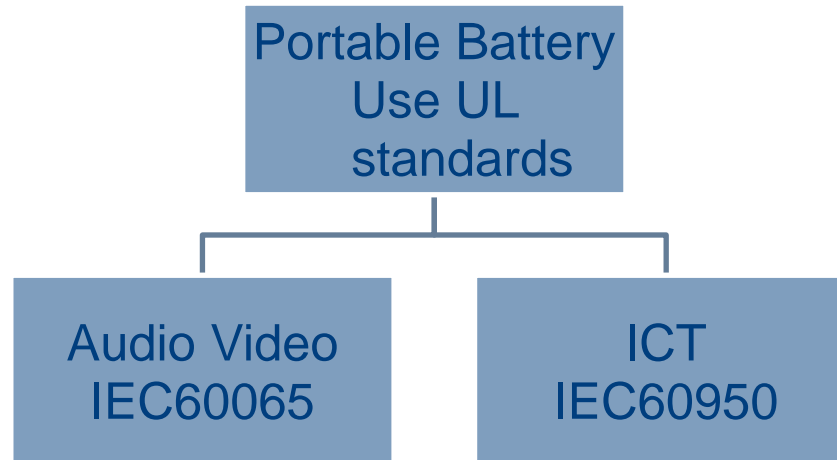
- Batteries tested to UL 1642 or UL 2054 will not be accepted for CB Scheme Certificates
- Rechargeable Batteries and cells must be CB Scheme certified to IEC 62133
- Non-Rechargeable Lithium Batteries and cells must be CB Scheme certified to IEC 60086-4 (specified in IEC 60601-1)



Who is affected by this regulatory change?



Who is NOT affected by this regulatory change?



NOTE: TC 108 still accepts UL 1642 and UL 2054 for CB Scheme certification

IEC 62133 2nd Edition

Released December 2012

Added to IECEE CB Scheme in Q1, 2013

EU adopted as EN 62133 2nd edition

Date of Withdrawal : 1/10/2016

- Majority of changes are for Lithium Ion cells.
- Lithium Ion Battery packs have minimal changes
- Nickel Batteries(NiMH and NiCD): almost no change

- Verify national deviations for other standards (such as IEC/UL 60950-1), which may specify other standards



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Transportation Test requirements are required for all Lithium and Lithium-Ion cells and batteries!

- Self Declaration
- Global requirement



LATEST and GREATEST UN MANUAL:

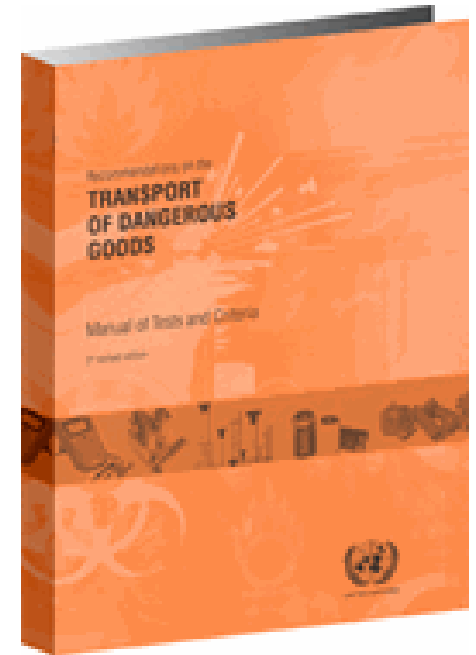
Recommendations on the Transport of Dangerous Goods. Manual of Tests and Criteria.

5th Revised Edition, amendment 1 (2011)

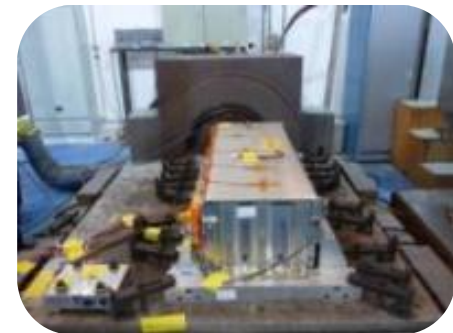
Section 38.3 refers to “Lithium Battery Testing Requirements”

Per Federal register 49 CFR sections 171.7

- 5th Ed. Rev 1 since January 2013



- T1: Altitude Simulation:** Simulated 50,000ft/15,000m cargo
- T2: Thermal Test:** Simulated min/max temperature extremes
- T3: Vibration:** Sine sweep-style vibration scan
- T4: Shock:** Simulation of severe drop and impact
- T5: External Short Circuit**
- T6: Impact/Crush (Cells Only):** simulated crush and internal short circuit
- T7: Overcharge (Rechargeable Batteries Only):** incorrect chargers used in the field.
- T8: Forced Discharge (Cells):** Simulates user error/incorrect installation



Samples Needed: SECONDARY BATTERIES (5th edition)

SMALL BATTERY:
Gross Mass up to 12 kg



LARGE BATTERY:
Gross Mass over 12 kg



	1 st Cycle CHARGED	25 Cycle CHARGED	TOTAL
Small Batteries	8	8 (50 cycles)	16
Large Batteries	4	4 (25 cycles)	8

NOTE: Sample quantity may be cut in half, but client needs to know

IF SAMPLES CAN BE RE-USED AFTER SHORT CIRCUIT TEST

Samples Needed: Very large batteries or “Battery Assemblies”

- Lithium Ion Rechargeable Packs
 - Up to 6,200 Wh rating
 - Cells/ Modules already tested
 - 1 (or 2) sample(s) only, cycled 25 times, fully charged
 - Tests 3,4,5 and 7 only
- More than 500g Lithium or 6,200 Wh Rating
 - No testing required if BMS (Battery Management System) in place.



Thank You.

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