Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

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4-8 December, 2017 I New Delhi

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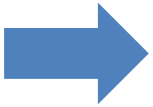
Takes 2 to Tango
CSDT/EP and Standards

Wing Gang SEET
Head, Regulatory Intelligence, Greater Asia
Becton Dickinson

What will we cover today?

Role of Standards in Assessment of Medical Devices



Essential Principles of Safety and Performance of Medical Devices

Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
or
Common Submission Dossier Template (CSDT)

What will we cover today?

Standards

- What is a Standard?
- Types of Standards
- Who publishes Standards
- Recognition of Standards

Essential Principles

- What is Essential Principles?
- Use of Standards
- Other approaches

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STANDARDS

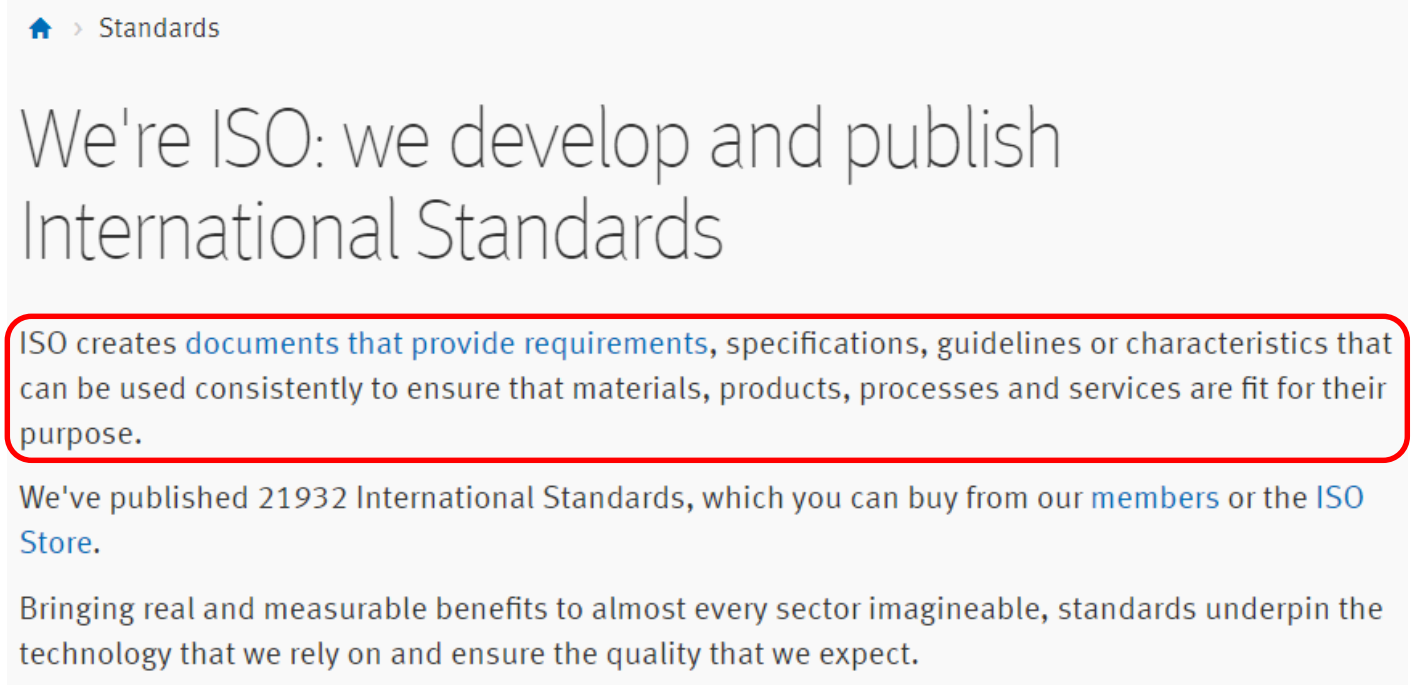
What is a Standard?

Standard - document, established by consensus and approved by a recognized body, 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

NOTE: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

ISO/IEC Guide 2:2004, Standardization and related activities -- General vocabulary.

What is a Standard?



Standards

We're ISO: we develop and publish International Standards

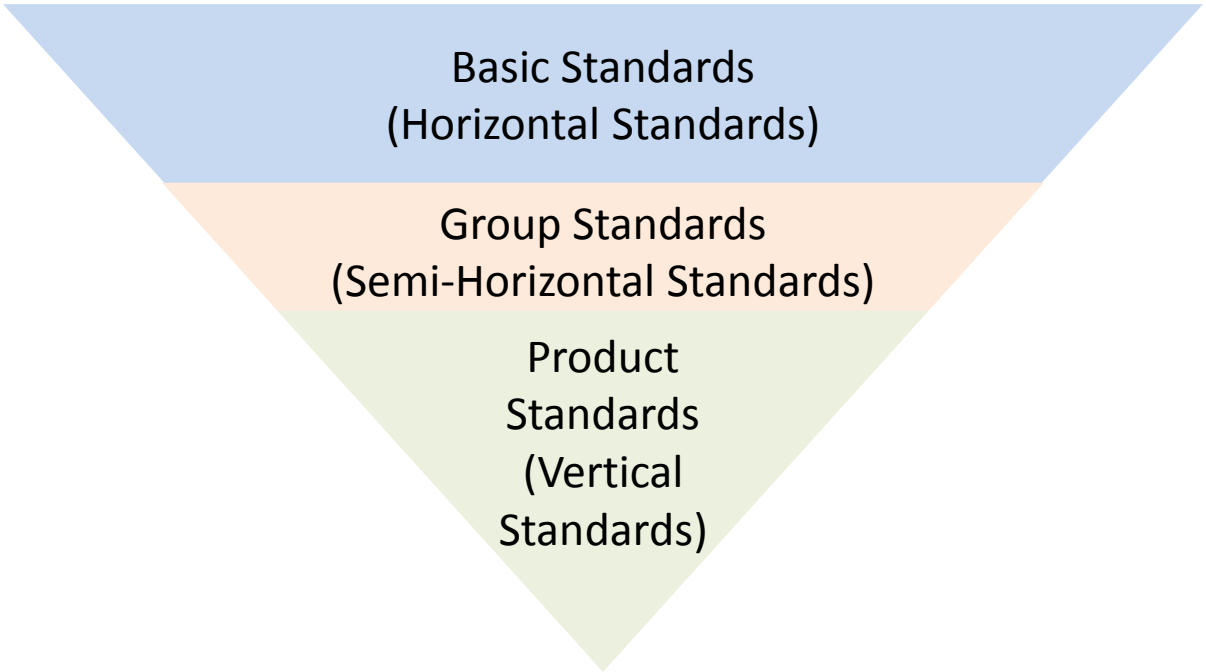
ISO creates documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

We've published 21932 International Standards, which you can buy from our members or the ISO Store.

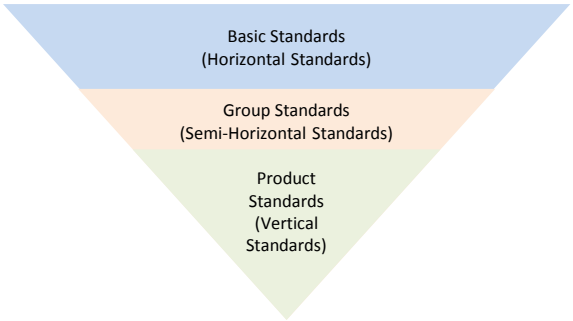
Bringing real and measurable benefits to almost every sector imagineable, standards underpin the technology that we rely on and ensure the quality that we expect.

https://www.iso.org/standards.html

Types of Standards



Types of Standards



Basic Standards (Horizontal Standards)

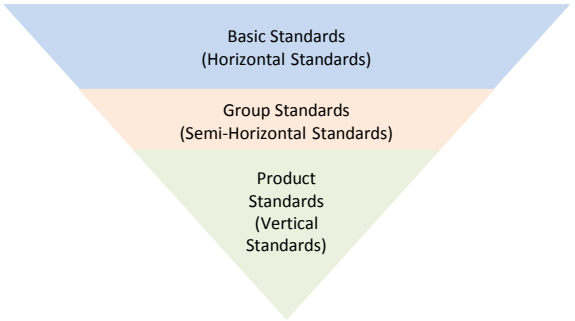
Standards indicating fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products and/or processes.

Note 1 to entry: Basic standards are sometimes referred to as horizontal standards and usually apply to more than one field (sector).

Example:

- Quality Management Standard: ISO 9001
- Environmental Management Standard: ISO 14001

Types of Standards



Group Standards (Semi-Horizontal Standards)

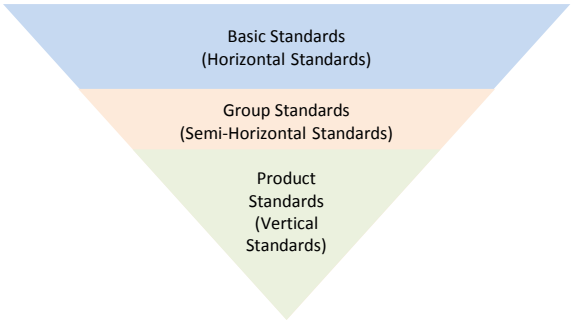
Standards indicating aspects applicable to families of similar products and/or processes making reference as far as possible to basic standards

Note 1 to entry: Group standards are sometimes referred to as semi-horizontal standards and usually apply to one field (sector).

Example:

- ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11607-1:2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems

Types of Standards



Product Standards (Vertical Standards)

Standard that specifies necessary safety and performance requirements for a specific or a family of product(s), process(es), or service(s) making reference, as far as possible, to basic standards and group Standards

Example:

- ISO 14708-1:2014 Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
- ISO 14708-2:2012 Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers
- ISO 14708-3:2017 Implants for surgery -- Active implantable medical devices -- Part 3: Implantable neurostimulators

Standard Bodies (Examples)

International

International Organization for Standardization

International Electrotechnical Commission

International Telecommunication Union

Regional

European Committee for Standardization

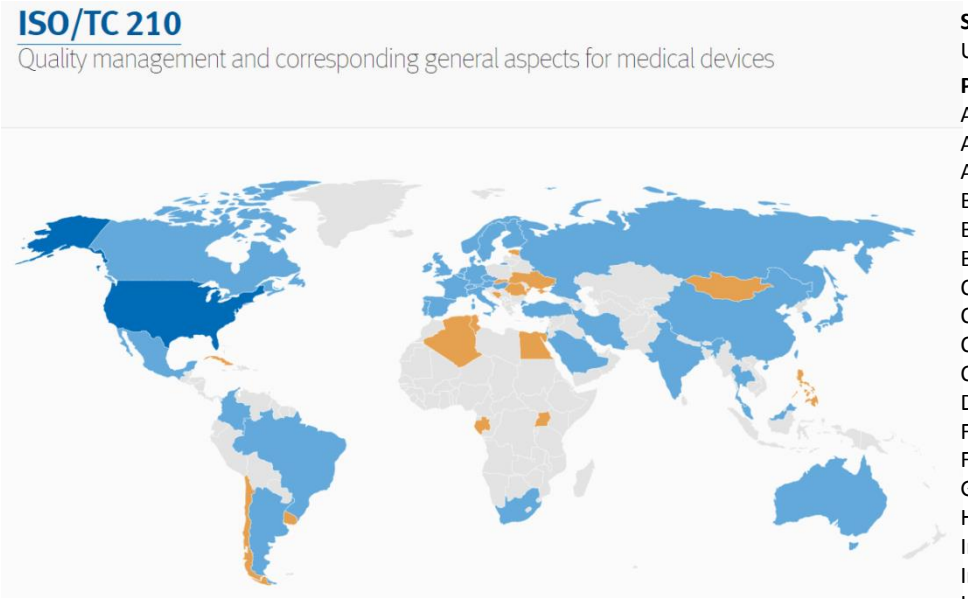
European Committee for Electrotechnical Standardization

African Organisation for Standardisation

Pan American Standards Commission

PASC PACIFIC AREA STANDARDS CONGRESS

National Standard Bodies



https://www.iso.org/committee/54892.html?view=participation

Secretariat
United States - American National Standards Institute (ANSI)

Participating Members (40)
Argentina (IRAM)
Australia (SA)
Austria (ASI)
Bahrain (BSMD)
Belgium (NBN)
Brazil (ABNT)
Canada (SCC)
China (SAC)
Colombia (ICONTEC)
Czech Republic (UNMZ)
Denmark (DS)
Finland (SFS)
France (AFNOR)
Germany (DIN)
Hungary (MSZT)
India (BIS)
Iran, Islamic Republic of (ISIRI)
Ireland (NSAI)
Israel (SII)
Italy (UNI)
Japan (JISC)
Korea, Republic of (KATS)
Kuwait (KOWSMD)
Luxembourg (ILNAS)
Malaysia (DSM)
Mexico (DGN)
Netherlands (NEN)
Norway (SN)
Portugal (IPQ)
Russian Federation (GOST R)
Saudi Arabia (SASO)
Singapore (SPRING SG)
South Africa (SABS)
Spain (UNE)
Sweden (SIS)
Switzerland (SNV)
Thailand (TISI)
Turkey (TSE)
United Kingdom (BSI)
United States (ANSI)

Observing Members (17)
Algeria (IANOR)
Bosnia and Herzegovina (BAS)
Chile (INN)
Cuba (NC)
Egypt (EOS)
Estonia (EVS)
Gabon (AGANOR)
Hong Kong (ITCHKSAR)
Mauritius (MSB)
Mongolia (MASM)
Philippines (BPS)
Romania (ASRO)
Slovakia (SOSMT)
Tunisia (INNORPI)
Uganda (UNBS)
Ukraine (DSTU)
Uruguay (UNIT)

“Recognised” Standard

Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Conformity with “Recognised” Standards

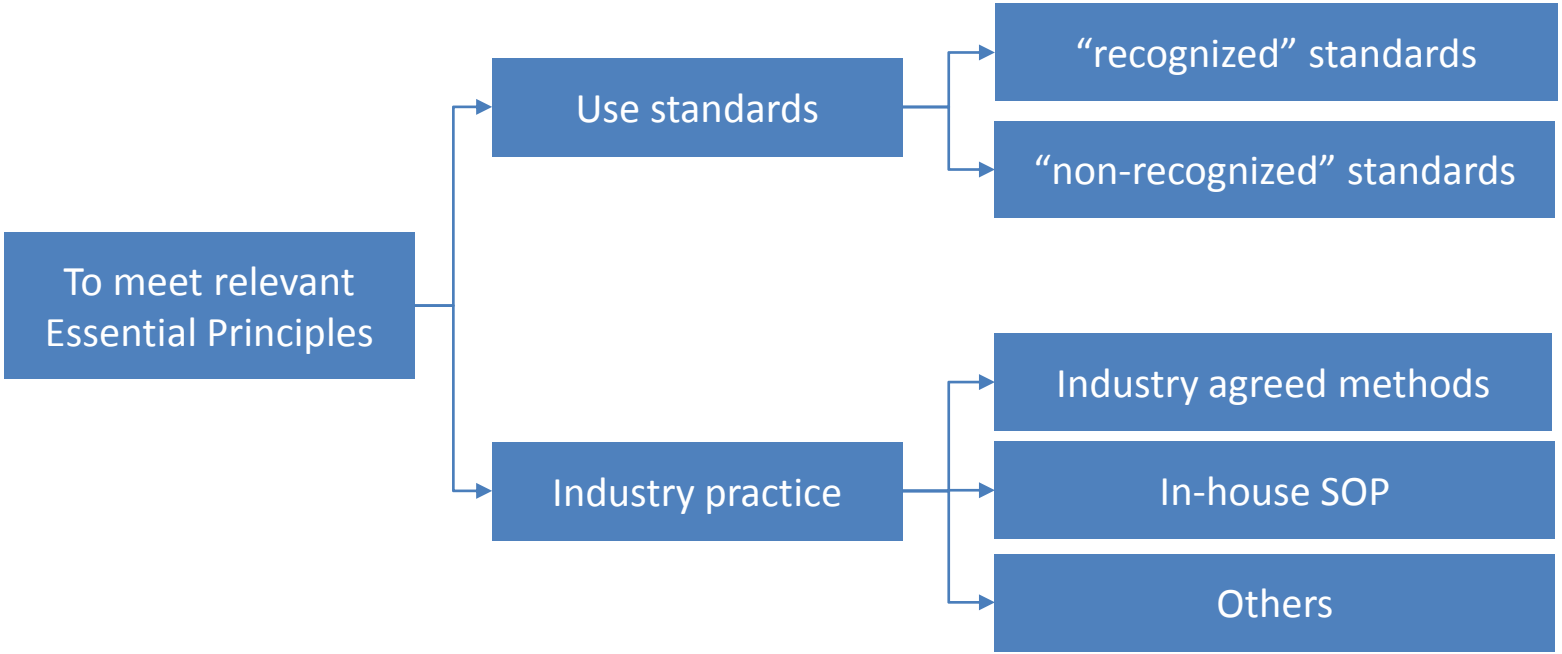
Conformity with “relevant” Essential Principles

“Recognised” Standard

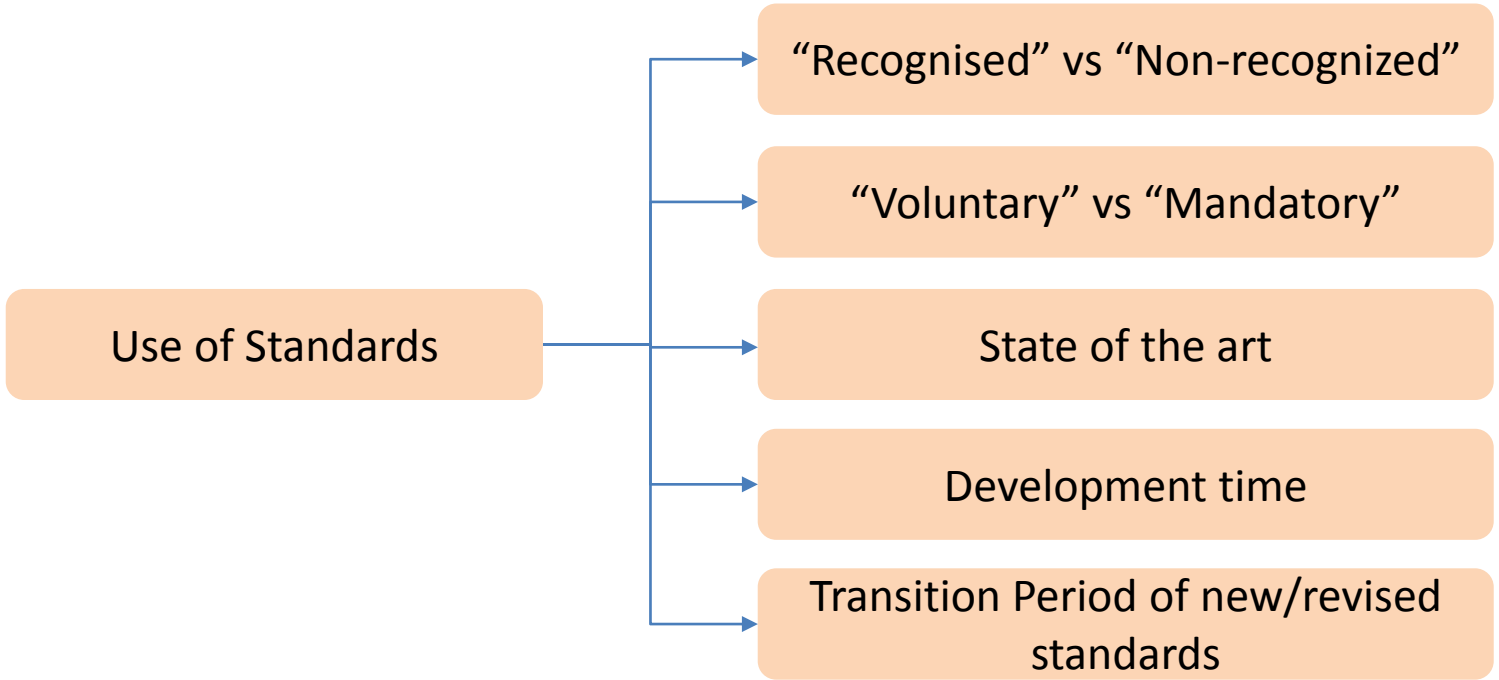
Use of Standards → Voluntary or Mandatory (Depending on Country)

If a manufacturer chooses not to apply a recognised standard in part or in full, then this is acceptable if conformity with the Essential Principles can be demonstrated by another means?

To meet relevant Essential Principles



Challenges for use of Standard



“Recognised” Standards

IMDRF/Standards/N15FINAL:2014

Final Report:
“List of international standards recognized by IMDRF management committee members”
Current as of: March 2014

Dr. Matthias Neumann

- The number of fully recognized standards (out of 1102 standards) varies between 261 and 44
- The number of partially and fully recognized standards varies between more than 390 and 44
- Three regions are using mandatory standards

Number of recognized/mandatory standards in IMDRF jurisdictions

	recognised	partially	mandatory	partially recognised and mandatory
USA	261	33		
EU	222	3		
Canada	181			
Japan	104	105		
Australia	44			
Brasil	102		78	
China	66	71	130	
Russia				239

State of the Art

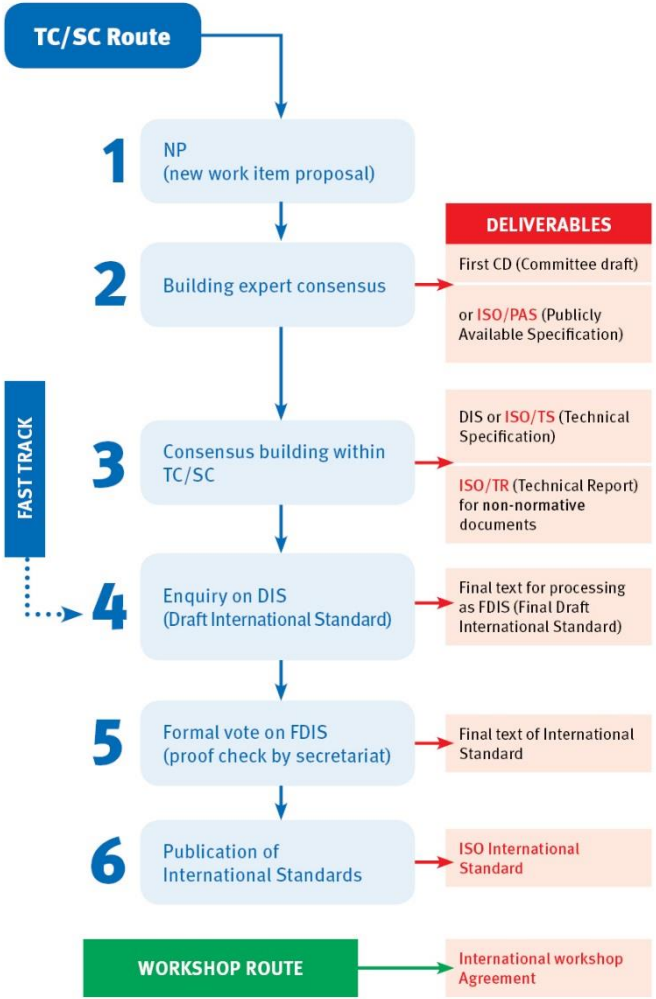
5.2 The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

- identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse,
- eliminate risks as far as reasonably practicable through inherently safe design and manufacture,
- reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,
- inform users of any residual risks.

state of the art

developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

ISO/IEC Guide 2:2004, 1.4



Standard Development Process

Accelerated standards development track

- 12 months to produce the DIS
- 24 months to publication

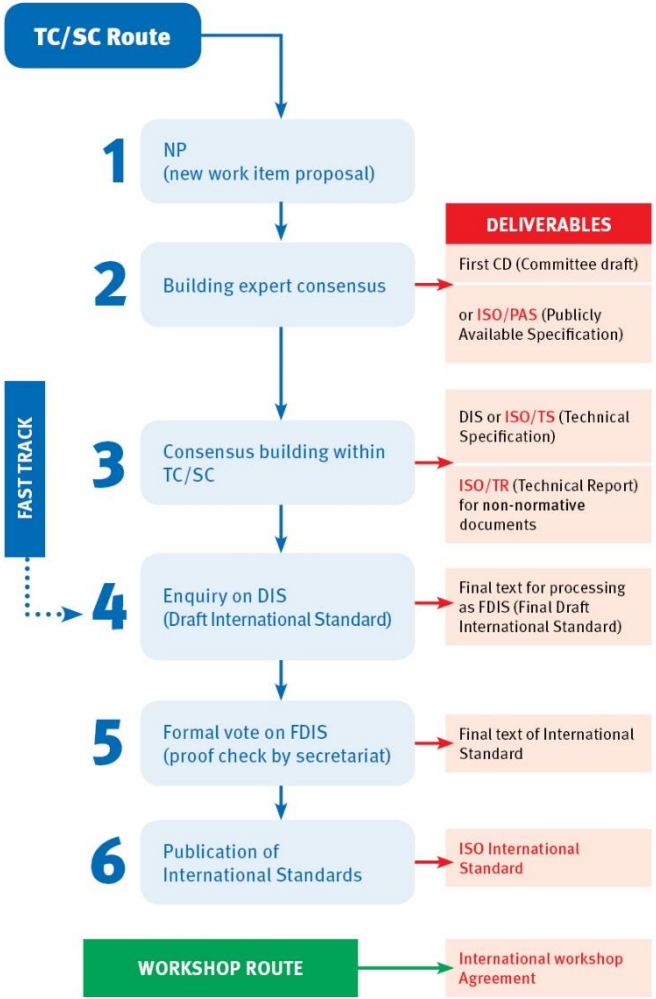
Default standards development track

- 24 months to produce the DIS
- 36 months to publication

Enlarged standards development track

- 36 months to produce the DIS
- 48 months to publication

https://www.iso.org/developing-standards.html



Standard Development Process

Deliverable	Max. elapsed time before Systematic Review	Max. number of times deliverable may be confirmed	Max. life
International Standard	5 years	Not limited	Not limited
Technical Specification (see 3.1.3)	3 years	Once recommended	6 years recommended
Publicly Available Specification (see 3.2.4)	3 years	Once	6 years (If not converted after this period, the deliverable is proposed for withdrawal)
Technical Report (see 3.3.3)	Not specified	Not specified	Not limited

Transition Period

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

Transition Dates - IEC 60601 3rd edition

European Union (EU) General Standard	**June 1, 2012**
European Union (EU) Particular Standards	**Varies***
Canada General Standard	**June 1, 2012**
Canada Particular Standards	**Varies***
United States of America (FDA)	**July 1, 2013**
Brazil	**Jan. 1, 2014**
Japan	**Published June 1, 2012 * (Transition potentially 2017)**
Taiwan, Singapore	**Recognize 3rd Edition, no transition date announced**
Other Countries	**TBD**

*Medical devices that fall within the scope of a particular standard are subject to various dates as noted by the Official Journal of the EU for EU and for Canada, a 3 year transition from the date of publication of the particular standard.

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ESSENTIAL PRINCIPLES

GHTF/SG1/N41R9:2005

GHTF

FINAL DOCUMENT

Title:	Essential Principles of Safety and Performance of Medical Devices
Authoring Group:	GHTF Study Group 1
Endorsed by:	The Global Harmonization Task Force
Date:	May 20, 2005

Abraao Carvalho, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

What is a Essential Principles?

fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

What is a Essential Principles?

- Six **general requirements** of safety and performance that apply to all medical devices.
- **Design and manufacturing requirements** of safety and performance, some of which are relevant to each medical device:
  - Chemical, physical and biological properties
  - Infection and microbial contamination
  - Manufacturing and environmental properties
  - Devices with a diagnostic or measuring function
  - Protection against radiation
  - Requirements for medical devices connected to or equipped with an energy source
  - Protection against mechanical risks
  - Protection against the risks posed to the patient by supplied energy or substances
  - Protection against the risks posed to the patient for devices for self-testing or self administration
  - Information supplied by the manufacturer
  - Performance evaluation including, where appropriate, clinical evaluation

Use of Standards (examples)

Essential Principles of Safety and Performance of Medical Devices	Applicable standards (examples)
5.1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety	ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes ISO 14971, Medical devices — Application of risk management to medical devices

Use of Standards (examples)

Essential Principles of Safety and Performance of Medical Devices	Applicable standards (examples)
5.8.6 Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.	ISO 11607-1:2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems ISO 11607-2:2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

Use of Standards (examples)

Essential Principles of Safety and Performance of Medical Devices	Applicable standards (examples)
5.8.10 The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.	ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements ISO 15223-2:2010 Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation

Alternatives to Recognised Standards

- The use of standards is voluntary, unless mandated.
- Alternative may include
  - national and international standards that have not been given the status of a "recognised standard" by the Regulatory Authority;
  - industry agreed methods;
  - internal manufacturer standard operating procedures developed by an individual manufacturer;
  - other sources that describe the current state of technology and practice related to performance, material, design, methods, processes or practices.
- The acceptability of such other solutions should be justified and may be subject to review

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WHEN?

Product LifeCycle

Need/ Opportunity

Design and Development

Production

Regulatory Pre-market Review

Post-Production

End of Life

Product LifeCycle

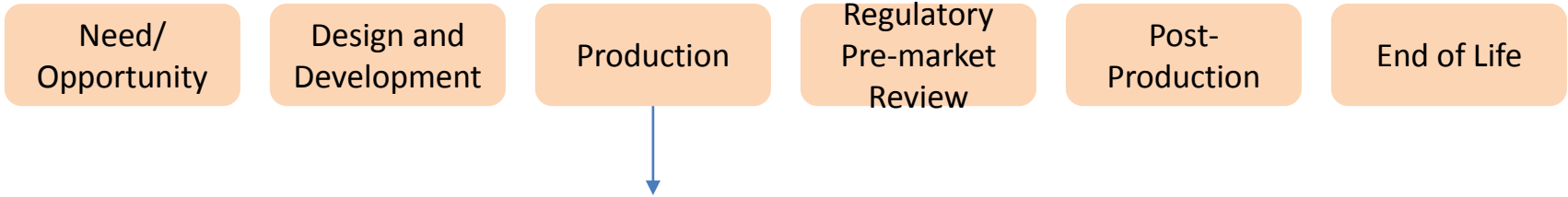
Need/ Opportunity | Design and Development | Production | Regulatory Pre-market Review | Post-Production | End of Life

Planning:

- Team Definition
- Schedule of activities
- Product development planning, including risk management planning and software development planning
- Development of regulatory strategy
- Initial business risk analysis
- Financial, market, other analysis, etc

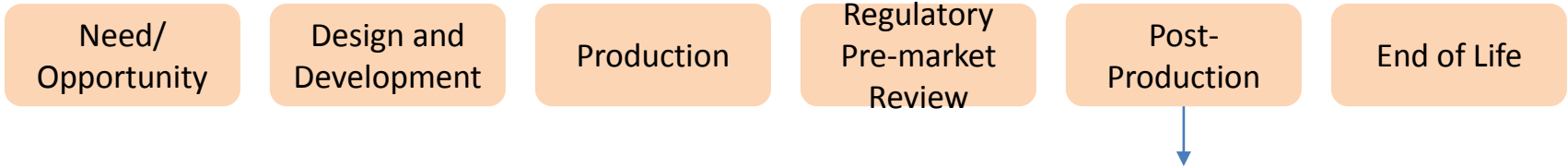
- Medical device requirements – functional, safety, usability, reliability, others
- Selection of standards
- Technical solutions to medical device design and risk control of hazardous situations
- Use of symbols
- Verification and Validation
- Clinical evaluation and clinical investigation

Product LifeCycle



- Risk management of the production process
- Regulatory premarket requirements
- Process validation

Product LifeCycle



- Regulatory post-production requirements including post-market surveillance
- Adverse events and Field Safety Corrective Action
- Nomenclature
- Risk Management feedback

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FINAL NOTE

Going Forward

- Support and contribute to the development of international standards for medical devices
- Encourage the use of international standards

Finally

Standards should represent the generally acknowledged state of technology and practice. The preference for the use of standards should not discourage the use of new technologies.

Not all devices, or elements of safety and/or performance, may be addressed by standards, especially for new types of devices and emerging technologies.

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THANK YOU