



LNE / G-MED North America presents

IEC 60601-1 (Third Edition): Prepare for Regulatory Questions

presented by

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Presenter Bios / Contact Information

- **Christophe Morellec**
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An experienced auditor and technical expert, Christophe led the implementation of the original electrical safety standard (IEC 60601-1) during his five years at LCIE – the federal agency overseeing electrical industry testing in France. Now with LNE, Christophe regularly oversees testing for medical devices to the 60601-1 standard.

- **Sebastien Hardy**
Manager, Active and External Use Medical Devices, LNE/G-MED

As Certification Project Manager, Sebastien has worked with many G-MED clients to assess compliance to the IEC 60601-1 standard. He is a regular presenter on topics related to EU Medical Device Directives, including standards for electrical medical devices.

Please submit your questions to gmedna@lne-gmed.com.

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Webinar Agenda

- **Main Differences in Third Edition**
- **Key Elements**
 - Insulation
 - Mechanical Hazards
 - Construction
- **Notified Body Assessment**
 - European Regulation (MDD / Essential Requirements)
 - European Harmonized Standards
- **Impact of Changes During NB Assessment**
- **Link Between IEC 60601-1 and EN 62304**

Main Differences in the Third Edition

- **The first major difference is the modification of the clause number**
 - For example
 - In Edition 2 leakage current are in clause 19
 - In Edition 3 leakage current are in clause 8.7
- **To help us to make the link between this two editions IEC have written a technical report**
 - IEC 62348/TR Ed 1
- **In this report, the link can be made easily in the two ways**

Main Differences in the Third Edition

- **Some collateral standards are included in the new edition**
 - IEC 60601-1-4 (programmable electrical medical systems) now clause 14
 - IEC 60601-1-1 (Medical electrical systems) now clause 16
- **Presence of normative Annex**
 - For AP, APG product
- **Second parts was or will be modified too**
 - For example IEC 60601-2-38 (electrical medical beds) is now IEC 60601-2-52

Main Differences in the Third Edition

- **Introduction of risk management file**
 - According to ISO 14971- Application of risk management to medical devices
 - Conclusion of test (pass / fail) could be dependent of the risk management file

- **Introduction of ESSENTIAL PERFORMANCE**
 - performance necessary to achieve freedom from unacceptable RISK
 - The manufacturer have to define “essential performance”.

- **New tests were added**
 - Examples: impact test, fire classification for enclosure,
...

Main Differences in the Third Edition

- **Alignment with basic IEC safety standards where possible eg:**
 - IEC 60950-1: IT equipment - safety requirements
 - IEC 60664: Insulation coordination within low-voltage systems
 - IEC 60990: Methods of measurement of touch current and protective conductor current
- **Reflects current advances in materials and technologies**
- **Caters for environmental effects on the Products (eg high altitude, pollution)**

Main Differences in the Third Edition

- **Reasons for Change to IEC 60601-1**
 - More flexibility for design of new products
 - Use of more readily available power sources - saves cost
 - Updating to keep pace with new technology
 - Make IEC 60601-1 more user friendly and understandable
 - Alignment with basic standards as required by IEC e.g. IEC 60664-1.
 - Reduce spacings where these do not need to be so large
 - Introduce the option for DC Dielectric Strength Testing.

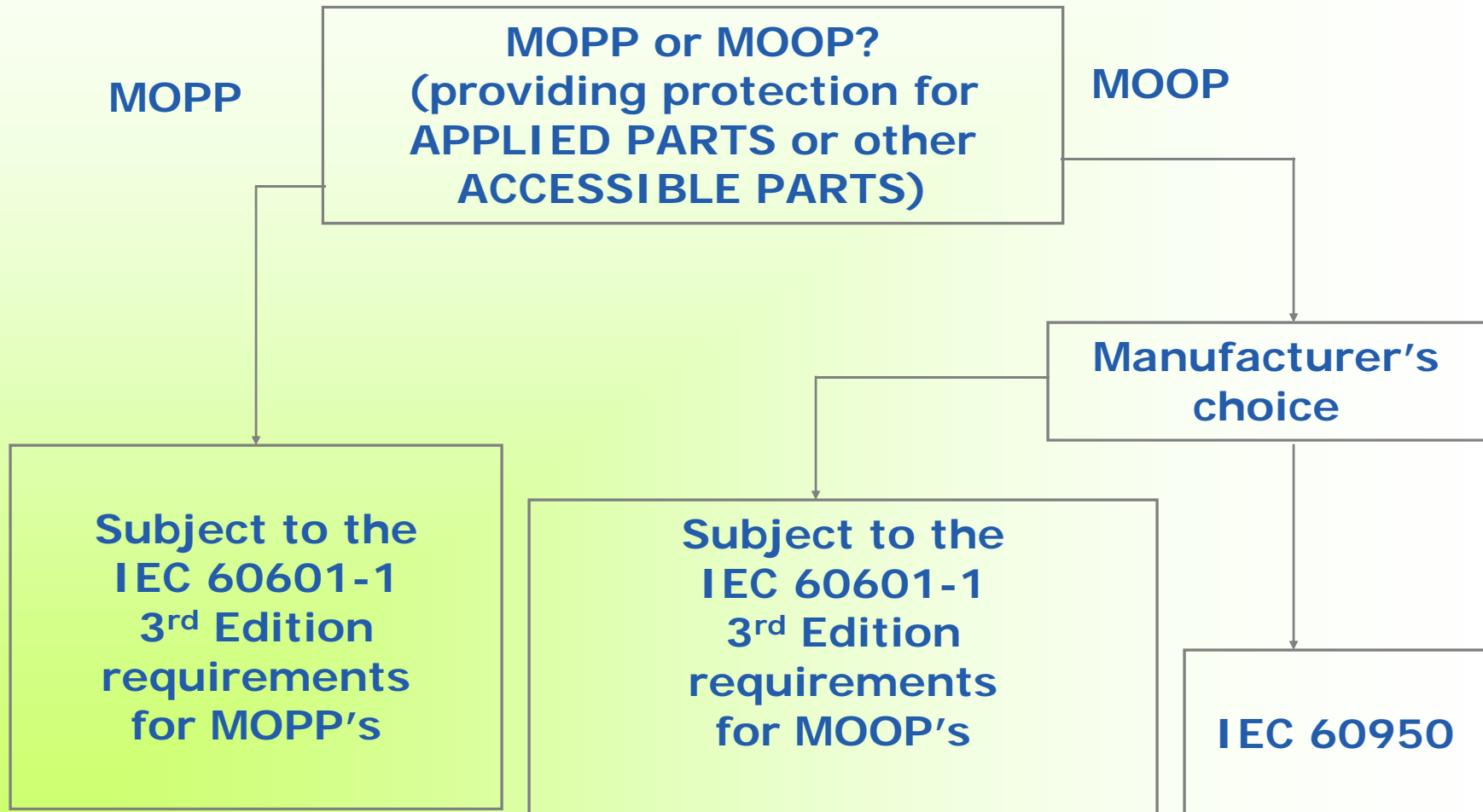
Insulation

- **In Second Edition it was:**
 - Clause 17 (separation)
 - Clause 20 (dielectric strength)
 - Clause 57.10 (creepage distances and air clearances)

- **In Third Edition it is:**
 - Clause 8.5 (separation of parts)
 - Clause 8.8 (Insulation)
 - Clause 8.9 (creepage distances and air clearances)

Insulation

“MOPPs” and “MOOPs”



Insulation

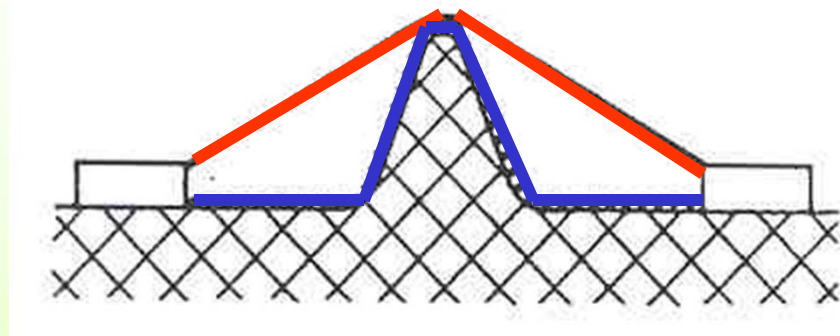
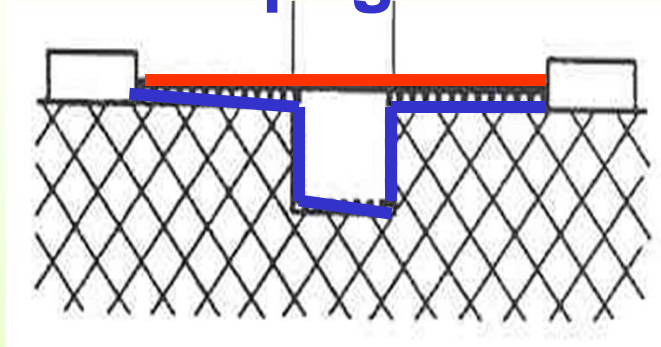
- Dielectric strength:
 - In Third Edition it is: (extract of table 6)

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 |
| $42,4 < U \leq 71$ | $60 < U \leq 71$ | 1 000 | 2 000 | See Table 7 | See Table 7 | 1 500 | 3 000 | 750 | 1 500 |
| $71 < U \leq 184$ | $71 < U \leq 184$ | 1 000 | 2 000 | See Table 7 | See Table 7 | 1 500 | 3 000 | 1 000 | 2 000 |
| $184 < U \leq 212$ | $184 < U \leq 212$ | 1 500 | 3 000 | See Table 7 | See Table 7 | 1 500 | 3 000 | 1 000 | 2 000 |
| $212 < U \leq 354$ | $212 < U \leq 354$ | 1 500 | 3 000 | See Table 7 | See Table 7 | 1 500 | 4 000 | 1 500 | 3 000 |
| $354 < U \leq 848$ | $354 < U \leq 848$ | See Table 7 | 3 000 | See Table 7 | See Table 7 | $\sqrt{2}U + 1 000$ | $2 \times (\sqrt{2}U + 1 500)$ | $\sqrt{2}U + 1 000$ | $2 \times (\sqrt{2}U + 1 500)$ |

Insulation

■ Creepage distances and air clearances



- interpolation is now permitted for creepage for both operator and patient
- for clearances interpolation is permitted above certain voltage limits for operator protection
- material group (CTI - Comparative Tracking Index) classification now brought in for operator protection
- pollution degree now brought in for operator protection
- mains transients (overvoltage category) now catered for in MOOPs

Insulation

- Creepage distances and air clearances
 - Ed. 3 (example)

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 |
| 924 | 660 | 10,5 | 6 | 21 | 12 |

Insulation

- Creepage distances and air clearances
 - Ed. 3

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 | | | |

Insulation

- **Leakage current**
 - Measure a current between a part of the device and the earth
- **Differentiates between PATIENT and OPERATOR**
- **EARTH LEAKAGE CURRENT**
- **TOUCH CURRENT**
- **PATIENT LEAKAGE CURRENT**
- **Total PATIENT LEAKAGE CURRENT**

Insulation

In Ed.3

Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION

Current in μA

| Current | Description | Reference | Measuring Circuit | | TYPE B APPLIED PART | | TYPE BF APPLIED PART | | TYPE CF APPLIED PART | |
|--|--|---------------------------|-------------------------|------|---------------------|-------|----------------------|-------|----------------------|-----|
| | | | | | NC | SFC | NC | SFC | NC | SFC |
| PATIENT AUXILIARY CURRENT | | 8.7.4.8 | Figure 19 | d.c. | 10 | 50 | 10 | 50 | 10 | 50 |
| | | | | a.c. | 100 | 500 | 100 | 500 | 10 | 50 |
| PATIENT LEAKAGE CURRENT | From PATIENT CONNECTION to earth | 8.7.4.7 a) | Figure 15 | d.c. | 10 | 50 | 10 | 50 | 10 | 50 |
| | | | | a.c. | 100 | 500 | 100 | 500 | 10 | 50 |
| | Caused by an external voltage on a SIP/SOP | 8.7.4.7 c) | Figure 17 | d.c. | 10 | 50 | 10 | 50 | 10 | 50 |
| | | | | a.c. | 100 | 500 | 100 | 500 | 10 | 50 |
| Total PATIENT LEAKAGE CURRENT ^a | With the same types of APPLIED PART connected together | 8.7.4.7 a) and 8.7.4.7 h) | Figure 15 and Figure 20 | d.c. | 50 | 100 | 50 | 100 | 50 | 100 |
| | | | | a.c. | 500 | 1 000 | 500 | 1 000 | 50 | 100 |
| | Caused by an external voltage on a SIP/SOP | 8.7.4.7 c) and 8.7.4.7 h) | Figure 17 and Figure 20 | d.c. | 50 | 100 | 50 | 100 | 50 | 100 |
| | | | | a.c. | 500 | 1 000 | 500 | 1 000 | 50 | 100 |
| Key NC = NORMAL CONDITION SFC = SINGLE FAULT CONDITION | | | | | | | | | | |

Mechanical Hazards

- **More Mechanical Hazards are covered by the new standard**
 - Crushing Hazard
 - Shearing Hazard
 - Cutting or severing Hazard
 - Entanglement Hazard
 - Trapping Hazard
 - Stabbing or puncturing Hazard
 - Friction or abrasion hazard
 - Expelled parts Hazard
 - High pressure fluid ejection Hazard
 - Falling Hazard
 - Instability Hazard
 - Impact Hazard
 - Moving and positioning of patient
 - Vibration and noise

Mechanical Hazards

- **Medical equipment with a Trapping zone (by inspection)**





NEW

- The Medical Equipment shall comply with the requirements of one or more of the following:

- Gaps according to table 20
- Safe distance (ISO 13852)
- Guards and protective measures
- Continuous activation

Mechanical Hazards

- Gaps according to table 20 (Extract)

| 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 |  |

Mechanical Hazards

- **Vibration and noise**

NEW

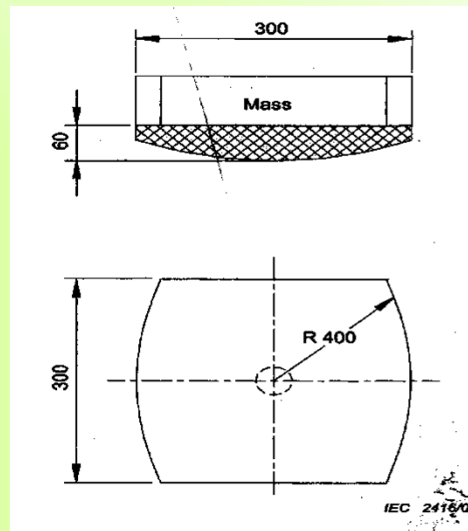
- Audible acoustic energy (By test)
- Infrasound and ultrasound (By Risk Management file analysis)
- Hand transmitted vibration (By test)

Mechanical Hazards

Dynamic forces (Test)

NEW

A safe working load (150kg min) is dropped from a distance of 150mm above the seat area



Construction

- **The new items are:**

- **Usability:**

- The manufacturer shall address in a usability engineering process the risk of poor usability (See IEC 60601-1-6)

- **Alarm system:**

- The manufacturer shall address in the risk management process the need for alarm systems, risks associated with operation or failure (See IEC 60601-1-8)

Construction

- **Requirements for fire enclosures equipment:**

NEW

- Alternative means of fault conditions test
- Flammability classification requirement, according to IEC 60695 standard series
 - for wire inside fire enclosure FV1 or better
 - Connector and printed circuit FV2 or better
 - For enclosure
- Requirement for opening in enclosure

Construction

- **Impact test:**

NEW

- Resistance of enclosure from impact to protect against unacceptable risk
- Impact with a mass of 500g, 50mm witch fall freely from 1.3 height or pendulum

Not applicable to flat panel displays, platen glass of ME, to cathode ray tubes

Construction

- **Rough handling test for mobile equipment:**

NEW

- Ascending step shock 0,4m/S 40 mm, 3 times against a step
- Descending step shock 0,4m/S 40 mm, 3 times fall over a step
- Door frame shock 0,4m/S 40 mm, 3 times against vertical obstacle

Construction

- **Mould stress relief test:**

NEW

- On enclosure of moulded or formed thermoplastic materials
- Test at minimum 70°C for 7h
- No shrinkage or distortion

How will Notified Bodies assess the IEC standards to European regulatory rules?

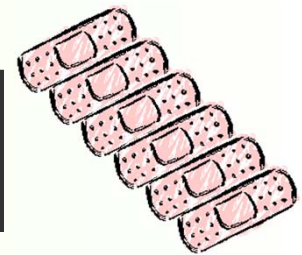
European Regulation (MDD / ER)

■ NB's Duty to review the Technical File

“The devices must meet the essential requirements (ER) set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.”

(Art. 3 MDD 93/42/EEC)

- For the Medical Device designed
- For all the products coming from the production line.



CE Mark is the tangible proof your product complies with ERs. (Conformity declared by the manufacturer through the Declaration of Conformity)

CE₀₄₅₉ identifies the intervention of LNE/G-MED



European Regulation (MDD / ER)

- **Essential Requirements**

1. Annex I of MDD 93/42/EEC enumerates a set of 13 ERs
2. Objective: Duty of manufacturer to answer to ERs to ensure that:
 - The MD will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons
 - any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient.
 - The MD is compatible with a high level of protection of health and safety

European Regulation (MDD / ER)

- **Examples of ERs related to the design**

- ERs # 9. Construction and environmental properties

(combination /connection with other devices must be safe and must not impair the specified performances; the risks of reciprocal interference with other devices must be minimized; the risks of fire or explosion must be minimized)

European Regulation (MDD / ER)

■ Examples of ERs related to the design

ERs #12. Requirements for medical devices connected to or equipped with an energy source

(Repeatability, reliability and performance of Electronic Programmable Systems; Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations; minimize the risks of creating electromagnetic fields; Protection against electrical, mechanical and thermal risks).

12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

European Harmonized Standards

- Solution to answer completely or partially to ERs
- List of Harmonized standards published through the Official Journal (EN).



- The Standard Committees/organization must indicate the Essential Requirements associated to a particular standard.

European Harmonized Standards

- **Include one or several MDD Essential Requirements, for one or several categories of products**
- **Deployment:**
 - Done by the manufacturer, at all the level of the organization (Design, manufacturing, final inspection, Testing, ...)
 - Done by the NB when it is appointed to assess the product according to Annexes III, II.4 or IV MDD)
- **Application of Harmonized Standards (HS) not mandatory, remains voluntary:**
 - If applied then they give presumption of conformity to applicable ERs
 - **If not then necessity for the manufacturers to justify and to make explicit the selected equivalent alternative methods.**

European Harmonized Standards

■ Standards used to Demonstrate Conformity of Electromedical Devices

— Few years ago:

- ISO 13485(96): Quality System assessment versus 20 chapters
- EN 1441: Risk analysis for medical products
- IEC 601-1, IEC 601-2-xx: Safety of products checked versus specific hazard (mechanical, ...)

— Today:

- ISO 13485 (03) based on process approach including risk management throughout product realization (clause 7.1)
- ISO 14971: Risk management including residual risks evaluation
- IEC 601-1 Ed 3 (§ 4.2): Requirements to established a risk management process complying with ISO 14971.
- ISO 62304: Introduction of this new standard to improve the validation of software

European Harmonized Standards

- **Current Status of IEC Standards**
 - IEC 601-x-x series published as European Harmonized standard to presume compliance to essential requirements:
 - IEC 601-1-2 for ER # 9.2 , 12.5
 - IEC 601-1-4 for ER # 12.1,

 - Standards used as a common language between manufacturers, Notified Bodies, Test labs,...
 - Recognition of testing made by accredited test labs, recognition between test labs.

IEC 60601-1 (Third Edition)

Impact of changes during NB assessment

Impact of Changes During NB Assessment

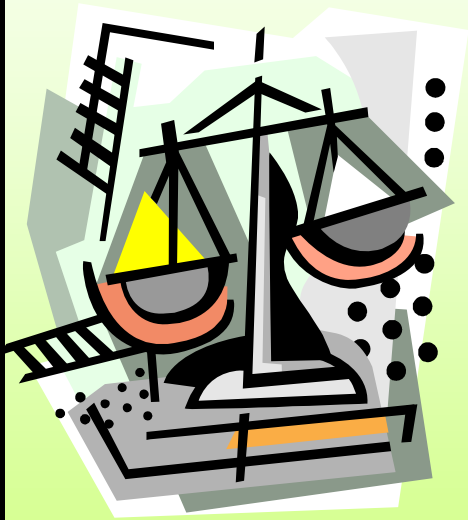
Calendar

- New IEC 60601 standard Ed 3 published in Dec. 05.
- Second edition will become obsolete in June 2012 if there is no particular standard 60601-2-XX is applicable to the Medical Device.
- If a particular standard applies to MD then Manufacturer should wait promulgation of harmonized IEC 601-2-xx Ed 3.

Impact of Changes During NB Assessment

IMPACT for Manufacturers:

- Major QMS difference compared to the 2nd Ed.:
Refers several times to Risk Management File (RMF).
- Impact:
 - Deploy a specific RMF for each product, in compliance with ISO 14971 requirements and covering all the items required by IEC 60601-1 3rd Edition.
 - For the R&D activities, necessity to established an efficient interface between Regulatory Affairs and Design team(s).
 - Deploy a Coherent Approach based on
 - the Technical state of the art,
 - the information raised in the field,
 - Analysis of information information derived from previous similar designs
- As long as the Ed. 3 of particular standard are not promulgated, the manufacturers still need to comply with Ed. 2 but necessity to start to work on the new edition upstream from this promulgation.



Impact of Changes During NB Assessment

IMPACT on Assessors (Testing Laboratory)

- The terminology “Unacceptable Risk is used as a criteria several times in the new edition, to determine:
 - The tests who need to be performed.
 - The acceptance criteria for the tests.
- Testing Laboratories need to have a good technical expertise associated to a good clinical knowledge of medical device under test.
- Need to be trained on ISO 14971 approach, requirements
- The documentation review is reinforced, beyond the realization of technical testing.
- Deeper discussion/debate between the Laboratory and the manufacturer



Impact of Changes During NB Assessment

IMPACT for Notified Bodies



- Risk Management File already constituted an important document of CE Technical File. It becomes one of the key documents with the introduction of 3rd Edition.
- During the Design Process review, a particular attention shall be paid to the choices and alternative solutions used by the manufacturer during the Design verification [demonstration of conformity to ERs], alternative solutions documented in the RMF.
- Recognition and Acceptance of IEC Test Reports will be based on the simultaneous and detailed review of test report and RMF.

All of the actors are impacted ...

As long as the collateral and particular standard Ed 3 are not promulgated

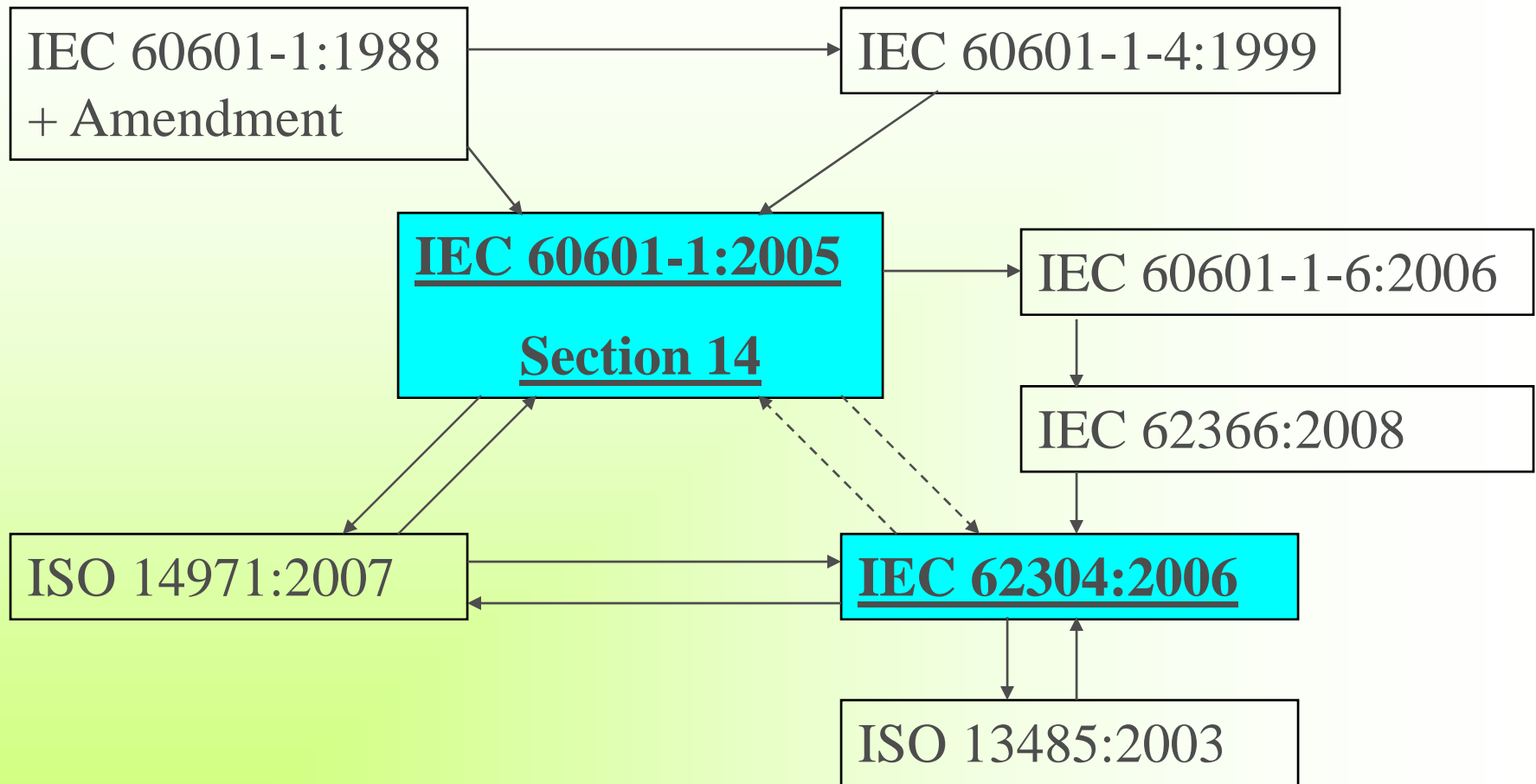
- Some processes need to be adjusted by each actor
- Training

Nevertheless, even if the standards and our practices are evolving, the initial goal and target remain identical:

.... All Medical Devices must offer a high level of protection of health and safety of patients, users or, where applicable, other persons.



Link Between IEC 60601-1 and EN 62304



Link Between IEC 60601-1 and EN 62304

Major Differences between Art. 14 IEC 60601-1 and EN 62304:

- EN 62304 does not cover software validation. PEMS validation is a system level activity and is outside the scope of this standard.
- Art 14.6.1 requires: « When compiling the list of know and foreseeable hazards, the manufacturer shall consider those hazards associated with software and hardware aspects of the PEMS including those associated with network/data coupling, ... ».
→ This Requirement for network/data coupling is not included in EN 62304.

Link Between IEC 60601-1 and EN 62304

Major Differences between Art. 14 IEC 60601-1 and EN 62304:

- Independance of personnel performing the verification is not included in EN 62304. It is considered covered in ISO 13485.