International Standards

State of Play and Future Trends in the medical domain

Nicole Denjoy
DITTA Chair
COCIR Secretary General

2nd WHO Global Forum on Medical Devices
Geneva, Switzerland
Friday 22 November 2013
DITTA - the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association

- DITTA is a global organization representing Industry Associations of Manufacturers around the world

- DITTA was officially incorporated in 2012 as a non-profit trade association in the United States after more than 12 years of existence
DITTA: 6 Operational Groups

DITTA Task Forces

- RPS
- UDI
- MSW
- MDSAP

ENVI

GRP

UNEP
BASEL CONVENTION
IMDRF

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION
Challenges

1. 35 million deaths from chronic disease
2. 60% of all deaths result from chronic disease
3. Deaths from chronic disease will increase by 17% by 2015
Innovation in Medical Devices

**Diagnostics**
- Faster, accurate imaging
- Molecular imaging
- Miniaturisation/portability
- Point of Care diagnostics
- Therapy selection/monitor

**Biotech & Genomics**
- Targeted therapy
- Proteomics/DNA
- Biomarkers
- Rapid screening tools
- Vaccine development

**IT & bioengineering**
- eHealth/Telemedicine
- Mobile solutions
- BioSensors
- Computer Aided Diagnostics
- Patient monitoring
Innovative technology will enable a shift in care

- Focus on acute conditions
- Hospital centred
- Physician dependent
- Episodic, reactive care
- Passive patient
- Slow uptake of technology
- Budget silos

✓ Focus on acute & long term conditions
✓ Community centred
✓ Team based
✓ Integrated preventive care
✓ Knowledgeable patient
✓ Localised integrated high tech solutions
✓ Fund continuum of care

Utilization

- Hospital
- Community clinic
- Home

PRESENT

FUTURE

High
Intermediate
Low
Introduction

International standards are everywhere. They are key in global trade and interoperability of all sorts of products and services, from battery operated camera’s to software systems to air transport. It is for a good reason that the WTO requires its members to base their technical regulation as much as possible on international standards. Standards, however, go well beyond the use in regulatory areas.
Introduction

In the healthcare domain, international standards provide in addition the best guarantee for equal levels of safety and performance of medical devices. International standards, developed by experts from the key stakeholders and kept up to date by periodic revisions, provide the world with a common set of safety and performance requirements. Uptake and recognition of these standards in national regulations give the best guarantee for availability and access to innovative and safe technology for the best possible health outcome at lowest cost.
Why Do We Need Standards?
Standards in the Regulatory Process
Reference Materials and Source Documents

  Procedures for the technical work
  Rules for the structure and drafting of International Standards
  Procedures specific to IEC
- IEC Statutes and Rules of Procedures
  IEC membership and participation procedures
- EU List of Harmonized Standards
- FDA Recognized Consensus Standards
Standardization is a global activity encompassing a myriad of interests.
In a global marketplace, the objective of the standardization process must be a single, technically valid and globally relevant standard with a single test of conformance to that standard. This will allow products to be distributed for worldwide commerce without change or modification.
Q: Why do we have standards?

• Make sure technology “fits”
• Example: plugs and sockets
• Common methods = Common language
• Test results can be compared and “trusted”
• A way to demonstrate you meet “the rules”
Roughly 80 percent of global merchandise trade is affected by standards and by regulations that embody standards.

Source:
National Institute of Standards and Technology
Testimony before the U.S. House of Representatives – Committee on Science, Subcommittee on Technology
September 13, 2000
Where do standards come from?

- International Standards Development Organizations
  - IEC, ISO
- Domestic Standards Development Organizations
  - ANSI, CEN, CENELEC
- Membership Associations (industry, professional)
  - AAMI, NEMA, WFUMB, ASTM
- Regulators
  - US FDA, SFDA, KFDA...
- Just about anyone who wants to.....
Q: Who writes standards?

- We do! ... mostly
- Committees of volunteers and stakeholders
- Members of professional & industry associations (private clubs)
- Regulators
  - Either internal or contracted (academic sources?)
Q: Why should one participate in the development of international standards?

- To facilitate the adoption of globally-accepted standards that will promote **interoperability** and **commercial acceptance** across the electrotechnical industry

- To **gain** access to foreign markets, to **improve** safety and health and promote the protection of consumers, to safeguard the environment, etc.

- To **anticipate** emerging standards and their impact on technology and global markets
Standards are strategic business tools which help develop new global markets for electrical and electro-technology-related products and services. International standards are frequently adopted, or used as the basis for, national and regional regulations.

Q: Why participate . . .
Importance of global cooperation and collaboration

Active participation in both international and regional standards-setting activities provides Philips experts with an . . .

- opportunity to influence domestic and international policy
- opportunity to benefit from unique networking opportunities and learn from international colleagues
- forum for the presentation of Philips positions
- opportunity to comment upon proposals submitted by others
Guiding Principles

International standards should meet societal and market needs and should not be developed to act as barriers to trade.

ISO and IEC follow globally accepted principles of standards development:

- Transparency
- Openness
- Impartiality
- Effectiveness and relevance
- Consensus
- Performance-based

- Coherence
- Due process
- Technical Assistance
Q: What is the difference between a “regulation” and a “standard”?

• Regulations tell you “what”
  • EU Directives, FDA CFRs
  • “your products shall be safe”

• Standards tell you “how”
Q: How do regulators use standards?

- “Mandatory” vs. “Voluntary”
  - Voluntary: Presumption of Compliance
    - US, CA, EU
    - Alternatives may be used
  - Mandatory: Enforced Compliance
    - CN
    - No alternatives
IEC 60601 Family

**General**
- IEC 60601-1
  - Medical electrical equipment Part 1
  - General requirements for basic safety and essential performance

**Collaterals**
- IEC 60601-1-x
  - Medical electrical equipment Part 1
  - General requirements ...

**Particulars**
- IEC 60601-2-y
  - Medical electrical equipment Part 2
  - Particular requirements for ...

1 7 >70
**Current situation in Europe**

**Regulated products**

*Safety, risk mgt, QA*

- **EU Directives***
  - EU New Approach Directives (such as MDD) (**mandatory**) allow EU harmonized standards to provide a presumption of conformity to essential requirements of the EU Directive because considered as « state of art » for product lines covered by such standards

- **EU Harmonized Standards***
  - Standards are voluntary that can be considered as part of the harmonized ones should be (1) linked to a mandate issued by EC (2) issued by a EU SDO (CEN, Cenelec or ETSI) (3) published to the JOCE

**Non regulated products**

- **EU Recognized Profiles**
- **Medical SW (Incl. Non-Regulated Devices) in Europe**
International Consensus Standardization: Characteristics

Based on WTO* Principles for the Development of International Standards

- only signed by IEC, ISO, and ITU!

Objective of these principles is

- to ensure transparency (source of the national delegation principle)
- to ensure openness (source of the national delegation principle)
- to ensure impartiality and consensus
- to ensure effectiveness and relevance
- to ensure coherence
- and to address the concerns of developing countries

*WTO: World Trade Organization
International Standardization: Two Key Directions

- Consensus standardization: safety, performance, processes, ...
  - IEC (International Electrotechnical Commission)
  - ISO (International Organisation for Standardization)
  - … and their national mirror committees

- Healthcare specific consortia: interoperability
  - DICOM: transfer of medical images
  - HL7: transfer of medical text messages
Standards Have Different Regulatory Impact

Healthcare IT standardization: no impact on the regulatory framework
- DICOM: communication of image based messages
- HL7: communication of text based messages

Process and safety standards: usually impact on the regulatory framework
- ISO/CEN/DIN
  - Risk Management
  - Quality Management System
- IEC/CENELEC/DKE
  - Basic Safety and Essential Performance
  - Horizontal collateral standards
  - Product specific particular standards

- STP FG focusses on standards related to market access, hence process and safety standards, published by ISO and IEC
Examples of technical committees involved in drafting international standards in the medical sector

<table>
<thead>
<tr>
<th>Committee</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO CS</td>
<td>ISO Central Secretariat</td>
</tr>
<tr>
<td>IEC CO</td>
<td>IEC Central Office</td>
</tr>
<tr>
<td>ISO/TC 76</td>
<td>Transfusion, infusion and injection equipment for medical and</td>
</tr>
<tr>
<td></td>
<td>pharmaceutical use</td>
</tr>
<tr>
<td>ISO/TC 84</td>
<td>Devices for administration of medicinal products and intravascular</td>
</tr>
<tr>
<td></td>
<td>catheters</td>
</tr>
<tr>
<td>ISO/TC 106</td>
<td>Dentistry</td>
</tr>
<tr>
<td>ISO/TC 121</td>
<td>Anaesthetic and respiratory equipment</td>
</tr>
<tr>
<td>ISO/TC 150</td>
<td>Implants for surgery</td>
</tr>
<tr>
<td>ISO/TC 168</td>
<td>Prosthetics and orthotics</td>
</tr>
<tr>
<td>ISO/TC 170</td>
<td>Surgical instruments</td>
</tr>
<tr>
<td>ISO/TC 173</td>
<td>Assistive products for persons with disability</td>
</tr>
<tr>
<td>ISO/TC 184</td>
<td>Industrial automation systems and integration</td>
</tr>
<tr>
<td>ISO/TC 194</td>
<td>Biological evaluation of medical devices</td>
</tr>
<tr>
<td>ISO/TC 198</td>
<td>Sterilization of health care products</td>
</tr>
<tr>
<td>ISO/TC 210</td>
<td>Quality Management Systems for Medical Devices</td>
</tr>
<tr>
<td>ISO/TC 212</td>
<td>Clinical laboratory testing and in vitro diagnostic test systems</td>
</tr>
<tr>
<td>ISO/TC 215</td>
<td>Health informatics</td>
</tr>
<tr>
<td>IEC/TC 62</td>
<td>Electrical equipment in medical practice</td>
</tr>
<tr>
<td>IEC/TC 66</td>
<td>Safety of measuring, control and laboratory equipment</td>
</tr>
<tr>
<td>IEC/TC 76</td>
<td>Optical radiation safety and laser equipment</td>
</tr>
<tr>
<td>IEC/TC 87</td>
<td>Ultrasonics</td>
</tr>
<tr>
<td>AAMI/HFE</td>
<td>Human Factors Engineering</td>
</tr>
<tr>
<td>CLC/TC 62</td>
<td>Electrical Equipment in Medical Practice</td>
</tr>
<tr>
<td>ISO/TC 210 WG1</td>
<td>Quality Management Systems for Medical Devices</td>
</tr>
<tr>
<td>CEN/TC 215 WG1</td>
<td>Anaesthetic equipment</td>
</tr>
<tr>
<td>CEN/CLC/JTC3</td>
<td>Quality Management Systems for Medical Devices</td>
</tr>
</tbody>
</table>
Important actors for international standards for healthcare:

Part 2: standards users

**EU (CEN, CENELEC):** standards are part of “New Approach” regulation

**USA:** recognized standards may be used alongside with FDA guidance for market clearance

**China:** many standards are mandatory (even when not developed for that approach)

**IMDRF:** (next slide)
Important actors for international standards for healthcare:
Part 2: standards users

**IMDRF** ¹): international standards project; investigate which standards are recognized commonly, to facilitate trade, reduce compliance cost overall as well as achieve level playing field on safety and performance. Improvement possible and contribution from WHO may be helpful, also for those countries not (yet) member in IMDRF

**IMDRF statement:**

Inte[riatinal standards, such as basic standards, group standards and product standards, are a tool for harmonising regulatory processes to assure the safety, quality and performance of medical devices.

¹) **IMDRF**: joint effort of medical device regulators from (currently) Australia, Brazil, Canada, China, Japan, EU, Russia, and the USA
Future trends in international standards for healthcare:

Key standards recently published/reconfirmed:

**ISO 14971** on risk management for medical devices
**ISO 14155** on clinical investigation for medical devices
**ISO 15223** on symbols for medical devices
**IEC 60601-1, Amd1** on requirements for medical electrical equipment
Future trends in international standards for healthcare:

Key standards under revision/development:

**ISO 13485** on Quality Management Systems for medical device manufacturers

**IEC 60601-1-2** on EMC requirements for medical electrical equipment

**IEC 62304** on software lifecycle requirements

**IEC 82304-1** on health software – product safety requirements
**Future trends in international standards for healthcare:**

Complications for standards development:

*Regulatory schemes are under development in almost all major jurisdictions*

*Regulatory schemes increasingly include “implementing measures”, to allow fast track adaption of the regulation*

*Standards development is by nature an iterative and democratic process*

*Enhanced desire by regulators to have national or regional implementation of international standard, either by additional requirements, local changes, Annexes Z ruling out certain chapters, etc.*
International Standards
State of Play and Future Trends in the medical domain

DITTA asks WHO to consider the following on international standards:

• Aim for maximum use of international expertise regarding safety and performance
• Refrain from “re-inventing” local solutions as this is contrary to the aim of harmonization
• Strive for increasing numbers of jointly recognised standards
• Align dates of applicability with appropriate transition times for revised standards
• Participate actively in the development and revision of standards, among others by providing information obtained from market surveillance
• Discuss concerns WHO members may have on the standards process and come with proposals for improvements
Standardization in Consortia: HL7 – Health Level 7

- Purpose: transfer of medical text messages
- Some characteristics
  - many versions are in use concurrently:
    - V2.x – established standards (clinical and administrative data), basically for message transfer within one entity
    - V3.0 – new approach, includes communication between different entities, definition of a data model
  - contributors: manufacturers and users
  - about 20 main working groups for specific categories of messages
  - ongoing publication of updates (e.g. three times a year)
  - HL7 International Inc. owns and exploits Intellectual Property (still FRAND)
- Test protocols: self-declaration
  - Healthcare Connectivity Competence Center (Andreas Klingler) provides test capabilities, helpdesk, training, conformity statements etc…
Consensus Standardization: ISO – International Organization for Standardization

- decision to found ISO: London, Oct 14 – 26, 1946
- ISO Central Secretariat is located in Geneva, Switzerland
- the world's largest developer of International Standards
- a network of 162 members
- members: one standards institute per country
- a non-governmental organization that forms a bridge between the public and private sectors
  - many of its member institutes are part of the governmental structure of their countries, or are mandated by their government
  - other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.
- ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.
- ISO adheres to the WTO principles for the development of international standards
- "ISO", derived from the Greek ισοσ, meaning "equal".

ISO – International Organization for Standardization ...

Central Secretariat
- the executing office
- publishes standards
- triggers maintenance of standards

Technical Committees consist of volunteers
- chairman
- secretary
- delegates from member countries

Source: www.iso.ch, Dec. 2011
Focus on ISO Standards for Medical Devices

Some ISO TCs of relevance for medical devices (out of 200+ in total):

- ISO TC121  Anesthetic and respiratory equipment
- ISO TC150  Implants for surgery
- ISO TC176  Quality management and quality assurance
- ISO TC194  Biological evaluation
- ISO TC198  Sterilization of health care products
- ISO TC210  Quality management and corresponding general aspects for medical devices
- ISO TC215  Health informatics
ISO TC 215 – Health Informatics

Scope:
Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to promote interoperability between independent systems, to enable compatibility and consistency for health information and data, as well as to reduce duplication of effort and redundancies.

Structure:
• WG 1 – Data structure
• WG 2 – Data interchange
• WG 3 – Semantic content
• WG 4 – Security
• WG 6 – Pharmacy and medicines business
• WG 7 – Devices
• WG 8 – Business requirements for Electronic Health Records
• WG 9 – SDO harmonization
ISO TC 210 – Quality Management and Corresponding General Aspects for Medical Devices

Scope:

- Standardization of requirements and guidance in the field of quality management and corresponding general aspects for medical devices.
- Standards for small bore connectors.

Excluded are

- generic quality management standards dealt with by ISO / TC 176;
- quality management standards for pharmaceutical products;
- technical requirements for specific types of medical devices

Structure

• WG 1 – Application of quality systems to medical devices
  - JWG 1 – Application of risk mgmt. to medical devices (with IEC SC62A)
• WG 2 – General aspects stemming from the application of quality principles to medical devices
  - JWG 2 – Medical device software (with IEC SC62A)
• ... various JWGs, e.g. JWG 3 – Usability
Consensus Standardization: IEC International Electrotechnical Commission

➤ the world´s leading organization for the preparation and publication of international standards in the field of electrotechnology

➤ founded in 1906

➤ IEC Central Secretariat is located in Geneva, Switzerland

➤ members: one standards institute per country

Source: www.iec.ch, Oct. 2010
# IEC Member Countries

(download from www.iec.ch, status: Dec 2011)

<table>
<thead>
<tr>
<th>ALBANIA (AM)</th>
<th>ICELAND (AM)</th>
<th>PHILIPPINES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALGERIA</td>
<td>INDIA</td>
<td>POLAND</td>
</tr>
<tr>
<td>ARGENTINA</td>
<td>INDONESIA</td>
<td>PORTUGAL</td>
</tr>
<tr>
<td>AUSTRALIA</td>
<td>IRAN</td>
<td>QATAR</td>
</tr>
<tr>
<td>AUSTRIA</td>
<td>IRAQ</td>
<td>ROMANIA</td>
</tr>
<tr>
<td>BAHRAIN (AM)</td>
<td>IRELAND</td>
<td>RUSSIAN FEDERATION</td>
</tr>
<tr>
<td>BELARUS</td>
<td>ISRAEL</td>
<td>SAUDI ARABIA</td>
</tr>
<tr>
<td>BELGIUM</td>
<td>ITALY</td>
<td>SERBIA</td>
</tr>
<tr>
<td>BOSNIA HERZEGOVINA (AM)</td>
<td>JAPAN</td>
<td>SINGAPORE</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>JORDAN (AM)</td>
<td>SLOVAKIA</td>
</tr>
<tr>
<td>BULGARIA</td>
<td>KAZAKHSTAN (AM)</td>
<td>SLOVENIA</td>
</tr>
<tr>
<td>CANADA</td>
<td>KENYA (AM)</td>
<td>SOUTH AFRICA</td>
</tr>
<tr>
<td>CHILE</td>
<td>KOREA (REPUBLIC OF)</td>
<td>SPAIN</td>
</tr>
<tr>
<td>CHINA</td>
<td>LATVIA (AM)</td>
<td>SRI LANKA (AM)</td>
</tr>
<tr>
<td>COLOMBIA</td>
<td>LIBYA</td>
<td>SWEDEN</td>
</tr>
<tr>
<td>CROATIA</td>
<td>LITHUANIA (AM)</td>
<td>SWITZERLAND</td>
</tr>
<tr>
<td>CUBA (AM)</td>
<td>LUXEMBURG</td>
<td>THAILAND</td>
</tr>
<tr>
<td>CYPRUS (AM)</td>
<td>MALAYSIA</td>
<td>The FYRep of Macedonia (AM)</td>
</tr>
<tr>
<td>CZECH REPUBLIC</td>
<td>MALTA (AM)</td>
<td>TUNISIA (AM)</td>
</tr>
<tr>
<td>DENMARK</td>
<td>MEXICO</td>
<td>TURKEY</td>
</tr>
<tr>
<td>EGYPT</td>
<td>MONTENEGRO (AM)</td>
<td>UKRAINE</td>
</tr>
<tr>
<td>ESTONIA (AM)</td>
<td>MOROCCO (AM)</td>
<td>UNITED ARAB EMIRATES</td>
</tr>
<tr>
<td>FINLAND</td>
<td>NETHERLANDS</td>
<td>UNITED KINGDOM</td>
</tr>
<tr>
<td>FRANCE</td>
<td>NEW ZEALAND</td>
<td>UNITED STATES OF AMERICA</td>
</tr>
<tr>
<td>GERMANY</td>
<td>NIGERIA (AM)</td>
<td>VIETNAM (AM)</td>
</tr>
<tr>
<td>GREECE</td>
<td>NORWAY</td>
<td></td>
</tr>
<tr>
<td>HUNGARY</td>
<td>PAKISTAN</td>
<td></td>
</tr>
</tbody>
</table>
A Strong Link between Standards and Regulations in the Medical Device Market

Legal regulations reference standards with differing strength

- USA: as FDA recognized standards (low)
- EU: after publication in the Official Journal of the EU (medium)
- China: IEC standards transformed into compulsory standards (strong)

Contributions to standards detail the regulatory frame

Governmental reviews ensure legal consistency
Regulatory authorities

t = 10 – 15 years

regulations "essential reqs."

int. standards

SDO reviews ensure state of the art
WGs, TCs, SCs

t = 3 – 7 years

Contributions to standards detail the regulatory frame
SDOs and Trade Associations: Two Roads to Influence Regulations

Regulatory authorities

SDOs

Industry informatics, hot topics

direct technical input

individual input, hot topics

WG, TC, SCs

reference regulations "essential reqs."

int. standards

common industry position
China – Transposition of Standards

- China usually “transposes” ISO and IEC standards
- Chinese editions may vary significantly from ISO or IEC editions
- Application of Chinese standards is mandatory
International Standards will continue to play an important role in the medical domain and will continue to be considered state of art.
THANK YOU !