IEC 60601-1: 3rd Edition with Amendment 1 (2012)

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Agenda

- Standard effective dates
- New requirements and changes for 3rd Edition Amendment 1
- Brief summary

Time Line

- Amendment 1 published July 2012
- US Version of ES 60601-1 with AM1 was published Nov. 2012
- CSA version published March 2014
- FDA indicated that Amendment 1 will become mandatory August 1, 2016

Effective Dates

- US FDA – Deadline for compliance with **AAMI ES 60601-1:2005(R)2012+A1:2012** (Third Edition with Amendment 1) is **2016-08-01**; required for new and existing equipment requiring FDA 510(k)

- EU - Deadline for compliance with **EN 60601-1, Ed.3 + Am.1** (Third Edition with Amendment 1) is **2018-01-01**; no equipment will be grandfathered. All medical equipment on the market shall meet this requirement.

- Canada – Deadline for compliance with **CSA C22.2 No. 60601-1:14** (Third Edition with Amendment 1) is still to be determined.

http://industries.ul.com/medical-and-laboratory/medical-devices/ul-60601

NOTE:

- OSHA NRTL's approved for **AAMI ES 60601-1 3rd edition + Amendment 1** (or edition 3.1)

Statistics of change

Published July 2012

~260 amendments

21 new requirements

63 modified requirements

47 deleted references to RM

19 technical corrections


IEC

IEC 60601-1

Edition 3.0 2012-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

New Risk Management Approach

☑ Alignment with ISO 14971: 2007

☑ Audit not required

☑ Limited documents to be reviewed for compliance:

- policy, plan and existence of the risk management file
- focus on technical details (criteria, requirements)
- focus only on clauses that need input from risk management

New Risk Management Approach (cont.)

☑ Number of clauses which *require* risk management reduced (~ 47 cases identified)

☑ Some cases revert to 2nd edition

☑ Some cases refer to basic safety, essential performance

Collaterals and Particular Standards

- IEC 60601-1-6 (Usability) now required for CB Reports

Annex C Use of Standards in the IECEE system according to the IEC 60601-1 Ed. 3 and Am.1

IEC 60601-1 3rd edition (2005-12), Am. 1 (2012), Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	Collateral & Related Standards Required to be included in CBTC		Acceptable to issue a separate CBTC and CBTR	
Standards	**Yes**	**No**	**Yes**	**No**
IEC 60601-1-2, ed.3:2007 or IEC 60601-1-2, ed.4:2014, Medical electrical equipment - Part 1-2: General requirements for Basic Safety and essential performances - Collateral standard: Electromagnetic compatibility (ed.3) / disturbances (ed.4) - Requirements and tests		X	X	
IEC 60601-1-3, ed.2:2008 or IEC 60601-1-3, ed.2:2008 and Am1:2013, Medical electrical equipment - Part 1-3: General requirements for Basic Safety and essential performances- Collateral Standard: Radiation protection in diagnostic X-ray equipment	X			X
IEC 60601-1-6, ed.2:2006 or IEC 60601-1-6, ed.3:2010 or IEC 60601-1-6, ed.3:2010 and Am1: 2013, Medical electrical equipment - Part 1-6 General requirements for Basic Safety and essential performance - Collateral standard: Usability IEC 62366, ed.1:2007 or IEC 62366, ed.1 and Am1:2014, Medical devices – Application of Usability Engineering to Medical Devices	X			X
IEC 60601-1-8, ed.2:2006 or IEC 60601-1-8, ed.2:2006 and Am.1:2012, Medical electrical equipment - Part 1-8: General requirements for Basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	X			X
IEC 60601-1-9, ed.1:2007 or IEC 60601-1-9, ed.1:2007 and Am.1:2013, Medical electrical equipment - Part 1-9:				

Clause 3 (Definitions)

- Basic Safety (3.10) – Freedom from unacceptable risk directly caused by physical hazards when ME Equipment is used under Normal Conditions and Single Fault Condition.

- Essential Performance (3.27) – Clinical function which degradation or loss beyond a limit set by the manufacturer results in an unacceptable risk

- Expected Service Life – (3.28) time period which the equipment remains safe for use (set by manufacturer)

Clause 4 (General Requirements)

- 4.2 has been rewritten
- 4.2.2 – General RM adds new clauses to review (now references 2007 Ed of ISO 14971)
- 4.2.3.1 – HAZARDS identified in the IEC 60601 series
- 4.2.3.2 – HAZARDS not identified in the IEC 60601-series

Clause 4 (Continued)

4.3 Essential Performance – Detailed steps for the manufacturer to identify and maintain ES

- Needs to be declared in the Technical Description
- Performance Limits are specified by the manufacturer
- Separate limits for Normal and Single Fault Conditions
- ES to be maintained after testing

Clause 4 (Continued)

- 4.5 – Alternate Risk Controls – Old “equivalent safety clause” – now looks for “scientific data or clinical opinion or comparative studies” to show residual risk remains acceptable

Clause 5 (General Requirements for Testing)

- 5.4a – Working conditions are specified in the accompanying documents

- 5.7 – Humidity – 2nd Ed requirements added (IPX0, 48 hours and IPX1-8, 168 hours) – RM Removed

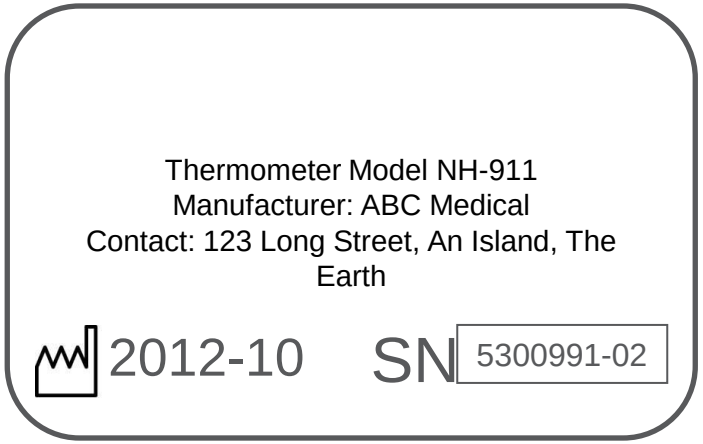
Clause 7 (Marking and Documents)

- 7.1.2 – Clarified test conducted at intended position but if not defined, tested at a distance of 1 M. Added need to read an N6 Jeager test card in “normal” room lighting.

- 7.1.3 – Methylated spirits changed to 96% ethanol

Clause 7 (Marking and Documents)

- 7.2.2 and 7.2.4 – added date of manufacturer and serial number/lot/batch identifier to the manufacturer and model



Clause 7 (Marking and Documents)

- 7.9.1 – Accompanying Documents – if electronic, must use usability engineering process (IEC 60601-1-6) to determine what is required to be provided in written text

- 7.9.2.1 – General Instruction – added requirements when patient is operator

- 7.9.3.1 – General technical description – information about EP required

Clause 8 (Electrical Hazards)

- 8.1b – SFC conditions removed RM for interruption of power carrying conductor and unintended movement of components

- 8.10.2 – (fixing of wiring), 8.10.4.2 (connection cords), and 8.10.5 (mechanical protection of wiring) removes reference to RM and references “Hazardous situations described in 13.1”

Clause 8.5.1 (Means of Protection (MOP))

Insulation required	3rd	3rd Amd 1
MOPP	1MOPP: 1Y1 2MOPP: 2 Y1 in series	1 MOPP: 1 Y1 or 1 Y2 2 MOPP: 2 Y1 in series or 2 Y2 in series 2MOPP: 1 Y1 Working voltage across a barrier <42,4 V peak a.c. or 60 V d.c.
MOOP	1 MOOP: 1 Y2 2 MOOP: 1 Y1 or 2 Y2 in series	1 MOOP: 1 Y1 or 1 Y2 2 MOOP: 1 Y1 or 2 Y2 in series or 2 Y1 in series

Clause 8.9 (Creepage and Clearance)

Table 11—Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s. up to and including	CREEPAGE DISTANCE mm	AIR CLEARANCE mm
17	12	0.8	0.4
43	30		0.5
85	60		0.7
177			
354			1.6
566			2.4
707	500	5.5	3
934	660	7	4
1,061	750	8	4.5
1,414	1,000	11	6

Table 11- Not Used

What is the required distance of BOP?

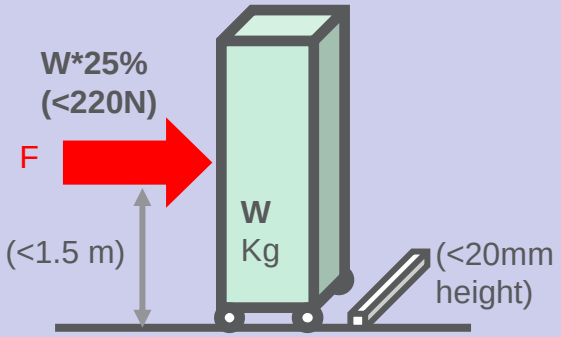
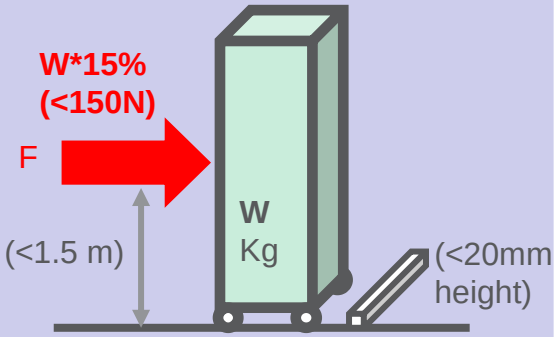
1MOOP in Table 13, 14 and 16

Clause 9 (Mechanical Hazards)

- 9.2.3.1 – Unintended movement from accidentally activated controls now references “usability engineering process”
- 9.2.3.2 – Overtravel includes requirements for end stop testing (same as 2nd Ed) and RM removed
- 9.3 – Sharp edges removes RM
- Test criteria modified for Horizontal Forces and Threshold tests

9.4.2.3 Instability from horizontal and vertical force

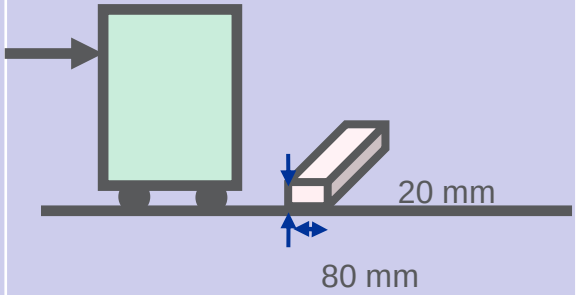
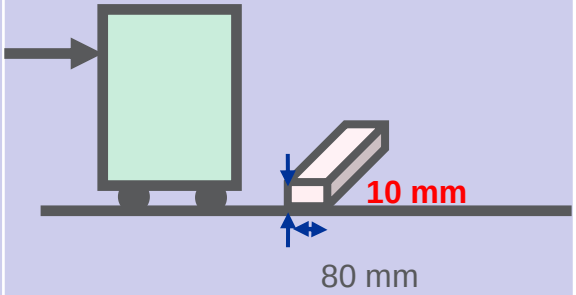
- Force reduced to 15% of mass or max. 150 N

	3rd	3rd Amd 1
		

Clause 9.4.2.4.3 (Movement Over A Threshold)

- Speed and threshold height modified

- Must maintain Basic Safety and Essential Performance

	3rd	3rd Amd 1
Mobile device Mobile “Step” Test	0.4m/s ± 0.1m/s 	**0.8m/s ± 0.1m/s** 

Clause 10 (Radiation Hazards)

- 10.3 – Microwave Radiation clauses removes RM and adds a limit (same limits as 61010-1)

- 10.4 – Laser clause no longer references LEDs and 60825 reference updated from 1993 to 2007

Clause 11 (Temperature and Other Hazards)

- 11.1.2.2 – Applied part limit is additionally clarified to state limit applies in NC and SFC (not new, just reworded)

- 11.6.3 – Spillage adds a review of basic safety and essential performance after the test

Clause 11 (Temperature and Other Hazards)

- 11.6.5 – Ingress of Protection adds a review of basic safety and essential performance after the test
- 11.6.6 – Cleaning adds a review of basic safety and essential performance after the test
- 11.8 – Interruption of the power supply adds a review of basic safety and essential performance after the test

Clause 12 (Accuracy of Controls and Hazardous Outputs)

- 12.2 – Usability compliance checked by IEC 60601-1-6 (**mandatory for all CB Report evaluations**)

- 12.3 – Alarm Systems compliance checked by IEC 60601-1-8

- 12.4.5 - Diagnostic X-ray compliance checked by IEC 60601-1-3

Clause 14 - PEMS

- 14.1 General - Subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the development or modification of software for each PESS.

- 14.6.1, 14.8, 14.13 – Addition of requirements for IT Networks. 14.13 includes the most IT Network changes.

- 14.11 – Adds requirement that PEMS Validation method shall be documented

Clause 15 (Construction)

- 15.1 – Arrangement of controls now references IEC 60601-1-6 (usability)
- 15.3.1 – Mechanical strength removes “unacceptable risk” and adds “basic safety and essential performance”
- 15.3.5 – Rough handling changes speed to 0.8 m/s

15.3.5 Rough Handling Test- Mobile MEE

	3rd	3rd Amd 1
a) Ascending step shock	Test Speed: 0.4 ± 0.1 m/s	Test Speed: 0.8 ± 0.1 m/s or Max. speed of Motor-driven
b) Descending step shock	Test Speed: 0.4 ± 0.1 m/s	Test Speed: 0.8 ± 0.1 m/s or Max. speed of Motor-driven
c) Door frame shock	Test Speed: 0.4 ± 0.1 m/s	Test Speed: 0.8 ± 0.1 m/s

Clause 15 (Construction)

- 15.4.3.4 – Lithium batteries for primary cells are IEC 60086-4 and secondary cells IEC 62133

- 15.5.2 – Dielectric test – not required for transformers operating at above 1kHz if tested per 8.8.3

- 15.5.3 – Construction of transformers now matches UL 60601-1, 2nd Ed.

Clause 16 (ME Systems)

- 16.8 – Interruption of the system supply add “loss of basic safety and essential performance”

- 16.9.2.1d, MSO transformers can use requirements of the standard instead of IEC 61558-2-1

- 16.9.2.2 – Protective earth of the system needs to be tested

Summary

- Effective dates set for US, EU

- New Risk Management approach:
  - Alignment with ISO 14971: 2007
  - Reduction in reliance on RM File

- Essential Performance definition and identification

- Equipment shall be evaluated against IEC 60601-1-6 for issuance of CB certificate.

Questions?

For more information:

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