

## IEC Standards, Imaging Equipment & Radiation Protection



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## Remit of IEC: Historical



- Founded officially in London in 1906 with Lord Kelvin as first President
- President 2005– is from Italy: Mr A Tani
- Membership now includes about 63 Countries (standards organisations)
- General Secretariat in Geneva

## IEC Participating countries

ARGENTINIA	FINLAND	LATVIA (AM)	SINGAPORE
AUSTRALIA	FRANCE	LITHUANIA	SLOVAKIA
AUSTRIA	GERMANY	(AM)	SLOVENIA
BELARUS	GREECE	LUXEMBURG	SOUTH
BELGIUM	HUNGARY	MALAYSIA	AFRICA
BOS.-HERZO. (AM)	ICELAND (AM)	MALTA (AM)	SPAIN
BRAZIL	INDIA	MEXICO	SWEDEN
BULGARIA	INDONESIA	NETHERLANDS	SWITZERLAND
CANADA	IRAN	NEW ZEALAND	THAILAND
CHINA	IRELAND	NORWAY	TUNISIA (AM)
COLOMBIA (AM)	ISRAEL	PAKISTAN	TURKEY
CROATIA	ITALY	PHILIPPINES	UKRAINE
CYPRUS (AM)	JAPAN	POLAND	UK
CZECH REP.	KOREA (D.P.R OF, AM)	PORTUGAL	USA
DENMARK	KOREA Rep	ROMANIA	VIETNAM (AM)
EGYPT		RUSSIAN FED.	YUGOSLAVIA
ESTONIA (AM)		SAUDI ARABIA	

AM = Associate member

## Member Bodies of IEC

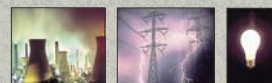
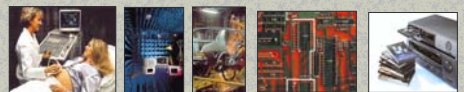
- National Committees of the participating countries
- Represent each country's interest from:
  - manufacturers, distributors, vendors etc.,
  - consumers, users
  - governmental agencies
  - professional societies
  - trade associations
  - standards developers

## Remit of IEC: Nature

- **Consensus based decision processes**
- Facilitates trade in global market for products and services
- Human health and safety
- Environmental protection
- Create conditions for interoperability of complex systems



## IEC



## Operation of IEC



- **110 Technical Committees:**
- 23- Plugs, Sockets, Switches;
- 45A- Instrumentation at Nuclear Facilities;
- 59- Household Electrical Appliances;
- 76- Optical Equipment and Lasers;
- 97- Beacons of Aerodromes;
- 110- Flat Panel Displays

## TC 62 & Subcommittees: Electro Medical Equipment

- A: Common Aspects
- B: Diagnostic Imaging Equipment
- C: Radiotherapy, Nuclear Medicine, Dosimetry
- D: Electromedical Equipment

## Remit of TC 62

- Standards and Technical Reports
- Manufacture, Installation, and +/- Application
- Electrical Equipment/Accessories used in Medical Practice (incl Dental)
- Patients, Operators, Environment

### Region

### Use of IEC TC 62 Standards

Europe	High use and adopted through the CEN / CENELEC, and the CE Mark; MED & MDD Regs
US	Increasing participation & commitment. NEMA and FDA Liaisons
Japan	Adopt Standards item by item on a statutory basis as they are produced.
China	High level of commitment and interest. Adopting the standards and hosting meetings.

## Membership in IEC TC62

- **5 Committees and Chairmen:** DE (1), US (2), AU (1), IE (1)
- **5 Secretaries:** DE (2), US (3)
- **41 Working Groups**
- **39 Convenors:** US (15), DE (12), NL (4), GB (3), CA (2), FR (1), IE (1), SE (1)
- **500 Experts:** AU, BE, CA, CN, DK, FI, FR, DE, HU, IR, IT, JP, NL, NO, PL, PT, RO, RU, SK, ZA, ES, SE, CH, UK, US

## Medical Equipment standards of TC 62

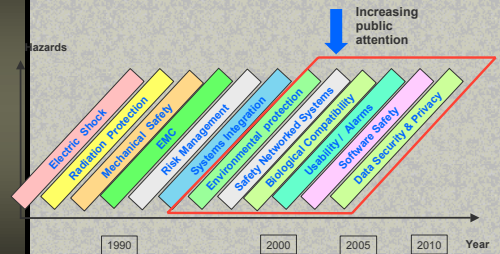
- **Safety Standards:** Requirements for medical equipment (Several Types)
- **Acceptance and QA Standards:** Test procedures for medical equipment in the field.
- **Performance Standards:** related to function of medical equipment
- No Standards for medical procedures

## Remit of SC 62B

- All X-Ray
- Ultrasound
- CT Systems
- Magnetic Resonance
  
- Mammography and Dental Equipment
  
- Acceptance Tests and QA



## Hazards covered by safety standards



## TC 62 B Officers

- Chairmen: Professor Jim Malone (formerly Professor Tossi, Italy)
  
- Secretary: Dr Norbert Bischoff (formerly Mr Hartmut Duschka and Mr W Puschert, Germany)

## Active Work Programme

- Working Groups established by NWIP, eg:
  - WG 28 and 35 Magnetic Resonance; WG 33 DQE; WG 36 Display Devices
- Maintenance Teams revise and update existing standards, eg:
  - MT 30 CT; MT 31 Mammography; MT 32 X-Ray Source Assemblies; MT 34 Diagnostic Ultrasound; MT 37 Radiation Safety; and,
  - **MT 38 Radiographic and Fluoroscopic QA and Equipment**

## X-Ray Components Standards

	Source Assembly	XRII	Grids	Digital Detectors	Protective devices
Performance	60336 60613 60522 60526 60806	61262-1 61262-2 61262-3 61262-4 61262-5 61262-6 61262-7	60627	62220-1 62220-1-2 62220-1-3	61331-1 61331-2
Safety	60601-2-28				61331-3

## X-Ray Modality Standards

	Radiog Fluoro	Interv Card	Mammo	CT	Imaging Network
Performance	62220-1-1 60336	62220-1-3 60336	62220-1-2 60336	60336	
Safety	60601-1 60601-1-3 60601-2-32 60601-2-28 60601-2-7	60601-1 60601-1-3 60601-2-32 60601-2-28 60601-2-28 60601-2-7 60601-2-43	60601-1 60601-1-3 60601-2-32 60601-2-28 60601-2-45	60601-1 60601-1-3 60601-2-32 60601-2-28 60601-2-28 60601-2-44	60601-1
QA	61223-3-1 61223-2-9 61223-2-11	61223-3-3 61223-2-9	61223-3-2 61223-2-10	61223-3-5 61223-2-6	61223-3-6

## Revised Strategy (Dublin 05)

- Proposed by Steering Group and now approved by National Committees
- Moving from Component and sub assembly to System Standards
- Presently effective Systems approach for:
  - MRI
  - Ultrasound
  - CT
  - Mammography

## Revised Strategy (Dublin 05)

- Multitude of existing X-Ray Standards will be streamlined and gradually replaced by System Standards for:
  - Radiology (and ? Simple Fluoro)
  - Complex Fluoro and Interventional
- Dental
- DEXA?

## Revised Strategy (Dublin 05)

- IEC QA, Acceptance Test and Constancy Test Standards are recognised not to have been taken up (except in Germany)
- Consultation and Liaison to take place on Acceptance Test development
- Approach will frequently rely on definition of measurement protocols without defining the performance norm to be achieved [[Essential Performance issues in Standards](#)]

## Revised Strategy (Dublin 05)

- Some Component Standards will be retained (eg. Tubes) where it is necessary for the industry.
- Radiation Protection Standard will be radically restructured, placing all modality parts with the appropriate system, and leaving a very generic standard,

## General Strategy Matters

Topic	Question/Comment
Essential performance according to 60601-1	What should be considered to be essential performance for x-ray modalities?
Regulations in EU (MDD), US, Japan, China and others	Standards and risk management are used to show compliance to regulations. Are the standards sufficiently useful in that respect?
DIMOND / SENTINEL results	How should these show up in the set of 62B standards? Maintenance projects? New work items?
DICOM / Radiation dose storage and evaluation	How should the Committee develop its activities in that direction.

## Particular Standards Strategy

	Topic	Question/Comment
1	IEC 60601-2-5X Safety of X-Ray equipment (New)	This new standard could replace the 60601-2-7 and include other requirements for radiography and simple fluoroscopy.
2	IEC 60601-2-7 Safety of X-Ray generators	This standard is not used for mammography and CT. Could be included in the IEC 60601-2-44 and 60601-2-5X and withdrawn.
3	IEC 60601-2-32 Safety of associated equipment of X-ray equipment	This standard has been included in the 60601-1 3rd edition and could be withdrawn.

## EU Medical Device and Exposure Directives

- Background
- Acceptance of Equipment to Standards defined by member states
- IEC defining assessment methodology
- International Functional Standards not being developed
- Stand-off between Physicists/Industry

## Important Liaisons



- ISO, WHO, IAEA et al.,
- In Europe CEN and CENELEC
- In US FOR 62b purposes the liaison through FDA staff and NEMA is critical
- Members of Professional Bodies, ACR, AAPM, EAR, IPEM, and SCVIR et al.
- Industry and National Standards Organisations
- SENTINEL et al.

## What we would like from You

- Better Liaison with end user professions
- Get involved, as end users, in commenting on draft standards through national committees
- Get involved through nomination to relevant WG's and MT's
- Bring professional body and research documents to IEC's attention so that your work finds maximum application
- And **THANK YOU!**

END

Project	Item	Start	End
60601-1-3 Ed 2.0 MT 37	Part 1: General requirements for safety - 3. Collateral standards: General requirements for radiation protection in diagnostic X-ray equipment	2003-12	2006-12
60601-2-5X	Part 2: Particular requirements for the safety of X-ray equipment and systems for radiography and radioscopy	2005-10	2007-12
60601-2-43	Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures	2005-10	2007-12
60601-2-44 Ed. 3.0 MT 30	Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography	2005-07	2006-12
60601-2-45	Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices	2005-10	2008-04
60601-2-28 Ed 2.0 MT 32	Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	2005-10	2007-12
60601-2-33 Ed 2.0 MT 40	Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis	2005-07	2007-09
60601-2-37 MT 34	Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment	2005-09	2007-09

## Two Dilemmas

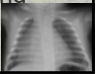
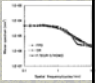
1. **For End Users:** Most Equipment Supply is Global. Purchase, use and healthcare systems, including regulation, are regional or local.
2. **For Suppliers and IEC:** Most purchase, use and healthcare systems, including regulation, are regional or local. Equipment Supply and Standardisation is Global

## Trends in Technology

- Influence of IT on design, function and safety
- Advances in Clinical Practice, and Academic Research
- Regulation, and Civil Liability
- Decentralisation of diagnostic procedures

## Functional Standards

- Definition by SC 62A
- Major Difficulty and Confusion
- Work in MT 38 Major Progress
- Background of requirement for defined functional standards arising from accountability issues



## Involvement of Endusers

- Low level of Enduser involvement
- Low level of Academic involvement
- Funding of Participation
- Recognition of work done; naming participants and authorship
- Concerted effort to recruit experts

## Particular Standards Strategy

Topic	Question/Comment
IEC 60601-2-28 Safety of X-Ray tubes	Could also be included into the safety standards for X-ray, mammography, Cardiac/interventional and CT. Do we need a separate safety standard for x-ray-tubes?
IEC 60601-1-3 General requirements for radiation protection in diagnostic X-ray equipment	Also the particular standards could include the radiation protection requirements.
IEC 60601-2-5Y Safety of image display systems (New)	WG 36 "Image display devices" is proposing a set of modality dependent minimum performance requirements for display systems used for diagnosis. Should such requirements be listed in a 60601 part 2 standard for image display systems (workstations)?

## Particular Standards Strategy

	Topic	Question/Comment	Recommendation
9	Tableside control proposal	The US national committee is currently about a proposal for table side controls for interventional. Should this be included in the upcoming maintenance project for 60601-2-43 without an NWI?	

Project	Item	Start	End
0613 Ed. 3.0 IT 32	Electrical, thermal and loading characteristics of rotating anode X ray tubes for medical diagnosis	2003-11	2007-12
1223-2-6 d. 2.0 IT 30	Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - X-ray equipment for computed tomography	2004-07	2006-05
1223-3-2 d. 2.0 MT 31	Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment	2002-11	2006-10
1223-3-6 d. 1.0 WG 36	Medical electrical equipment - Magnetic resonance equipment for diagnostic imaging - Part 1: Determination of characteristics	2003-01	2006-12
1223-3-7 Ed. 1.0 WG 35	Medical electrical equipment - Magnetic resonance equipment for diagnostic imaging - Part 1: Determination of characteristics	2001-12	2006-10
2220-1-2 d. 1.0 WG 33	Medical electrical equipment characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Dynamic Imaging Detectors	2005-06	2006-06
2220-1-3 d. 1.0 WG 33	Medical electrical equipment characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Dynamic Imaging Detectors	2005-06	2007-06
0601-2-7	Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	2006-10	2008-12
1223-3-1	Evaluation and routine testing in medical imaging departments - Part 3-1: Acceptance tests - Imaging performance of X-ray equipment for radiographic and radioscopy systems	2005-10	2008-10
1223-3-3	Evaluation and routine testing in medical imaging departments - Part 3-3: Acceptance tests - Imaging performance of X-ray equipment for digital subtraction angiography (DSA)	2005-10	2008-10
1223-3-4	Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment	2005-10	2008-10
1331-1	Protective devices against diagnostic medical X-radiation - Part 1: Determination of attenuation properties of materials	2006-06	2009-06

## A possible future approach

	Radio- graphy Fluoro	Inter- vent / Cardio	Mamm o	CT	Medical Imaging Network
Perfor- mance	62220-1-1 60336	62220-1-3 60336	62220-1-2 60336	60336	
Safety	60601-1 60601-2-5X New	60601-1 60601-2- 43	60601-1 60601-2-45	60601-1 60601-2- 44	60601-1 60601-2-5Y New
QA	61223-3-1 61223-2-9 61223-2-11	61223-3-3 61223-2-9	61223-3-2 61223-2-10	61223-3-5 61223-2-6	61223-3-6

## Quality Assurance Standards

### Strategy

IEC 61223-3-1 Acceptance test for x-ray equipment and related safety standards	The field is complex. Should we define separate projects for radiography, fluoroscopy and interventional / cardiac?
IEC 61223-2-xx Constancy tests	One of the earlier 62B CAG meetings had concluded not to pursue the constancy test standards. Should they be withdrawn? Or revised? For CT the working group has concluded however to provide a new revision of the constancy test standard due to software standardization reasons.
1 IEC 61223-2-1 Constancy film processors	Revise, withdraw or prolong? Extend for CR and DR?

## Active Work Programme 3 Other

- Selection of New Work Items
- Ultrasound
- Glossary of Terms
- Trends in Technology
- Functional Standards
- Involvement of End Users and Recruiting Experts
- Tolerances and Drop Out of Powerlines