A Physicist's Guide to the International Electrotechnical Commission

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Member, WG-1
Chair, US TAG to WG-1

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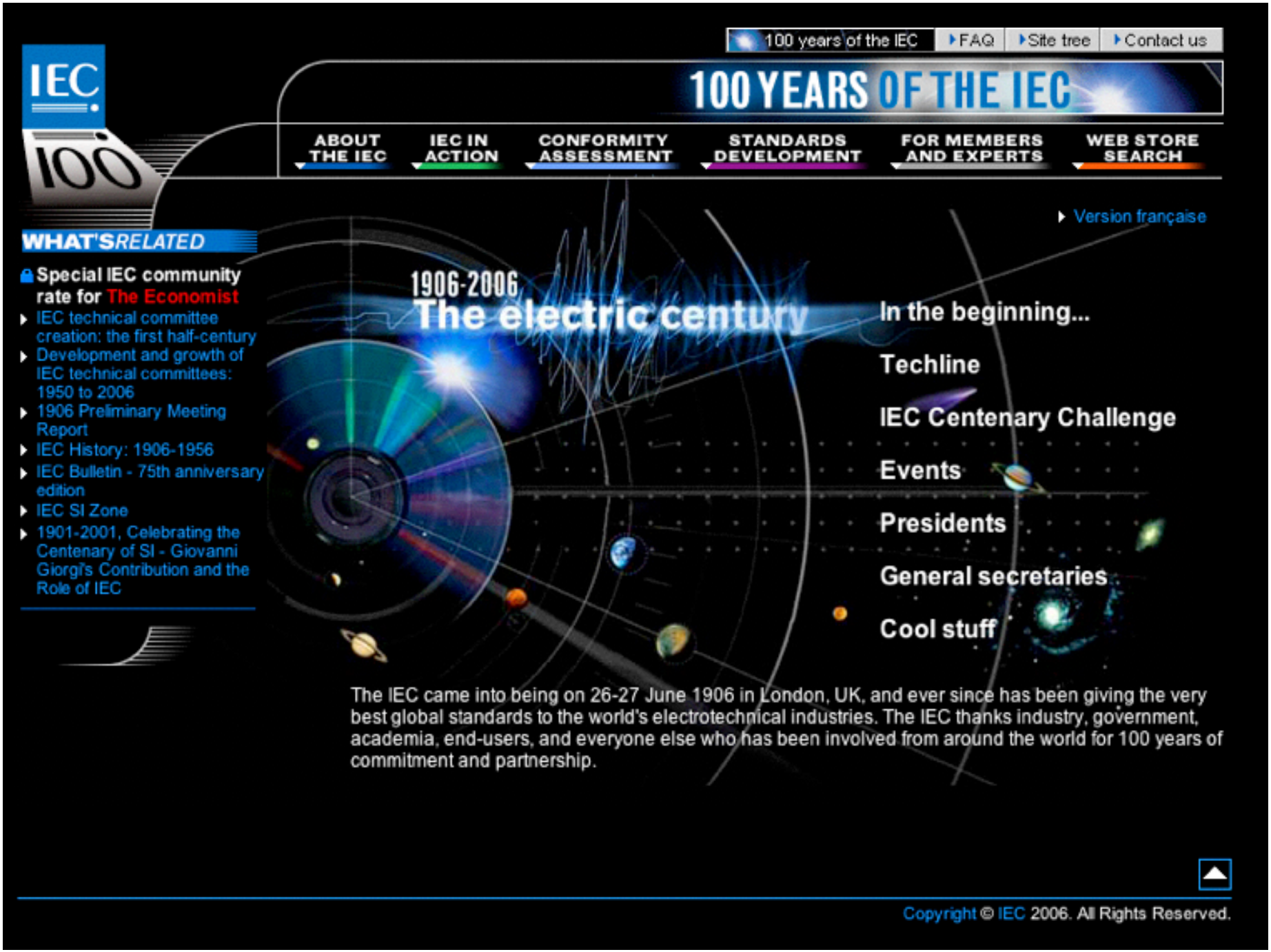
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ABOUT THE IEC
IEC IN ACTION
CONFORMITY ASSESSMENT
STANDARDS DEVELOPMENT
FOR MEMBERS AND EXPERTS
WEB STORE SEARCH
Version française
WHAT'S RELATED
Special IEC community rate for The Economist
IEC technical committee creation: the first half-century
Development and growth of IEC technical committees: 1950 to 2006
1906 Preliminary Meeting Report
IEC History: 1906-1956
IEC Bulletin - 75th anniversary edition
IEC SI Zone
1901-2001, Celebrating the Centenary of SI - Giovanni Giorgi's Contribution and the Role of IEC
1906-2006
The electric century
In the beginning...
Techline
IEC Centenary Challenge
Events
Presidents
General secretaries
Cool stuff
The IEC came into being on 26-27 June 1906 in London, UK, and ever since has been giving the very best global standards to the world's electrotechnical industries. The IEC thanks industry, government, academia, end-users, and everyone else who has been involved from around the world for 100 years of commitment and partnership.
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Role of the IEC and Impact of its Standards

- IEC's international standards facilitate world trade by removing technical barriers to trade, leading to new markets and economic growth.
- They also represent the core of the World Trade Organization's Agreement on Technical Barriers to Trade (TBT), whose 100-plus central government members explicitly recognize that international standards play a critical role in improving industrial efficiency and developing world trade.
- Using IEC standards for certification at the national level ensures that a certified product has been manufactured and type-tested to well established international standards. The end user can be sure that the product meets minimum (usually high) quality standards, and need not be concerned with further testing or evaluation of the product.

The International Electrotechnical Commission

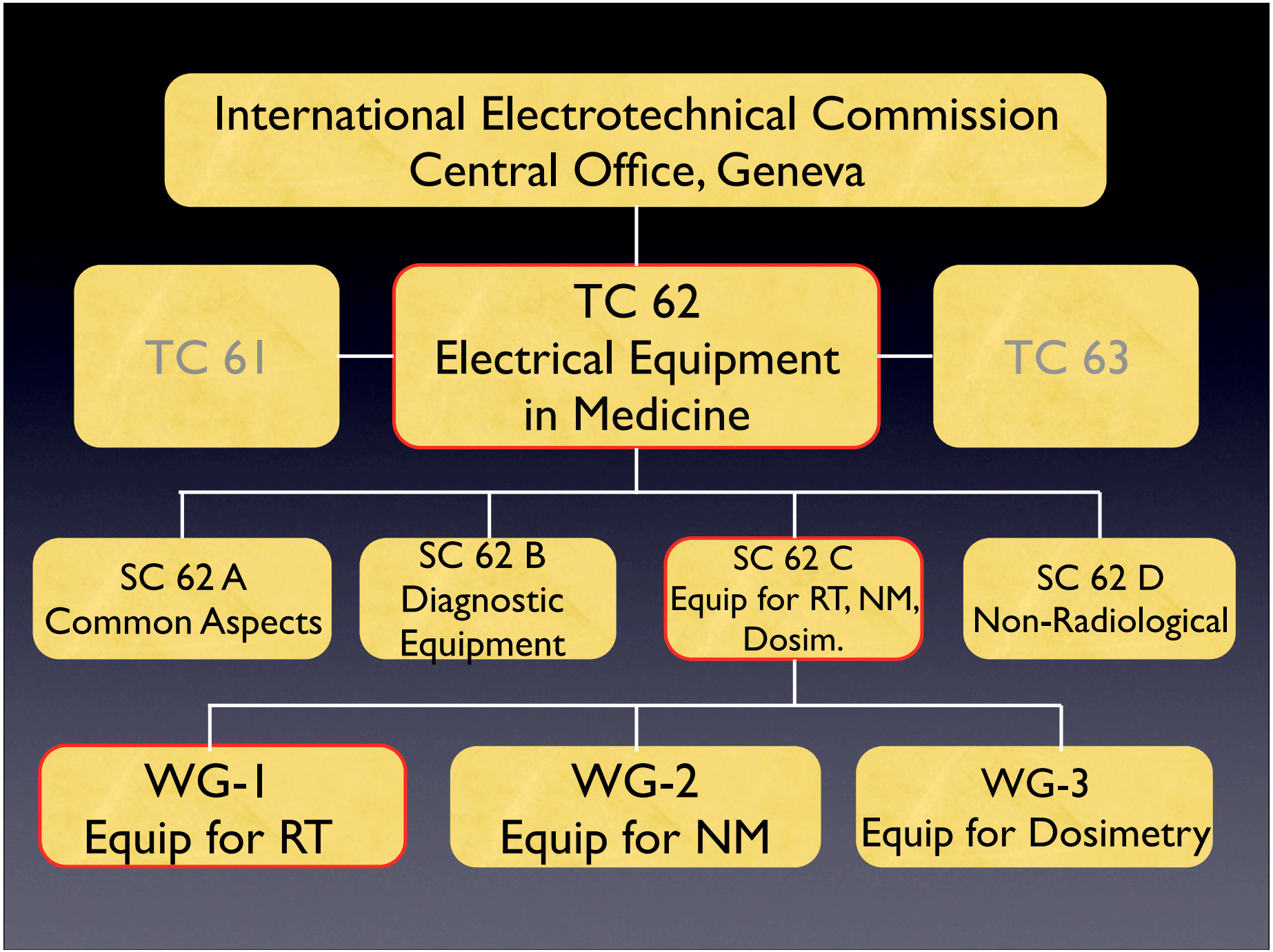
- 68 member nations (including associate members
- Produces standards addressing the design of electrotechnical equipment.
- Safety and performance standards apply to manufacturer's design and construction
- Compliance tests can be *type tests*, or *site tests*
- Site tests sometimes incorporated into acceptance testing procedures

Adoption of IEC Standards

- In Europe:
  - IEC standards selected for “parallel voting” by CENELEC
  - When approved, assigned “EN” number
  - Standards adopted as written and carry the force of law
  - However, up to EC members to enforce

Adoption of IEC Standards

- In US:
  - IEC standards (or sections) incorporated into ANSI standards, FDA regulations, NEMA guidelines, etc.
  - IEC standards can be used as written; FDA requires vendor to report compliance
- Elsewhere?

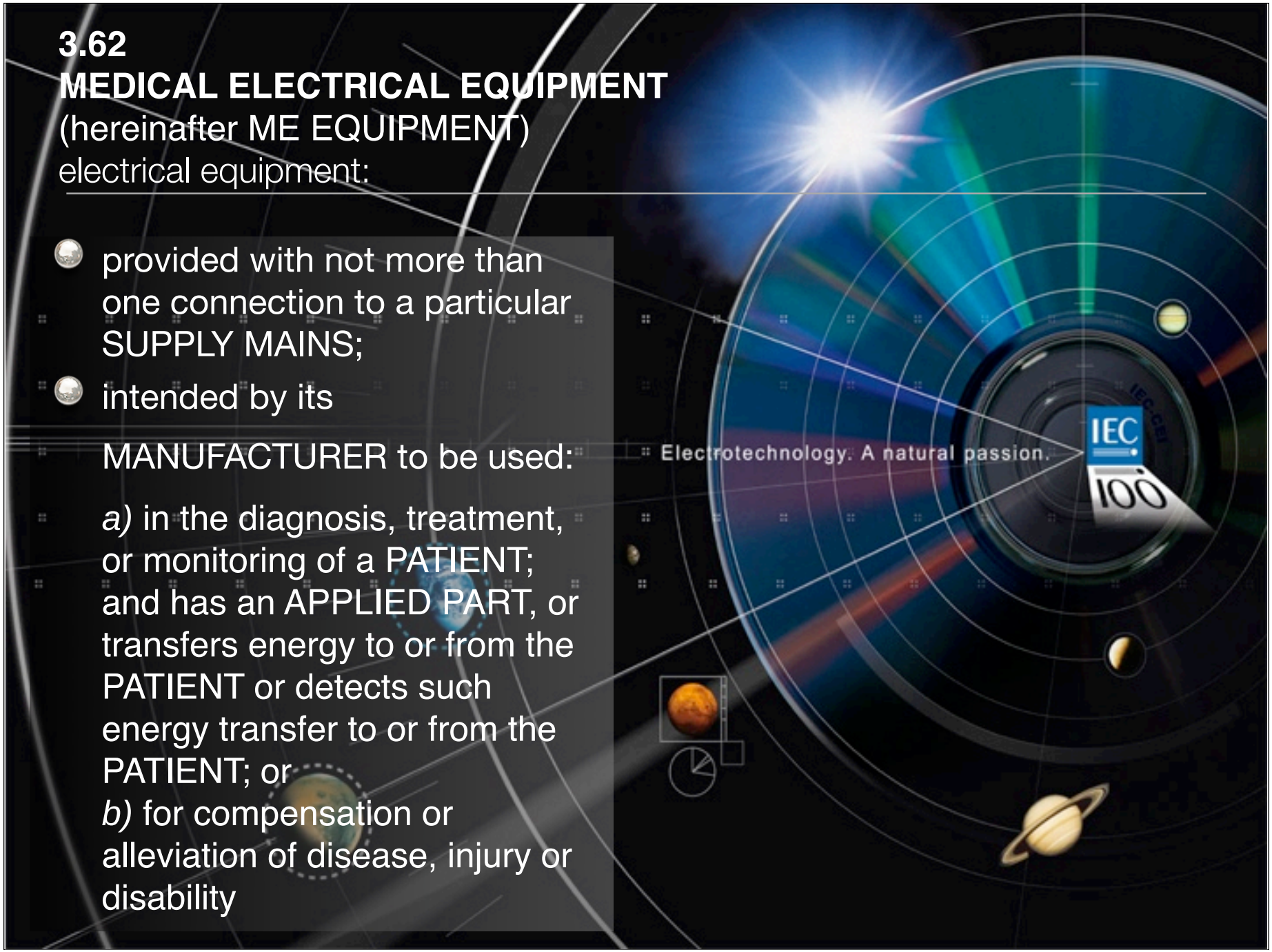

International Electrotechnical Commission
Central Office, Geneva
TC 61
TC 62
Electrical Equipment
in Medicine
TC 63
SC 62 A
Common Aspects
SC 62 B
Diagnostic
Equipment
SC 62 C
Equip for RT, NM,
Dosim.
SC 62 D
Non-Radiological
WG-1
Equip for RT
WG-2
Equip for NM
WG-3
Equip for Dosimetry

3.62
MEDICAL ELECTRICAL EQUIPMENT
(hereinafter ME EQUIPMENT)
electrical equipment:

- provided with not more than one connection to a particular SUPPLY MAINS;
- intended by its

MANUFACTURER to be used:

a) in the 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 alleviation of disease, injury or disability



Role of Working Group

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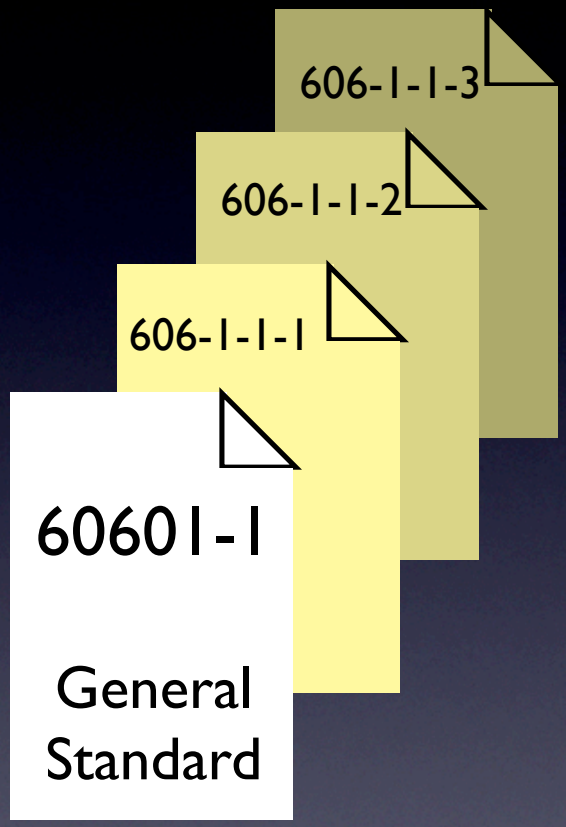
- Develop Standards
  - Safety Standards
    safety and “essential performance”
  - Technical Reports
  - Performance Standards
  - Performance Guidelines

IEC 60601-series



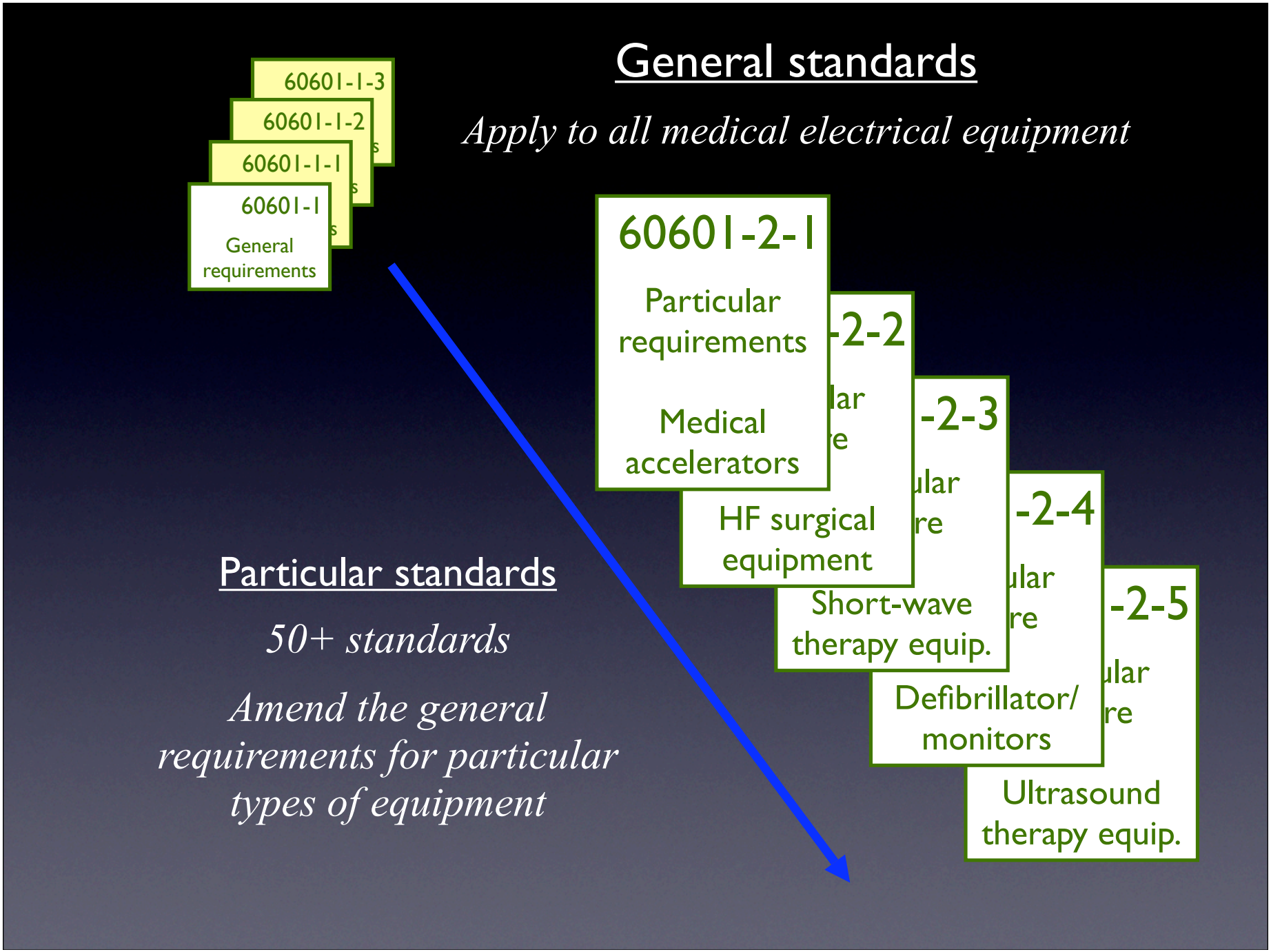
Collateral standards

More general requirements:

60601-1-1	Medical electrical systems
60601-1-2	Electromagnetic compatibility
60601-1-3	X-ray - radiation protection
60601-1-4	Programmable medical electrical systems
60601-1-5	X-ray - image quality/dose
60601-1-6	Usability
60601-1-7	Not used
60601-1-8	Alarm systems

Electromagnetic Compatibility

- For medical equipment, see 60601-1-2 (9/2001)
- To be included in 60601-1 3rd edition


General standards
Apply to all medical electrical equipment
60601-1-3
60601-1-2
60601-1-1
60601-1
General requirements
60601-2-1
Particular requirements
Medical accelerators
-2-2
-2-3
HF surgical equipment
-2-4
Short-wave therapy equip.
-2-5
Defibrillator/ monitors
Ultrasound therapy equip.
Particular standards
50+ standards
Amend the general requirements for particular types of equipment

62C Safety Standards

62C Safety Standards

60601-1
General Standard

⇩

60601-1-X
Collateral Standards

62C Safety Standards

62C Safety Standards

60601-1
General Standard

60601-1-X
Collateral Standards

60601-2-X
Particular Standards

6XXXX
Safety Standards

6XXXX
Technical Reports

Publications from WG-1

Equipment for Radiation Therapy

- Linear Accelerators
- Cobalt Units (including Gammaknife)
- Orthovoltage Treatment Units
- Simulators
- Brachytherapy Remote Afterloaders
- Treatment Planning Systems
- Record & Verify Systems

Safety Standards from Working Group 1

- 60601-2-1: Safety of Linear Accelerators
  - Indicator lights, light field, scales & coordinates
  - Range and speed of motions
  - Function of dose monitoring systems
  - Selection and display of modality, energy, modifiers, accessories
  - Safety interlocks
  - Leakage radiation
  - Amendment for MLC

Defined Terms

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IEC 100

201.3.215
redundant dose monitoring combination
utilization of two dose monitoring systems where both systems are arranged to terminate irradiation according to the pre-selected number of dose monitor units

201.7.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition:

Where indicator lights are used on the TREATMENT CONTROL PANEL (TCP) or other control panels, the colours of the lights shall accord with the following:

RADIATION BEAM "on"	yellow
READY STATE	green
Urgent action required in response to an unintended state of operation	red
PREPARATORY STATE	other colour

Light emitting diodes (LEDs) are not considered to be indicator lights when

- on any one TCP, all indications for which no particular colour is required are given by LEDs of the same colour, and
- the indications for which particular colours are required are clearly distinguishable.

201.9 Protection against mechanical hazards of me equipment and me systems

b) Rotational movements

1) The minimum speed available for each movement shall not exceed $1^{o}\ s^{-1}$.

2) No speed shall exceed $7^{o}\ s^{-1}$.

3) When rotating at the speed nearest to, but not exceeding, $1^{o}\ s^{-1}$, the angle between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed $0{,}5^{o}$; for speeds faster than $1^{o}\ s^{-1}$, it shall not exceed 3^{o}.

Exception – Requirement 2) above does not apply to the beam limiting system (bls).

201.7.1 Marking on the outside of equipment or equipment parts

d) Minimum requirements for marking on EQUIPMENT and on interchangeable parts

Addition:

The dimensions of the GEOMETRICAL RADIATION FIELD at NTD and the distance from the distal end to NTD shall be clearly legible on the outside of all interchangeable and non-adjustable BLDs and ELECTRON BEAM APPLICATORS.

Each manually interchangeable WEDGE FILTER shall be clearly marked to establish its identity.

22.4.3 Operation of movements of equipment parts from outside the treatment room

a) It shall be impossible to initiate or maintain movements associated with automatic set-up without continuous personal action by the operator simultaneously on the automatic set-up switch and a switch common to all movements. Each switch, when released, shall be capable of stopping movement; at least one of the switches shall be hard-wired.

201.10.1.101.1.1 Dose monitoring systems

The radiation detectors specified in 201.10.1.1.2 shall form part of two dose monitoring systems from whose outputs, displayed as dose monitor units, the absorbed dose at a reference point in the treatment volume can be calculated. The dose monitoring systems shall satisfy the following requirements:

a) malfunctioning of one dose monitoring system shall not affect the correct functioning of the other;

b) failure of any common element that could change the response of either dose monitoring system by more than 5 % shall terminate irradiation;

c) when separate power supplies are used, failure of either supply shall terminate irradiation

201.10.1.101.5 Monitoring of distribution of absorbed dose

To protect against gross distortion of the distribution of ABSORBED DOSE, e.g. resulting from failure of fixed ADDED FILTERS, electronic control systems or computer based control systems

a) the RADIATION DETECTORS described in 201.10.1.1.2, or other RADIATION DETECTORS, shall monitor different parts of the radiation beam to detect symmetrical and nonsymmetrical changes of the dose distribution;

b) means shall be provided to TERMINATE IRRADIATION before an additional ABSORBED DOSE of 0,25 Gy is delivered when, at the depth specified for flatness measurements, either the ABSORBED DOSE distribution is distorted by more than 10 %, or the signals from the RADIATION DETECTORS indicate a change greater than 10 %, in the ABSORBED DOSE distribution.

201.10.1.103 Absorbed dose rate

c) If, under any fault conditions, the EQUIPMENT can deliver an ABSORBED DOSE RATE at NTD of more than ten times the maximum SPECIFIED in the technical description, a RADIATION BEAM monitoring device, which shall use a circuit independent of the DOSE RATE MONITORING SYSTEM, shall be incorporated on the PATIENT side of the radiation beam distribution system. This shall limit the excess ABSORBED DOSE at any point in the radiation field to less than 4 Gy. The value of the excess ABSORBED DOSE shall be given in the technical description.

201.10.1.103 Absorbed dose rate

c) If, under any fault conditions, the E
deliver an ABSORBED DOSE R
ten times the m
do

c) Type test grade A – Statement regarding the design of radiation beam monitoring device and the value of the excess absorbed dose that causes termination of irradiation.

c) Site test grade C – Principle: verification of the functioning of the radiation beam monitoring device by generating or simulating excess electron beam current.

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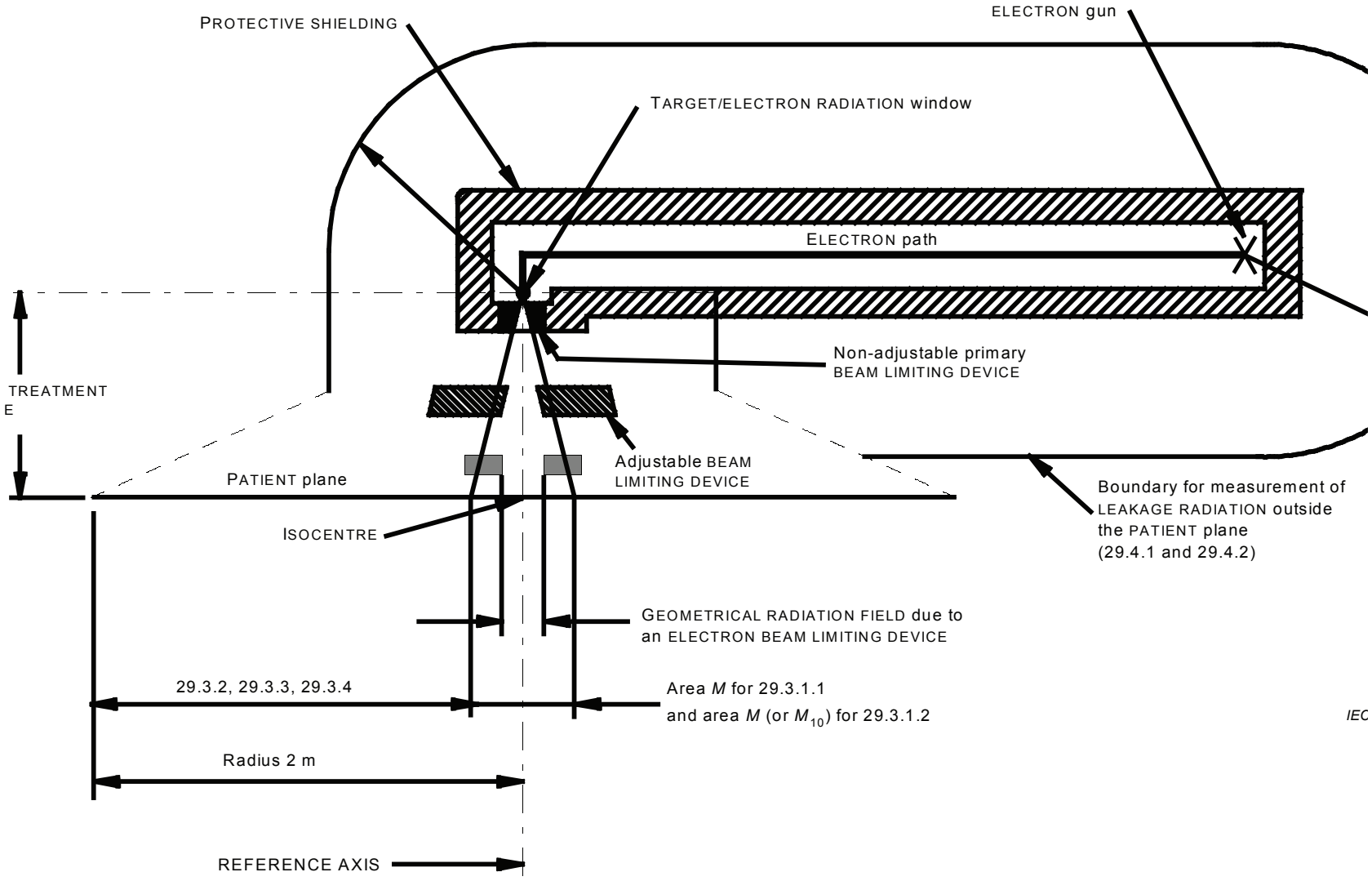
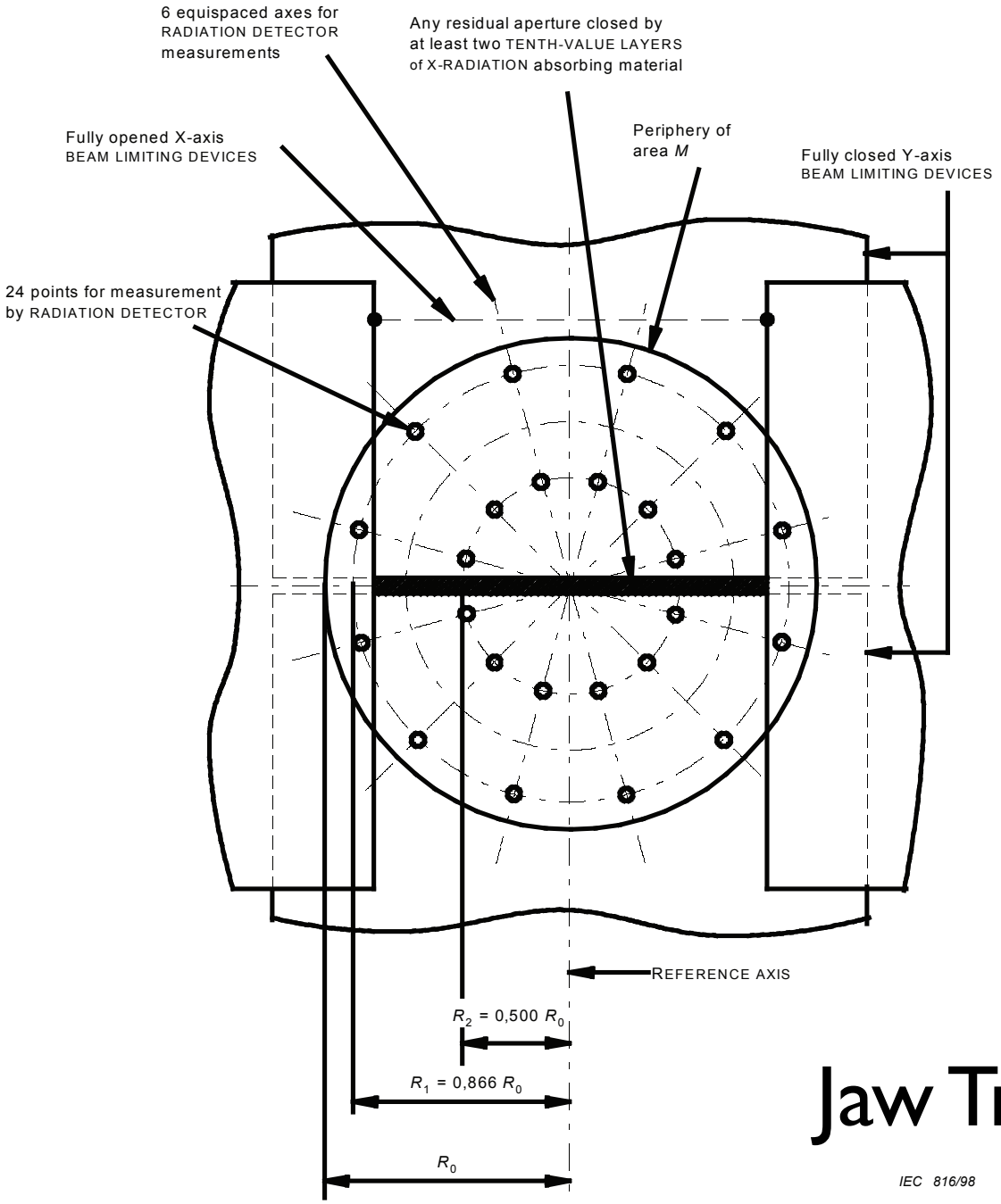
value of the
be given in the technical

Measurement of Leakage Radiation





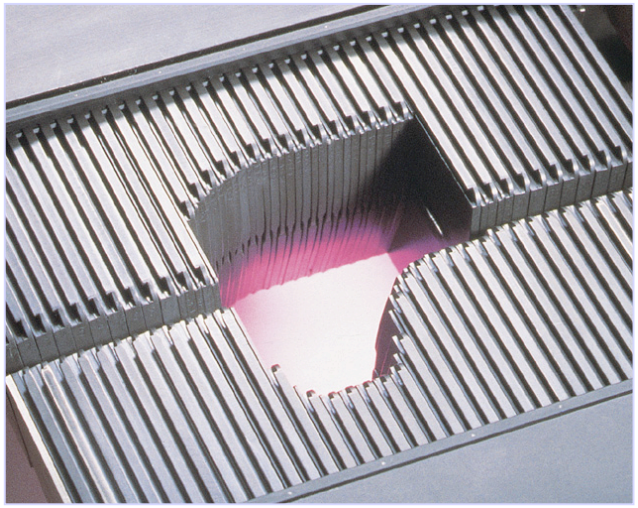
Jaw Transmission

Proposed new safety clauses for SRS

- Positioning accuracy
- Strain caused by moving parts
- Collision avoidance

Proposed new safety clauses for IMRT

- Incorrect field shape
- Incorrect MU for part of field
- Record and verify capability
- Neutron dose
- Whole body dose



Proposed new safety clauses for EPIDs

- Correct image orientation
- Correct scale factor of image
- Adequate detail
- Correct field of view
- Collision avoidance
- Artifacts

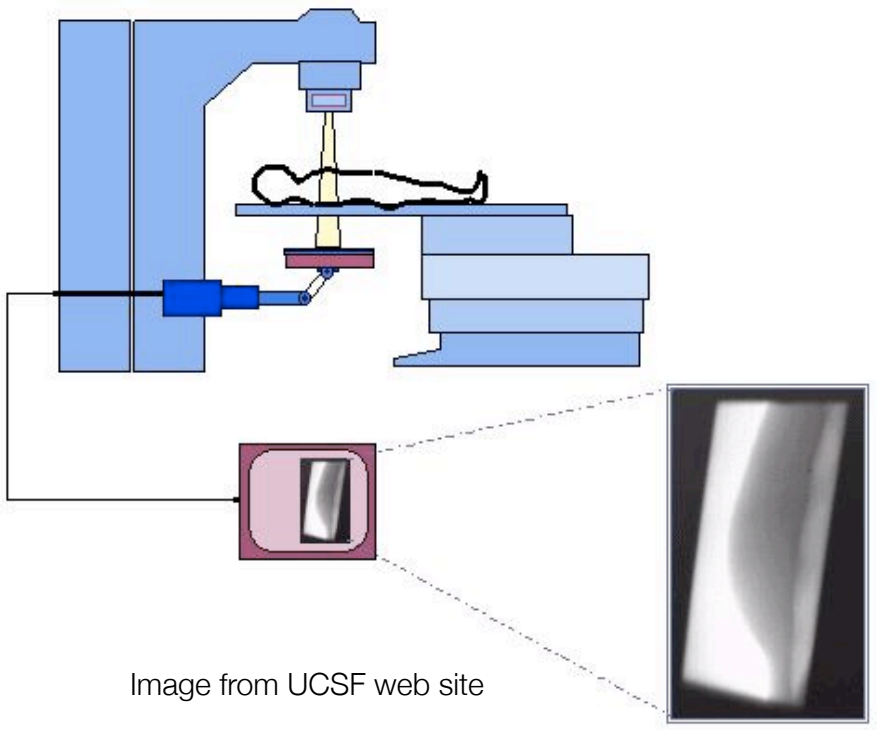
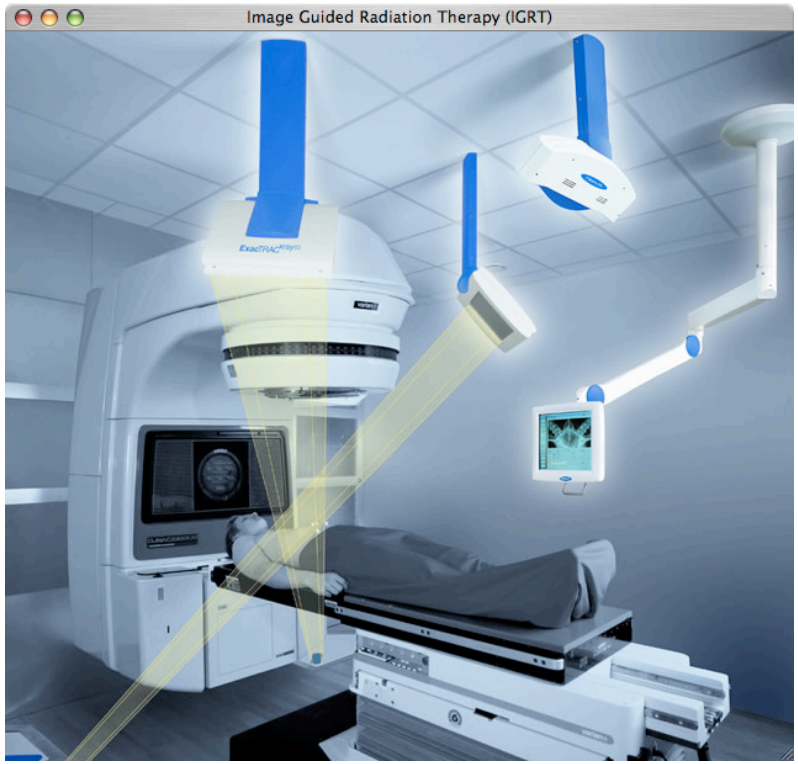


Image from UCSF web site

Proposed new safety clauses for IGRT

- Registration of images
- Accuracy of movement of patient support
- Movement of MLC in response to imaging
- Movement of gantry in response to imaging
- ...



Additional Safety Standards

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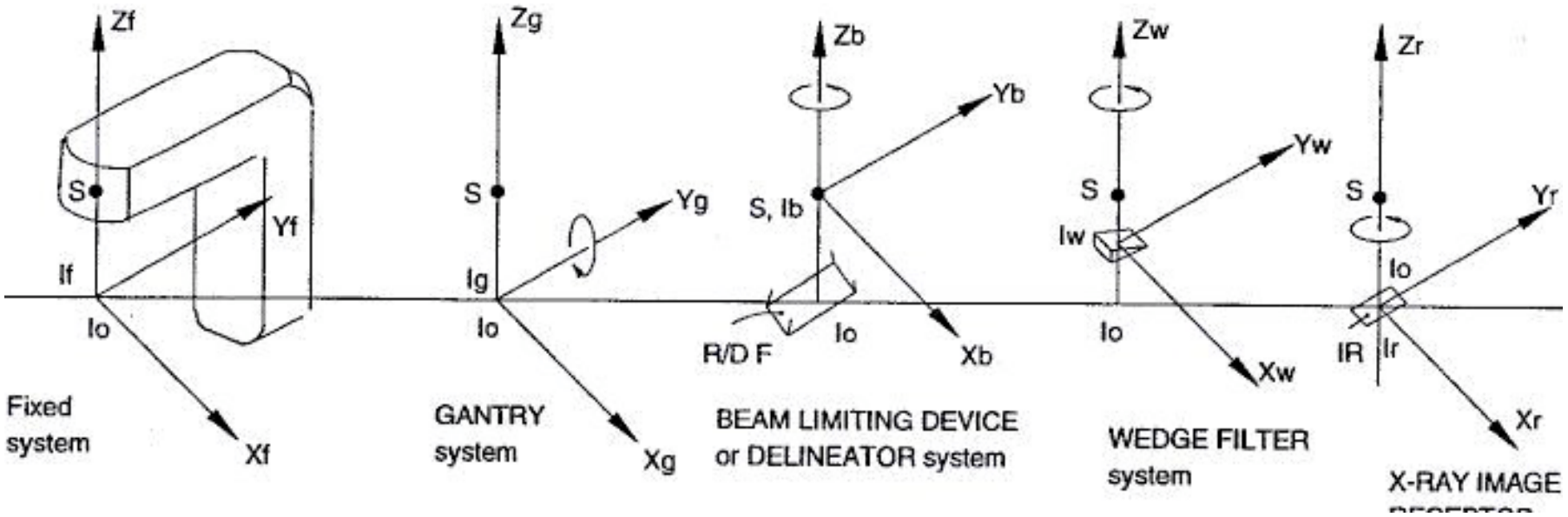
- 62083: Safety of radiotherapy treatment planning systems
- 62274: Safety of radiotherapy record and verify systems

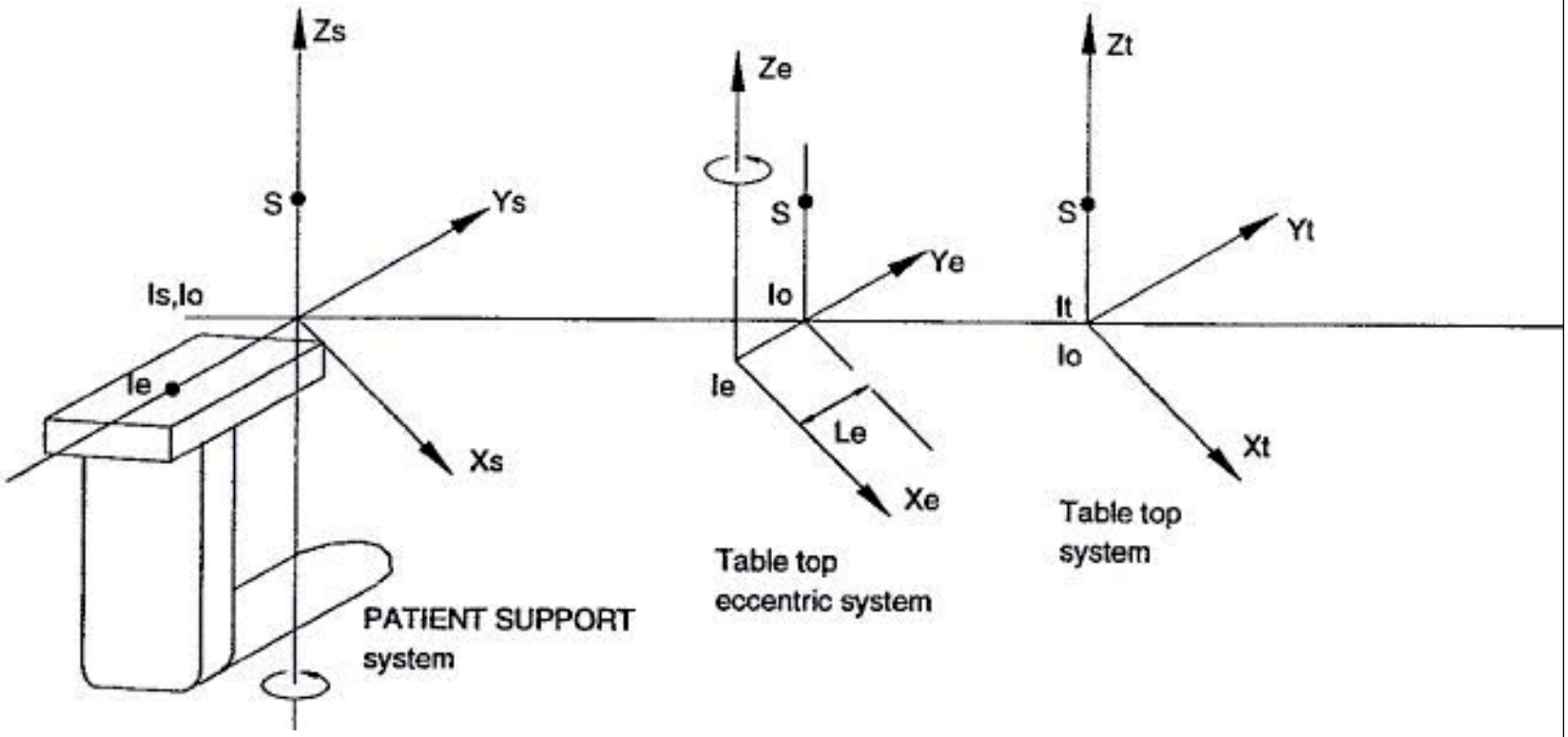
IEC 62083 - Safe Operation of Treatment Planning Systems

- Format of displays, units, date & time
- Data limits, transfer
- Saving and archiving data
- Equipment and source model
- Patient model
- Treatment planning
- Dose calculation
- Treatment plan report

IEC 61217. Coordinates, Movements & Scales

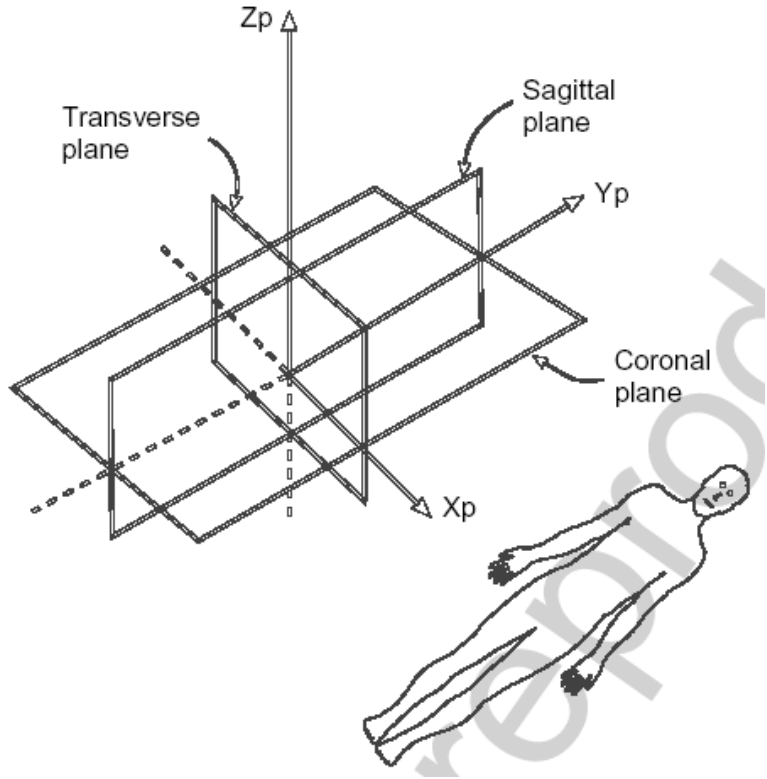


IEC 61217. Coordinates, Movements & Scales



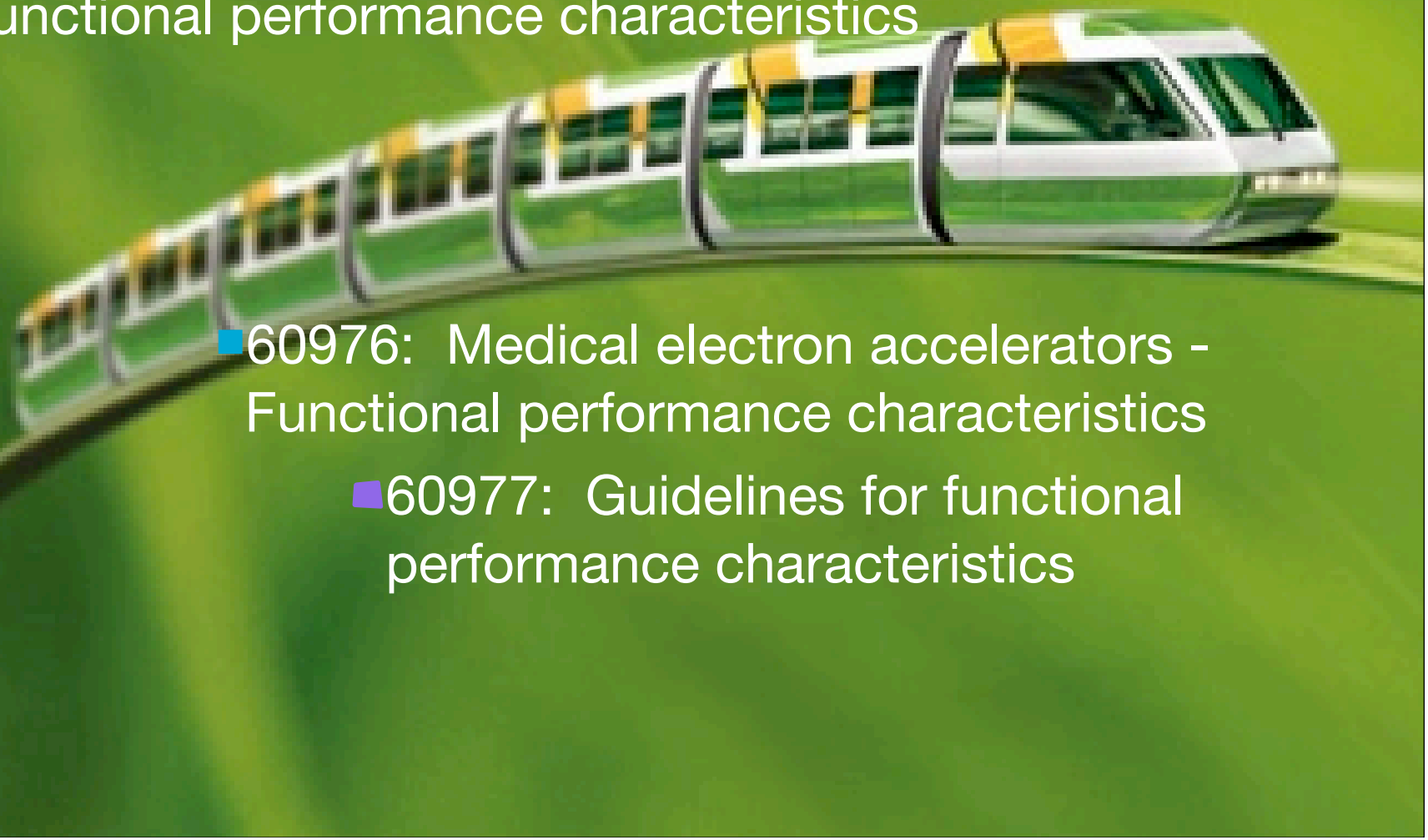
61217: Coordinates, movements and scales

- Amendment for patient coordinate system



Performance Standards from WG-1

- 61168: Radiation therapy simulators - Functional performance characteristics
- 60976: Medical electron accelerators - Functional performance characteristics
- 60977: Guidelines for functional performance characteristics



IEC 60976. Medical electron accelerators - Functional performance characteristics

"... specifies test procedures for the determination and disclosure of functional performance characteristics,

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knowledge of which is deemed necessary for proper application and use of a medical ELECTRON ACCELERATOR and which are to be declared in the ACCOMPANYING DOCUMENTS together with the greatest deviation or variation to be expected under specific conditions in NORMAL USE."

6.4 Dependence on angular positions

6.4.1 Information to the USER

*[**R** is dose per MU]*

The ACCOMPANYING DOCUMENTS shall state the maximum differences between the maximum value and the minimum value of the ratio *R* for both X-RADIATION and ELECTRON RADIATION when the equipment is placed in different positions through the full range of rotations.

The maximum differences shall be expressed as percentages of the mean value of *R* for both X-RADIATION and ELECTRON RADIATION.

IEC 60977. Guidelines for functional performance characteristics

Provides a suggested format for the reporting of performance characteristics

Provides suggested performance levels

Clause	Abbreviation of Statement in Disclosure Standard		Values declared (suggested)
6.4	**Dependence on angular positions**		
	Maximum difference between the maximum and minimum values of $\bar{R}$ over the full angular ranges of the GANTRY and BEAM LIMITING SYSTEM...		
	X-RADIATION		
	Declared maximum difference...	_____ %	(3)
	ELECTRON RADIATION		
	Declared maximum difference	_____ %	(3)
6.5	**Dependence on GANTRY rotation**		
	As the GANTRY moves, the maximum deviation of $\bar{R}$ from the arithmetic mean of the maximum and minimum values of $\bar{R}$ determined in 5.3		
	X-RADIATION		
	Declared maximum deviation...	_____ %	(3)
	ELECTRON RADIATION		
	Declared maximum deviation...	_____ %	(2)

6.4 Dependence on angular positions

Maximum difference between the maximum and minimum values of R over the full angular ranges of the GANTRY and BEAM LIMITING SYSTEM ...

X-RADIATION

Declared maximum difference ... _____ % (3)

[Where R is the average dose per MU]

IEC 60976. Performance standard

4. General information to user
5. Standardized test conditions
6. Tests of dose monitoring system
7. Depth dose characteristics
8. Uniformity of radiation fields
9. Indication of radiation fields
10. Indication of radiation beam axis
11. Isocenter
12. Indication of distance along the beam axis
13. Zero position of rotational scales
14. Congruence of opposed radiation fields
15. Movements of the patient table
16. EPIDs

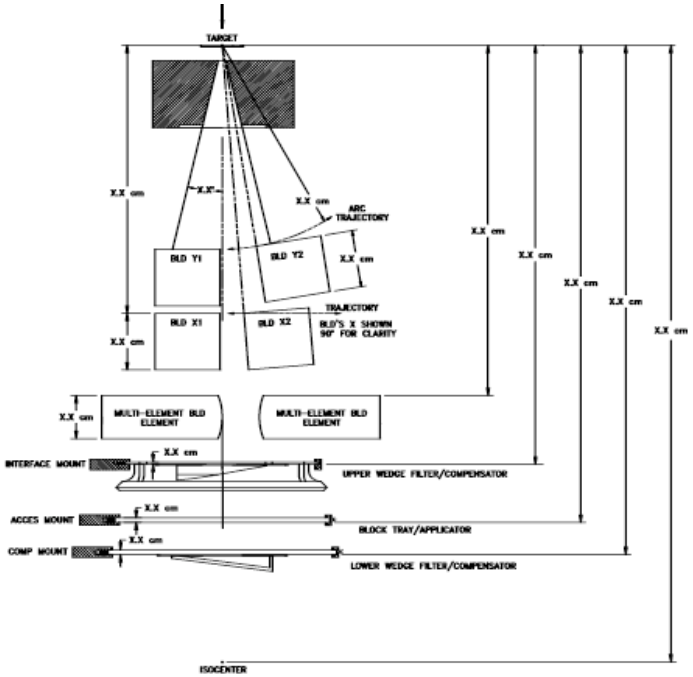

Figure 10 – RADIATION HEAD showing X-RADIATION BLDs and ACCESSORIES (see 4.11)

IEC 60976. Performance standard

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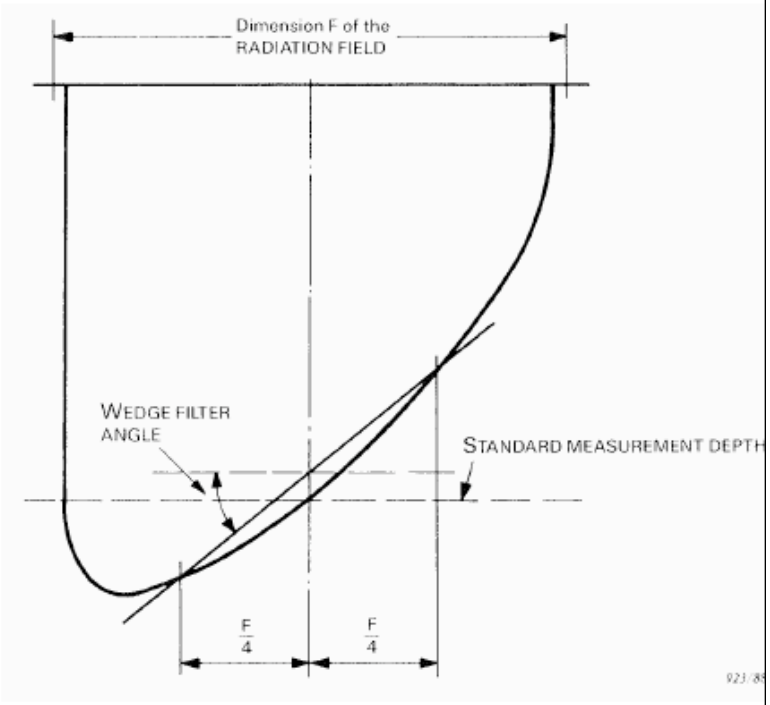

Figure 1 – Explanatory diagram for the definition of wedge

IEC 60976. Performance standard

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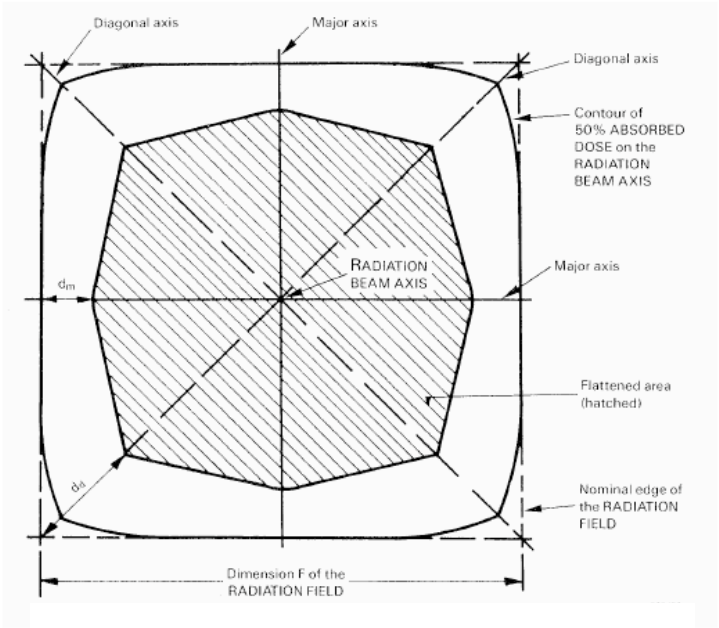

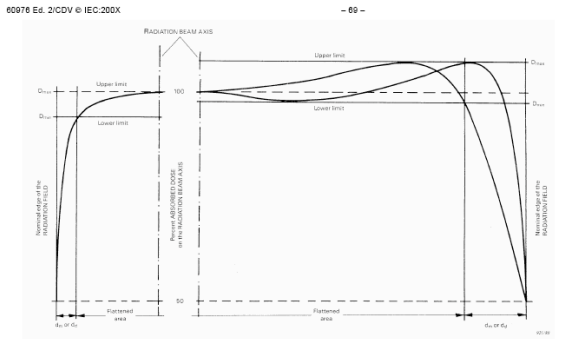

Figure 6 – Examples of profiles of ABSORBED DOSE along the major axes or the diagonal axes. All profiles lie within the permitted limits. Shown in the figure are halves of the profile for a small RADIATION FIELD (left) and a large RADIATION FIELD F>30 cm (right)

IEC 60976. Performance standard

4. General information to user
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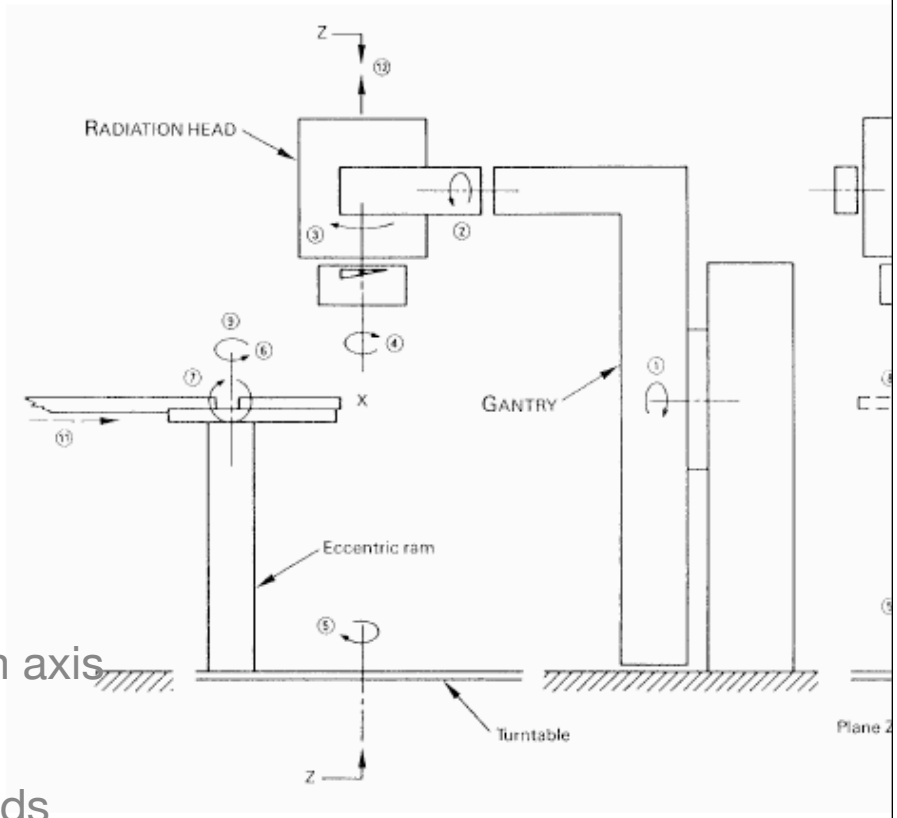

Legend:

1. Rotation of the GANTRY, Axis 1
2. Roll of the RADIATION HEAD, Axis 2
3. Pitch of the RADIATION HEAD, Axis 3
7. Pitch of the table, Axis 7
8. Roll of the table, Axis 8
9. Height of the table, Directi

Additional Performance Standards

61852: Medical electrical equipment - Digital imaging and communications in medicine (DICOM) - Radiotherapy objects

61859: Guidelines for radiotherapy treatment rooms design

Gestation of an IEC Standard

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- Typical for a new standard to take at least 5 years in development
- IEC requires standards to be revised every 5 years; review begins 3 years after publication
- General Standard has been revised; will require revision of all particular standards


Thank You!
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