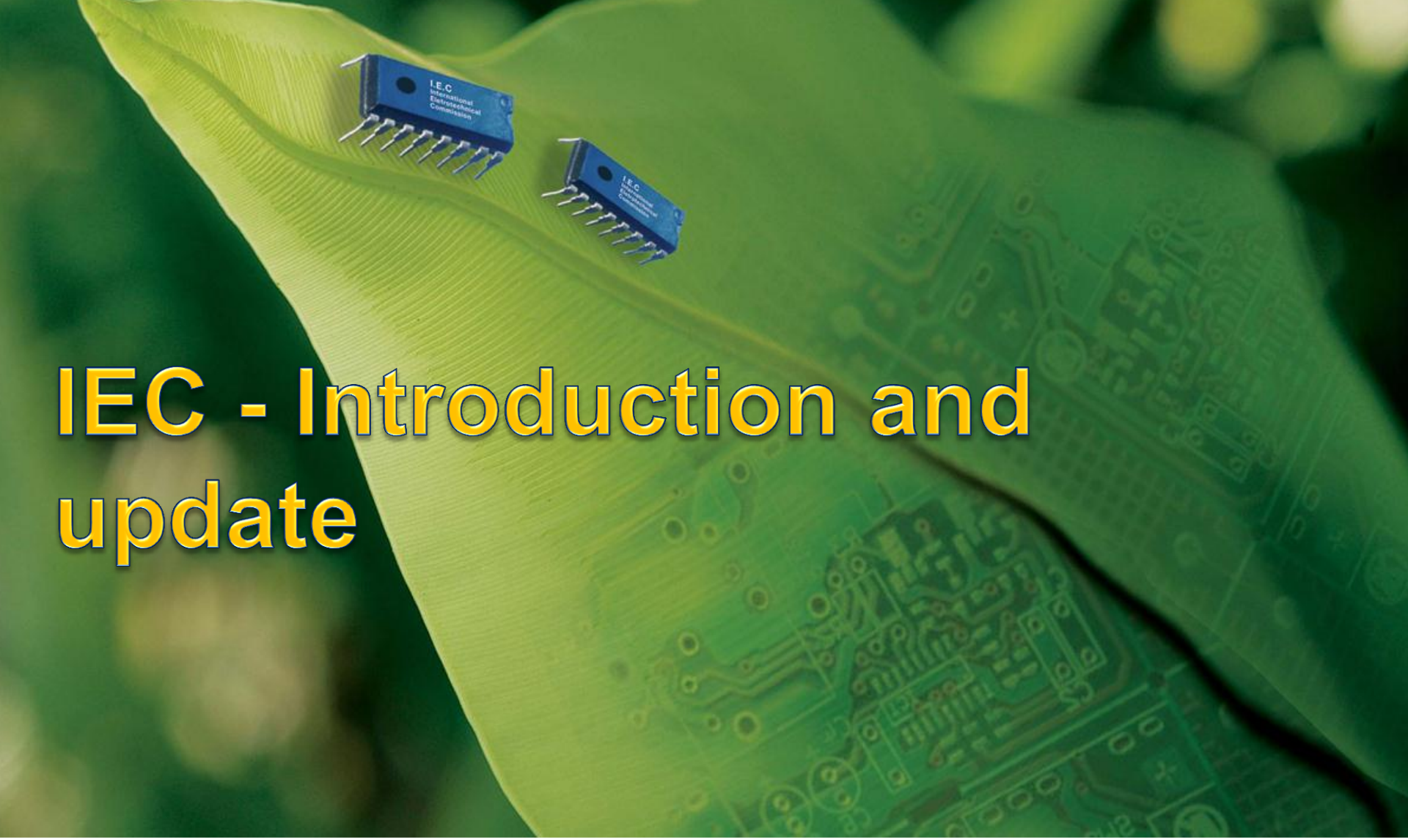

IEC - Introduction and update

Dennis Chew
Regional Director, APRC
dch@iec.ch

AHWP Annual Meeting
6 November 2015
Bangkok

International Electrotechnical Commission

A

Refrigerators

B

freeZwel

A

B

freeZwel

A

B

$ 500

$ 300

freeZwel

A

Refrigerator safety standard
IEC 60335-2-24

B

$ 500

SDoC

$ 300

SDoC

freeZwel

A

Refrigerator safety standard
IEC 60335-2-24

B

$ 500

Certified

$ 300

Certified

IEC

freeZwel

A

Refrigerator safety standard
IEC 60335-2-24

B

$ 500

Certified

$ 400

Certified

IEC

Contents

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

Contents

- **What is IEC?**
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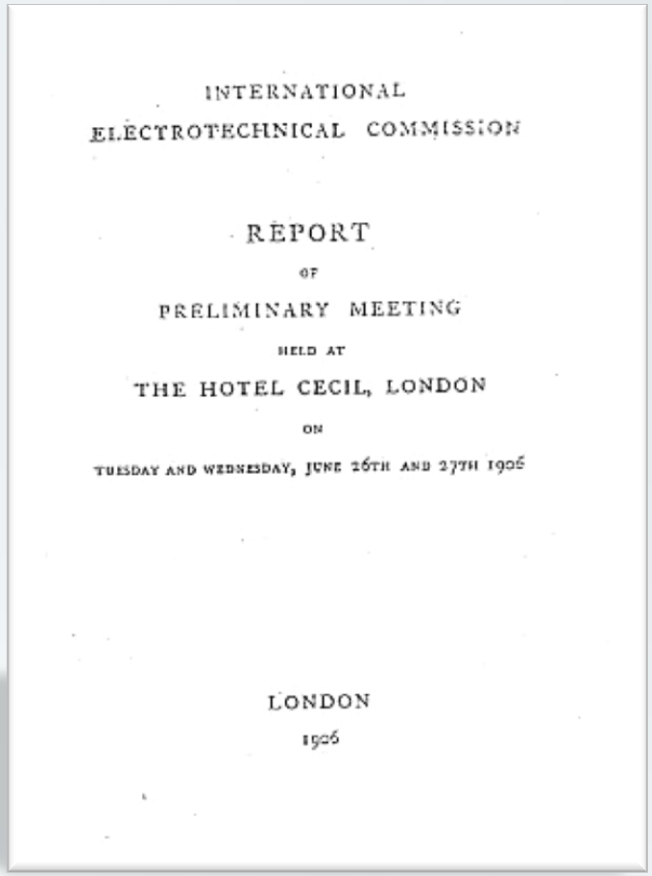
The world of standards

The organization



INTERNATIONAL
ELECTROTECHNICAL COMMISSION

REPORT
OF
PRELIMINARY MEETING
HELD AT
THE HOTEL CECIL, LONDON
ON
TUESDAY AND WEDNESDAY, JUNE 26TH AND 27TH 1906

LONDON
1906

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

➡ About the IEC > Global reach

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.















global reach:
166 countries
83 Members
83 Affiliates
98% of world population

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
IRELAND
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
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
UK
USA
VIETNAM (AM)

23 Associate Members

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

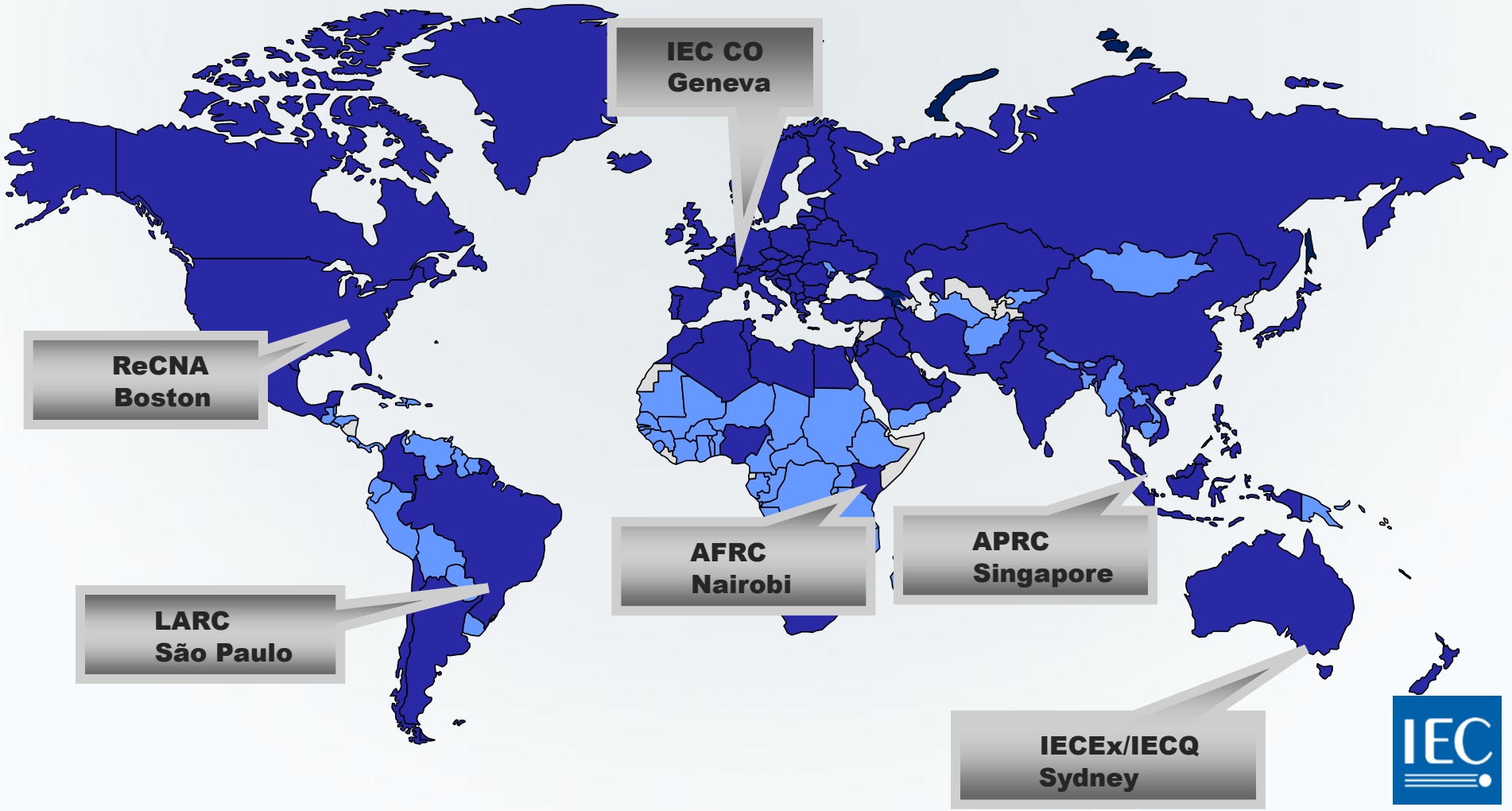
ASIA
Afghanistan
Armenia
Azerbaijan
Bangladesh
Bhutan
Kyrgyzstan
Lebanon
Mongolia
Myanmar
Nepal
Palestine
Turkmenistan
Yemen

ASIA-PACIFIC
Brunei Darussalam
Cambodia
Fiji
Lao PDR
Papua New Guinea

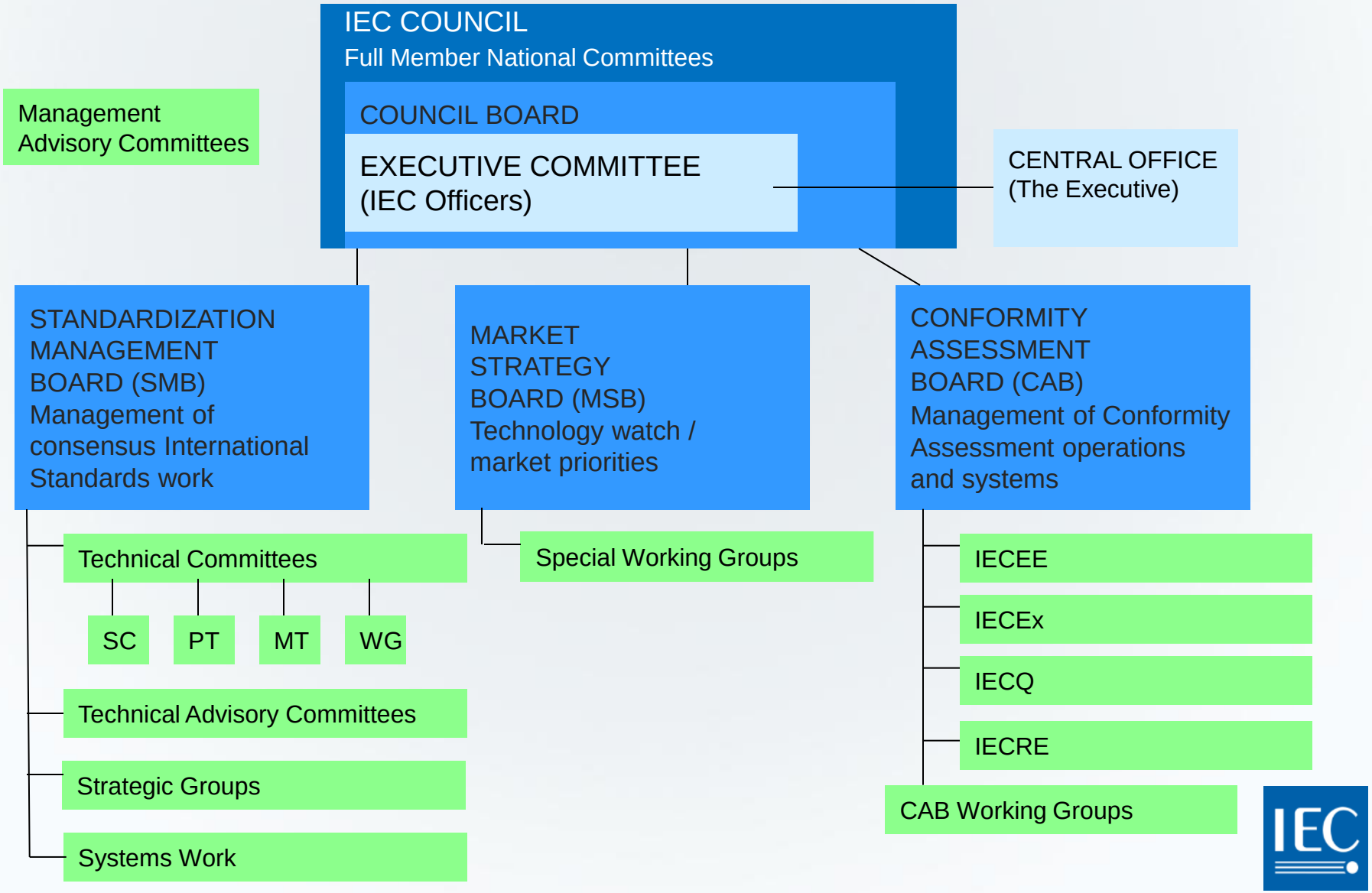
Types of participation

- 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 CO
Geneva
ReCNA
Boston
AFRC
Nairobi
APRC
Singapore
LARC
São Paulo
IECEx/IECQ
Sydney

IEC structure



SMB: Standardization Management Board

Responsible for the technical work

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

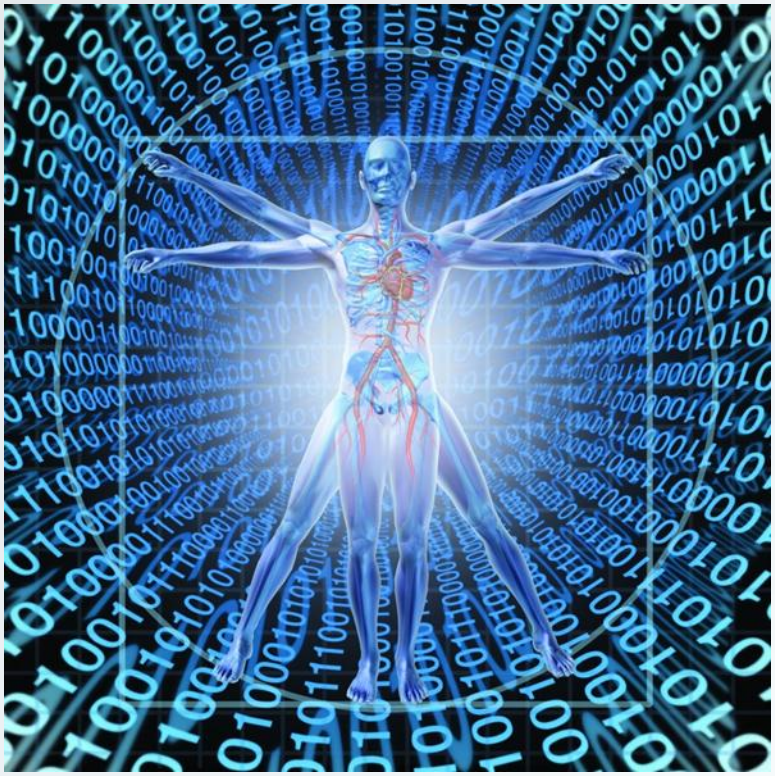
➡ About the IEC > Who we are > Management Structure> SMB

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

- System Committee on Active Assisted Living
- 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**

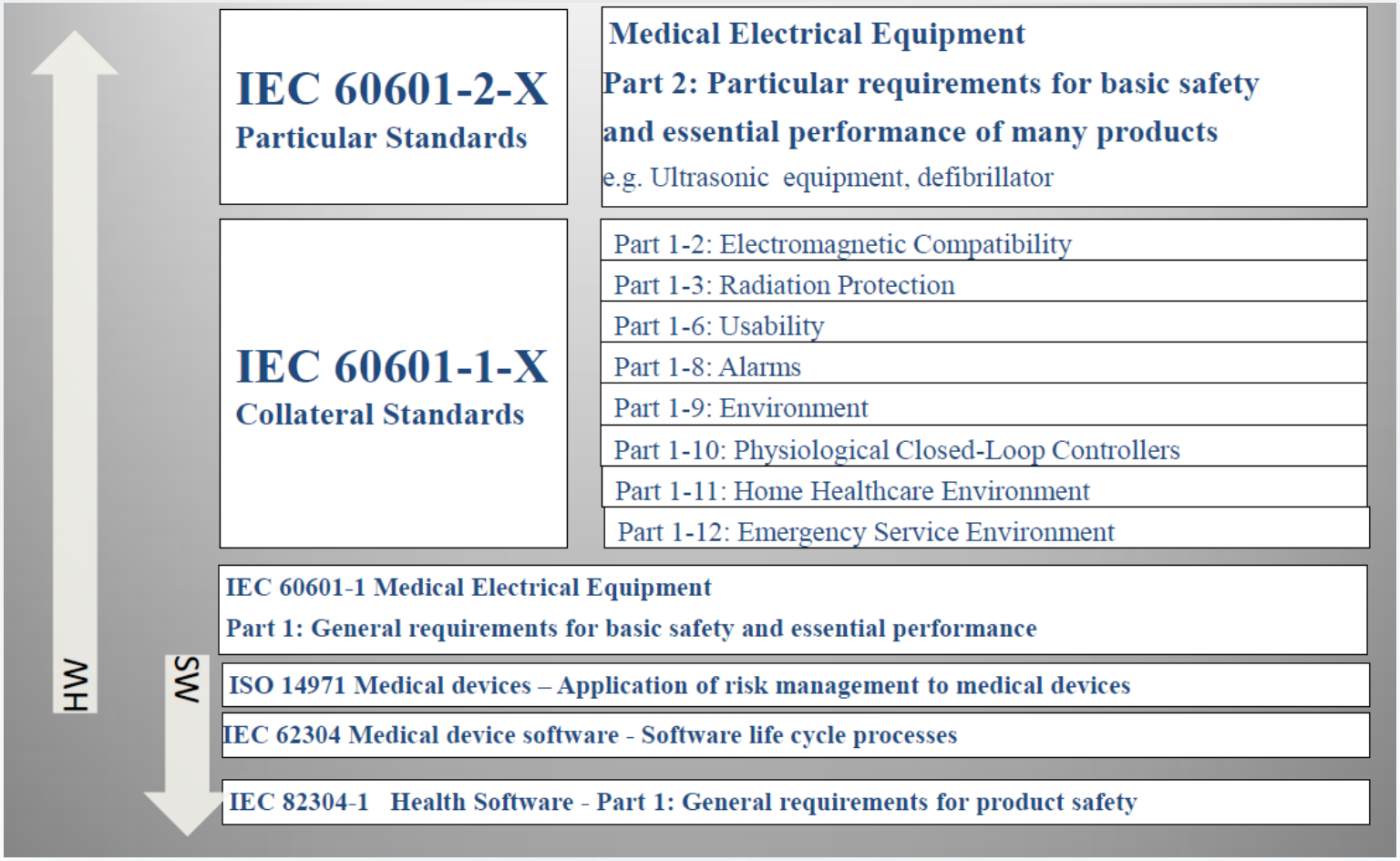
Subcommittees and Advisory Groups

- 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



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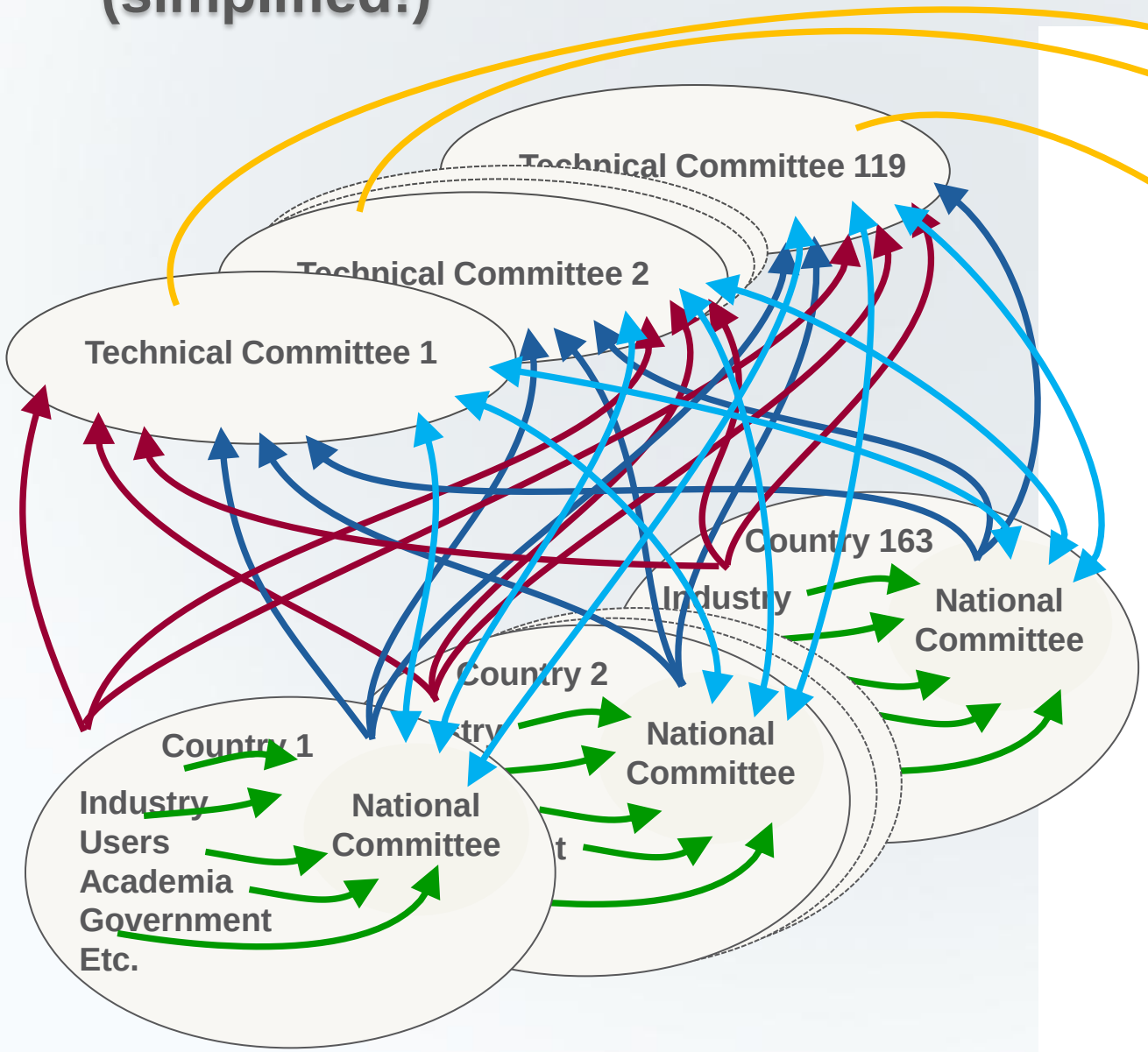
How IEC Standards are developed

- 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
(simplified!)



Requirements

Work Items

Expert Resources

Votes Drafts

Standards Output

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

Increasing consensus

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
- 15 members

➡ About the IEC > Who we are > Management Structure> SMB

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)

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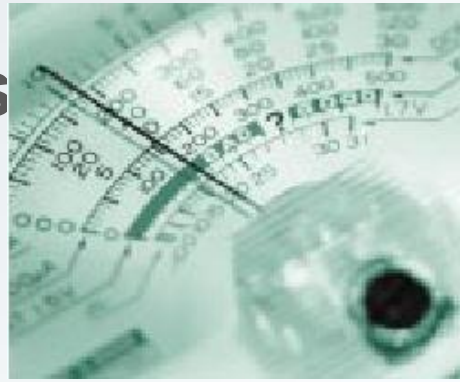
Benefits of IEC International Standards: use and participation

- 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

Dennis Chew
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