# The European Standardization System





Cinzia Missiroli Director Standardization & Digital Solutions











Alberto Simeoni Account Manager Technical Boards

# Content



- 1. The actors of the European Standardization System
- 2. European Standards and other European Deliverables
- 3. The international dimension Agreements with ISO and IEC
- 4. Standardization and Legislation: EU Regulation 1025/2012
- 5. Requesting funding for developing standards
- 6. Updates on Guide 23 and 29











1. The actors of the European Standardization System









# Standardization happens on different levels...

















Kingdom DSi.















International

**National** 

Recognised also in Art. 2 (8) and Annex I of EU Regulation 1025/2012!

Recognised also in Art. 2 (9) of EU Regulation 1025/2012!













#### Article 2

#### **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

(8) 'European standardisation organisation' means an organisation listed in Annex I;

ANNEX I

#### **EUROPEAN STANDARDISATION ORGANISATIONS**

- 1. CEN European Committee for Standardisation
- 2. Cenelec European Committee for Electrotechnical Standardisation
- 3. ETSI European Telecommunications Standards Institute

(9) 'international standardisation body' means the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU);









### Other actors in standardization



**National Delegations** 

Industry, including **SMEs Professionals** Academia Certification bodies Laboratories Public authorities Consumers etc.

NSBs send experts

ΓC - Standards development



European organizations

Partner Organization, Liaison Organizations, European stakeholder organizations, etc.

Observers send experts

**CEN-CENELEC** Guide 25



Policy needs

### MARKET NEEDS













# CEN-CENELEC Management Centre





Sébastien Simon

Sophie Vandriessche

CENELEC CEN – European Committee for Standardization
CENELEC – European Committee for Electrotechnical Standardization

Technical

Boards

Alberto

Joëlle Colaers Sébastien Houman

Mirna Vuletic

#### **CUSTOMER RELATIONSHIP MANAGERS**

Constant Kohler EU & EFTA Andreea Gulacsi INDUSTRY To be appointed ISO & IEC Catherine Vigneron MEMBERS Alberto Simeoni

15 October 2020

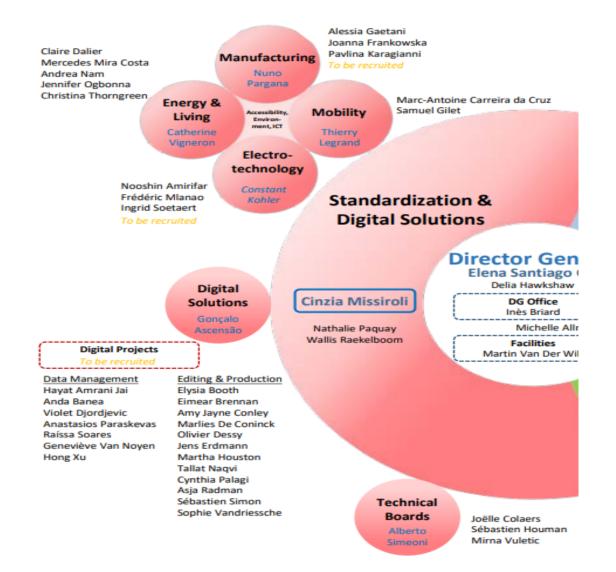
Director General Committee (DGC

Alessia Gaetani Joanna Frankowska Claire Dalier Pavlina Karagianni Manufacturing Mercedes Mira Costa Andrea Nam Jennifer Ogbonna Pargana Communication Christina Thorngreer Cécile Andrianne Marc-Antoine Carreira da Cruz Energy & Anissa Azifi Samuel Gilet Mobility Finance, Legal & IT Living Giovanni Collot ment, ICT Patrick Meert Thierry Catherine Engagement Vigneron Legrand Whitney Clark Accounting & Reporting Electro-Frédéric Delporte Ana Maria Martín Finance Laurent Van Den Berghe technology Els Somers Deborah Wautier Governance Nooshin Amirifar Constant Specific Agreements Frédéric Mlanao Kohler Standardization & Laurent Chavée & Partnerships Strategy & Ingrid Soetaert Membership Nicoleta Tăran Bugărin **Digital Solutions** Emanuele Di Bello Brecht Lein Sarah Penny Director General Legal Andreea Gulacsi Jovana Radevic-Bartolucci Elena Santiago Cid Danielle Dewarier Delia Hawkshaw Digital **Business Applications** Cinzia Missiroli DG Office Solutions Anna Gaugeler Inès Briard IT Mélanie Herfurth Michelle Allmanns Nathalie Paguay Ascensão Bruno Jodard Market Wallis Raekelboom **Facilities** Elisa Matarrese Digital Projects Martin Van Der Wilt Perspectives & Innovation IT Infrastructure Data Management Editing & Production Jean-Pierre Breedstraet Hayat Amrani Jai Elysia Booth Innovation Anda Banea Eimear Brennan Livia Mian Violet Djordjevic Amy Jayne Conley Ashok Ganesh Samira Nik Anastasios Paraskevas Marlies De Coninck **Talents & Performance** Luc Van den Berghe Raíssa Soares Olivier Dessy Françoise Wanson Isabel Quintana-Soria Geneviève Van Noven Jens Erdmann Hong Xu Martha Houston Laureen Boom International Tallat Nagvi Isabelle Burton Zhuohua Chen Cynthia Palagi Jarita Christie Asia Radman Eric Marchand

The CFN-CFNFLFC Management Centre (CCMC), located in Brussels, is in charge of the daily operations, coordination and promotion of all CEN and CFNFIFC activities.

# SDS Department







# 2. European Standards and other European Deliverables









# Technical Boards (BTs) - Responsibilities



### RESPONSIBILITIES

- Decides on all matters concerning organization, working procedures, coordination and planning of standards work
- Approves CEN / CENELEC technical policies and technical strategies
- Is in charge of **Operational management** 
  - Manages by exception
  - Examines and decides on proposals for new work items
  - Approves TC business plans
  - Imposes or releases the standstill obligations
  - Coordinates work between TB to avoid overlaps
  - Organizes technical liaison with European(based) associations
  - Considers and rules upon appeals
  - Follow up requests from CEN/CA or CLC/AG



EN 50575

September 2014

#### English Version

Power, control and communication cables - Cables for general applications in construction works subject to reaction to fire

ernal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration

This European Standard exists in three official versions (English, French, German). A version in any other language made by translatic

ENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Crostia, Cyprus, the Czech Republic Dermark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Iteland, Italy, Latvia, Lituania, Lucembourg, Mata, the Natherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovania, Spain, Sweden, Switzerland,



Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marris 17. B-1000 Brussels

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Rwf. No. EN 50575:2014 E



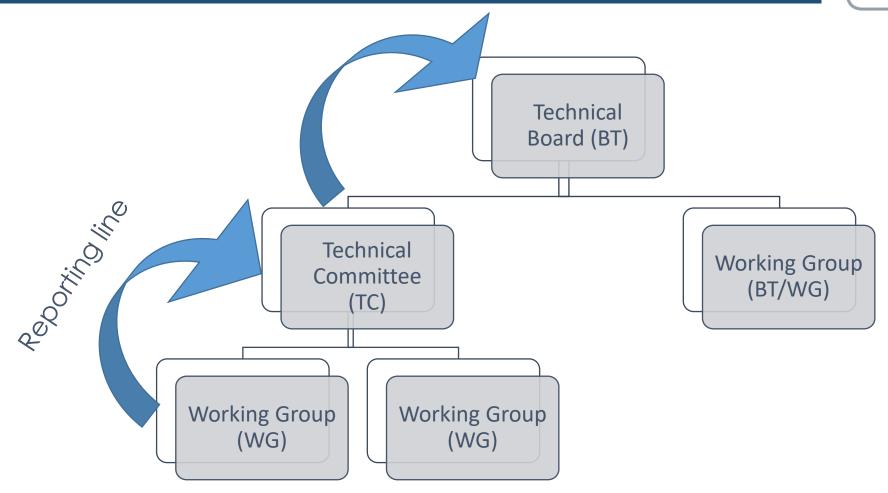






# 3-layer structure for technical work













# What do CEN & CENELEC deliver?



Technical documents that prescribes technical requirements to be fulfilled by a product, process, service or system, which are:

- ✓ Voluntary in use
- ✓ Produced by all interested parties in a transparent, open and consensus based process
- ✓ Intended for a common and repeated use
- ✓ Approved by a recognized body
- ✓ Possible tools to underpin legislation



EUROPEAN STANDARD NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2014

EN 50575

ICS 13.220.50; 29.060.20

#### English Version

Power, control and communication cables - Cables for general applications in construction works subject to reaction to fire requirements

Câbles d'érergle, de commande et de communication -Câbles pour applications générales dans les ouvrages de Stankstromkabel und -leitungen, Steuer- und Kommunikstionskabel - Kabel und Leitungen für allgemeine Anwendungen in Bauwerken in Bezug auf die

is European Standard was approved by CENELEC on 2014-08-11. CENELEC members are bound to comply with the CENECENELEC ternal Regulations which atipulate the conditions for giving this European Standard the status of a national standard without any attention.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Measurement Continues to the CEN-CENELEC Advancement Continues to the CENELEC Advancement Continues to the CE

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

Demmirk, Eathoria, Friend, Former Yugosiav Republic of Macedoria, France, Germary, Greeck, Hunger, Jesind, Iveland, Island, Islay, Lathu Lithurnia, Luosmboug, Mats, the Natherlands, Romay, Poland, Portugal, Romania, Stovabla, Sloveria, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

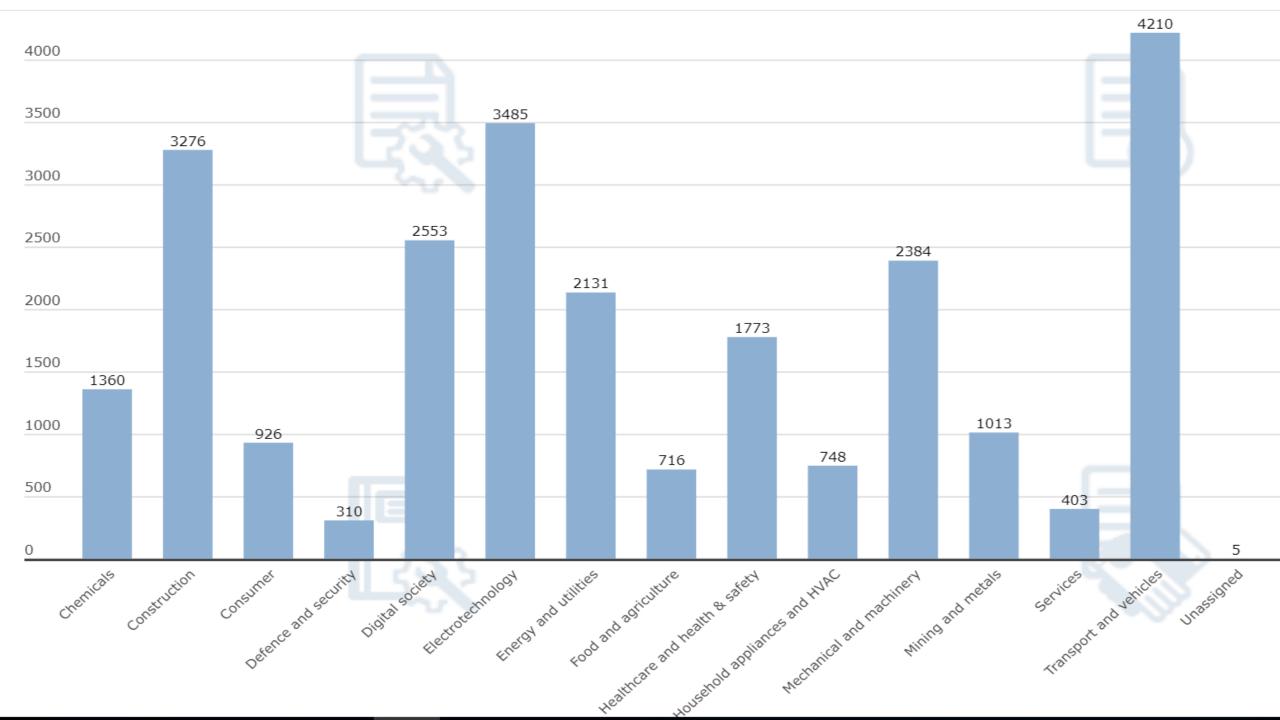
### CENELE

European Committee for Electrotechnical Standardizatio Comité Européen de Normalisation Electrotechnique Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Mamtx 17, B-1000 Brussel:

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Ref. No. EN 50575:2014 E



# Examples of sectors covered by CEN&CENELEC



Food and agriculture

Mining and metals

Chemicals

Construction

Mechanical and machines

Transport, vehicles and packaging

Energy and utilities

Electrotechnology

Household appliances and HVAC (Heating, Ventilation and Air Conditioning)

Digital society

Healthcare and health & safety

Consumer

Defence and security

Services









# Examples of topics covered by CEN&CENELEC





Accessibility



Artificial Intelligence



Ecodesign / resource efficiency



eMobility



Energy efficiency and Management



Environment and sustainability



Personal Protective Equipment



**Public Procurement** 

# CEN and CENELEC Deliverables



## **European Standards (EN)**

Prime deliverable by excellence

# Technical Specifications (TS)

Pre-standard

## Technical Reports (TR)

Informative document / Guide

## Workshop Agreements (CWA)

Document, developed by a Workshop, which reflects an agreement between identified individuals and organizations responsible for its contents

## Harmonization Documents (HD) - only for CENELEC









# 1- European Standard (EN)



- Quality, safety or performance requirements
- ▲ Result of a transparent, open and consensual development process
- Published in 3 official languages (EN, FR & DE) + national translations
- ▲ Implemented at national level by CEN and CENELEC Members
  - Identical adoption as a national standard
  - Conflicting national standards must be withdrawn
- ▲ Available for purchase at NSBs/NCs only
- ▲ Reviewed maximum every five years







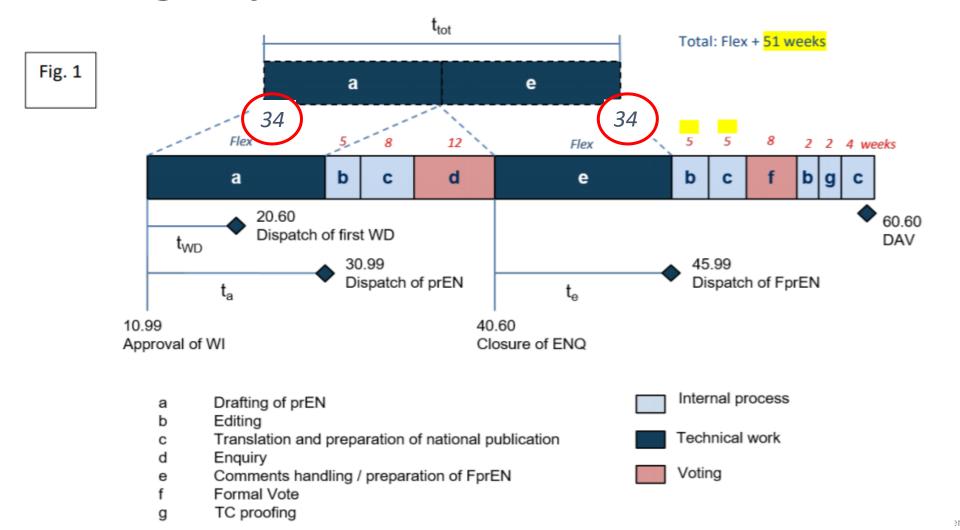




# The NEW (flexible) Standards development process



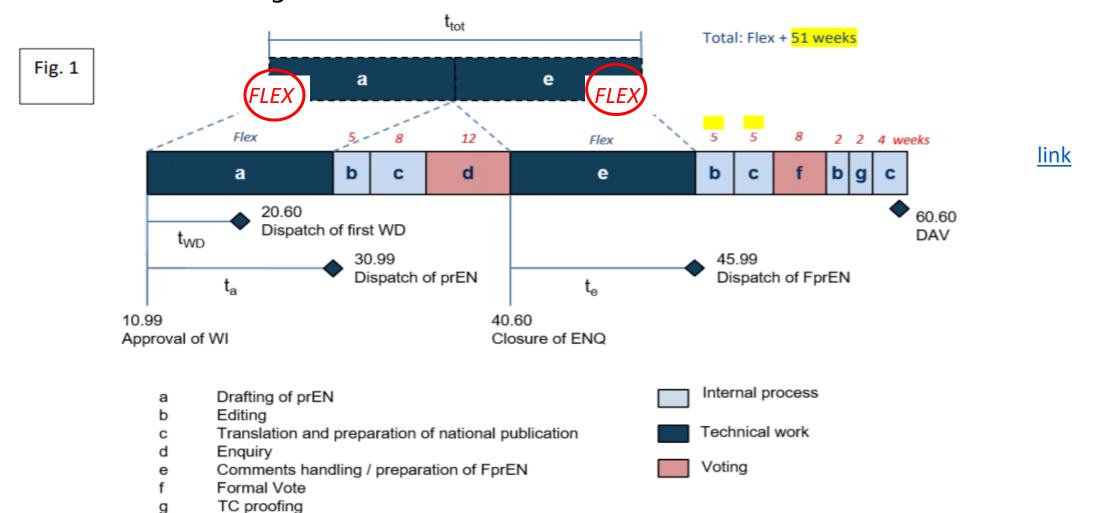
# From rigidity...



# The NEW (flexible) Standards development process



# ...to flexibility!



# 1 - European standards - Examples



### Test and measurement standards

Measure content or parameter

### **Product standards**

Specify product performance

# Management standards

Models for managing activities

### Service standards









# 2 - Technical Specification (TS)



- Normative document published in at least one of the three official languages (EN, FR and DE)
- ▲ Enquiry not mandatory
- Announced and made available at national level
  - Conflicting national standards may continue to exist
  - May conflict with other TS
- ▲ Cannot conflict with an existing European Standard (EN)
- ▲ Reviewed every three years (at least)









# 3 - Technical Report (TR)



- Informative document
  - to provide information on the technical content of standardization work
  - may include e.g. data obtained from a survey, laboratory tests, data on work in other organizations
  - Does not contain requirements
- Adoption at simple majority
- Made available to the CEN/CENELEC national members by the CEN-CENELEC Management Centre
- ▲ No time limit is specified for its lifetime









## 4 - CWA



- Consensual document developed in a Workshop -> NOT withing a TC!
  - Flexible working platform with light procedures
  - Workshop participants are responsible for the CWA content
- Open to any company or organization inside / outside Europe
- Published in one language only
- Voluntary in application
- Listed in the CEN Members' national catalogues
- Can form the basis for future European or international standard
- CEN/CENELEC copyright
  - CWAs cannot be distributed or published freely on any website









# CEN and CENELEC deliverables - Comparison



EN	TS	TR	CWA
Standstill	No Standstill	No Standstill	No Standstill
Enquiry Mandatory	No Enquiry	No Enquiry	Enquiry optional, but recommended
Approval: NSBs/NCs	Approval: NSBs/NCs	Approval: NSBs/NCs	Approval: Registered Workshop participants
Weighted vote	Weighted vote	Simple majority	Consensus
Mandatory publication	Announcement	Announcement	Announcement
Developed in: Technical Body	Developed in: Technical Body	Developed in: Technical Body	Developed in: CEN/CENELEC Workshop











# 3. International dimension -Vienna & Frankfurt Agreements









## International dimension – Vienna Agreement















# CEN/ISO - Vienna Agreement



#### What?

Formal agreement on technical cooperation between ISO and CEN

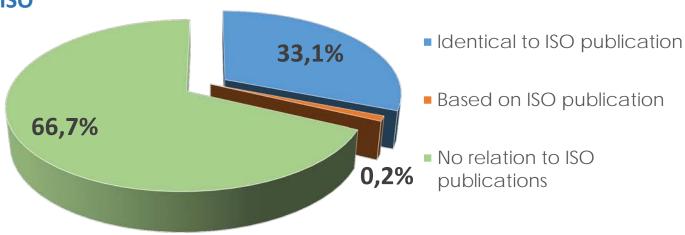
#### When?

- 1991 Published 2001 - Revision
- 2016 'Guidelines on implementation'

### Why?

- Avoid duplication of work at International
  - & European levels
- **Promote global economy**
- **Ensure rational use of back** office resources

CEN - Portfolio - relation to ISO











# CENELEC/IEC - Frankfurt Agreement



#### What?

Agreement on common planning of new work and parallel voting between **IEC and CENELEC** 

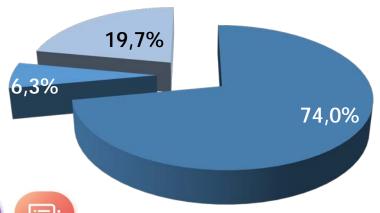
#### When?

- 1996 Signature **Dresden Agreement**
- 2016 Signature Frankfurt Agreement

### Why?

- Underline commitment of IEC & CLC to undertake work at Intl. level
- Promote global economy
- Ensure rational use of back office resources

#### CENELEC - Portfolio - relation to IEC



- Identical to IEC publications
- Based on IEC publications
- No relation to IEC publications









# 4. Standardization and Legislation: EU **Regulation 1025/2012**









## Link with EU legislation & Standardization Requests



European law (Directives / Regulations) regulates important industrial sectors:

- PPE
- Medical devices
- ▲ Low voltage equipment
- Machinery
- ▲ Lifts
- ▲ Fertilizers
- Packaging and packaging waste
- ✓ Standards are a tool to support EU policy and legislation according. to the principles of the New Legislative Framework (New Approach)

Link to EC page on Harmonised standards









## Link with EU legislation & Standardization Requests



### New Approach Directives

- Define essential requirements (e.g. health and safety)
- Indicate WHAT shall be achieved without specifying HOW

### Reference to standards

- At EC's request, CEN and CENELEC develop Harmonized Standards (hENs)
- ENs set out technical specifications to meet Directives' requirements

Help manufacturers to comply with the essential requirements!



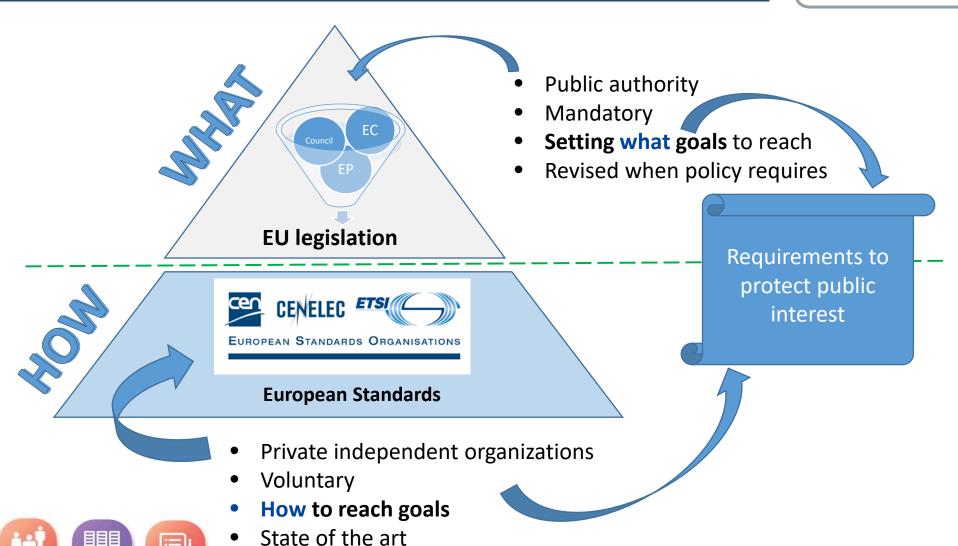




## Hierarchy How Standardization supports legislation

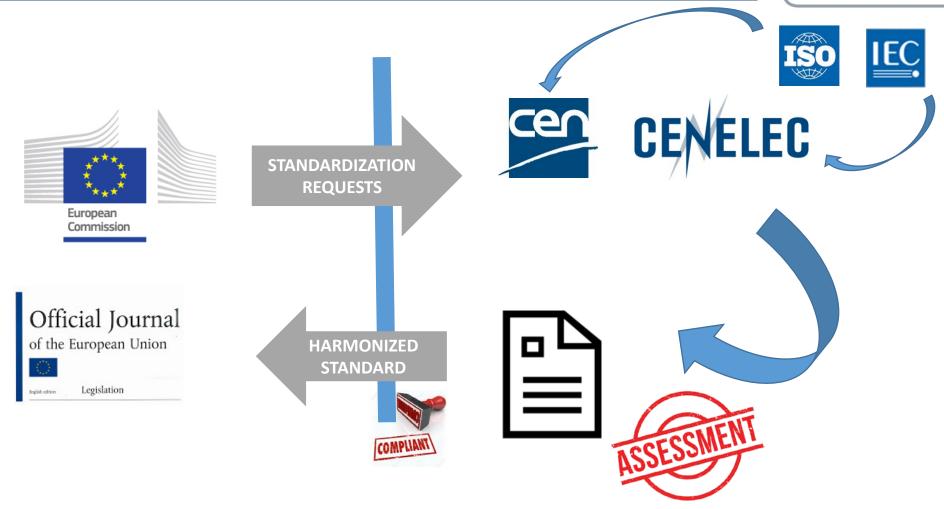
TB OFFICERS STANDARDS PROCEDURES





## Link with EU legislation & Standardization Requests













> 3000 harmonized standards listed in the OJEU

## Regulation on European Standardization 1025/2012



L 316/12

ΕN

Official Journal of the European Union

14.11.2012

REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012

on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council

(Text with EEA relevance)









# Regulation on European Standardization: main concepts



- ▲ Art 3 Transparency of Work Programme
- ▲ Art 4 Transparency of Standards
- ▲ Art 5 Stakeholder participation
- ▲ Art 6 SMEs
- ▲ Art 7 Participation of Public Authorities
- ▲ Art 8 Annual Union Work Programme (AUWP)
- ▲ Art 9 Research facilities
- ▲ Art 10 Standardization requests (SReq)
- ▲ Art 11 Formal objections
- ▲ Art 15 & 17 Financial arrangements









# Main principles



- Standardization Request a precondition for citation of harmonized standards in Official Journal of the European Union (OJEU)
- **Assessment** of compliance with requirements in the SReq
- Annex ZA in CEN and Annex ZZ (+Annex ZA) in CENELEC obligatory for candidate harmonized standards
- Citation in the OJEU always **EC responsibility** CEN and CENELEC offer candidate hENs to EC for citation
- The lists of hENs are **published in the OJEU** and continuously updated: https://ec.europa.eu/growth/single-market/europeanstandards/harmonised-standards en







#### Annex ZA



Annex ZA (informative)

#### Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

Table ZA.1— Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes	
4 5	6	4 and 5: Not fully covered as the requirements will be depended on the specific product.	
4.3	7.1	The requirement only covers biocompatibility.	
4.1	7.2	Not fully covered as the requirements will be depended on the specific product.	
6.2 h)	7.2	Required if any special handling conditions.	
6.2 h)	7.2	Required if any special storage conditions.	
4.5	7.3	Covers substances in design process.	
4.9	7.3	Covers gases in design process.	
4.10	7.3	Covers gases in design process.	
4.4	7.3	Covers manufacturing process.	
4.9	7.3	Covers administration of medicinal products.	
4.10	7.3	Covers administration of medicinal products.	
4.4	7.5	Covers lubricants limited size drops on surfaces in design and manufacturing.	
4.1 6.2 c) and d)	8.1	All testing is done on devices in the sterile condition after design and manufacturing.	
4.1 6.2 c) and d)	8.3	All testing is done on devices in the sterile condition after design and manufacturing.	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

All harmonised standards must include an Annex ZA, demonstrating the relationship between the clauses of the standard and the regulatory requirements







## Annex ZZ



#### Annex ZZA (informative)

#### Harmonized

#### **European Standards**

Technical requirements; Voluntary; Vienna and Frankfurt Agreements: primacy of ISO and IEC work

> All harmonized standards must include an **Annex ZZ**, demonstrating the relationship between the clauses of the standard and the regulatory requirements









#### Relationship between this European Standard and the essential requirements of Directive 2014/30/EU [2014 OJ L96] aimed to be covered

This European Standard has been prepared under the European Commission standardization request C(2016) 7641 final of 30.11.2016 4), ('M/552'), as regards harmonized standards in support of Directive 2014/30/EU relating to electromagnetic compatibility, to provide one voluntary means of conforming to essential requirements of Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility [2014 OJ L96].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table ZZA.1 - Correspondence between this European Standard and the Essential Requirements set out in Directive 2014/30/EU [2014 OJ L96]

Essential requirements of Directive 2014/30/EU	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
Annex I. 1(b) (electromagnetic immunity)	Clause 5 Immunity requirements Table 1 – Immunity requirements for enclosure ports	Not applicable for broadcast receivers (Annex A) under 2014/30/EU
	Clause 5 Immunity requirements Table 2 – Immunity requirements for analogue/digital data ports	Not applicable for broadcast receivers (Annex A) under 2014/30/EU
	Clause 5 Immunity requirements Table 3 – Immunity requirements for DC network power ports	Not applicable for broadcast receivers (Annex A) under 2014/30/EU
	Clause 5 Immunity requirements Table 4 – Immunity requirements for AC mains power ports	Not applicable for broadcast receivers (Annex A) under 2014/30/EU

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

## Citation in the Official Journal of the EU



The European Commission changed in 2019 the way to publish the references of harmonised standards in the OJFU:

Before - a consolidated list of all applicable hENs was published in the C Series of the OJEU

Example: <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.C\_.2018.118.01.0004.01.ENG">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.C\_.2018.118.01.0004.01.ENG</a>

After – standards are cited in the L series of the OJEU through a Commission Implementing Decision.

Example: <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1863">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1863</a>

More: <a href="https://eur-lex.europa.eu/content/help/faq/intro.html#help3">https://eur-lex.europa.eu/content/help/faq/intro.html#help3</a>











# 5. Request for funding to develop deliverables



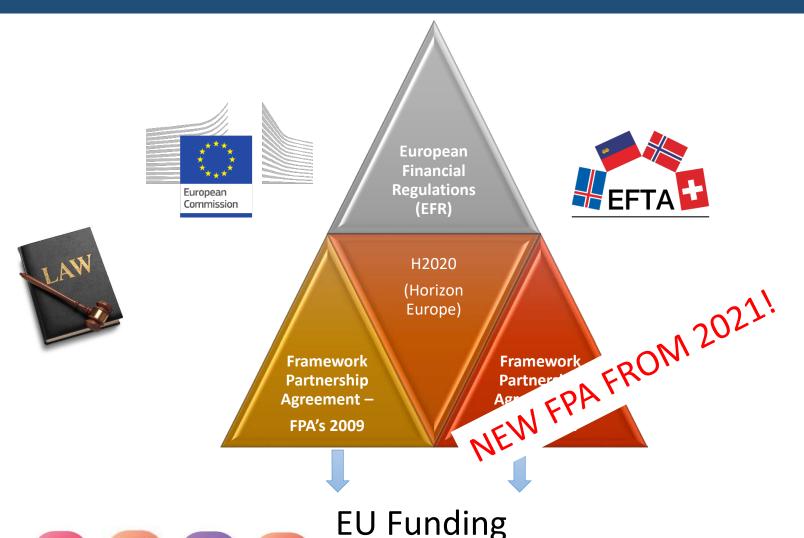






# Legal Framework





- EFR General funding principles
- ➤ CEN FPA's & CENELEC FPA'S – UE Reg. 1025:2012
- > EU Framework Programme for Research&innovation (Horizon)
- Public money











## WHAT technical work can be funded?



- > Standardization activities related to topics of possible interest of the **European Commission!** 
  - Consult upfront the EC desk officer before launching the process!





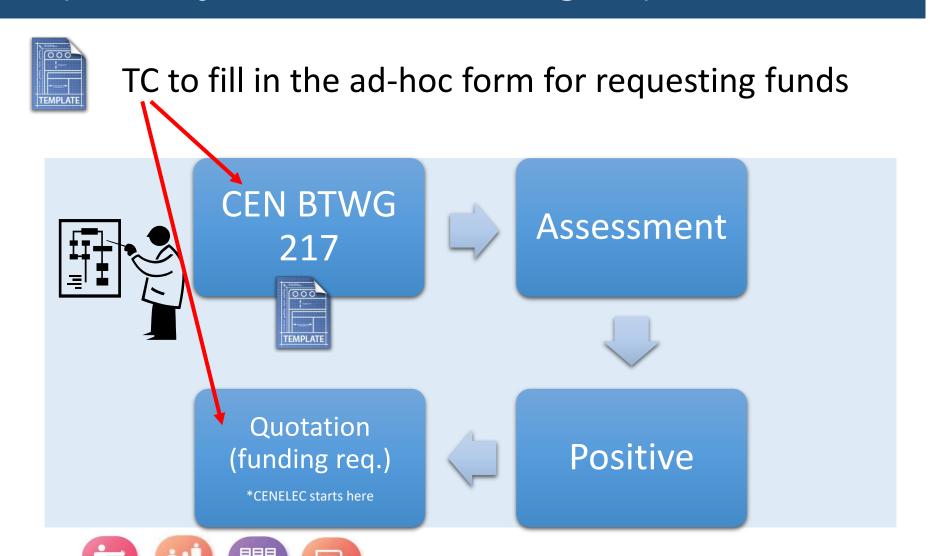




# Preparatory work to the funding req. - CEN

TB OFFICERS STANDARDS PROCEDURES



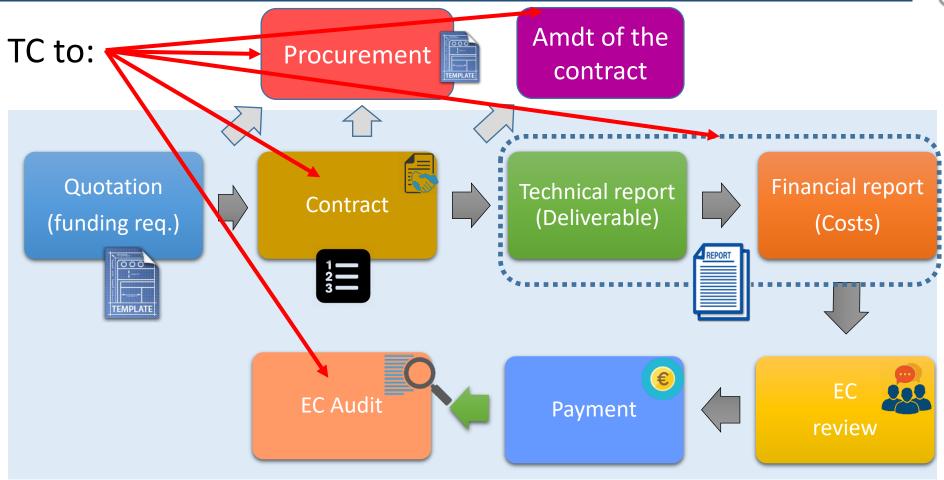


- Prioritization of contracts proposals
- > BT members
- Assessment criteria
- Scoring
  - < 30 points</p>
  - 30 & 34 points
  - ≥ 35 points
- 'Green light' to proceed with quotation



# Project flow





- Proposal to EC/EFTA (€) (What shall we do?)
- Quotation EC assessment (30/60 days)
- Contract signature (30 days)
- Report (Max. 60 days)
- EC review & payment (Max. 60 days)
- Payment (Max. 30 days)
- Possible EC Audit → Max.5 years later



# Questions or doubts for quotations and contracts?



Contact CCMC!









# Updates on Guide 23 and 29



6. Updates on Guide 23 and 29









## Updates on Guide 23 and 29



#### Link to Innovation Plan:

- Action #5 Develop best practice on how to involve research consortia (Horizon 2020 and national or similarly financed consortia) in standardization (for example by developing CWAs or other timely deliverables) – thereby channeling innovation towards CEN – CENELEC
- Action #6 Develop and make available a 'fast track process' to transform, if required, CWA (or any other deliverable or reference document) into a consensus standard (EN)









#### Guide 23



## "Research Consortium Bridge- Addressing Research and Innovation in European Standardization activities and deliverables"

▲ Aim: to promote engagement with Research and innovation community to the Members and be a focal point for good practice









#### Guide 23 - Content



## → Partnership of R&I projects with CEN/CENELEC Technical Bodies

→ Project Liaisons

# Interaction with R&I projects

ightharpoonup Via CEN/CENELEC national member ightharpoonup propose the development of new CEN/CENELEC deliverables (TS, TR, CWA ...)

# ■ Support from CEN and CENELEC Members

- ▲ Raising awareness
- Monitoring new topics in which standardization shall be relevant
- ▲ Participation in R&I projects

# **▲** Recognition for Contributions









#### Guide 29



### "CEN/CENELEC Workshop Agreements - A rapid way to standardization"

Aim: provide mechanisms and details the characteristics and development process of the CEN/CENELEC deliverable known as the 'CEN/CENELEC Workshop Agreement'.









#### Guide 29 - Introduction



- ▲ A CWA is a deliverable, which may take various forms such as text file or computer. code, developed and agreed by the participants in a temporary working group (CEN/CENELEC Workshop);
- It is designed to meet an immediate need;
- It can be quickly developed and can be used as fast track to future. standardization activities.
- The stakeholder involvement is limited to those directly interested in the subject.
- Important: An overview of actions, responsibilities, and timeframes throughout the CEN/CENELEC Workshop Agreement process is provided in Annex C
  - Work repartition between Member and CCMC
  - Indications of time needed: better planning by Member (e.g. in H2020 project)









# Start of a new Workshop



## ■ Two possibilities:

#### → First contact is Member

- Member (Secretariat) to produce proposal form and contact TCs!
- CCMC: PM, BT-decision if needed, announce KO-mtg, inform BT, allocation of an identifier in the format 'CWA xxxx'

#### ▲ First contact is CCMC

BT-process to appoint Member where Member cannot be identified









#### Guide 29 - Content



#### ■ Initiation

- Allocation of WS
- Creation of Proposal
- ▲ Launch of the WS
- Responsibilities/Drafting
- ▲ Co-existence with TBs
- ▲ Lifetime and Review
  - ▲ Conversion into a CEN-CENELEC Deliverable

#### ▲ Annexes:

- Template for WS proposal
- Standard text for forward and coverage
- Overview of actions and responsibilities









# Questions?



Cinzia MISSIROLI
Director
Standardization & Digital Solutions
<a href="mailto:cmissiroli@cencenelec.eu">cmissiroli@cencenelec.eu</a>

Alberto SIMEONI
Customer Solution Manager
Members & Technical Boards
asimeoni@cencenelec.eu

www.cencenelec.eu

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