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Roundtable 2: The IEC perspective 2012-12-04

Norbert Bischof

Secretary IEC TC62 ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE

Secretary IEC SC62B DIAGNOSTIC IMAGING EQUIPMENT

ISO International Organisation for Standardization, founded 1946

IEC International Electrotechnical Commission, founded 1906

- share a set of common directives
- standards fit seamlessly together
- are voluntary associations of **MEMBER COUNTRIES** establishing National Committees fully representing stakeholders in their countries: industry, government, consumers ..., etc.
- **ONE member per country**
- follow the **WTOs* TBT** Code of Practice**

*WTO World Trade Organisation
**TBT Technical Barriers to Trade



81 full and associate members (2011-07-01)

- 
- ALBANIA (AM)
ALGERIA
ARGENTINA
AUSTRALIA
AUSTRIA
BAHRAIN (AM)
BELARUS
BELGIUM
BOSNIA-HERZEGOVINA (AM)
BRAZIL
BULGARIA
CANADA
CHILE
CHINA
COLOMBIA
CROATIA
CUBA (AM)
CYPRUS (AM)
CZECH REP.
DENMARK
EGYPT
- ESTONIA (AM)
FINLAND
FRANCE
GEORGIA (AM)
GERMANY
GREECE
HUNGARY
ICELAND (AM)
INDIA
INDONESIA
IRAN
IRAK
IRELAND
ISRAEL
ITALY
JAPAN
Jordan (AM)
KAZAKHSTAN (AM)
KENYA (AM)
KOREA, REP. OF
- LATVIA (AM)
LIBYA
LITHUANIA (AM)
LUXEMBOURG
MALAYSIA
MALTA (AM)
MEXICO
MONTENEGRO (AM)
MOROCCO (AM)
NETHERLANDS
NEW ZEALAND
NIGERIA (AM)
NORWAY
OMAN
PAKISTAN
PHILIPPINES
POLAND
PORTUGAL.
QATAR
ROMANIA
- RUSSIAN FEDERATION
SAUDI ARABIA
SERBIA
SINGAPORE
SLOVAKIA
SLOVENIA
SOUTH AFRICA
SPAIN
SRI LANKA (AM)
SWEDEN
SWITZERLAND
THAILAND
THE FYR OF MACEDONIA (AM)
TUNISIA (AM)
TURKEY
UKRAINE
UNITED ARAB EMIRATES
UNITED KINGDOM
UNITED STATES OF AMERICA
VIETNAM (AM)



82 affiliates (2011-07-01)

- 
- AFGHANISTAN
 - ANGOLA
 - ANTIGUA AND BARBUDA
 - ARMENIA
 - AZERBAIJAN
 - BANGLADESH
 - BARBADOS
 - BELIZE
 - BENIN
 - BHUTAN
 - BOLIVIA
 - BOTSWANA
 - BRUNEI DARUSSALAM
 - BURKINA FASO
 - BURUNDI
 - CAMBODIA
 - CAMEROON
 - CENTRAL AFRICAN REPUBLIC
 - TCHAD
 - COMOROS
 - CONGO
 - CONGO (DEMOCRATIC REP. OF)
 - COSTA RICA
 - COTE D'IVOIRE
 - DOMINICA
 - DOMINICAN REPUBLIC
 - ECUADOR
 - EL SALVADOR
 - ERITREA
 - ETHIOPIA
 - FIJI
 - GABON
 - GAMBIA
 - GHANA
 - GRENADA
 - GUATEMALA
 - GUINEA
 - GUINEA BISSAU
 - GUYANA
 - HAITI
 - HONDURAS
 - JAMAICA
 - KYRGYZSTAN
 - LAO PEOPLE'S (DEMOCRATIC REPUBLIC)
 - LEBANON
 - LESOTHO
 - MADAGASCAR
 - MALAWI
 - MALI
 - MAURITANIA
 - MAURITIUS
 - MOLDOVA
 - MONGOLIA
 - MOZAMBIQUE
 - MYANMAR
 - NAMIBIA
 - NEPAL
 - NIGER
 - PALESTINE
 - PANAMA
 - PAPUA NEW GUINEA
 - PARAGUAY
 - PERU
 - RWANDA
 - SAINT LUCIA
 - SAINT VINCENT AND THE GRENADINES
 - SENEGAL
 - SEYCHELLES
 - SIERRA LEONE
 - SUDAN
 - SURINAME
 - SWAZILAND
 - TANZANIA
 - TOGO
 - TRINIDAD AND TOBAGO
 - TURKMENISTAN
 - UGANDA
 - URUGUAY
 - VENEZUELA
 - YEMEN
 - ZAMBIA
 - ZIMBABWE

TC 62 Electrical equipment in medical practice

Chair Rudy Godinez /
Sec DE Norbert Bischof

CAG
Chairman Advisory
Group

SNAG
Software and Networks
Advisory Group

SC 62A Common aspects of electrical equipment used in medical practice
Chair Justin McCarthy Sec US Charles Sidebottom

SC 62B Diagnostic imaging equipment
Chair Jim Malone Sec DE Norbert Bischof

SC 62C Radiotherapy, nuclear medicine and radiation dosimetry
Chair Geoffrey S Ibbott Sec DE Claus-Peter Hoeppe

SC 62D Electromedical equipment
Chair Robert Schaefer Sec US Mike Schmidt



IEC TC 62 Key Data*

- **Founded in 1968**
- **116 active publications**
- **18 publications last year**
- **58 active projects**
- **27 Participating Member Countries**
- **17 Observing Member Countries**
- **70 Working Groups**
- **960 Experts from BE, BR, CA, CN, DK, FI, FR, DE, HU, IN, IE, IT, JP, NL, NO, PK, PT, RO, RU, ZA, ES, SE, CH, GB, US**
- **Liaisons with DICOM, IAEA, ICRP, COCIR, GHTF**



IEC TC 62s safety standards are recognized

- **66 recognized consensus standards by the US Food and Drug Administration**
- **67 IEC standards harmonized under the EU Medical Device Directive 93/42/EEC**
- **used for market approval**



IEC TC 62 Meetings

IEC TC 62 has met September 2011 in Nuremberg in conjunction with its subcommittees.

The next meeting of IEC TC 62 and subcommittees will be held in Shanghai, China from April 8 to 19, 2013.



Modular Structure of IEC 60601-Series

Part 1: Generic

IEC 60601-1: General requirements

Collateral Standards

IEC 60601-1-2: Electromagnetic Compatibility

IEC 60601-1-3: Radiation Protection

IEC 60601-1-6: Usability

IEC 60601-1-8: Alarms

IEC 60601-1-9: Environment

IEC 60601-1-10: Physiological Closed-Loop Controllers

IEC 60601-1-11: Home Healthcare Environment

IEC 60601-1-12: Emergency Services Environment**

ISO 14971 Risk management

Part 2: Particular

IEC 60601-2-x standards rule

- Within its scope a part 2 takes priority over all part 1 standards.
- 70 in IEC, many more in ISO
- Specific to a category of products.
- Modifications to requirements in part 1
 - Addition,
 - Replacement or
 - Exemption
- Dated references to part 1 standards.

** publication 2013



Imaging: Particular Standards of IEC 60601-1

Device	IEC Standard
X-ray	60601-2-54
Interventional x-ray	60601-2-43
Mammography	60601-2-45
Dental intra-oral	60601-2-65
Dental extra-oral	60601-2-63
Computed tomography	60601-2-44
X-ray tube assemblies	60601-2-28
MRI	60601-2-33
Ultrasound	60601-2-37



- **60601-2-1 Electron Accelerators**
- **60601-2-8 Therapeutic X-ray Equipment**
- **60601-2-11 Gamma Beam Therapy Equipment**
- **60601-2-17 Brachytherapy Afterloading Equipment**
- **60601-2-29 Radiotherapy Simulators**



- **60580 Dose Area Product Meters**
- **60731 Dosimeters with Ionization Chambers used in Radiotherapy**
- **61267 Radiation conditions for use in the determination of characteristics**
- **61303 Radionuclide calibrators - Particular methods for describing performance**
- **61674 Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging**
- **61676 Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology**
- **62467-1 Dosimetric instruments as used in brachytherapy – Part 1: Instruments based on well-type ionization chambers**

Thank you

**Questions welcome
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