





European Standardization on healthcare

Maitane OLABARRIA UZQUIANO

Agenda



- About CEN & CENELEC
- European Standards
- Activities in the area of healthcare
- Cooperation with other organisations & with EUNETIPS



About CEN & CENELEC



European Standards Organisations



European Committee for Standardization
(non-electrotechnical and non-communications)



European Committee for Electrotechnical
Standardization



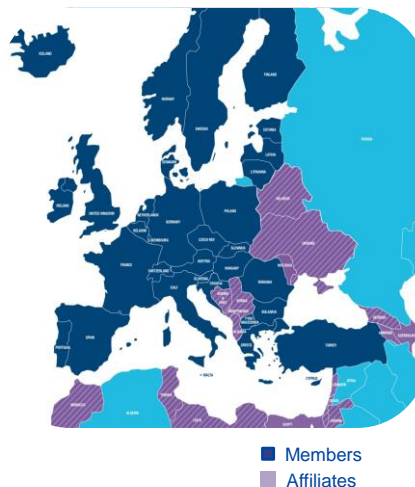
European Telecommunications Standardization
Institute

The **three** recognized European bodies for standardization
(Directive 98/34/EC amended by the Regulation 1025/2012)



About CEN & CENELEC

- Non-for-profit organisation
- 33 Members:
 - National Standardization Bodies
 - 28 EU members, 3 EFTA countries, Turkey & FYROM
- Joint CEN-CENELEC Management Centre in Brussels
- Cooperation agreements with ISO and IEC:
 - Vienna agreement (CEN-ISO)
 - Dresden agreement (CENELEC-IEC)



CEN & CENELEC Members



Link to the list of [CEN members](#) & [CENELEC members](#)

The role of CEN & CENELEC

- We provide a **platform** for stakeholders in a specific area to come together and reach consensus at European level
- We help to ensure that the system respects the principles of transparency, openness, coherence, consensus,...



European Standards



A standard is...

An agreed, repeatable way of doing something. It is a published document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition



Standards are reference documents that can virtually reflect any agreed issue between parties

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Different types of standards

Test methods and measurement standards

- Measure content or parameter



Product standards

- Specify requirements & product performance

Management standards

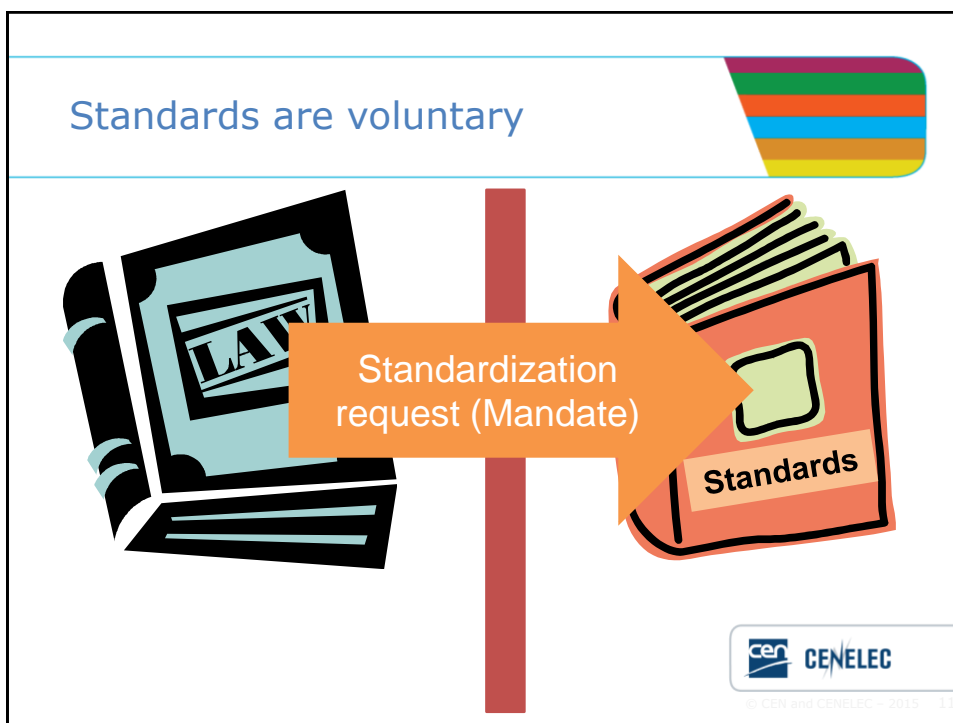
- Models for managing activities

Service standards

- Specify requirements for service provision, good practice...

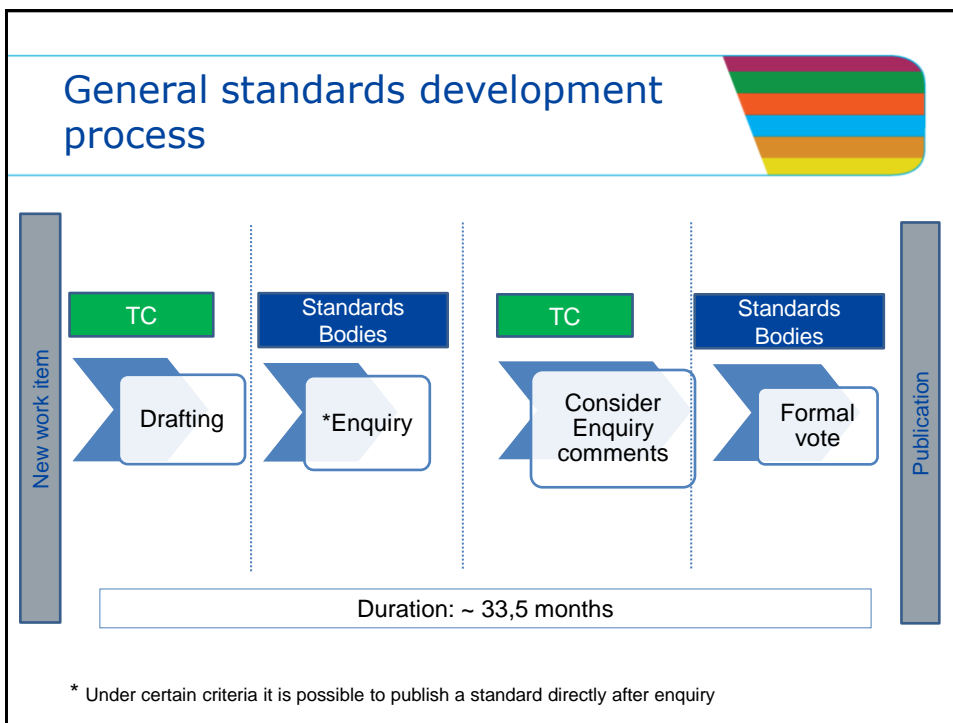
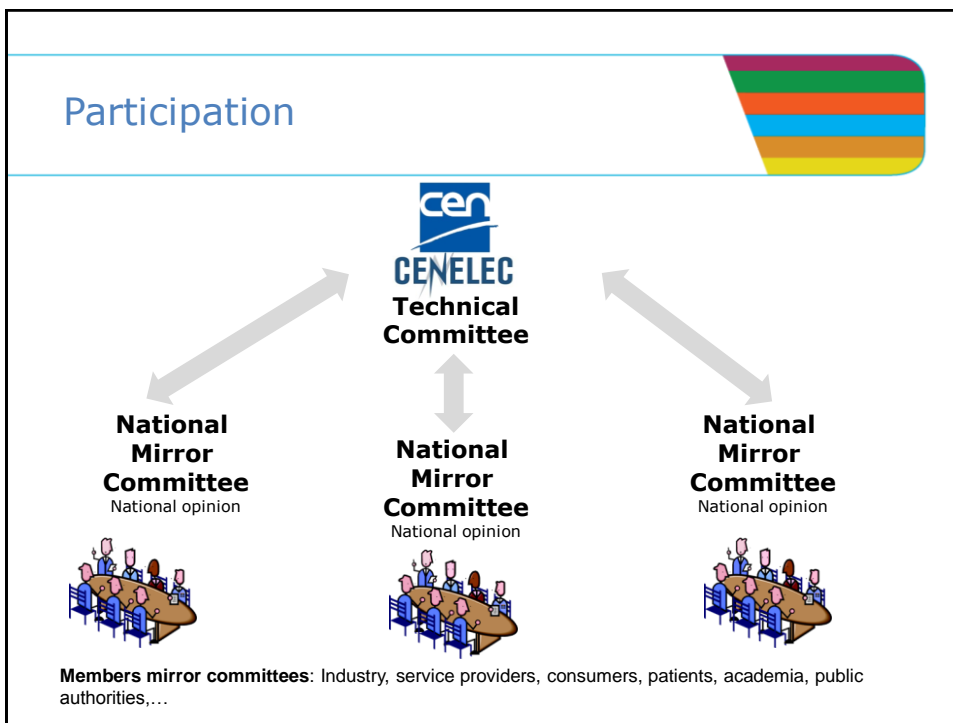


cen CENELEC



Added value of standards

- Developed in a **neutral platform** by all **interested parties**
- **Transparent** and **open** process
- Everybody is entitled to comment on draft standards through a **public enquiry**
- Reached through **consensus**
- **Common** reference document **in 33 countries**
 - Implemented as national standards
 - Conflicting national standards are withdrawn
- Possibility of **integration with international standardization work** (cooperation agreement between CEN and ISO)



Types of publications

- European Standard (EN) – the same everywhere
- Technical Specification (TS) – try it out and/or compete
- Technical Report (TR) – give information
- CEN-CENELEC Workshop Agreement (CWA) – agreement between parties

[Further information](#) on different publications



Activities in the area of healthcare



Standardization in healthcare sector

- **Traditionally:** medical devices, eHealth
- **Recently:** increasing number of initiatives in the area of healthcare services
- Started at the **request of specific stakeholders** (health professionals, patients...)



Published documents

- **EN 15927:2010** Services offered by hearing aid professionals
- **EN 16224:2012** Healthcare provision by chiropractors
- **EN 15224:2012** Health care services - Quality management systems - Requirements based on EN ISO 9001:2008
- **EN ISO 15189:2012** Medical laboratories - Requirements for quality and competence
- **CWA 16642:2013** Health care services- Quality criteria for health checks
- **EN 16372:2014** Aesthetic surgery services
- **CEN/TR 16824:2015** Early care services for babies born with cleft lip and/or palate



Under development

- **FprEN 16686** Osteopathic healthcare provision
 - To be published by mid-2015
- **prEN 16872** Services of Medical Doctors with additional qualification in Homeopathy (MDQH) - Requirements for health care provision by Medical Doctors with additional qualification in Homeopathy
 - Enquiry to be launched end of May 2015
- **prEN 16844** Aesthetic medicine services - Non-surgical medical procedures
 - Enquiry to end on 26 June 2015



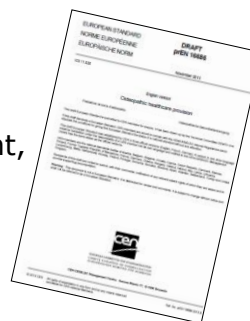
Context and reasons behind the proposals

- **Increasing mobility of patients**
 - Patients look for better financial deals
 - Cheap flights make them mobile
- **Increase patient safety**
 - Build trust and confidence of patients
- **Improved service quality**
 - Minimum requirements, benchmark & best practices
- **Mobility of health professionals**
 - Mutual recognition of qualifications
- **Level playing field at European level**
 - Complement legislation where it exists, or provide reference document where it does not



Content of standards

- Requirements and/or recommendations
- Quality of service provision before, after & during intervention
- Good practices
- Information to patients, patient management, safety requirements
- Requirements on facilities and equipment
- Code of conduct, ethical framework
- Education and training, competences



New activities

- **SAGS** (Strategic Advisory Group on Services) **ABHS** (Advisory Board for Healthcare Standards) **Ad-hoc group on healthcare services**
- **Purpose:** Develop a strategy on how to approach the healthcare sector by the end of 2015
- Identify **where European standards can add value** to healthcare services
- **Exchange of experiences at national level** between National Standardization Bodies
- Define priorities/follow-up actions



Cooperation with other organisations and with EUNETIPS



How to get involved



- Through national standardization bodies (national mirror committees)
- Participation to the CEN-CENELEC Advisory Board for Healthcare Standards (ABHS)
- Direct liaison with existing CEN and/or CENELEC technical/Project Committees
- Initiate new standardization work



Liaison organisation

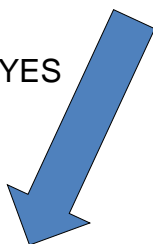
- Once request approved by Technical/Project Committee they can:
 - Participate in meetings
 - Access to documents
 - Submit technical contributions/participation in discussions
- **Without voting rights**
- Procedure: CCMC pre-evaluation → TC decision
- Need to pay an annual fee (€500 per year per TC)
- [CEN/CLC Guide 25](#) for further information



Initiate new standardization work

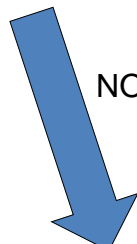
Does it fit within the scope of existing CEN/TC?

YES



Contact CEN/TC and propose new work item

NO



Propose a new European project/field of work



New field of work

- Once a proposal for a new field of work has been officially proposed it is sent to all the CEN members for **approval for a period of 3 months**
- **CEN members will vote after consultation with national stakeholders:**
 - Important to involve stakeholders in other European countries from the beginning (e.g. through relevant European association/organisation) and that they contact CEN national member as soon as possible once formal proposal has been made and for the whole duration of the standardization process (~3 years)



Maitane OLABARRIA

Programme Manager

Sustainability & Services Unit

E-mail: molabarria@cencenelec.eu

Interested to know more?

www.cen.eu



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Annex-

List of CEN-CENELEC Technical bodies



Medical devices & Health informatics (active technical bodies)

- [CEN-CLC/TC 3](#) - Quality management and corresponding general aspects for medical devices
- [CEN/TC 55](#) - Dentistry
- [CLC/TC 62](#) - Electrical equipment in medical practice
- [CEN/TC 102](#) - Sterilizers for medical purposes
- [CEN/TC 140](#) - In vitro diagnostic medical devices
- [CEN/TC 170](#) - Ophthalmic optics
- [CEN/TC 204](#) - Sterilization of medical devices
- [CEN/TC 205](#) - Non-active medical devices
- [CEN/TC 206](#) - Biological evaluation of medical devices
- [CEN/TC 215](#) - Respiratory and anaesthetic equipment
- [CEN/TC 216](#) - Chemical disinfectants and antiseptics
- [CEN/TC 239](#) - Rescue systems
- [CEN/TC 258](#) - Clinical investigation of medical devices
- [CEN/TC 285](#) - Non-active surgical implants
- [CEN/TC 293](#) - Assistive products for persons with disability
- [CEN/TC 316](#) - Medical products utilizing cells, tissues and/or their derivatives
- [CEN/TC 367](#) - Project Committee - Breath-alcohol testers
- [CEN-CLC/JWG AIMD](#) - CEN-CENELEC Joint Working Group on Active Implantable Medical Devices
- [CEN/TC 251](#) - Health informatics

Management systems and healthcare services (active technical bodies)

- [CEN/TC 362](#) - Project Committee - Healthcare services - Quality management systems
- [CEN/TC 403](#) - Project Committee - Aesthetic Surgery and aesthetic non-surgical medical Services
- [CEN/TC 424](#) - Project Committee - Care services for cleft lip and/or palate
- [CEN/TC 427](#) - Project Committee - Services of Medical Doctors with additional qualification in Homeopathy