

**IEC International Electrotechnical Commission  
SC 62B Diagnostic imaging equipment and the  
SENTINEL project**

Jim Malone and Norbert Bischoff  
Chair and Secretary IEC 62B



## Remit of IEC: Historical



- Founded officially in London in 1906 with Lord Kelvin as first President
- Membership now includes >65 Countries (standards organisations)
- General Secretariat in Geneva

## 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

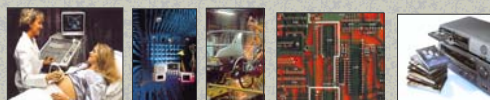
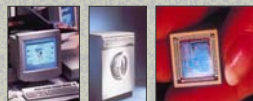
## Remit of IEC: Nature

### ■ *Consensus based decision processes*

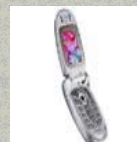


- Facilitates trade in global market for products and services
- Human health and safety
- Environmental protection
- Create conditions for interoperability of complex systems

## 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- Beaconing of Aerodromes;
- 110- Flat Panel Displays

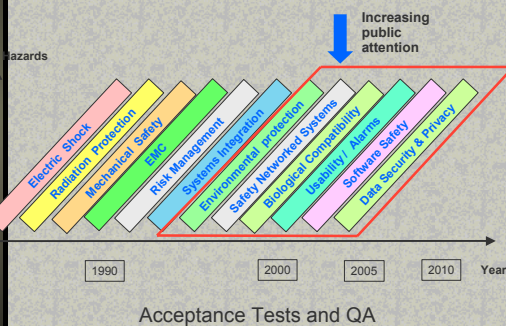
## TC 62 & Subcommittees: Electro Medical Equipment

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

## IEC/62B Diagnostic imaging equipment



## Hazards covered by safety standards



## Types of Safety Standard

- **Part 1: General requirements for basic safety and essential performance** IEC 60601-1 (Medical electrical equipment ---)
- **General requirements not considered in the 60601-1** (IEC 60601-1-X, eg radiation protection)
- **Particular requirements for medical equipment** (IEC 60601-2-X, eg interventional radiology)

## Example: CT Safety Standards

- IEC 60601-1 Medical electrical equipment - General requirements for basic safety and essential performance  
2005-12 edition 3 published (Committee IEC/62A)
- IEC 60601-1-3 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation Protection  
under revision in IEC/62B/MT37 (CDV)
- IEC 60601-2-44 Ed.3: Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography  
under revision in IEC/62B/MT38 (CD)

## IEC 60601-1-3: Collateral standard on Radiation Protection:

- Project IEC 60601-1-3 Ed. 2.0 will increase the transparency in radiation protection
- Particular requirements will be moved to the particular standards
  - 60601-2-54 radiography and radioscopy (new)
  - 60601-2-43 interventional x-ray
  - 60601-2-44 computed tomography
  - 60601-2-45 mammography
  - 60601-2-XX dental x-ray (open)
- Readability will be increased
- Publication is intended to be end of 2007

## Revised Strategy (Dublin 05)

- Proposed by Steering Group; now approved by National Committees Aand TC 62/SC 62B
- Moving from Component and sub assembly to System Standards. Multitude of existing X-Ray Standards will be streamlined and gradually replaced.
- Presently effective Systems approach for:
  - MRI
  - Ultrasound
  - CT
  - Mammography

## 62B Active Working Groups

MT 30:	<i>John Jaeklec</i>	Computed tomography
MT 31:	<i>Christian Lavole</i>	Mammographic X-ray equipment
MT 32:	<i>Thos Bengtsson</i>	Requirements for X-ray source assemblies
WG 33:	<i>Raoul Bastiens</i>	Characteristics of digital X-ray imaging devices
WG 35:	<i>Herbert Koestler</i>	Determination of the detective quantum efficiency
WG 36:	<i>Matthias Wedel</i>	Magnetic resonance equipment for diagnostic imaging -
MT 34:	<i>John Abbott</i>	Determination of characteristics
MT 37:	<i>Ursula Kniesberg</i>	Image display devices
MT 38:	<i>Steve Balter</i>	Revision of 60601-2-37: Medical electrical equipment -
MT 39:		Part 2-37: Particular requirements for the safety of
MT 40:	<i>Hans Engels</i>	ultrasonic medical diagnostic and monitoring
MT 41:	<i>Lionel Desponds</i>	equipment
WG 42:	<i>Ursula Kniesberg</i>	IEC 60601-1-3 Ed. 2 Medical electrical equipment - Part
WG 43:	<i>Ulrich Neitzel</i>	1-3: General requirements for radiation protection in
		diagnostic X-ray equipment
		X-ray testing standards
		Dental Imaging Equipment
		Magnetic resonance equipment for medical diagnosis
		Revision of IEC 60601-2-43
		IEC 60601-2-54 New standard for general X-ray
		Exposure Index

## Safety standards

Project	Item	Start	End	Current / Next Step
60601-2-43	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures	2006-04	2007-12	DC/CD
60601-2-44 Ed. 3.0 MT 30	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography	2005-07	2007-12	CD/CDV
60601-2-45	Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices	2005-10	2008-04	J/CD
61223-3-6	Evaluation and routine testing in medical imaging departments - Part 3-6 Acceptance Tests - Image Display Devices Scope and title will be changed according to NCs voting	2003	2010	CD
Extract from Work Programme				

## IEC 62494-1: Exposure index of digital x-ray imaging systems


- Project IEC 62494-1 will provide a common approach for the exposure index of digital x-ray images
- Deals with definitions and measurement methods
- Will provide the basic methods that can be referenced from the safety standards
- Publication is expected by end 2008

## IEC and SENTINEL Input to Industry through Standards

- Direct Input to Industry both through Representation and as working participants in Standardisation Bodies
- Brings research results directly to bear on Equipment Design Process and Industry thinking


## IEC and SENTINEL

- SENTINEL approached IEC to give effect to its findings
- SENTINEL participation in many groups including mammography, interventional etc.
- Formal Meeting at IEC request with SENTINEL in Delft, Sept 2006




## Formal Collaboration with IEC

- Agreement (Oct 2007) between SENTINEL and IEC Industry representatives agreed to work on establish common approach.
- Acceptance Testing/Commissioning/QA
- Long term differences and lack of trust between industry engineers, end user physicists, et al.
- DICOM initiative of IEC and NEMA stimulated by SENTINEL



## Regulations for medical imaging equipment in Europe

- Medical imaging equipment must be compliant to relevant regulations.
- In the European Community the council directives 93/42/EEC concerning medical devices and 97/43/EURATOM must be followed. It was desirable to implement 97/43/EURATOM in the Member Countries using harmonized requirements and tests for medical imaging equipment, as is the case for 93/42/EEC.
- Important for the revision of RP 91 which is immanent



## Finally: What can you contribute?

- Better Liaison with end user professions
- Get involved, as end users, in commenting on draft standards through national committees, even if only by correspondence.
- 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
- **Thank You!**