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AHWP Annual Meeting 6 November 2015 Bangkok



A)

Refrigerators



В



freeZwel

A





В



freeZwel

A



\$ 500



В

\$ 300



freeZwel

Α



Refrigerator safety standard IEC 60335-2-24



В

\$ 500 SDoC \$ 300 SDoC



freeZwel

A



Refrigerator safety standard IEC 60335-2-24

В

\$ 500 Certified \$ 300 Certified



freeZwel

A



Refrigerator safety standard IEC 60335-2-24

В

\$ 500 Certified \$ 400 Certified



Contents

- What is IEC?
- How are IEC international standards developed?
- What are IEC conformity assessment systems relating to medical equipment?
- Why IEC?



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The world of standards

International:

IEC, ISO, ITU, OIML

Regional:

Africa (e.g. AFSEC, SADC)

Americas (e.g. COPANT, CANENA, MERCOSUR)

Asia-Pacific (e.g. ASEAN, APEC SCSC)
Europe (e.g. CENELEC, ETSI, EASC)

National Committees/Affiliates:

(e.g. Austria, Brazil, Cambodia, China, France, Germany, Italy, Japan, Korea, Malaysia, Mongolia, Russia, South Africa, UK, USA)



The organization

INTERNATIONAL ELECTROTECHNICAL COMMISSION REPORT PRELIMINARY MEETING THE HOTEL CECIL, LONDON TUESDAY AND WEDNESDAY, JUNE 26TH AND 27TH 1905 LONDON

- The IEC is a not-forprofit, nongovernmental organization founded in 1906
- One member per country
- International Standards and Conformity
 Assessment Systems for all electrical and electronic components, devices and systems

scope of the IEC

Millions of devices and systems that use or produce electricity and contain electronics. Interoperability, safety, performance, EMC, waste management and environment.







83 National Committees

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 REPUBLIC**

DEM. PEOPLE'S REP. OF

KOREA (AM) DENMARK **EGYPT**

ESTONIA (AM)

FINLAND FRANCE

GEORGIA (AM)

GERMANY GREECE HUNGARY ICELAND (AM)

INDIA

INDONESIA

IRAN **IRAQ** IRFI AND **ISRAEL ITALY JAPAN**

JORDAN (AM)

KAZAKHSTAN (AM)

KENYA (AM) KOREA, REP. OF LATVIA (AM)

LIBYA

LITHUANIA (AM)

LUXEMBOURG MALAYSIA

MALTA (AM)

MEXICO

MOLDOVA (MD)

MONTENEGRO (AM)

MOROCCO (AM)

NETHERLANDS

NEW ZEALAND

NIGERIA (AM)

NORWAY

OMAN

PAKISTAN

PHILIPPINES

POLAND

PORTUGAL

QATAR ROMANIA SFRBIA SINGAPORE

SLOVAKIA

SLOVENIA

SOUTH AFRICA

SAUDI ARABIA

RUSSIAN FEDERATION

SPAIN

SRI LANKA (AM)

SWEDEN

SWITZERLAND

THAILAND

THE FYR OF MACEDONIA (AM)

TUNISIA (AM)

TURKEY **UKRAINE**

UNITED ARAB EMIRATES

UK

USA

VIETNAM (AM)



83 Affiliates

AMERICAS

Antigua & Barbuda

Bahamas

Barbados

Belize

Bolivia

Costa Rica

Dominica

Dominican Republic

Ecuador

El Salvador

Grenada

Guatemala

Guyana

Haiti

Honduras

Jamaica

Panama

Paraguay

Peru

Saint Kitts & Nevis

Saint Lucia

St Vincent & the Grenadines

Suriname

Trinidad & Tobago

Uruguay

AFRICA

Angola

Benin

Botswana

Burkina Faso

Burundi

Cameroon

Central African Rep.

Chad

Comoros

Congo

Côte d'Ivoire

DRC Congo

Eritrea

Ethiopia

Gabon

Gambia

Ghana Guinea

Guinea Bissau

Lesotho

Madagascar Malawi

Mali

Mauritania

Mauritius

Mozambique

Namibia

Niger

Rwanda

Senegal Seychelles

Sierra Leone

South Sudan

Sudan

Swaziland

Tanzania

Togo

Uganda

Zambia

Zimbabwe

ASIA

Afghanistan Armenia Azerbaijan Bangladesh Bhutan

Bhutan Kyrrayratu

Kyrgyzstan Lebanon

Mongolia

Myanmar

Nepal Palestine

Turkmenistan

Yemen

ASIA-PACIFIC

Brunei Darussalam

Cambodia

Fiji

Lao PDR

Papua New Guinea

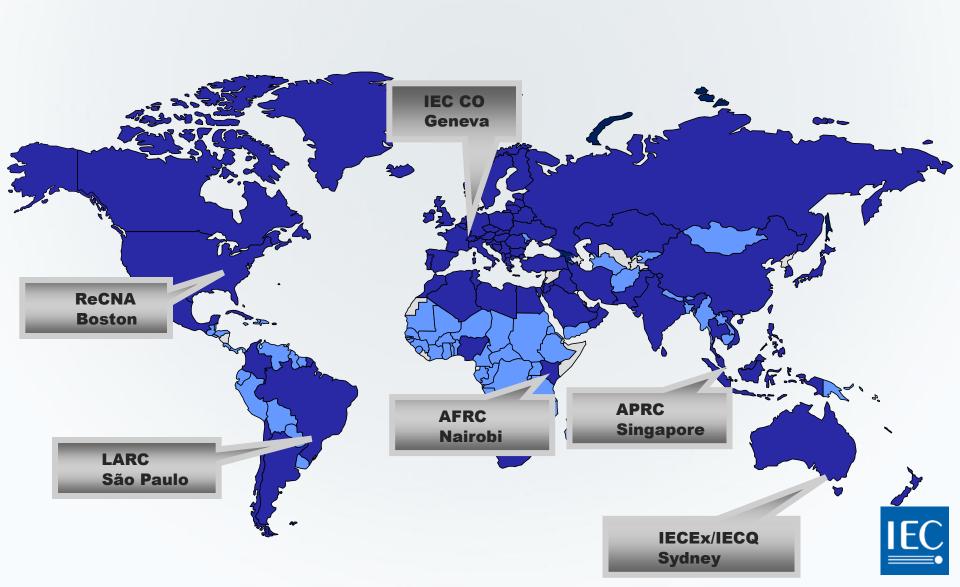


Types of participation

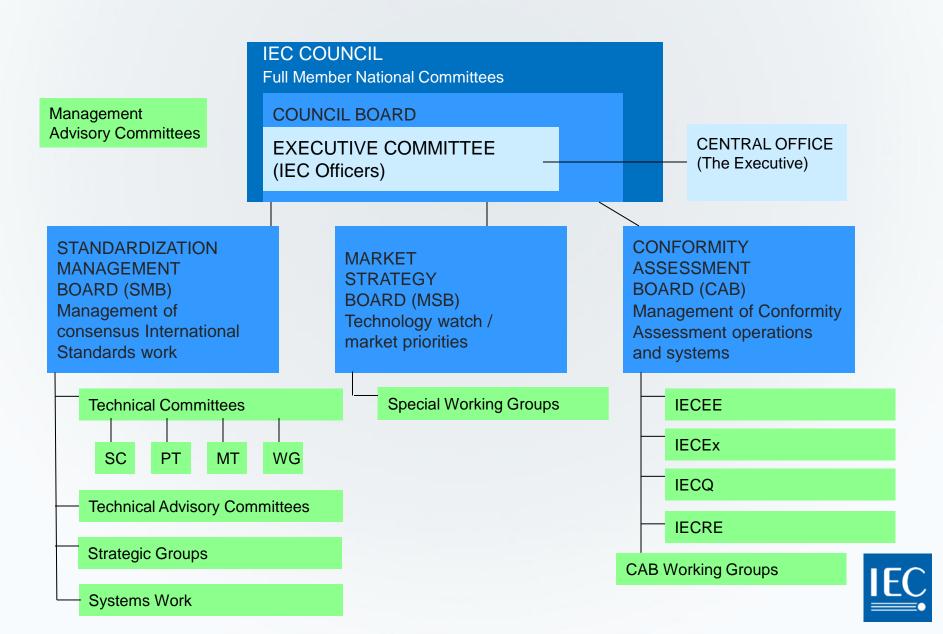
- IEC is a voluntary association of National Committees that fully represent electrotechnical interests in their countries
 - Government, industry, testing laboratories, academia, consumer groups...
- Membership one member per country
 - Full Members (60) e.g. China, India, Japan, Korea, Thailand
 - Associate Members (23) e.g. Viet Nam
- Affiliate Country programme
 - 83 participants e.g. Lao PDR



IEC offices



IEC structure



SMB: Standardization Management Board

Responsible for the technical work

- 174 TCs/SCs
 - About 15 500 experts
- Strategic Groups
- Advisory Committees
- Systems Work





IEC Technical Committees in medical field

- IEC/TC 25 Quantities and Units (new activities in eHealth)
- IEC/TC 29 Electroacoustics (hearing aids)
- IEC/TC 62 Electrical equipment in medical practice (~100 standards)
- IEC/TC 66 Safety of measuring, control and laboratory equipment (2 standards)
- IEC/TC 76 Optical radiation safety and laser equipment (Medical Lasers)
- IEC/TC 87 Ultrasonics



Other related future activities

- Strategic Group
 10 on Wearable
 Smart Devices





Electrical equipment in medical practice (TC 62)

To prepare International Standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.

- Secretariat: Germany
- P-members: 28
- O-members: 20



Subcommittees and Advisory Groups

- SC 62A Common aspects of electrical equipment used in medical practice
- SC 62B Diagnostic imaging equipment
- SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry
- SC 62D Electromedical equipment

Advisory Groups

- AG 1 CAG Chairman Advisory Group
- AG SNAG Software and Networks Advisory Group



IEC 60601 series structure

IEC 60601-2-X

Particular Standards

IEC 60601-1-X

Collateral Standards

Medical Electrical Equipment

Part 2: Particular requirements for basic safety and essential performance of many products

e.g. Ultrasonic equipment, defibrillator

Part 1-2: Electromagnetic Compatibility

Part 1-3: Radiation Protection

Part 1-6: Usability

Part 1-8: Alarms

Part 1-9: Environment

Part 1-10: Physiological Closed-Loop Controllers

Part 1-11: Home Healthcare Environment

Part 1-12: Emergency Service Environment

IEC 60601-1 Medical Electrical Equipment

Part 1: General requirements for basic safety and essential performance

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ISO 14971 Medical devices – Application of risk management to medical devices

IEC 62304 Medical device software - Software life cycle processes

IEC 82304-1 Health Software - Part 1: General requirements for product safety

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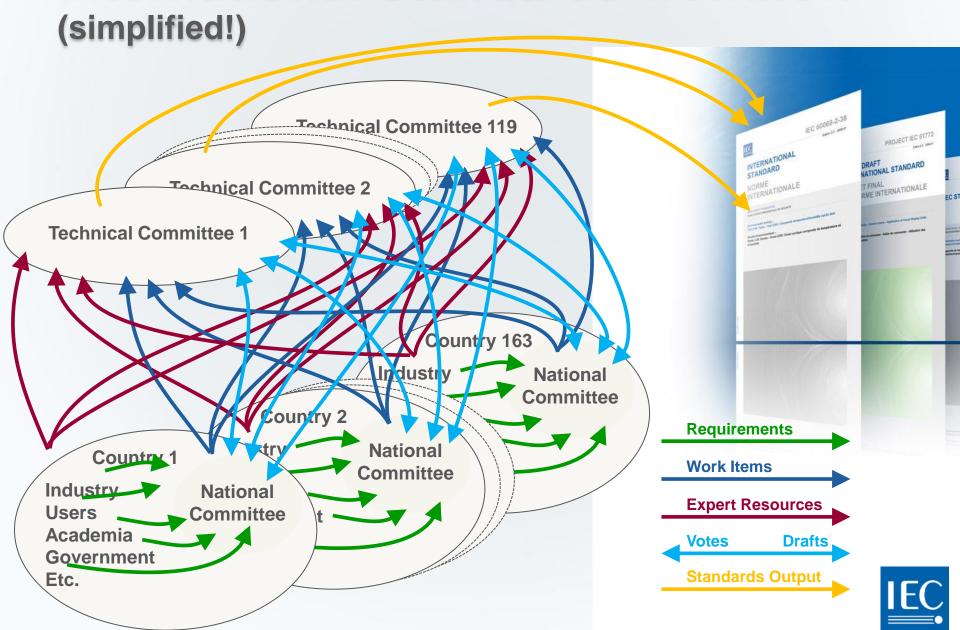
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How IEC Standards are developed

- Technical Committees cover specific fields of activity
 - Working Groups/Project Teams
- Experts nominated by National Committees
- Established standards development process – ISO/IEC Directives

International Standards workflow



Standards development stages

•	New Proposal	NP
•	Working Draft	WD
•	Committee Draft	CD
•	Committee Draft for Vote	CDV
•	Final Draft International Standard	FDIS
•	International Standard	IS

Two broad categories

- Normative publications
 agreement on technical description of characteristics to be fulfilled by the product, system, service or object
- Informative publications
 background information
 such as implementation,
 procedures or guidelines



Developed based on result of full or limited international consensus among IEC Members



Types of IEC publications

- Normative publications
 - International Standards (IS)
 - Technical Specifications (TS)
 - Publicly Available
 Specifications (IEC-PAS)
- Informative publications
 - Technical reports (TR)
- Guides





International Standard (IS)

A document, established by consensus and approved by IEC, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context





Technical Specification (TS)

Published when:

- Insufficient consensus for approval of an IS is available
- There is doubt that consensus has been achieved
- The subject is still under technical development
- Other reason precluding immediate publication of an IS





Publicly Available Specification (PAS)

A publication responding to an urgent market need, representing either:

- a consensus in an organization external to the IEC or,
- a consensus of experts within a working group

Published after verification that no conflict with existing IS by the committee concerned





Technical Report (TR)

Informative document

Data of a different kind, e.g.

- Scientific supporting material
- Data collection
- Results of surveys
- State of the art
- Supplementary information or explanation





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CAB: Conformity Assessment Board

 Responsible for setting the IEC's conformity assessment policy, promoting and maintaining relations with international organizations on conformity assessment matters







CAB - Conformity Assessment Board

IECEE

System for Conformity Testing and Certification of Electrotechnical Equipment and Components

IECEx

System for
Certification to
Standards
Relating to
Equipment for
use in Explosive
Atmospheres

IECQ

Quality
Assessment
System for
Electronic
Components

IECRE

IEC General System for
Certification to
Standards relating to
plant, equipment and
services associated with
Renewable Energy
Systems



IECEE covers

- IT and office equipment
- Electronics, entertainment
- Electrical equipment for medical use
- Installation accessories and connection devices
- Safety transformers and similar equipment
- Luminaires
- Switches for appliances and automatic controls for electrical household appliances
- Industrial Automation
- Electromagnetic Compatibility
- Hazardous Substances Testing Service
- Miscellaneous

- Portable tools
- Photovoltaics
- Household and similar equipment
- Measurement, Control and Laboratory equipment
- Low voltage, high power switching equipment
- Installation protective equipment
- Capacitors as components
- Batteries
- Cables and Cords
- Energy Efficiency
- Electric Vehicles
- Electric Toys



IECEE

Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components: MED (Medical)



Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE)

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About the IECEE	IECEE CB Scheme	Peer Assessment	Members Only
Search:	for	<u>a-In</u> Restricted Access	IEC TECEE

CB Bulletin

The National differences and Group differences, National Deviations, Special National conditions (SNC) and Regulatory Requirements, are based on information provided by the IECEE Member Bodies and/or NCBs and other sources.

Group Differences are applicable for CENELEC member countries: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Latest updates to national and group differences

1. Select product category: MED v 2. Select a standard:	60601-1(ed.2);am1;am2 60601-1(ed.2);am2	Á
To print the entire MED standard list, please click here	60601-1(ed.3)	
To view all product categories and standards, please <u>click here</u>	60601-1(ed.3);am1	
To download all or selected National/Group Differences at	60601-1-1(ed.1)	+
once, please click here		

Standard:		60601-1(ed.3)		
Product catego	ry:			
Title:	Medical electrical equipment essential performance	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance		
Year:	2005-12-15	2005-12-15		
Click on the	e icon to open the associated docu	iment	FCS FCS member	
National diffe	erences Group differences	Issuing/Recognizi	ng Recognizing only	
Electros	uisse			
National	standard reference: SN EN 60601-	1:2006	Modified 2009-12-15*	
FCS BSI				
National	standard reference: BS EN 60601-	1:2006	Modified 2014-07-15*	
Regulatory requirement reference: Medical Devices Direct		Devices Directive	Modified 2014-07-15*	
	UkrTEST		Modified 2014 07 15	
		<u> </u>	Modified 2014 07 15	
UkrTEST	ernational		Modified 2014 07 13	
UkrTEST CSA Inte		.2 No. 60601-1:08	Modified 2008-10-27*	
UkrTEST CSA Inte National	ernational	_		



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Benefits of IEC International Standards: use and participation

- WTO encourages use by regulators
- Build acceptance in global markets
- Save time and money
- Assurance safety and quality
- Influence the content of standards
- Develop business intelligence and network

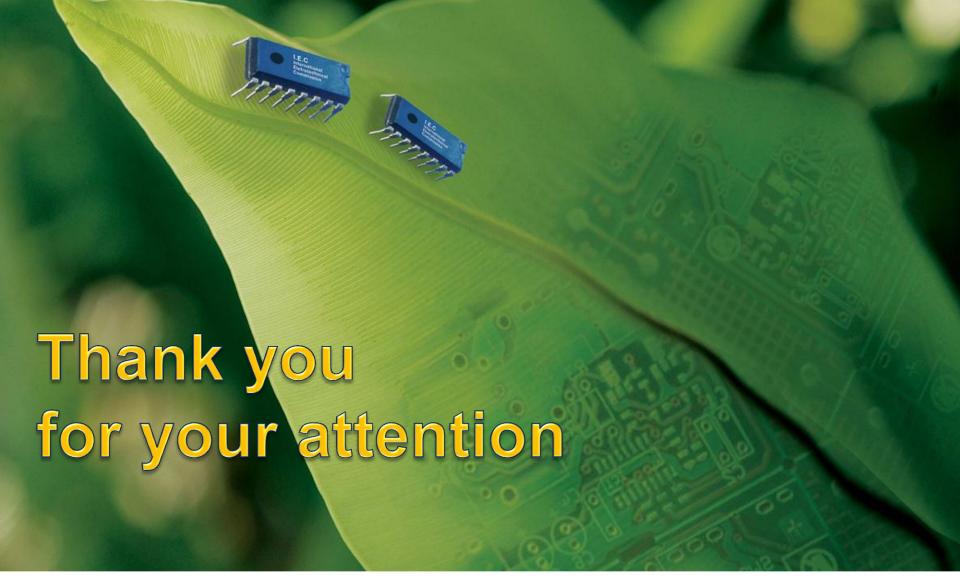


What value do the IEC CA Systems create?

World trade & a level playing field.

- One "reference" world-wide CA organisation
- Higher safety, quality & interoperability
- Aid regulatory recognition of safety & quality
- Create opportunity for smaller players
- Reduce industry's time & cost to enter markets
- Global market access and encourage world trade





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