

The European Standardization System



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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



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STANDARDS



PROCEDURES

1. The actors of the European Standardization System



Standardization happens on different levels...



National

European

International

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



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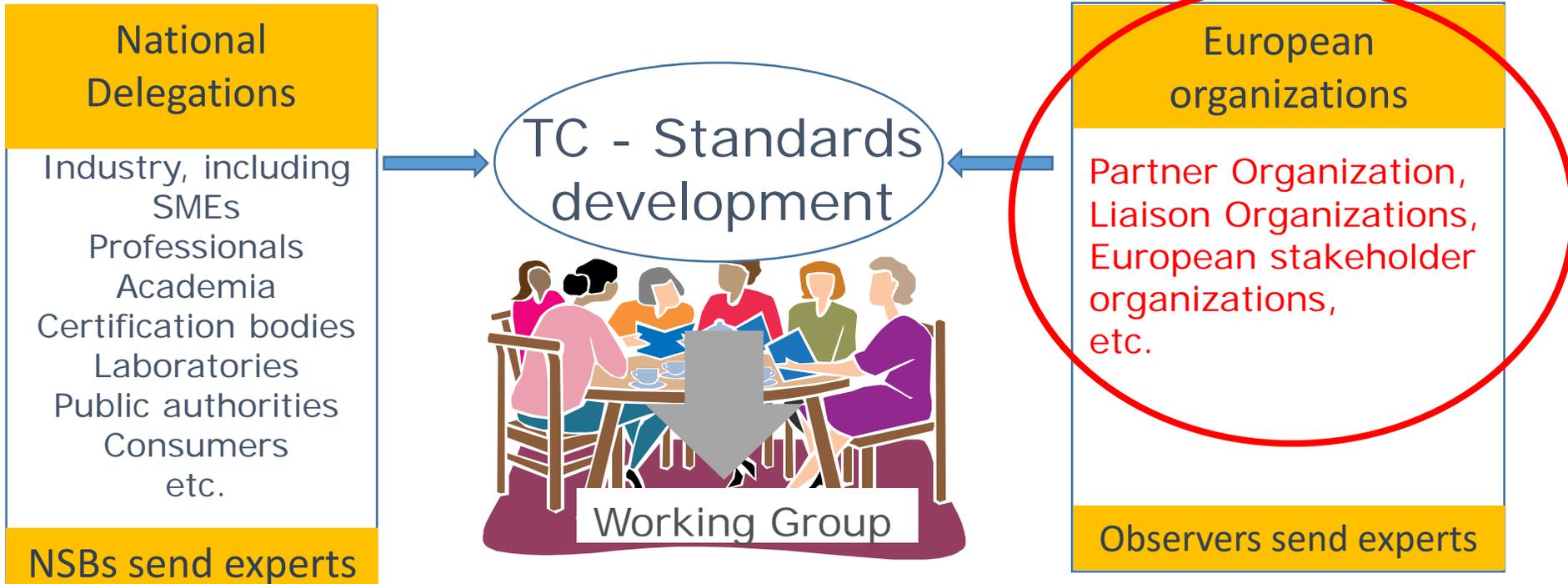


STANDARDS



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Other actors in standardization



CEN-CENELEC
Guide 25

MARKET NEEDS

Policy needs



CEN-CENELEC Management Centre



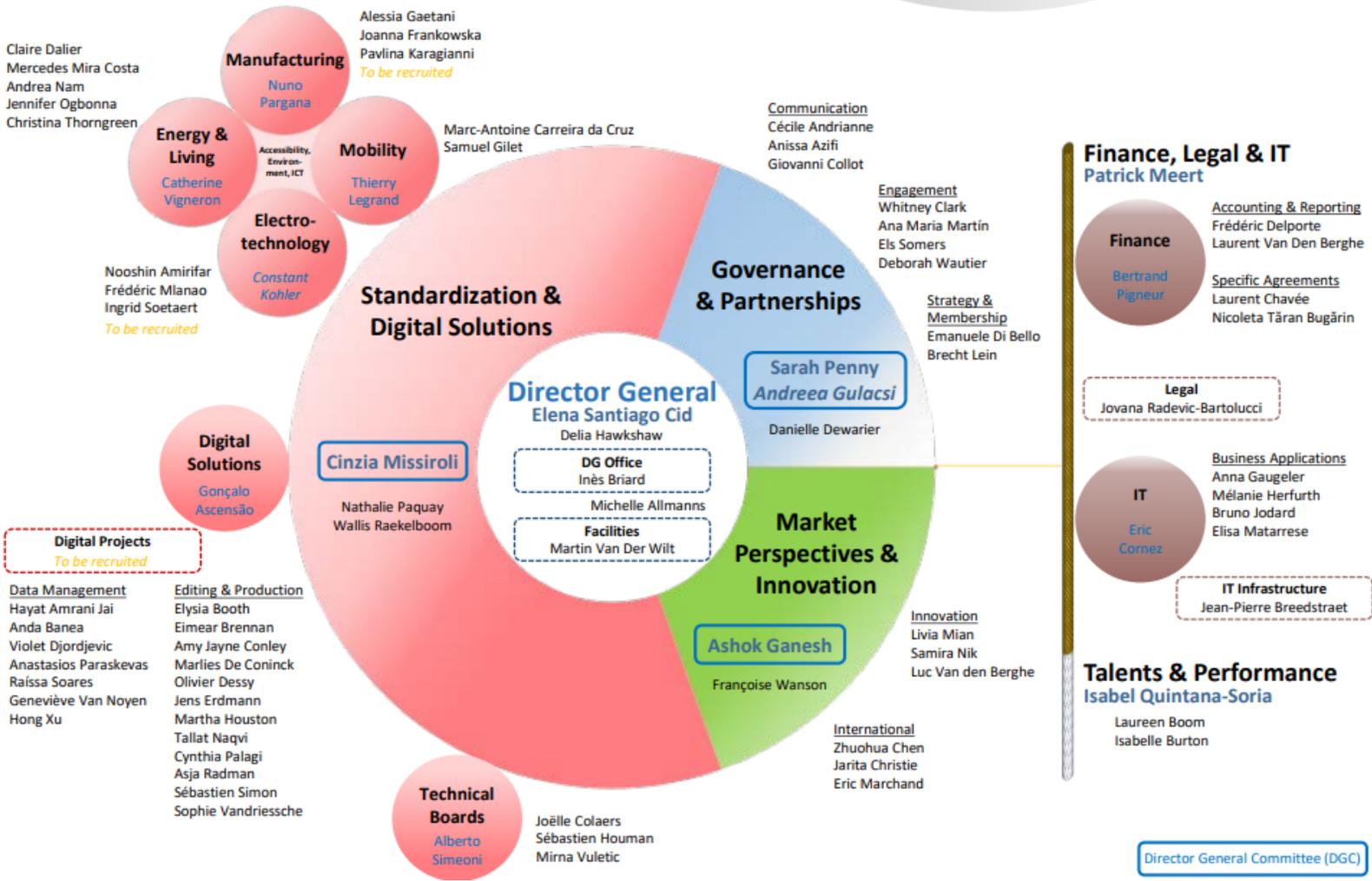
CEN – European Committee for Standardization
CENELEC – European Committee for Electrotechnical Standardization

CUSTOMER RELATIONSHIP MANAGERS

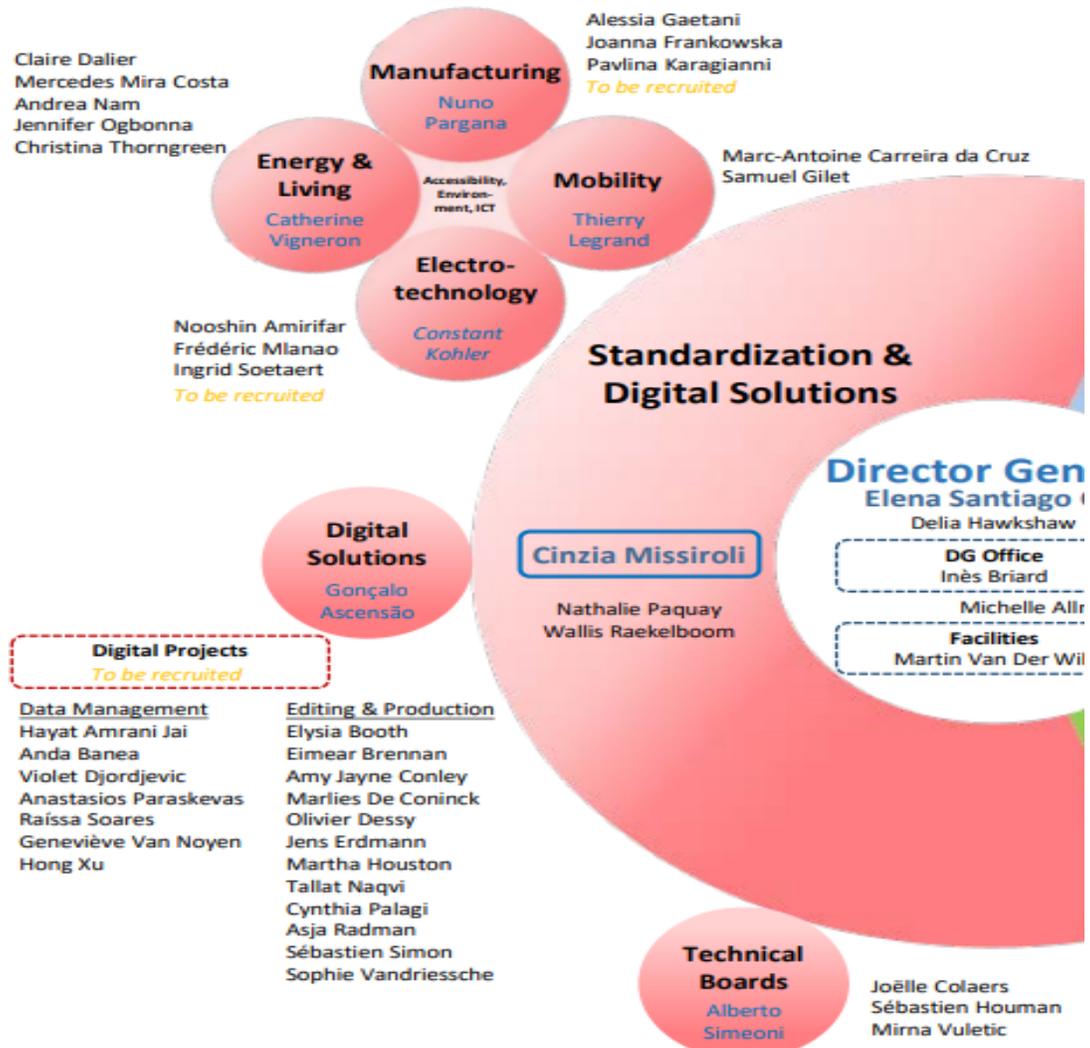
ETSI
 EU & EFTA
 INDUSTRY
 ISO & IEC
 MEMBERS

Constant Kohler
 Andreea Gulacsi
To be appointed
 Catherine Vigneron
 Alberto Simeoni

15 October 2020



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



2. European Standards and other European Deliverables



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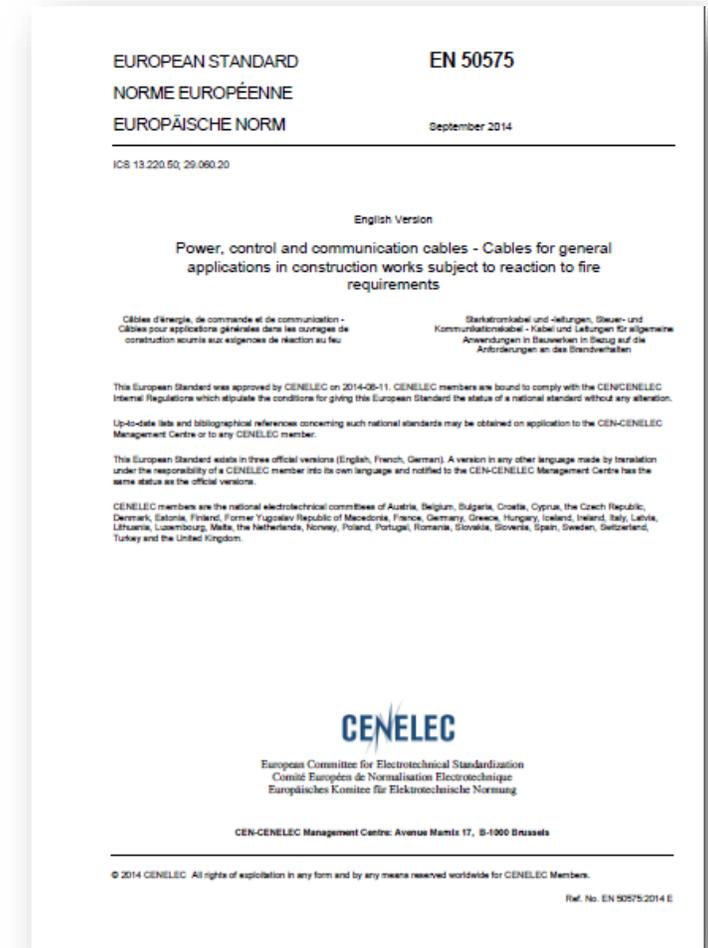
PROCEDURES

Technical Boards (BTs) - Responsibilities

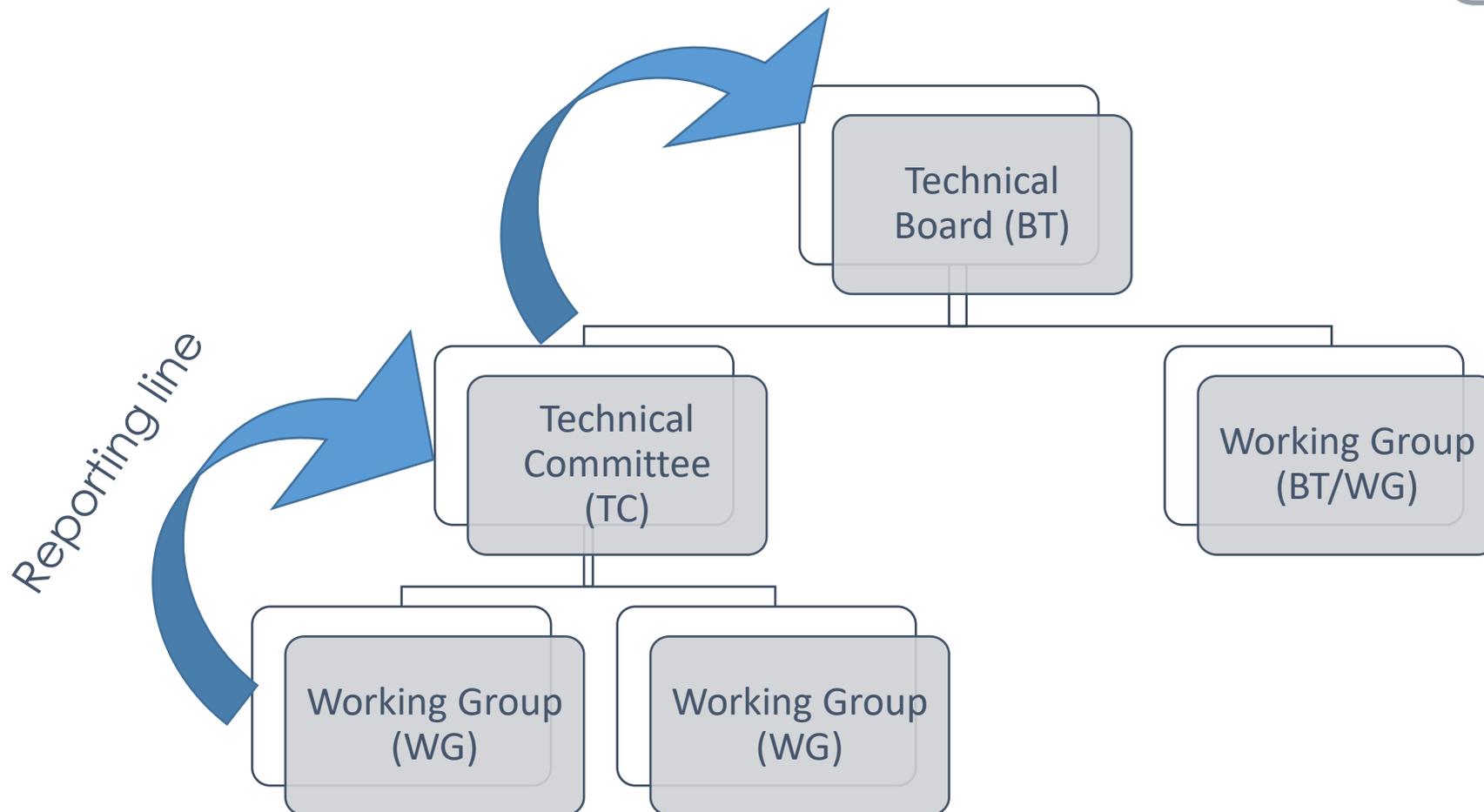


RESPONSIBILITIES

- 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



3-layer structure for technical work



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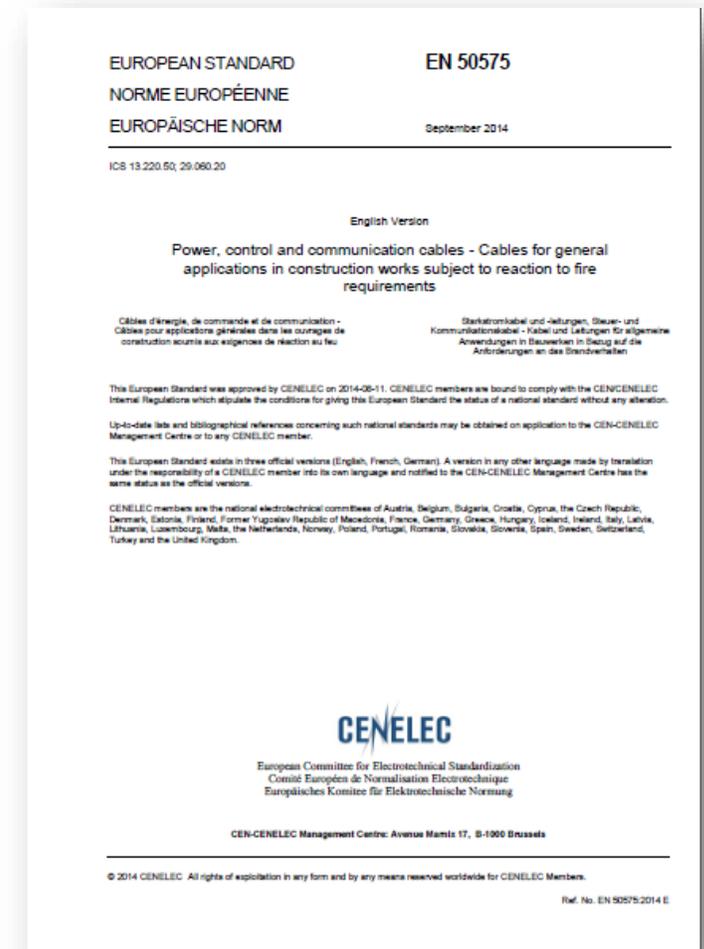
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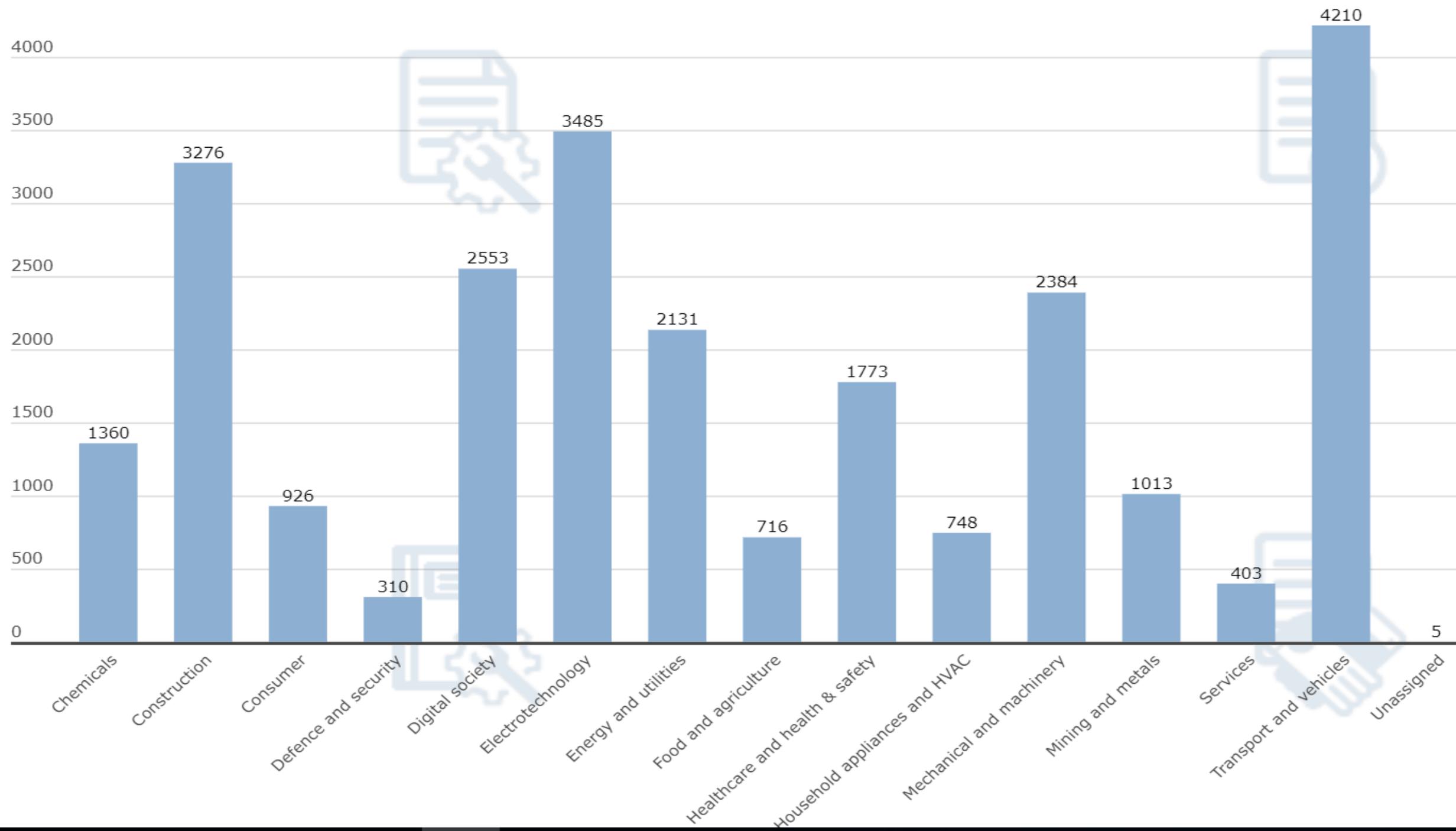
What do CEN & CENELEC deliver?



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**





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

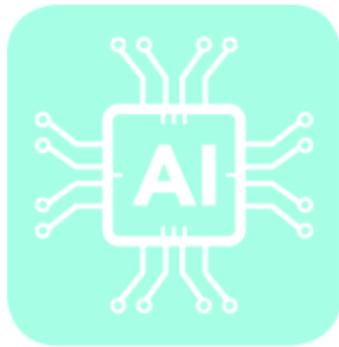
Electrotechnology
Household appliances and HVAC (Heating, Ventilation and Air Conditioning)
Digital society
Healthcare and health & safety
Consumer
Defence and security
Services



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
- ▲ Can be in **support of EU legislation**
- ▲ 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**

Standstill



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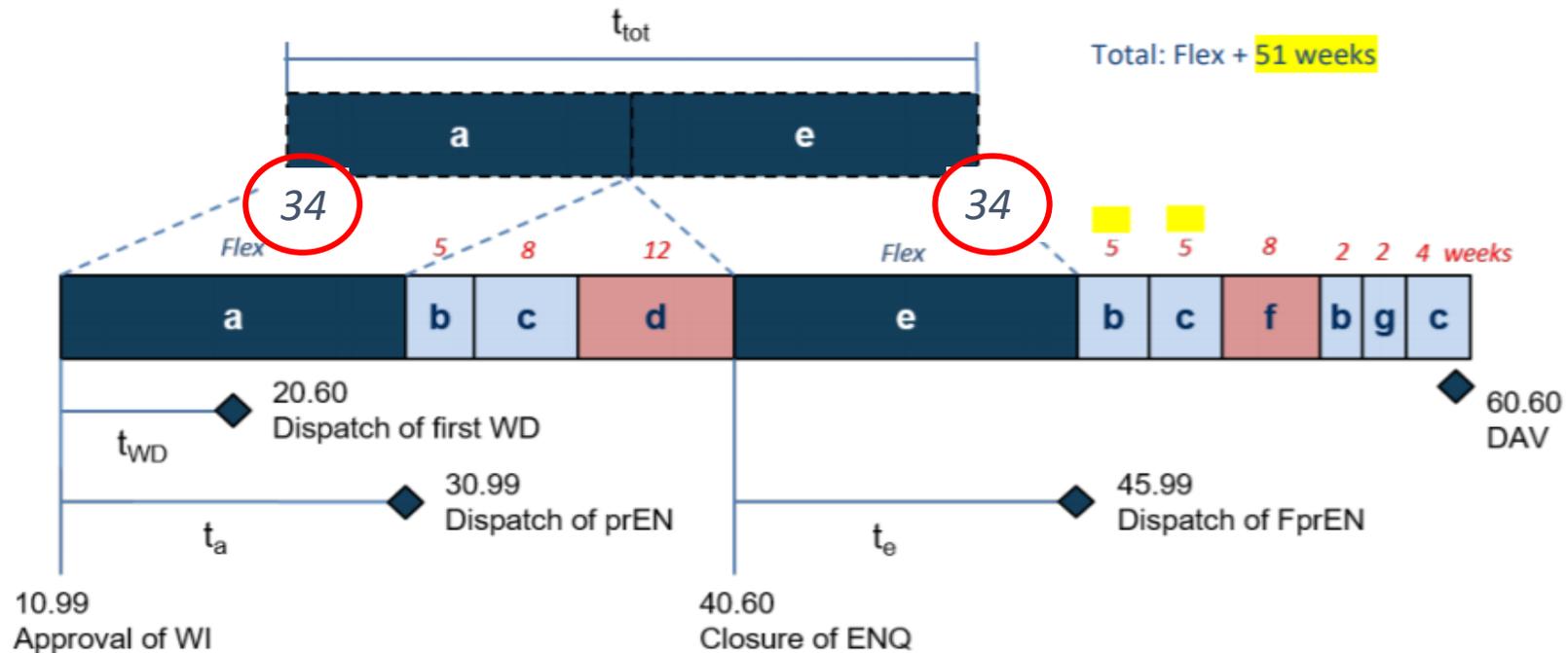


PROCEDURES

The NEW (flexible) Standards development process

From rigidity...

Fig. 1



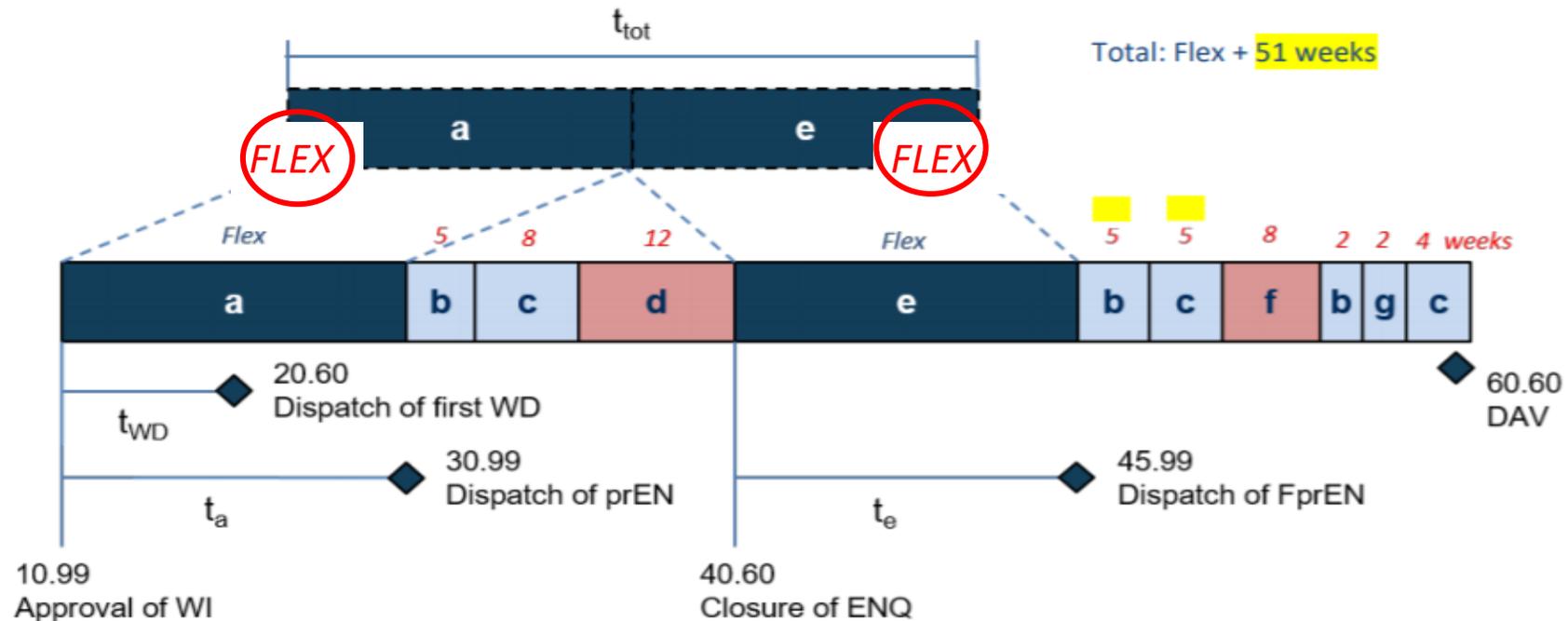
- a Drafting of prEN
- b Editing
- c Translation and preparation of national publication
- d Enquiry
- e Comments handling / preparation of FprEN
- f Formal Vote
- g TC proofing

- Internal process
- Technical work
- Voting

The NEW (flexible) Standards development process

...to flexibility!

Fig. 1



[link](#)

- | | | | |
|---|---|--|------------------|
| a | Drafting of prEN | | Internal process |
| b | Editing | | Technical work |
| c | Translation and preparation of national publication | | Voting |
| d | Enquiry | | |
| e | Comments handling / preparation of FprEN | | |
| f | Formal Vote | | |
| g | TC proofing | | |

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
- ▲ Can be in (temporary) support
- ▲ 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)
- ▲ Can be transformed into a European Standard later
- ▲ Reviewed every three years (at least)



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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



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- ▲ **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



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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



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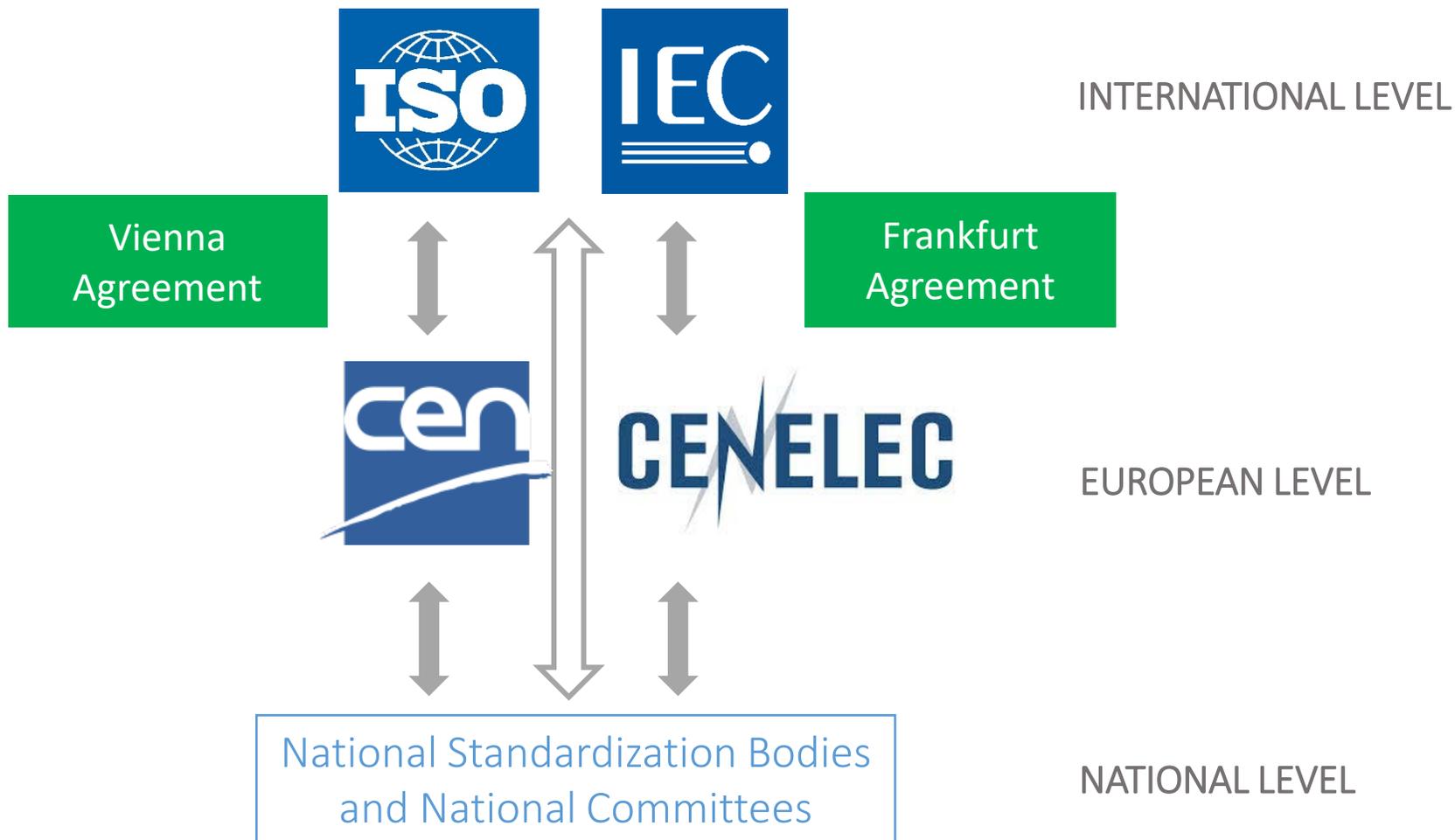


STANDARDS



PROCEDURES

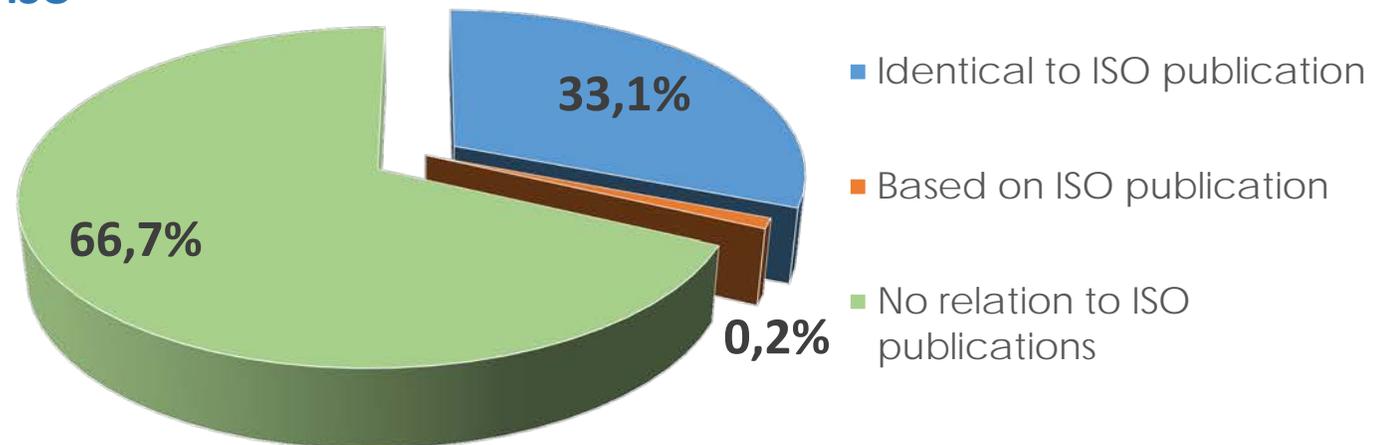
International dimension – Vienna Agreement



CEN/ISO – Vienna Agreement

What?	When?	Why?
<ul style="list-style-type: none">• Formal agreement on technical cooperation between ISO and CEN	<ul style="list-style-type: none">• 1991 - Published• 2001 - Revision• 2016 'Guidelines on implementation'	<ul style="list-style-type: none">• Avoid duplication of work at International & European levels• Promote global economy• Ensure rational use of back office resources

CEN – Portfolio – relation to ISO

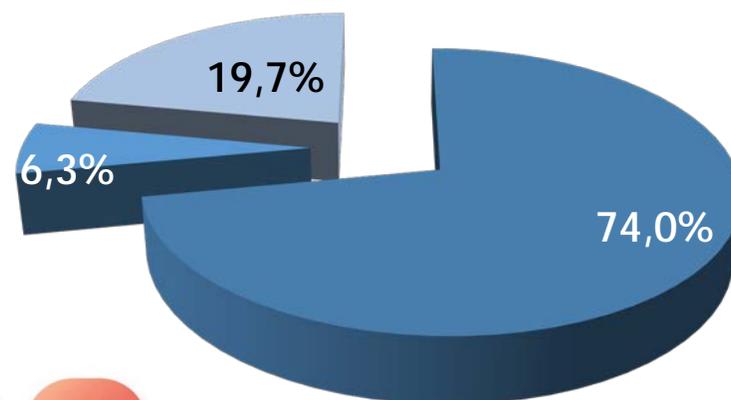


CENELEC/IEC – Frankfurt Agreement



What?	When?	Why?
<ul style="list-style-type: none">• Agreement on common planning of new work and parallel voting between IEC and CENELEC	<ul style="list-style-type: none">• 1996 – Signature Dresden Agreement• 2016 – Signature Frankfurt Agreement	<ul style="list-style-type: none">• 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



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

- ▲ PPE
- ▲ Medical devices
- ▲ Low voltage equipment
- ▲ Machinery
- ▲ Lifts
- ▲ Fertilizers
- ▲ Packaging and packaging waste

[Link to EC page on Harmonised standards](#)

✓ Standards are a tool to support EU policy and legislation according to the principles of the New Legislative Framework (New Approach)



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- **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



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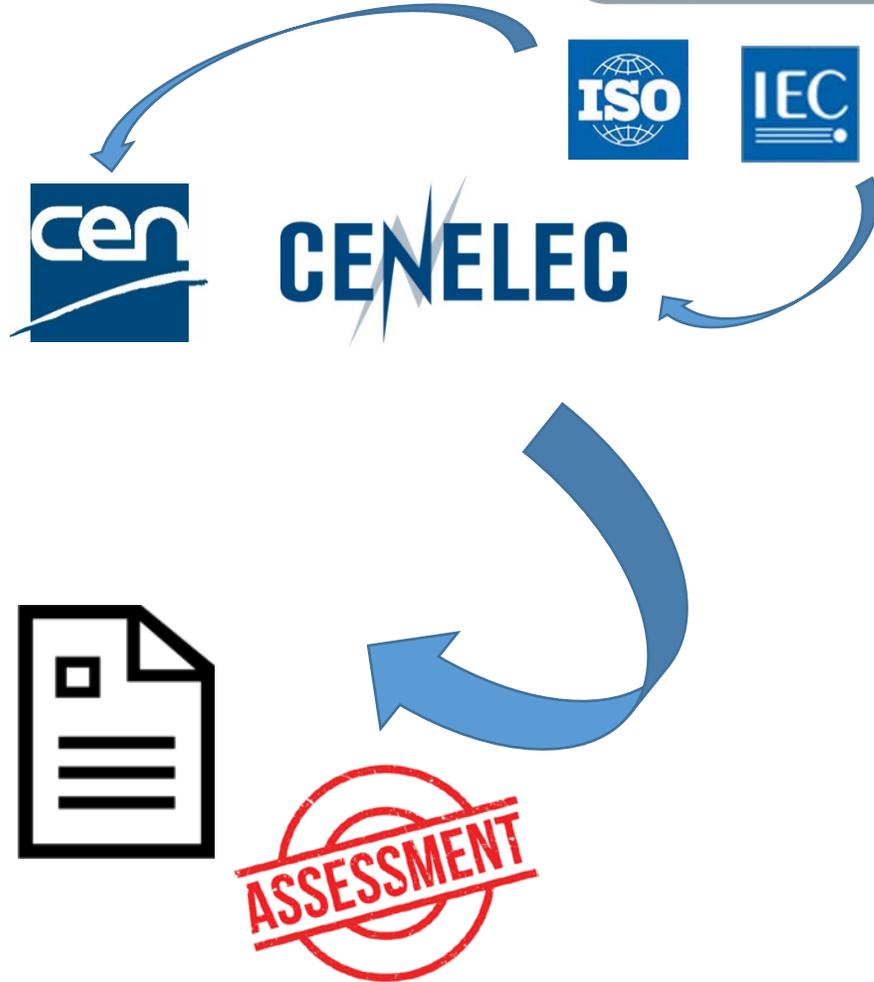
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Link with EU legislation & Standardization Requests



STANDARDIZATION REQUESTS

HARMONIZED STANDARD



> 3000 harmonized standards listed in the OJEU

**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)



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PROCEDURES

- ▲ 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



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PROCEDURES

- **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/european-standards/harmonised-standards_en



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Annex ZA (informative)

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

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

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.



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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 30.11.2016⁴⁾, ('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 Union.

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

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

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

Example: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.C_.2018.118.01.0004.01.ENG

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

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

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



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5. Request for funding to develop deliverables



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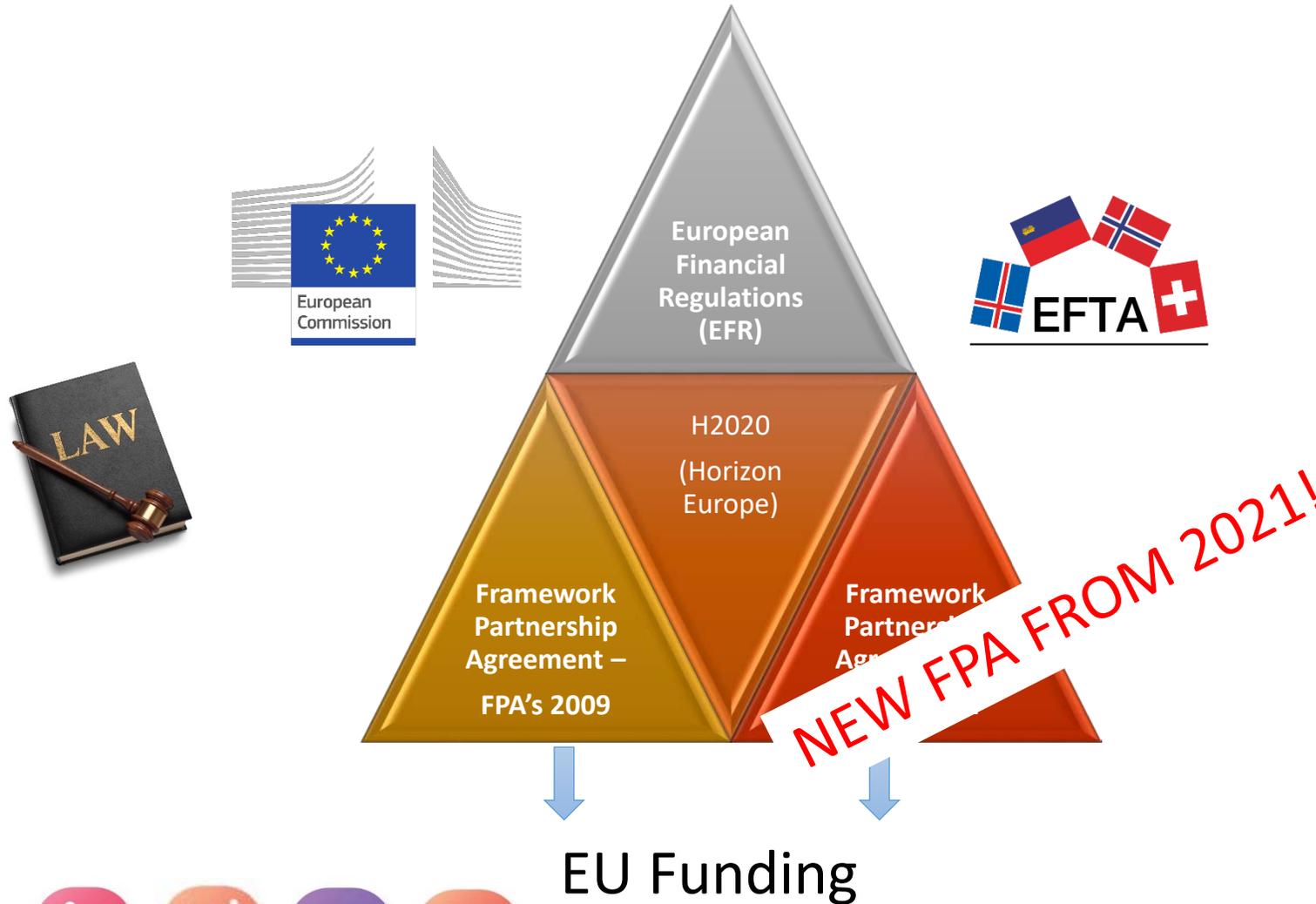
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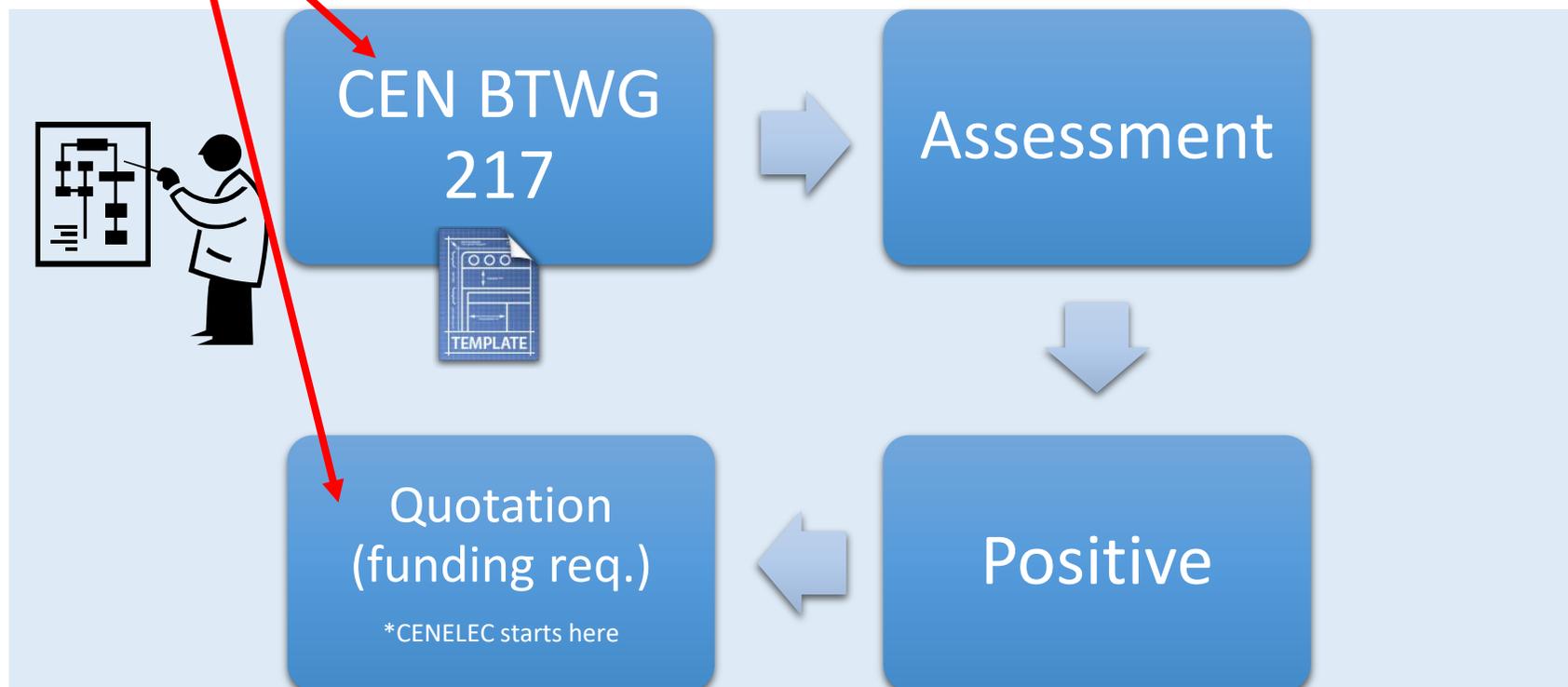
- EFR – General funding principles
- CEN FPA's & CENELEC FPA's – UE Reg. 1025:2012
- EU Framework Programme for Research&innovation (Horizon)
- Public money

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!



TC to fill in the ad-hoc form for requesting funds



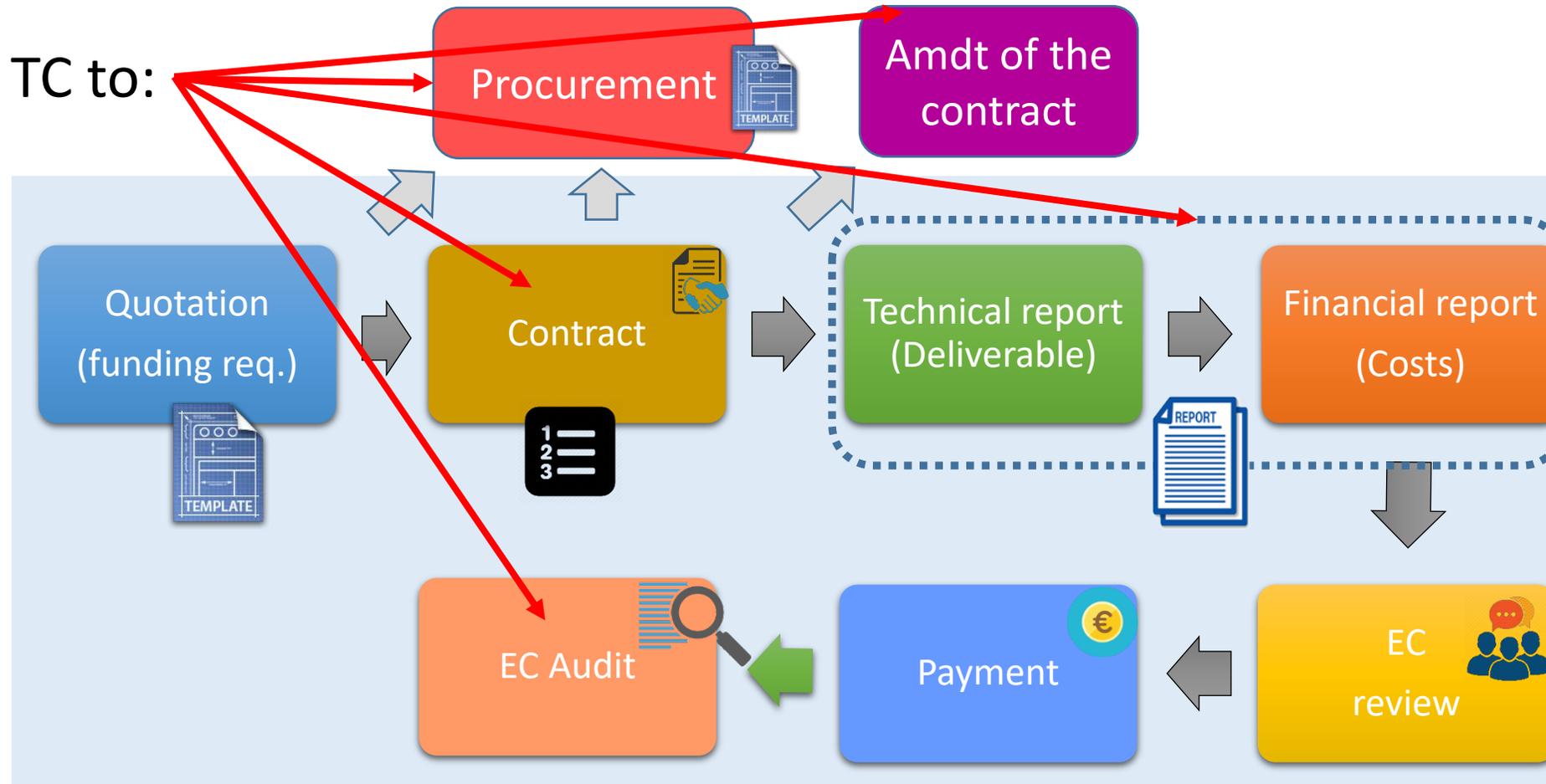
- Prioritization of contracts proposals
- BT members
- Assessment criteria

- Scoring
 - < 30 points
 - 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!



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PROCEDURES

6. Updates on Guide 23 and 29



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PROCEDURES

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)



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“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



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PROCEDURES

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

- ▲ *Project Liaisons*

▲ Interaction with R&I projects

- ▲ *Via CEN/CENELEC national member → 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



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PROCEDURES

“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'.



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- ▲ 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)*



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▲ 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



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PROCEDURES

▲ 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*



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Questions?



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