Major IEC 60601-1 3rd Ed. changes

- **Why 90% of Medical Products Do Not Comply**

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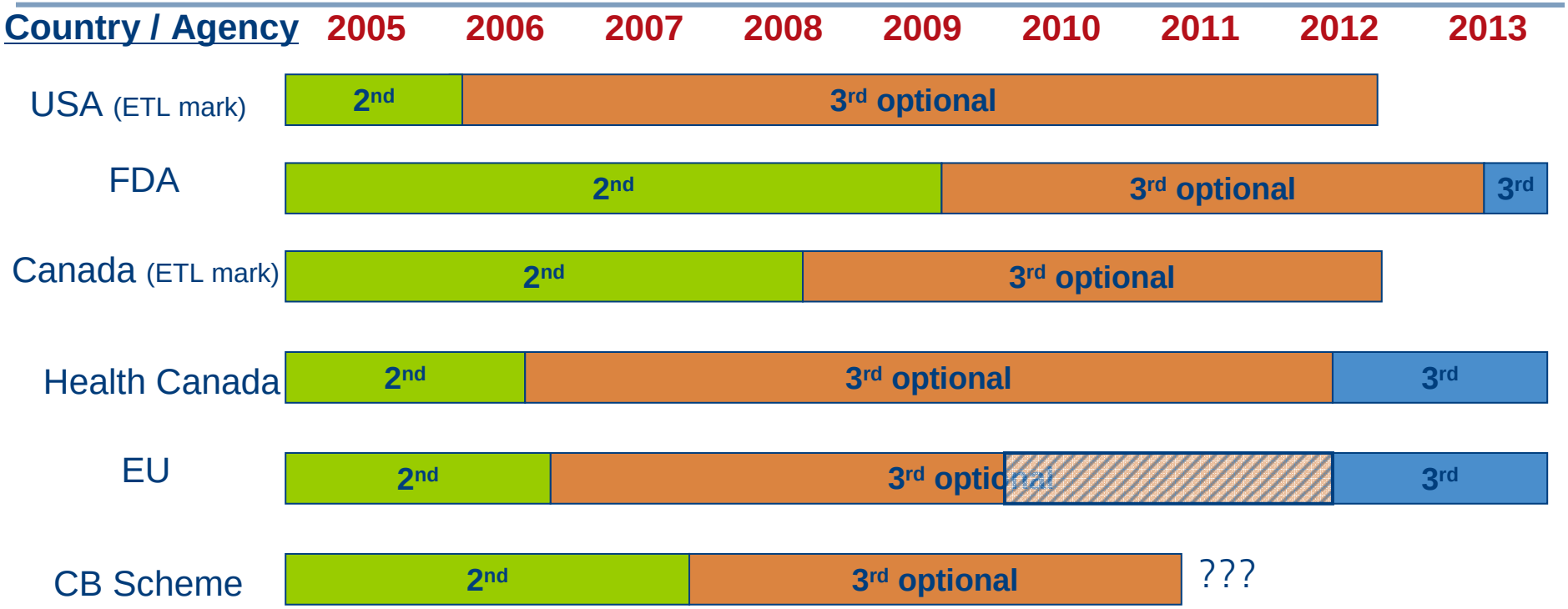
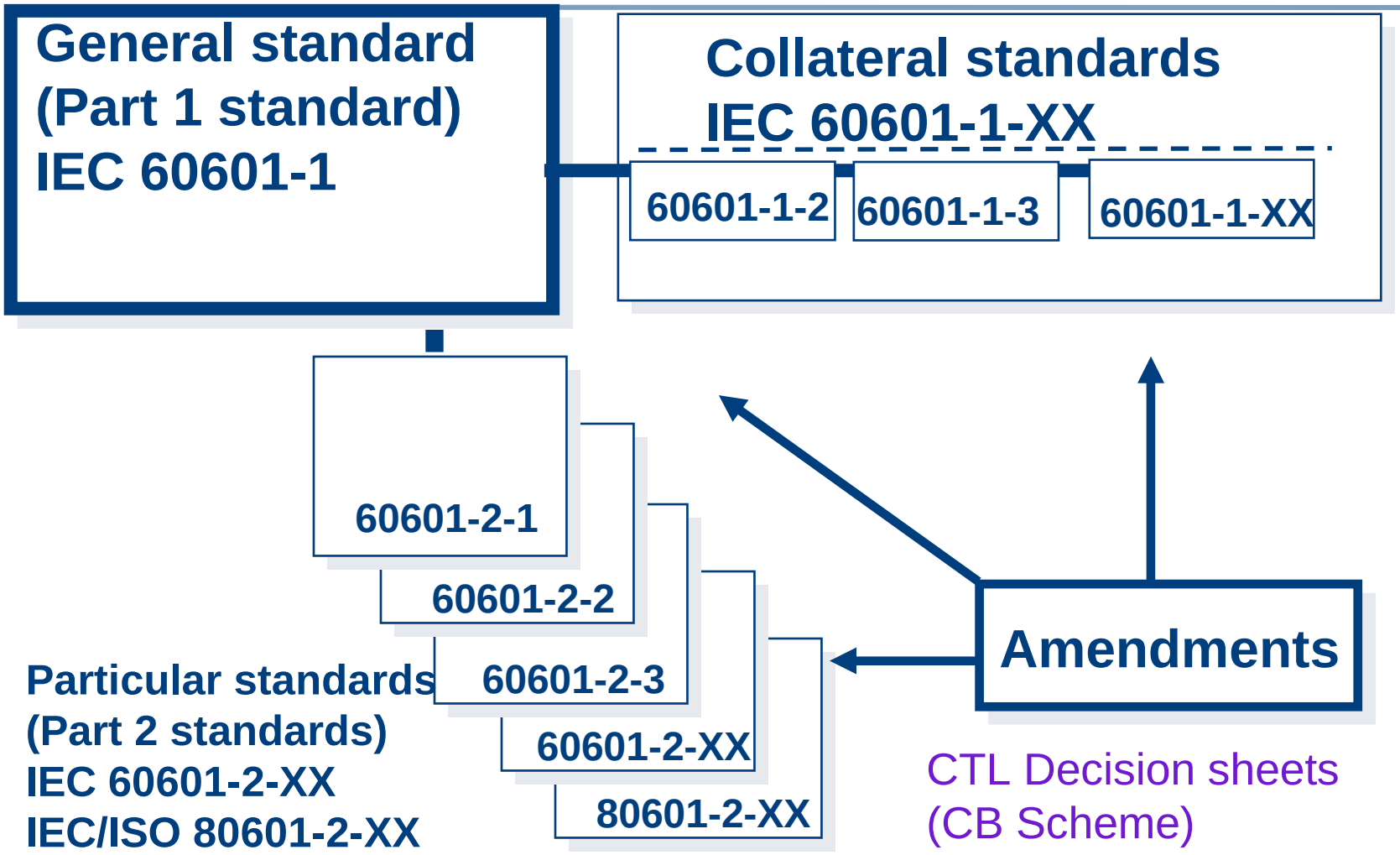
Transition to 60601-1, 3rd Edition

(In the EU part 2 standards may complicate this, however)



FDA has announced an official date of 2010-06 when they will accept submissions to 3rd edition.
The 3rd Edition will be Mandatory 2013-06-01
Health Canada has announced a mandatory date of 2012-06-01
The EU date of 2012-06-01 has been published in the Official Journal.
CB Scheme mandatory use for 3rd edition varies per the policy of each member country.

Structure of IEC 60601



Collateral Standards

Obsolete standards

IEC 60601-1-1	medical systems	incorporated (cl. 16)
IEC 60601-1-4	Software	incorporated (cl. 14)
IEC 60601-1-2	EMC risks	incorporated (cl. 17)

Retained standards

IEC 60601-1-2 (2007)	EMC	issued (2012-06-01)
IEC 60601-1-3 (2008)	Radiology	issued (2012-06-01)
IEC 60601-1-6 (2006)	Usability	issued (2012-06-01)
IEC 60601-1-8	Alarms	issued (2012-06-01)

New standards

IEC 60601-1-9	Environment	Issued
IEC 60601-1-10	Closed loop cont.	Issued
IEC 60601-1-11	Home health care	Issued

Particular Standards Retained

IEC 60601-2-1	Electron accelerators
IEC 60601-2-2	HF surgical equipment (2012-04-01)
IEC 60601-2-5	Ultrasonic physiotherapy equipment
IEC 60601-2-16	Haemodialysis equipment
IEC 60601-2-18	Endoscopic equipment
IEC 60601-2-19	Baby incubators (2012-04-01)
IEC 60601-2-20	Transport incubators
IEC 60601-2-21	Infant radiant warmers (2012-04-01)
IEC 60601-2-22	Laser equipment
IEC 60601-2-28	X-Ray Tube Assemblies for Medical Diagnosis
IEC 60601-2-29	Radiotherapy simulators (2011-11-01)
IEC 60601-2-31	External cardiac pacemakers with internal power source
EC 60601-2-37	Ultrasonic medical diagnostic and monitoring equipment (2010-10-01)
IEC 60601-2-39	Peritoneal dialysis equipment (2011-03-01)
IEC 60601-2-41	Surgical luminaires and luminaires for diagnosis
IEC 60601-2-43	X-ray equipment for Interventional Procedures
IEC 60601-2-44	X-ray equipment for computed tomography (2012-05-01)
IEC 60601-2-50	Infant phototherapy equipment (2012-05-01)

More to come… many are in various stages of the development process

Particular Standards New or Partly New

IEC 60601-2-52	Medical beds
IEC 60601-2-54	X-ray equipment for radiography and radioscopy
IEC 80601-2-30	Automated non-invasive sphygmomanometers
IEC 80601-2-35	Blankets, pads and mattresses
ISO 80601-2-56	clinical thermometers
IEC 80601-2-58	Lens removal devices and vitrectomy devices
IEC 80601-2-59	Screening thermographs for human febrile temperature screening

More to come… many are in various stages of the development process

2nd vs. 3rd edition
Which edition is best at the moment?

- **No consistent answer… but 3rd edition is now usually the better choice for new devices.**

- It depends on the goals & preparedness of the manufacturer, and the type of device.

- Intertek issues the ETL certification mark to 3rd edition for devices where all the standards have been issued.

Classes

Protection class	***I, II, (III) & internally powered***	
Degree of protection	*Type* ***B, BF & CF***	
Product class (MDD)	***I, Im, Is, IIa, IIb & III***	
Overvoltage category	***I, II, III & IV***	
Material group	***I, II, IIIa & IIIb***	
Pollution degree	***1, 2, 3 & 4***	
Laser class	***1, 1M, 2, 2M, 3R, 3B & 4***	
IP-class (solids & water)	***IP20 - IP68***	
FDA product class	***I, II & III***	*(not same as MDD)*
USA laser class	***1, 2, …***	*(not same as IEC)*

New philosophy versus ed. 2

- Introduces the concept **Essential Performance**
- Introduces **Risk Management** - ISO 14971 as normative
- **Risk Management File** must be submitted with type testing
- More completely addresses many types of hazards, not just electric shock, fire & energy hazards.
- Covers aids for disabled persons
- *Comprises 17 clauses, 390 pages (ed. 2 = 59 clauses, 250 pages)*

Risk related terms

3.100 Residual risk

3.102 Risk (666 hits)

3.103 Risk analysis

3.104 Risk assessment

3.105 Risk control

3.106 Risk evaluation

3.107 Risk Management (236 hits)

3.108 Risk Management File (109 hits)

Defined terms (3)

- *There are 139 terms in alphabetic order.*
- *Index on pages 749 to 777 states the pages where the term is used (even numbered pages are in French).*
- *The term **LIVE** deleted !*
- Some examples: →

3.63 Medical Electrical Equipment

- *Electrical equipment, provided with not more than one connection to a particular supply mains; and*

- *2. intended to be used:*

  a) in diagnosis, treatment, or monitoring of a PATIENT; and has an APPLIED PART or transfers energy to or from the patient or detects such energy transfer to or from the patient;

  or

  b) for compensation or allevation of a disease, injury or disability.

  - (”under medical supervision” deleted)
  - Very similar to MDD Article 1

3.76 Patient

- *Living being (person or animal) undergoing a medical, surgical or dental procedure*

3.8 Applied Part

- *Part of the ME E that in NORMAL USE necessarily comes into physical contact with the PATIENT for the ME E or ME S to perform its function*

- *Some parts, that are not Applied Parts, may have to be treated as Applied Parts.*

RMF

Applied Part

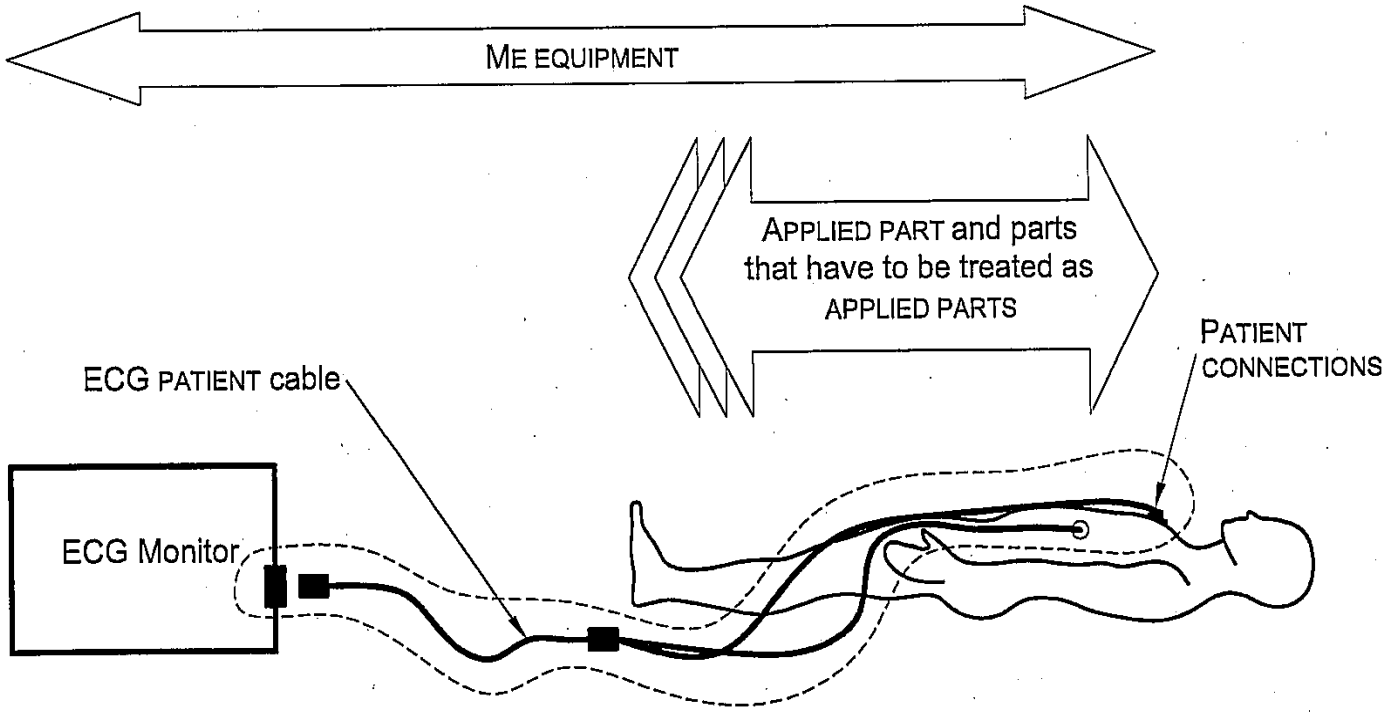


Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT

Applied Part

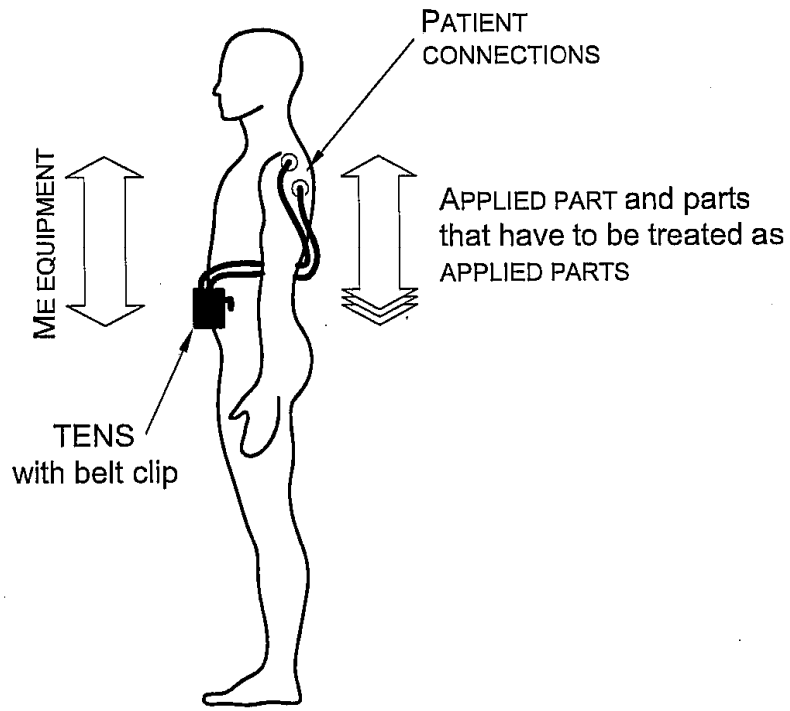


Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the PATIENT's belt and connected to electrodes applied to the PATIENT's upper arm

Defined Terms Continued

3.28 ***Expected Service Life***

Maximum expected service life as defined by the manufacturer

3.38 ***Harm***

Physical injury or damage to the health of people or animals or damage to property or the environment

3.39 ***Hazard***

Potential source of "Harm"

3.27 * Essential Performance

- ***Performance necessary to achieve freedom from unacceptable risk.***

- ***EP criteria must be defined by the manufacturer.***

- *Present versions of 2nd Edition Part 2 standards that have been recently issued have substantial performance requirements! For example, see clause 50 – Accuracy of operating data & 51 – Protection against hazardous output 201.12 – Accuracy of controls and instruments and protection against hazardous outputs*

RISK MANAGEMENT (subclause 4.2)

- A risk management process according to ISO 14971 shall be performed.

  meaning

- Certification to IEC 60601-1 **not possible** without compliance with ISO 14971.

- IEC 60601-1 is intended to serve as a tool in the risk management process.
  - The manufacturer must have a policy for establishing acceptable risks and acceptance of residual risks.
  - *Fault conditions" in ISO 14971 include, but are not limited to, SFC in IEC 60601-1.*
  - *All risks are not covered by IEC 60601-1.*

RISK MANAGEMENT (subclause 4.2)

- *The requirements of this standard, referring to inspection of the **RMF**, are considered to be satisfied if the manufacturer has:*
  - - established a risk management process
  - - established acceptable levels of risk
  - - shown that the residual risks are acceptable (according to the policy for determining acceptable risk)

RISK MANAGEMENT (subclause 4.2)

- ***Downside to the concept of Risk:***
  - - More work to be done before sending device to the test house.
  - - Less concrete requirements in standard.
  - - More work to be done by the test house.

- ***Upside to the concept of Risk:***
  - - Reduces the uncertainty of the safety of the device.
  - - Greater design flexibility.
  - - Provides Objective Evidence when using the “escape clause.”

Essential Performance (4.3)

- Concept is not new.

- Old 3.1 of 60601-1, 2nd edition:

> 3.1 EQUIPMENT shall, when transported, stored, installed, operated in NORMAL USE, and maintained according to the instructions of the manufacturer, cause no SAFETY HAZARD which could reasonably be foreseen and which is not connected with its intended application, in NORMAL CONDITION and in SINGLE FAULT CONDITION.

  - Lack of specific means in old standard to address this meant it was usually not completely addressed.

- More specific requirements in some Part 2 standards.
  - For example, Accuracy requirements.

- Also Annex I “Essential Requirements” of MDD.

Essential Performance (4.3)

- What happens when there is not a Part 2 standard to dictate essential performance?
  - Go back to the definition:

3.27

* **ESSENTIAL PERFORMANCE**

performance necessary to achieve freedom from unacceptable RISK

NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

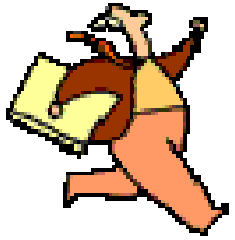
- All applicable fault condition testing cannot be identified without identifying Essential Performance in the RMF.
  - Conversely, all fault conditions that should not be considered cannot be adequately justified without the RMF.

”Escape clause” (subclause 4.5)

- *Alternative means of addressing a risk is acceptable,*

- *provided that the manufacturer can justify that the Residual Risk is at least as low as if the standard’s requirement of addressing that particular Risk had been applied.*

RMF



Identification, Marking & Documentation
(clause 7)

- *Marking clearly legible at any angle of 30° maximum from 1 meter away and the least favorable light between 100 - 1500 lux*

  with normal log MAR scale

- *sight = 0*
- *(sight 1.0 in Europe)*
- *(20/20 in the US)*

- *Clearly legible after being rubbed for 15 s with water, methylated spirit and isopropyl alcohol and the cleaning agents specified by the manufacturer*

(clause 7) Continued

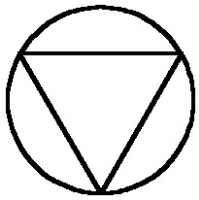
- *The risk of poor Usability shall be addressed in Risk Management Process*
-
- *- design, marking and instructions*
- *- arrangement of controls, signals and instruments (15.1)*
  - **RMF**
- *Usability IEC 60601-1-6*

Markings and Instructions

Consult accompanying documents
(old meaning in 2nd edition)

Caution
(new meaning in 3rd edition)

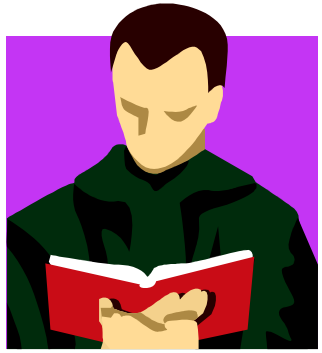
Operating instructions
(new for 601-1, 3rd edition)



Stop (often was used for emergency stop)

Emergency stop
(new for 601-1, 3rd edition)

Documentation (subclause 7.9)

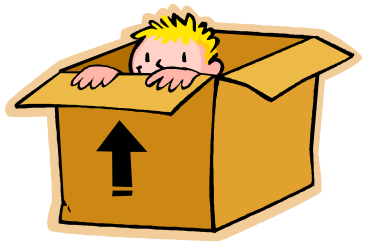


Accompanying documentation shall:

- *State the skills, training and knowledge required of the Operator or the Responsible Body.*
- *Be written on a level consistent with the education, training, and special needs of the person for whom the document is intended.*
- *The documentation shall written in a language understandable by the reader.*
- *The Operating manual may be provided in electronic (not internet) form and the Risk Management Process shall establish what parts that may be required also as hard copy*

Packaging (clause 7.2)

- *Packaging shall be marked with the requirements for transport and storage*

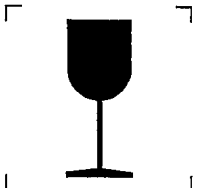


- *- Environmental conditions*
- *Special handling / transportation means*

- *ISO 780 and ISO 15223 shall apply* →

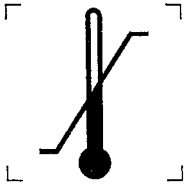
Packaging (clause 7.2)

Symbols acc. to ISO 780

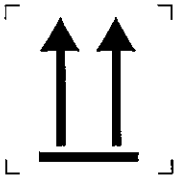


Fragile

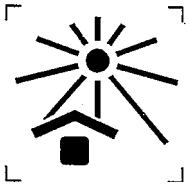
Keep away from rain



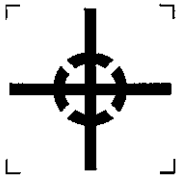
Temperature limits



This way up

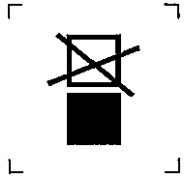


Keep away from sunlight



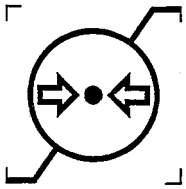
Centre of gravity

Use no forks

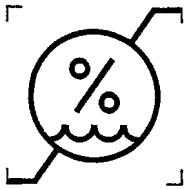


Do not stack

Symbols acc. to ISO 15223



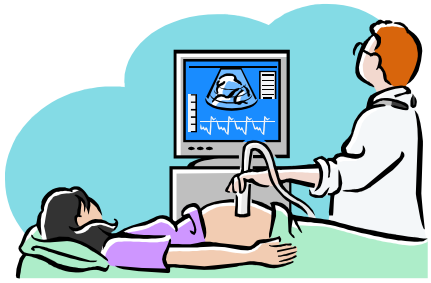
Atmospheric pressure limitation



Humidity limitation

Means of Protection (MOP) (subclause 8.5.1)

- *MOP divided into two categories*
- *MOOP (Means of Operator Protection)*
- *MOPP (Means of Patient Protection)*



RMF

Insulation coordination

- Working Voltage

- Air Clearances &
- Creepage Distances

Old vs. new methods

- *2nd edition has a table that is easier to use.*
  - But the table relies on knowing how to use strange alphanumeric codes for types of insulation.
- *3rd edition has 9 tables for the same thing!*
  - These tables allow for a more compact and less costly design.
  - Overall these tables are difficult for the layperson to understand unless they also have experience with IEC 60950-1 (for information technology equipment).
- ***Highlighted areas on tables are most typical figures.***

Old versus new isolation requirements

- *Continuing to use old approach of 2nd edition is generally acceptable for 3rd edition.*
  - **Old approach has less complex tables and more familiar**.
- *New approach has much more complex tables, but can allow a more compact design and at less cost in many cases.*
- *The philosophy of two means of protection has not changed, nor have the major locations where insulation is required.*

Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s. up to and including	Spacing providing one MEANS OF PATIENT PROTECTION		Spacing providing two MEANS OF PATIENT PROTECTION	
		CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm
17	12	1,7	0,8	3,4	1,6
43	30	2	1	4	2
85	60	2,3	1,2	4,6	2,4
177	125	3	1,6	6	3,2
354	250	4	2,5	8	5
566	400	6	3,5	12	7
707	500	8	4,5	16	9
934	660	10,5	6	21	12
1 061	750	12	6,5	24	13
1 414	1 000	16	9	32	18
1 768	1 250	20	11,4	40	22,8
2 263	1 600	25	14,3	50	28,6
2 828	2 000	32	18,3	64	36,6
3 535	2 500	40	22,9	80	45,8
4 525	3 200	50	28,6	100	57,2
5 656	4 000	63	36,0	126	72,0
7 070	5 000	80	45,7	160	91,4
8 909	6 300	100	57,1	200	114,2
11 312	8 000	125	71,4	250	142,8
14 140	10 000	160	91,4	320	182,8

Up to 1000 V_{RMS}, AC & CD in this table is exactly the same as the old Table XVI of 2nd edition.

However, DC working voltages to not correlate to the old table.

Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART

AIR CLEARANCE in mm

WORKING VOLTAGE up to and including		NOMINAL MAINS VOLTAGE ≤ 150 V (MAINS TRANSIENT VOLTAGE 1 500 V)				150 V < NOMINAL MAINS VOLTAGE ≤ 300 V (MAINS TRANSIENT VOLTAGE 2 500 V)		300 V < NOMINAL MAINS VOLTAGE ≤ 600 V (MAINS TRANSIENT VOLTAGE 4 000V)	
Voltage peak or d.c.	Voltage r.m.s (sinusoidal)	Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1, 2 and 3		Pollution degrees 1, 2 and 3	
V	V	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP
210	150	1,0	2,0	1,3	2,6	2,0	4,0	3,2	6,4
420	300	1 MOOP 2,0 2 MOOP 4,0						3,2	6,4
840	600	1 MOOP 3,2 2 MOOP 6,4							
1 400	1 000	1 MOOP 4,2 2 MOOP 6,4							
2 800	2 000	1 or 2 MOOP 8,4							
7 000	5 000	1 or 2 MOOP 17,5							
9 800	7 000	1 or 2 MOOP 25							
14 000	10 000	1 or 2 MOOP 37							
28 000	20 000	1 or 2 MOOP 80							
AIR CLEARANCES for WORKING VOLTAGES above 20 kV r.m.s. or 28 kV d.c. can be prescribed by particular standards if necessary.									
NOTE AIR CLEARNACES are a function of peak voltage in the circuit. The r.m.s. voltage column is provided for the special case where the voltage has a sinusoidal waveform.									

This table is for the typical situation of Overvoltage Category II, as the Mains Transient Voltage for the Nominal Mains Voltage corresponds to that in Table 10.

For equipment connected to an Overvoltage Category III mains, the next higher column is used. Be mindful of the Overvoltage Category as that is the real criterium one uses for which column is employed.

Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION [a]

CREEPAGE DISTANCE in mm

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
50	Use the AIR CLEARANCE from the appropriate table	0,6	0,9	1,2	1,5	1,7	1,9
100		0,7	1,0	1,4	1,8	2,0	2,2
125		0,8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1,0	1,4	2,0	2,5	2,8	3,2
250		1,3	1,8	2,5	3,2	3,6	4,0
300		1,6	2,2	3,2	4,0	4,5	5,0
400		2,0	2,8	4,0	5,0	5,6	6,3
600		3,2	4,5	6,3	8,0	9,6	10,0
800		4.0	5,6	8,0	10,0	11,0	12,5
1 000		5,0	7,1	10,0	12,5	14,0	16,0

NOTE Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.

[a] CREEPAGE DISTANCES within this table apply to all situations.

Table 13 is 2 mm for 150 V > AC ≤ 300 V for the typical Overvoltage Category II.

Note that this table is not specifically for mains or secondary circuits as is the case for AC.

For voltages above 1000 V, CD = AC.

Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION

PEAK WORKING VOLTAGE (*U*) V peak	PEAK WORKING VOLTAGE (*U*) V d.c.	A.C. test voltages in V r.m.s.							
		MEANS OF OPERATOR PROTECTION				MEANS OF PATIENT PROTECTION			
		Protection from MAINS PART		Protection from SECONDARY CIRCUITS		Protection from MAINS PART		Protection from SECONDARY CIRCUITS	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOPP	Two MOPP	One MOPP	Two MOPP
U < 42,4	*U* < 60	1 000	2 000	No test	No test	1 500	3 000	500	1 000
42,4 < *U* ≤ 71	60 < *U* ≤ 71	1 000	2 000	See Table 7	See Table 7	1 500	3 000	750	1 500
71 < *U* ≤ 184	71 < *U* ≤ 184	1 000	2 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
184 < *U* ≤ 212	184 < *U* ≤ 212	1 500	3 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
212 < *U* ≤ 354	212 < *U* ≤ 354	1 500	3 000	See Table 7	See Table 7	1 500	4 000	1 500	3 000
354 < *U* ≤ 848	354 < *U* ≤ 848	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
848 < *U* ≤ 1 414	848 < *U* ≤ 1 414	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
1 414 < *U* ≤ 10 000	1 414 < *U* ≤ 10 000	See Table 7	See Table 7	See Table 7	See Table 7	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
10 000 < *U* ≤ 14 140	10 000 < *U* ≤ 14 140	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
U > 14 140	*U* > 14 140	If necessary, to be prescribed by particular standards							

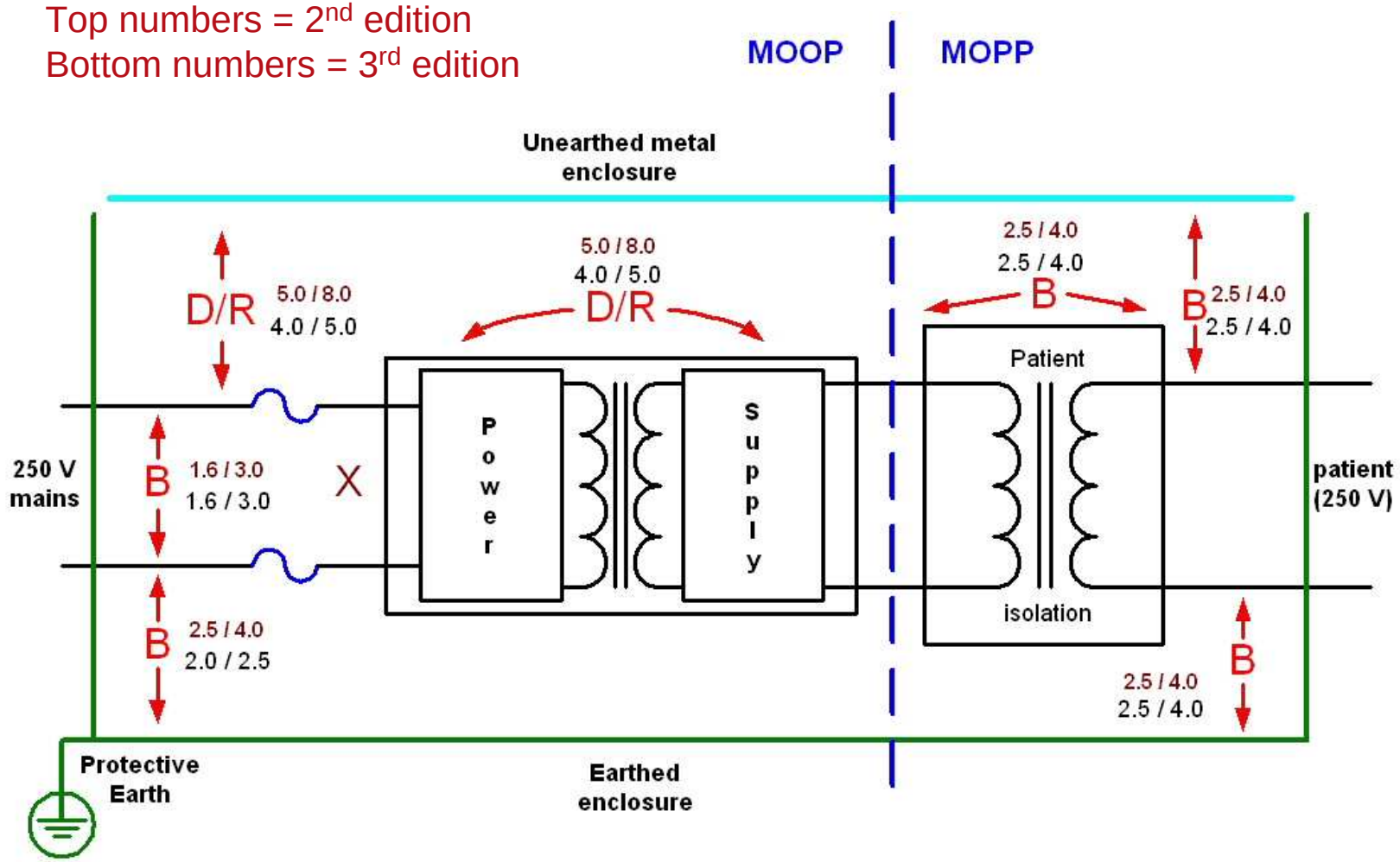
For MOOP and MOPP

Old versus new Type BF & CF isolation MOOP & MOPP

- *Actual spacings are based on measured working voltages.*
- *MOOP parts can always be classified as MOPP, at the manufacturer's choice based on the RMF.*
- *"X" means you can short parts after the fuse in lieu of spacings.*

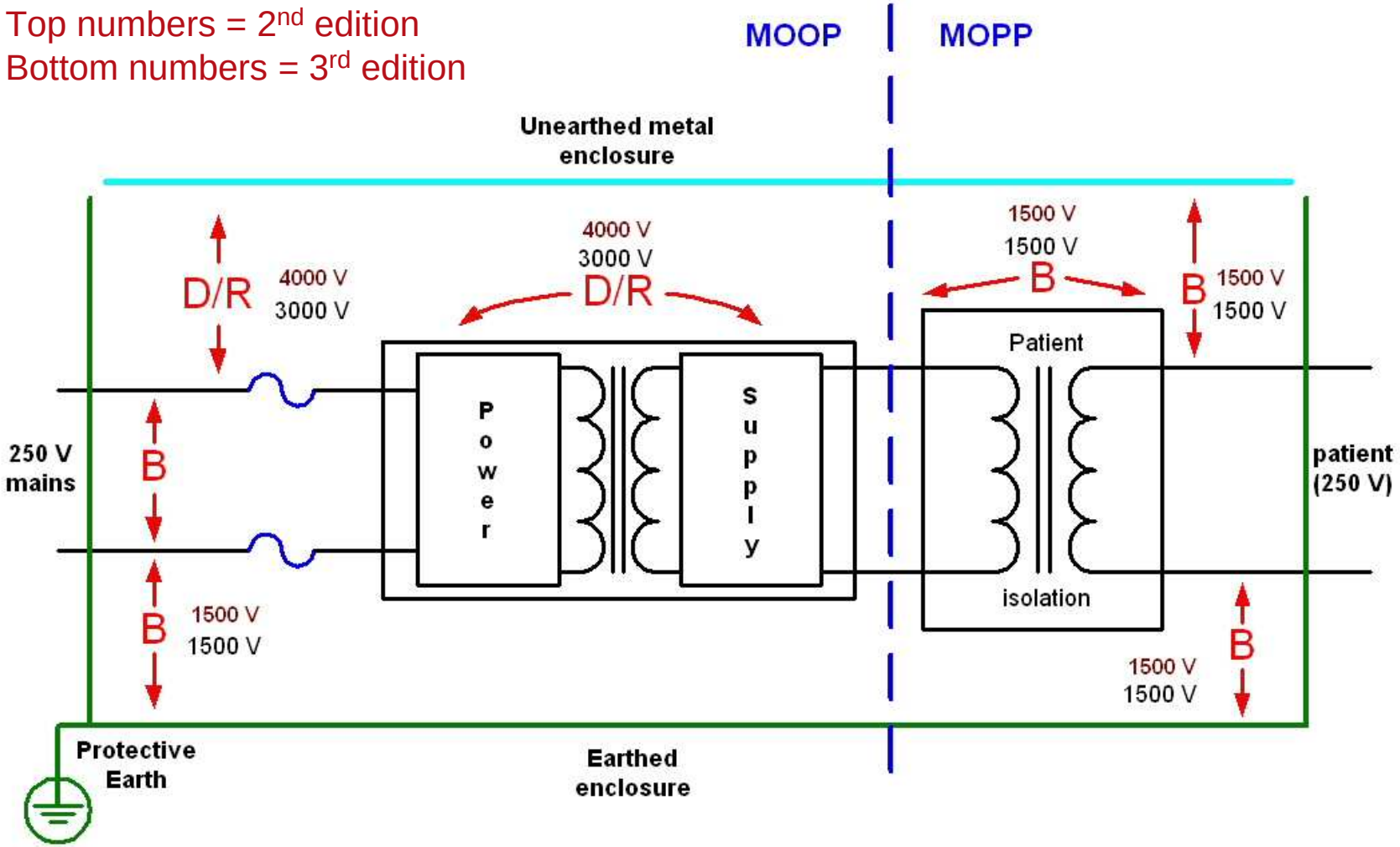
Old versus new Type BF & CF isolation
MOOP & MOPP

Top numbers = 2nd edition
Bottom numbers = 3rd edition

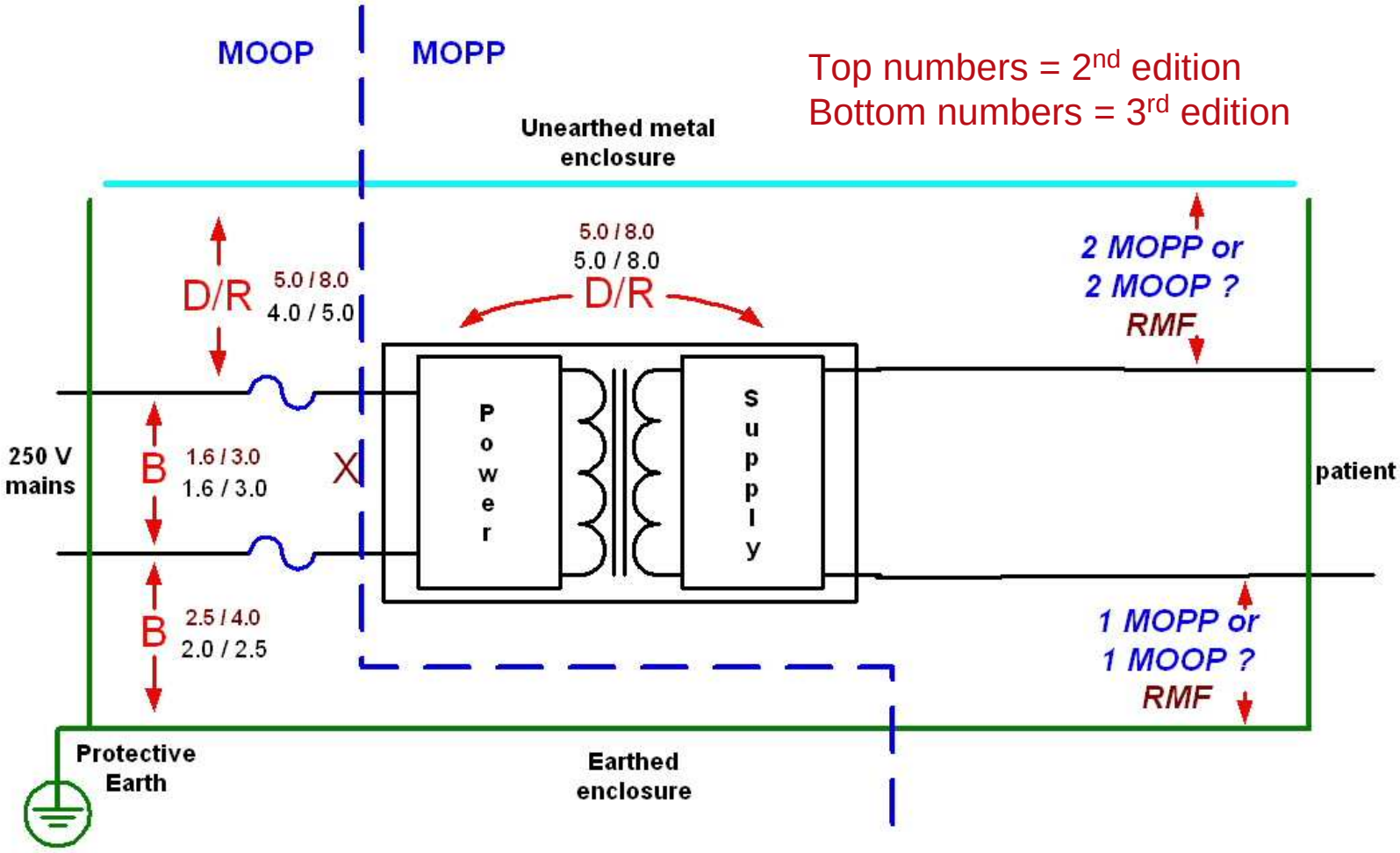


Old versus new Type BF & CF isolation
MOOP & MOPP

Top numbers = 2nd edition
Bottom numbers = 3rd edition

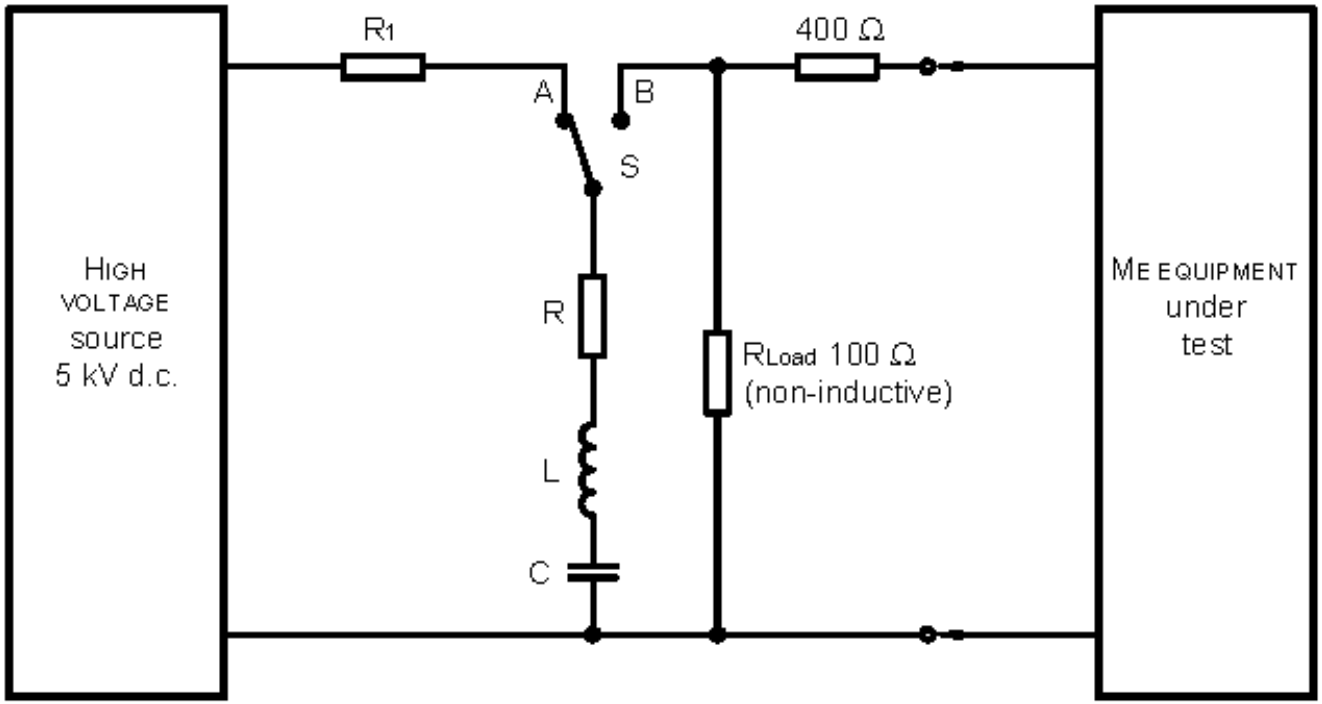


Old versus new Type B isolation
MOOP & MOPP



Energy reduction test (subclause 8.5.5)

During defibrillation ≥ 90% of the energy shall go to the patient

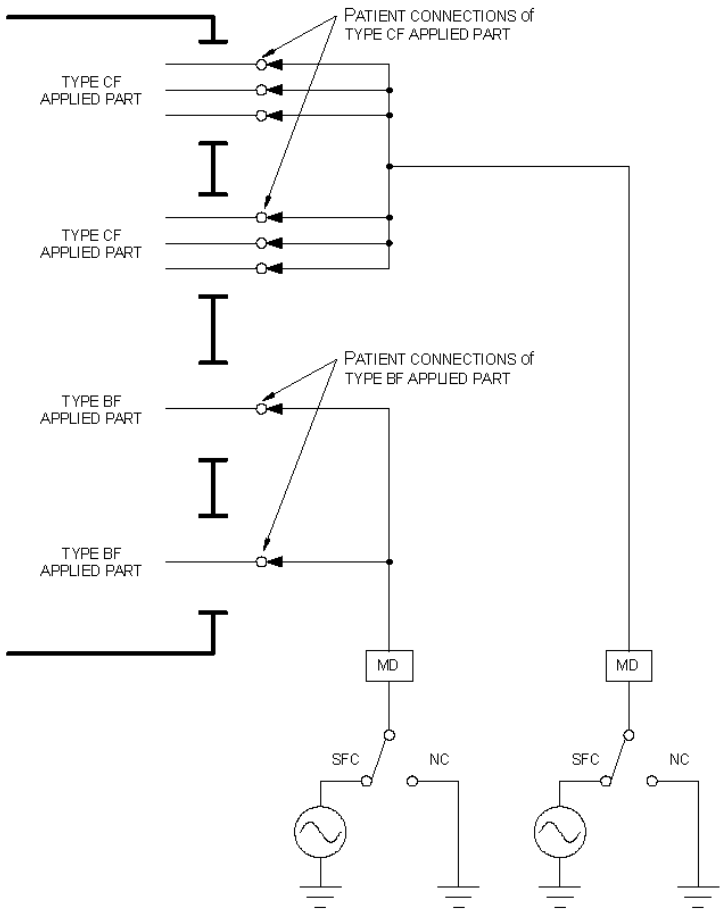


Leakage current (subclause 8.7)

- Earth Leakage Current
- Touch Current: Same as Enclosure Leakage Current in old edition
- Patient Leakage Current
- Total Patient Leakage Current
- Patient Auxiliary Current

(Total) patient leakage current

Figure 20



Allowed current levels (subclause 8.7)

	NC	*SFC*
Earth leakage	*5 mA*	*10 mA*
Touch current	*100 µA*	*500 µA*

Irrespective of frequency no leakage current may be over 10 mA through 1 kohm

- **Patient leakage values have not changed**

Hand and foot controls (subclause 8.10)

- *Secondary circuit isolated by min. 2 MOOP*
- *Max. 42.4 V peak or 60 V DC*

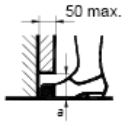
- *IP X1* *General*
- *IP X6 (15.4.7)* *ICW / Op-room*

RMF

- *Cord anchorage* *same req. as for the mains cord !*
- *and cord guard*

- *Foot control* *135 kg on 30 mm,*
- *not activated in wrong position*

Table 20 Acceptable gaps (clause 9.2)

Part of body	Adult gap *a* mm	Children gap *a* mm	Illustration
Body	>500	>500	
Head	>300 or <120	>300 or <60	
Leg	>180	>180	
Foot	>120 or <35	>120 or <25	
Toes	>50	>50	
Arm	>120	>120	
Hand, wrist, fist	>100	>100	
Finger	> 25 or < 8	> 25 or < 4	

[a] The values in this table are taken from ISO 13852:1996.

Based on Machinery Directive standard EN 349

Part 2 standards will augment and modify these requirements.

Stability and mobility (subclause 9.4)

- *Must not tip over at 5 degrees in Normal Condition*
- *If tipping over at 5 - 10 degrees a warning sign is required*
- *Must not tip over at 10 degrees in transport mode*
- *If >25 kg must not tip over at a static pressure of 25% of the weight but maximum 220 N (even if labelled)*

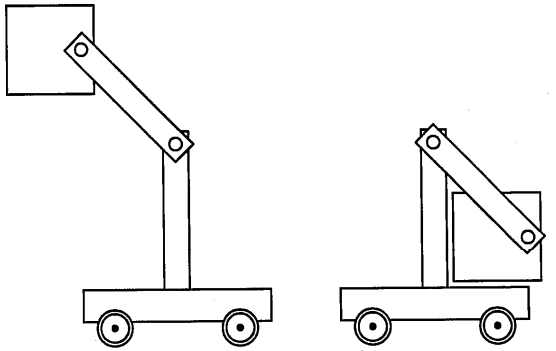


Figure A.15 – Instability test conditions

Noise & Vibration (subclause 9.6)

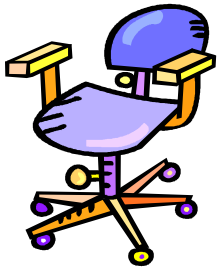
- ***Noise:***
  - *Max. 80 dBA accumulative 24 h for 24 h (allowed +3 dBA for each half value of accumulative)*
  - *Max. 140 dB un-weighted for impulse*
  - *Ultra and Infra sound*

- ***Vibration "White fingers"***
  - *Max.. 2.5 m/s² cumulative 8 h for 24 h*

Mechanical strength (safety factor from 2.5 to 12)
(subclause 9.8)

Supports (tables, chairs etc.) 135 + 15 = 150 kg

- Weight of patient plus accessories.



- RMF
- Chairs tested with 135 kg free fall from 15 cm
- Foot rest tested with 270 kg on 0.1 m^2
- Surfaces (20 x 20 cm) on which one may
- stand or sit are tested with 800 N

Table 21 – Determination of Tensile Safety Factor (Clause 9.8)

Situation			Minimum TENSILE SAFETY FACTOR [a]	
No.	System Part	Elongation	A [b]	B [c]
1	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
2	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
3	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	5	8
4	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break of less than 5 %	8	12
5	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
6	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
7	MECHANICAL PROTECTIVE DEVICE (or back-up system of multiple support system)		2,5	4

Equipment not intended to emit radiation
(clause 10)

- *Standards used*
  - *Non intentional X-ray limits from* *IEC 60950-1* *(5 uSv/h at 5 cm)*
- *Infrared and laser* *IEC 60825-1* *(IEC 60601-2-22)*

- *Radiation hazards to be controlled via* ***RMF***

  - *Alfa, Beta, Gamma and Neutron*
  - *Microwave* *(IEC 61010-1 = 1 GHz - 100 GHz, 10 W/m^2)*
- *Visual electromagnetic (except laser)*
  - *UV*

Temperatures on accessible parts

(Clause 11.1 & Table 23)

ME EQUIPMENT and its parts		Maximum temperature [a] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "*t*"	*t* < 1 s	74	80	86
	1 s ≤ *t* < 10 s	56	66	71
	10 s ≤ *t* < 1 min	51	56	60
	1 min ≤ *t*	48	48	48

[a] These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

RMF

At specified ambient temperature

Temperatures on applied parts at specified ambient temperature (Clause 11.1 & Table 24)

APPLIED PARTS of ME EQUIPMENT		Maximum temperature [a b] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
APPLIED PART having contact with the PATIENT for a time "*t*"	*t* < 1 min	51	56	60
	1 min ≤ *t* < 10 min	48	48	48
	10 min ≤ *t*	43	43	43

[a] These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

[b] Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 24 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.

> 41 ˚C = Statement in manual &

Clinical effects and justification in the *RMF*

Old vs. new optional fire enclosure requirements (Clause 55 vs. Sub-clause 11.3)

Part	Old UL 60601-1 *	New
Enclosure (Transportable equipment)	V-2	V-2
Enclosure (Fixed or Stationary equipment)	V-0	V-1
Large panel (100 ft^2 / 9.47 m^2)	Flame spread 75	N/A
Large panel (50 ft^2 / 4.74 m^2)	Flame spread 75	N/A
Internal parts		
Connectors	N/A	V-2
PC boards (& insulating material)	N/A	V-2
Internal wiring	N/A	equivalent to V-1

* The IEC 2nd edition standard has no requirements!

Software (clause 14)

- *Major part of the content of the old IEC 60601-1-4 for IEC 60601-1, 2nd edition constitutes clause 14.*

- *Clause 14 applies when the use of ISO 14971 is not sufficient*

RMF

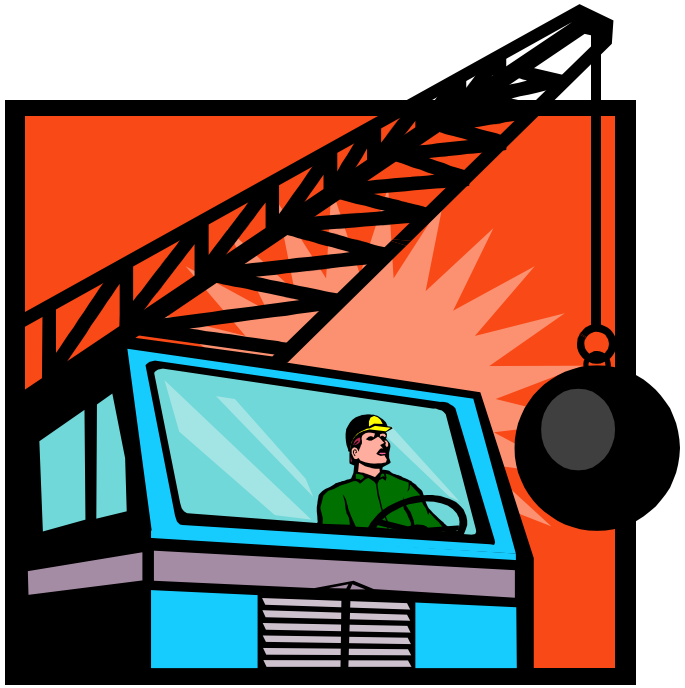
Enclosure rigidity
(clause 15)

- *Impact test with steel ball 0.5 kg from 1.3 m.*

RMF

- *Drop test for hand-held parts from 1 m on a 50 mm hardwood surface with a density of >600 kg/m^3. Three different start positions*

- *Portable equ. Tested with drop height 2-5 cm depending on weight*

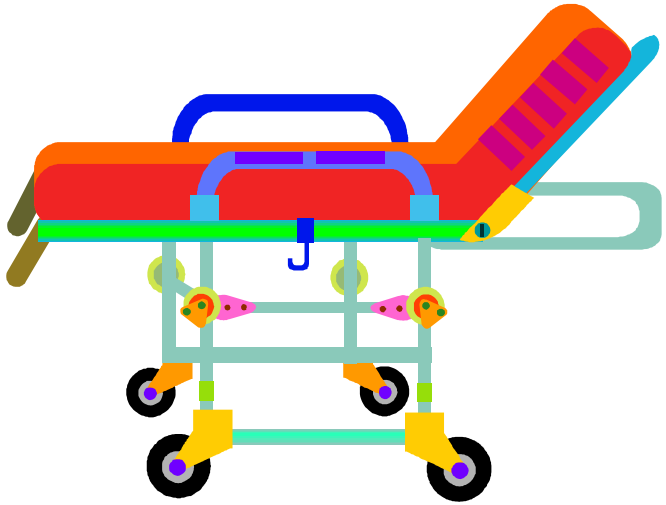


- *Press test: 250 N with 30 mm diameter probe*

RMF

Mobile equipment

RMF



- *- Threshold obstruction (0.4 m/s against 40 mm height)*

- *- Descending step (0.4 m/s down 40 mm height)*

- *- Door obstruction (0.4 m/s against pole 40 x 40 mm)*

ME System (clause 16)

- *Major part of the content of the old IEC 60601-1-1 for IEC 60601-1, 2nd edition constitutes clause 16.*

RMF

- *Group of products, at least one of which is a MEE, functionally inter-connected or supplied from a Multiple Socket Outlet (MSO).*

- *Separation Device shall be used to limit leakage currents.*

EMC (clause 17)

- The manufacturer shall in the **RMF** address the risks associated with electromagnetic phenomena that may degrade the performance of the ME equipment and the ME equipment's affect on other products.

- IEC 60601-1-2 presented separately.

The keys to failure

- ***The approximate failure rate for all types of medical devices:***
- *95 % have incomplete manuals*
- *95 % have inadequate markings*
- *95 % have Risk Analysis deficiencies*
  - *Most, but not all, relate to electric shock, energy, and mechanical hazards*
- *60 % have component related problems*
  - *Particularly transformers and power supplies.*
- *50 % have insulation or spacing deficiencies*
- *30 % have excessive temperatures on the patient applied parts*
  - *Risk Management File does not justify temperature of applied part.*
- *30 % did not address all applicable particular and collateral standards*

The keys to Complying
Design reviews (earlier in process)

Almost all design mistakes or failures per 60601 can be lessened or eliminated with design (pre-compliance) review

- Submit drafts of manuals.
- Submit artworks when there is uncertainty.
- Significant constructional & component problems caught before EMC & safety testing.
- Temperatures, spacings, insulation, flammability, ratings, sample requirements etc.
- Risk Analysis is not comprehensive.
  - Need help? Annex E of ISO 14971: 2007 *Examples of hazards, foreseeable sequences of events and hazardous situations* is a good place to start.
  - Intertek's RMF checklist.

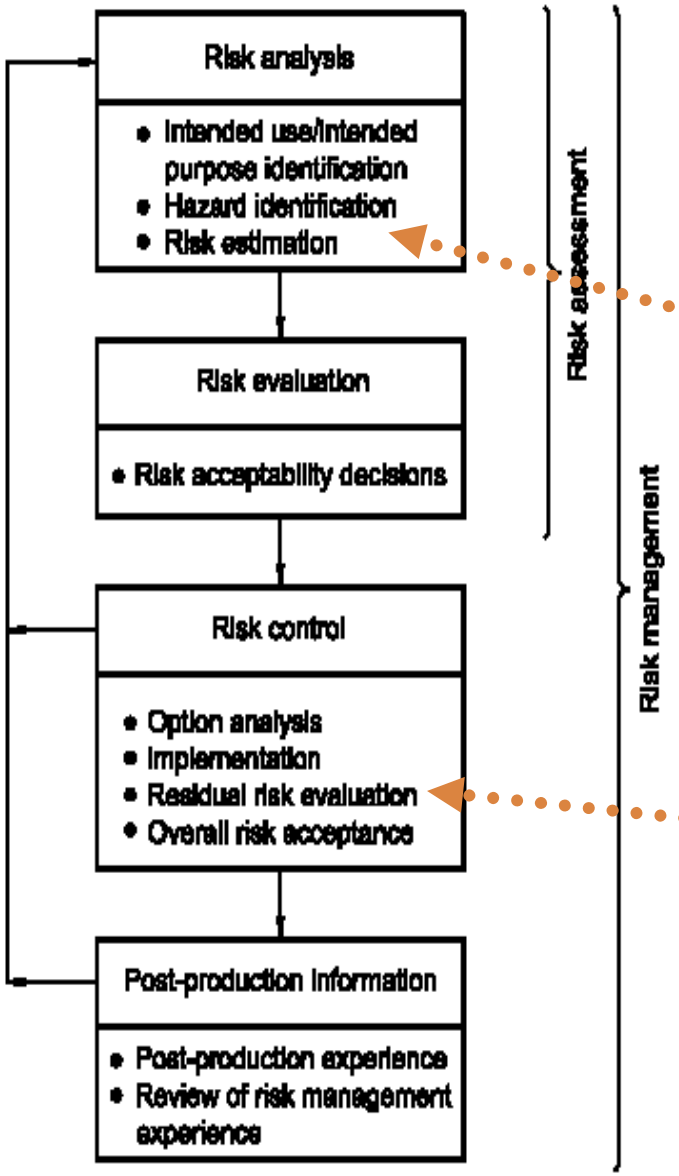
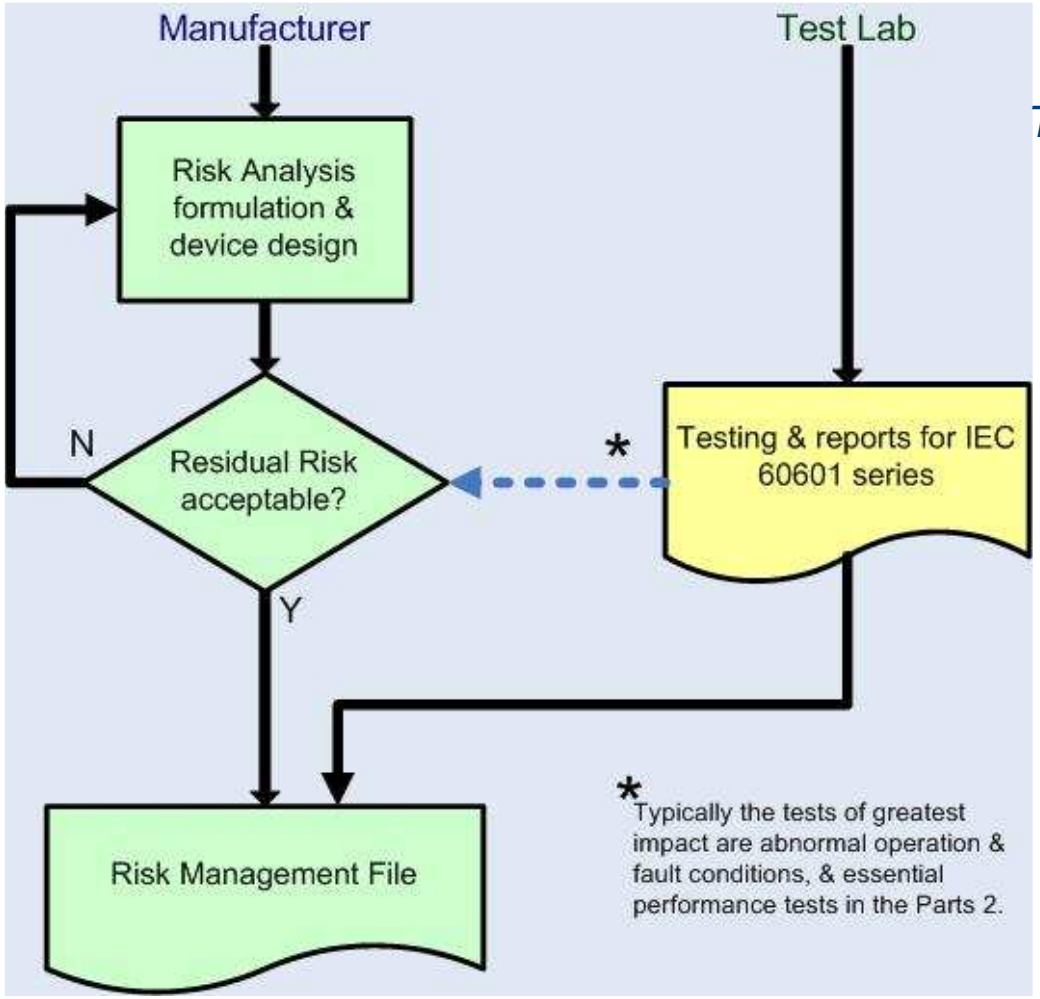


Figure 1 — Schematic representation of the risk management process

(4.3 of 14971)
Test house input during design review?

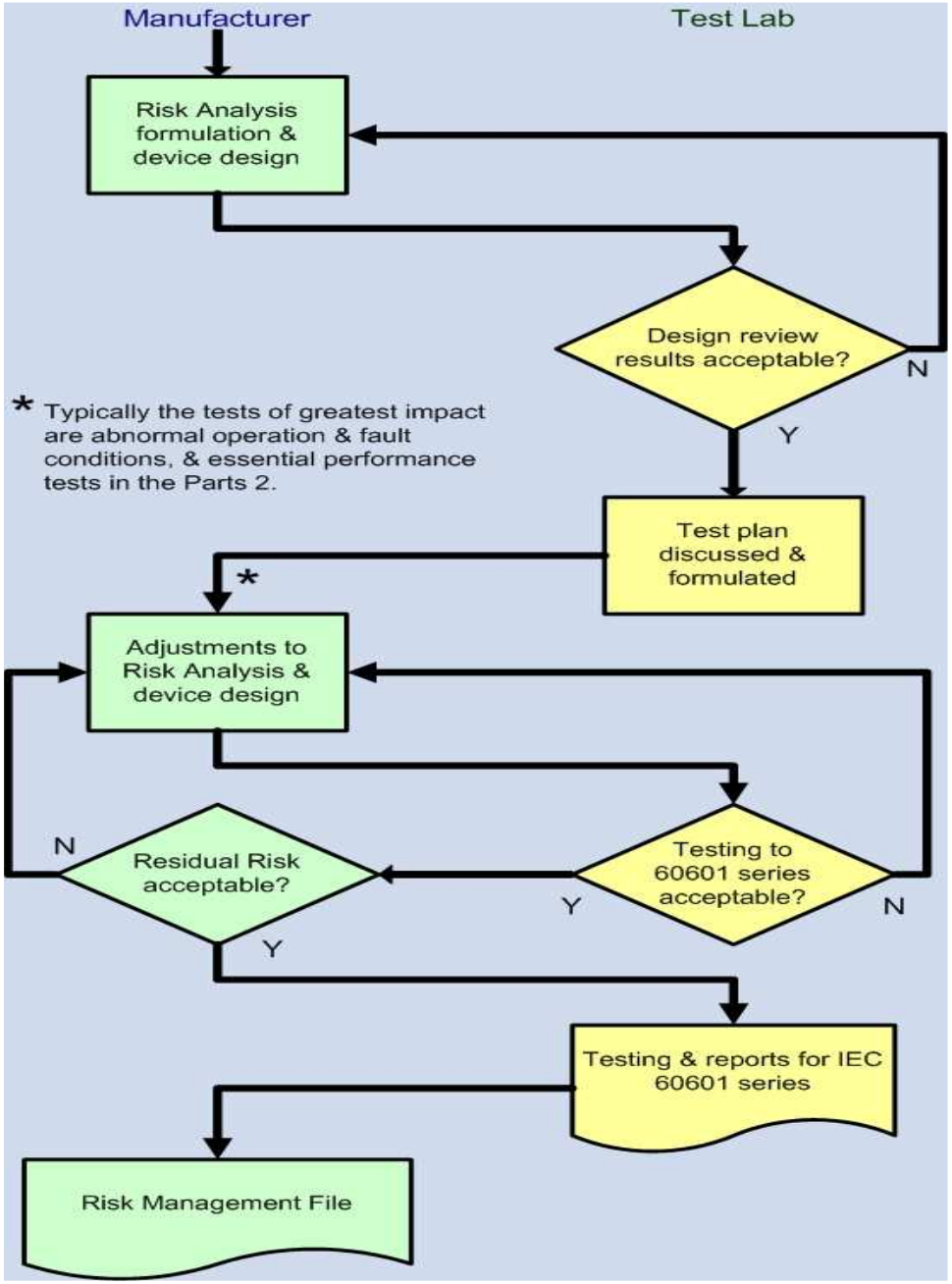
Examination of old reports for similar devices?

(6.4 of 14971)
Testing to 60601-1 & examination of results, particularly SFCs.



The typical 2nd edition process

- Interaction between the manufacturer & test lab is minimal.
- A design review after the risk analysis & initial design is ideal, but often does not happen.



The ideal 3rd edition process

- Interaction between the manufacturer & test lab is much greater.
- The manufacturer & test lab must work together for a 3rd edition evaluation to be successful.

Don’t let this happen to you!