

The European Standardization System

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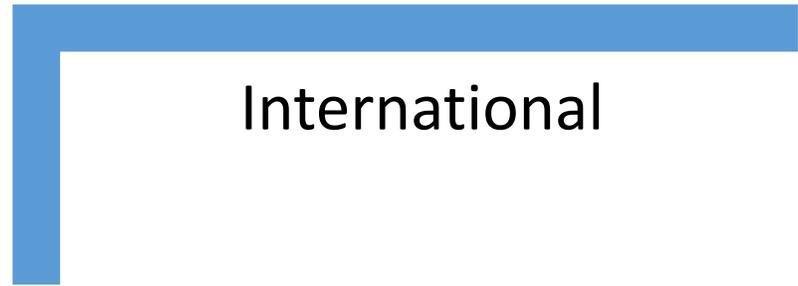
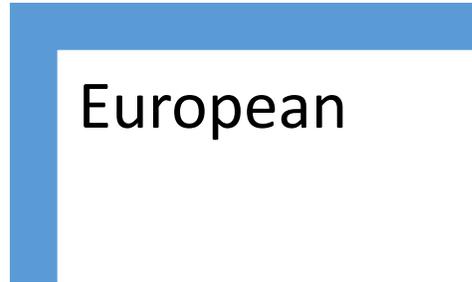
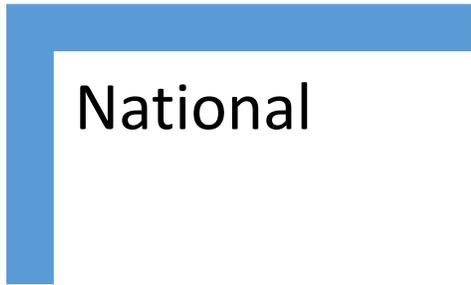
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1. The actors of the European Standardization System
2. European Standards and other European Deliverables
3. The international dimension – Agreements with ISO and IEC
4. Standardization and Legislation: EU Regulation 1025/2012
5. Requesting funding for developing standards
6. New guidance documents

1. The actors of the European Standardization System



Standardization happens on different levels...



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);

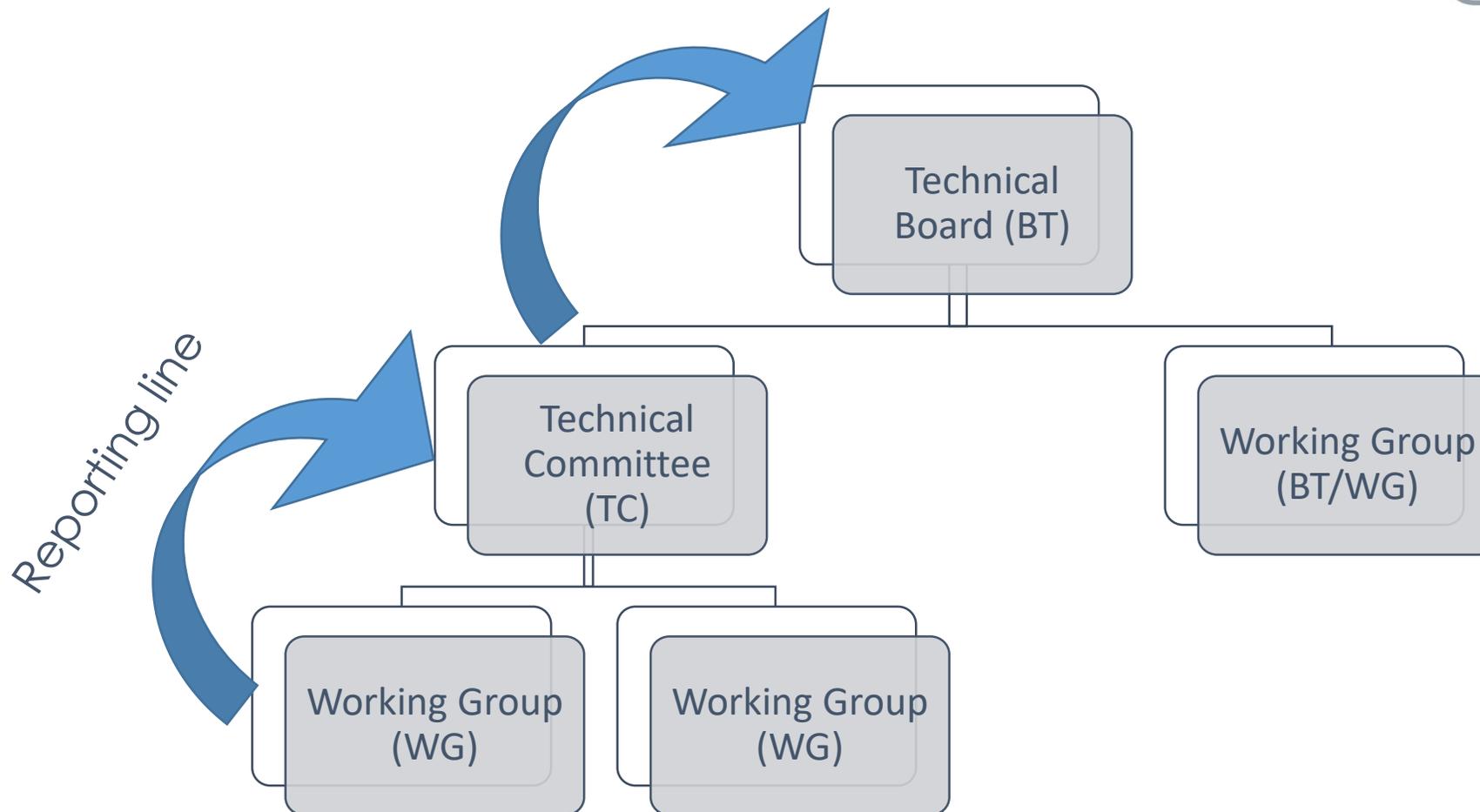
Other actors in standardization



2. European Standards and other European Deliverables



3-layer structure for technical work



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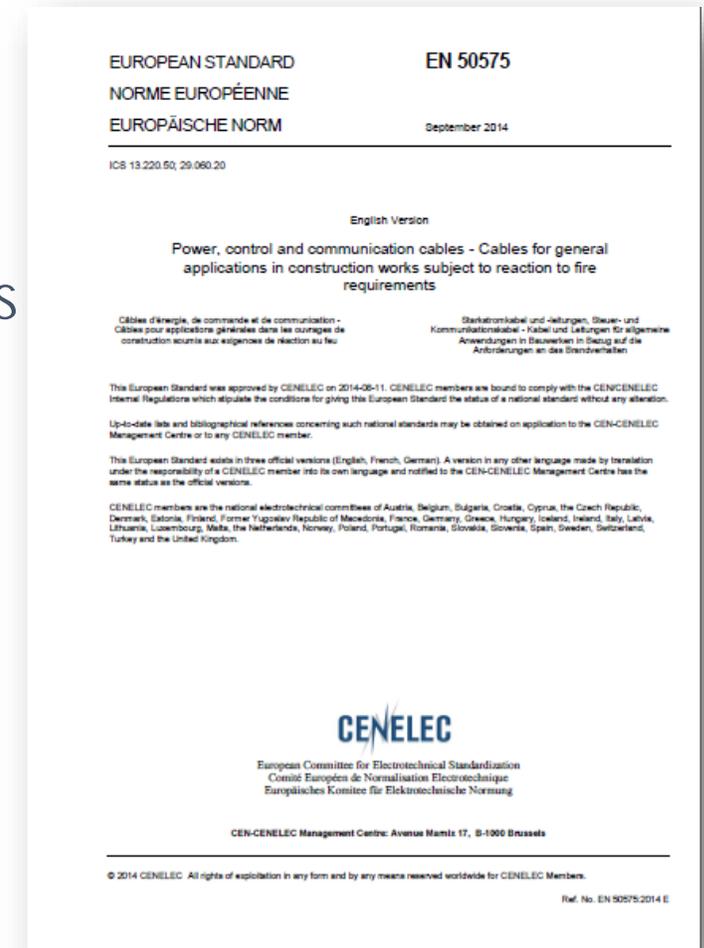
PROCEDURES

What do CEN & CENELEC deliver?



Technical documents designed to be used as a rule, guideline or definition, which are:

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



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



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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

Harmonised Documents (HD) - *only for CENELEC*



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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 at least 3 languages (EN, FR & DE)
- ▲ **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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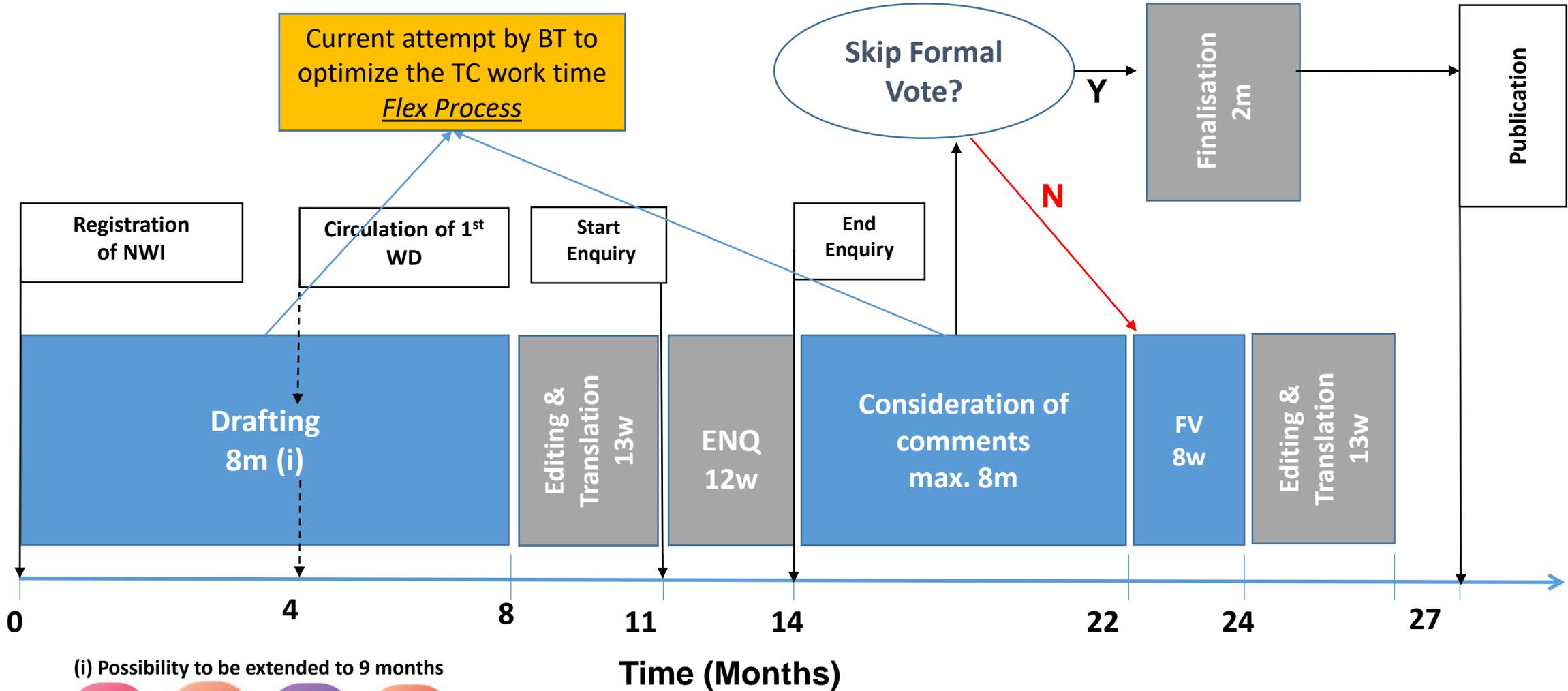


STANDARDS



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1 – European Standard



(i) Possibility to be extended to 9 months



2.1 Flexible Standards development process

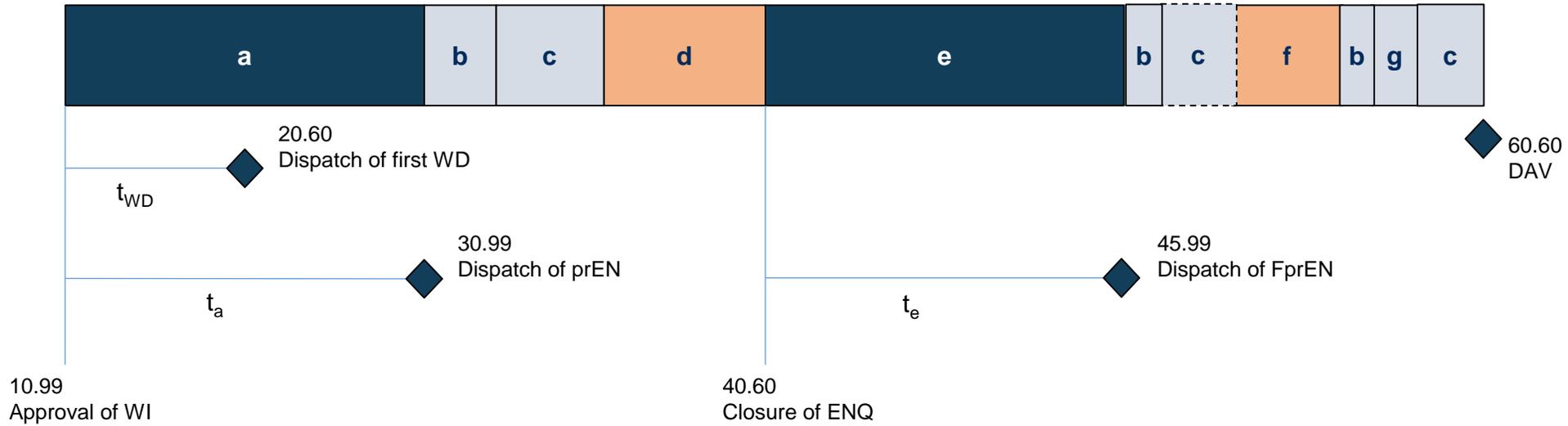


34

5 8 12

34

2 5 8 2 2 4 weeks



- 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

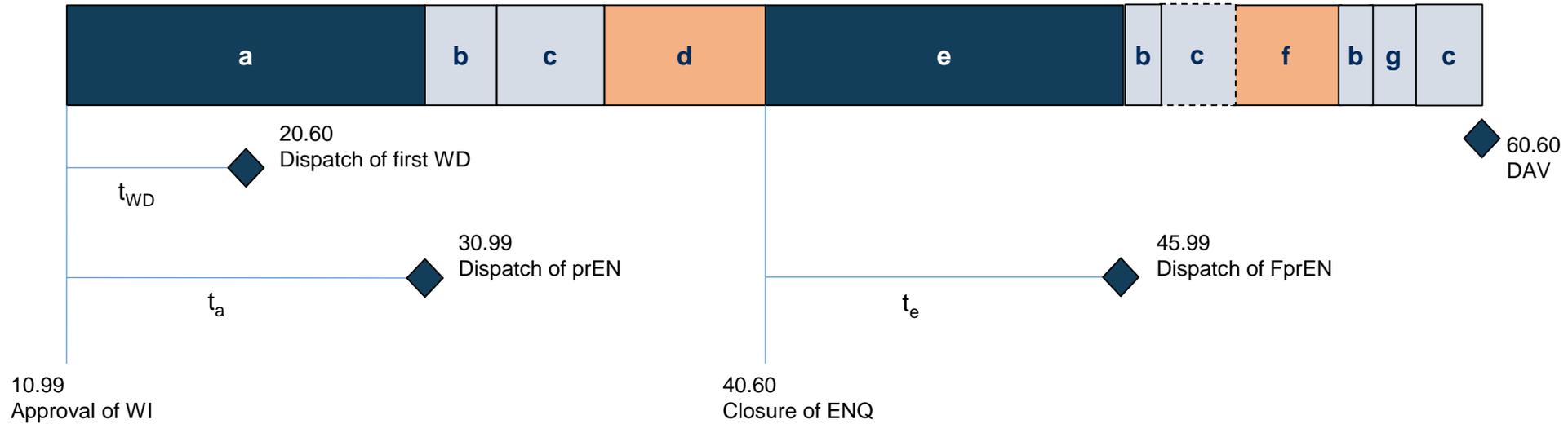
-  Internal process
-  *Optional* internal process
-  Technical work
-  Voting

flex

5 8 12

flex

2 5 8 2 2 4 weeks



- a Drafting of prEN
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-  Internal process
-  *Optional* internal process
-  Technical work
-  Voting

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)
- ▲ 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)

3 – Technical Report (TR)

- ▲ Informative document
 - ▲ to provide information on the technical content of standardization work
 - ▲ it may include e.g. data obtained from a survey, laboratory tests, data on work in other organizations
- ▲ 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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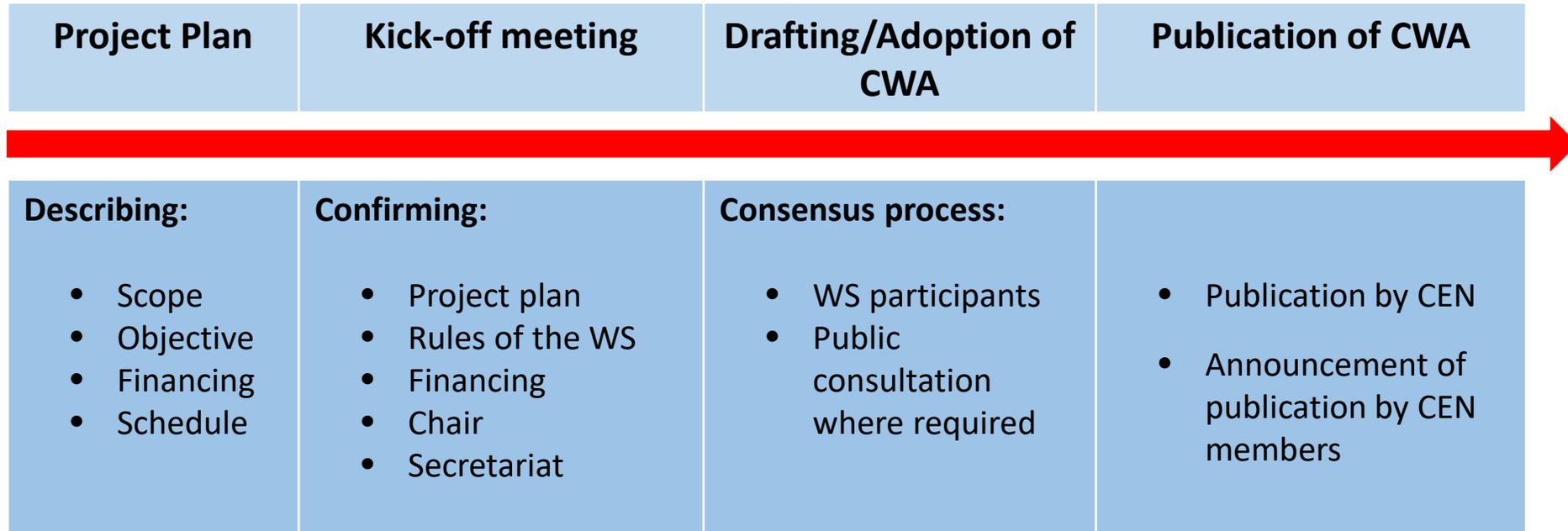
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- ▲ **Consensual** document developed in a Workshop
 - ▲ Flexible working platform with light procedures
 - ▲ Workshop participants are responsible for the CWA content
- ▲ **Open** to any company or organization inside / outside Europe
- ▲ Published 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 copyright
 - ▲ CWAs cannot be distributed or published freely on any website

4 - CWA



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



In Europe, harmonization means
1 solution instead of 34

Whenever possible, Europe's preference is

1 global solution



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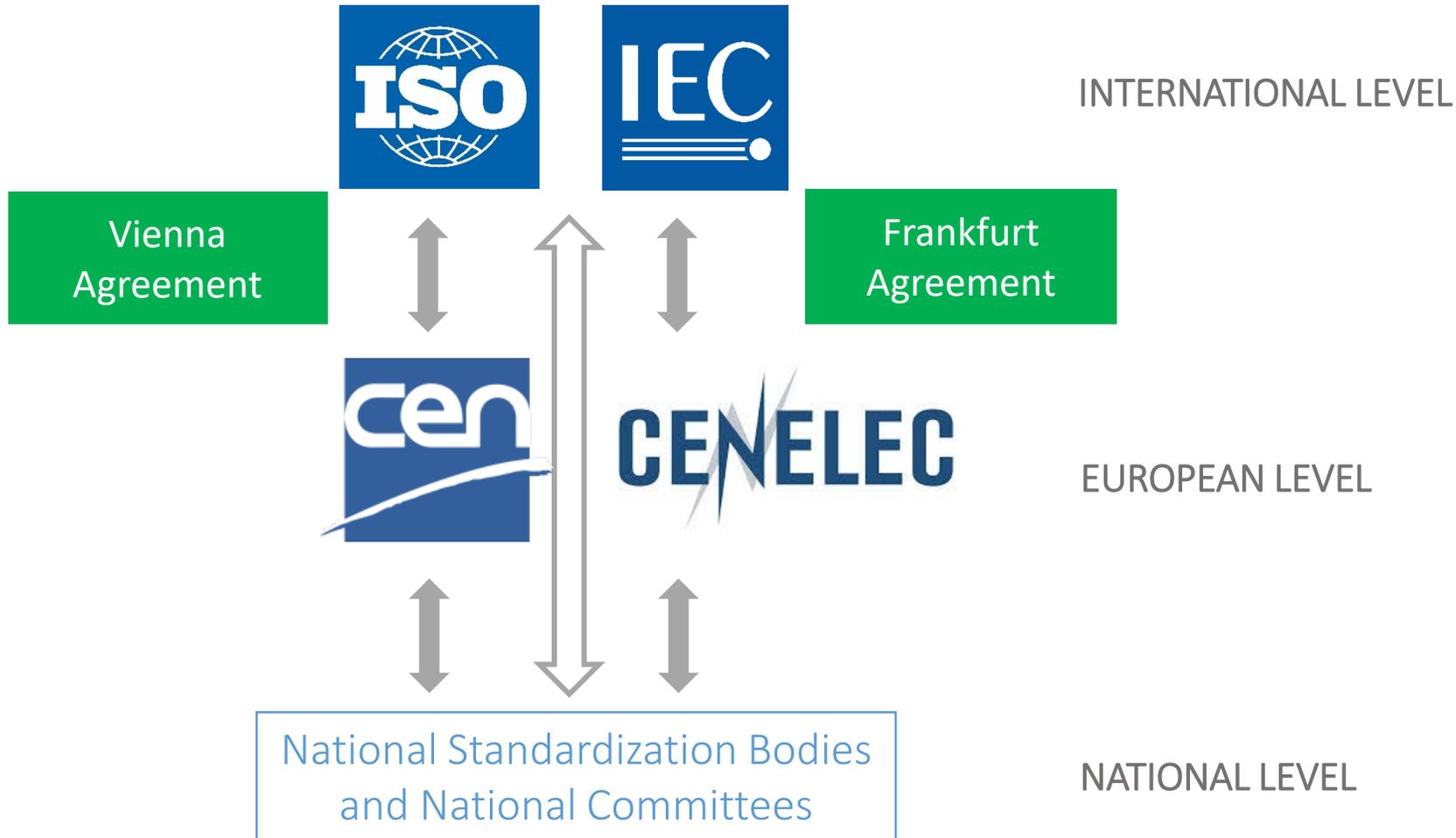
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3. International dimension – Vienna & Frankfurt Agreements

International dimension – Vienna Agreement



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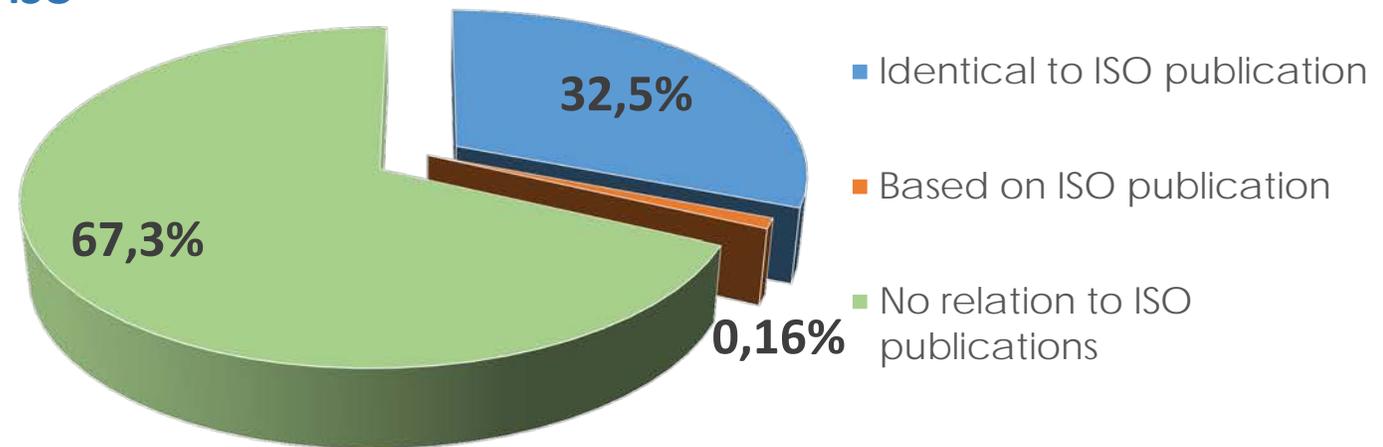
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What?	When?	Why?
<ul style="list-style-type: none">• Formal agreement on technical cooperation between ISO and CEN	<ul style="list-style-type: none">• 1991 - Published• 2001 - Revision• 2016 'Guidelines on implementation'	<ul style="list-style-type: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

CEN – Portfolio – relation to ISO

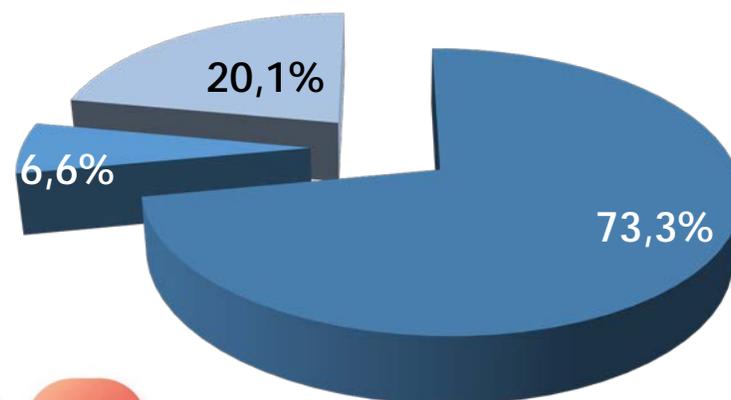


CENELEC/IEC – Frankfurt Agreement



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:

- ▲ Machinery
- ▲ Lifts
- ▲ Construction
- ▲ Low voltage equipment
- ▲ Pressure equipment
- ▲ Packaging and packaging waste
- ▲ Medical devices

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

✓ Standards can be developed in support of the legislation through 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



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Hierarchy

How Standardization supports legislation



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**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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

standardisation process. National standardisation bodies should also encourage and facilitate the participation of stakeholders.

- (3) European standardisation also helps to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation. European standardisation reinforces the global competitiveness of European industry especially when established in coordination with the international standardisation bodies, namely the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU). Standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved



Evolution from **Directives 83/189/EEC** of 28 March 1983 and **98/34/EC** of 22 June 1998

- ▲ 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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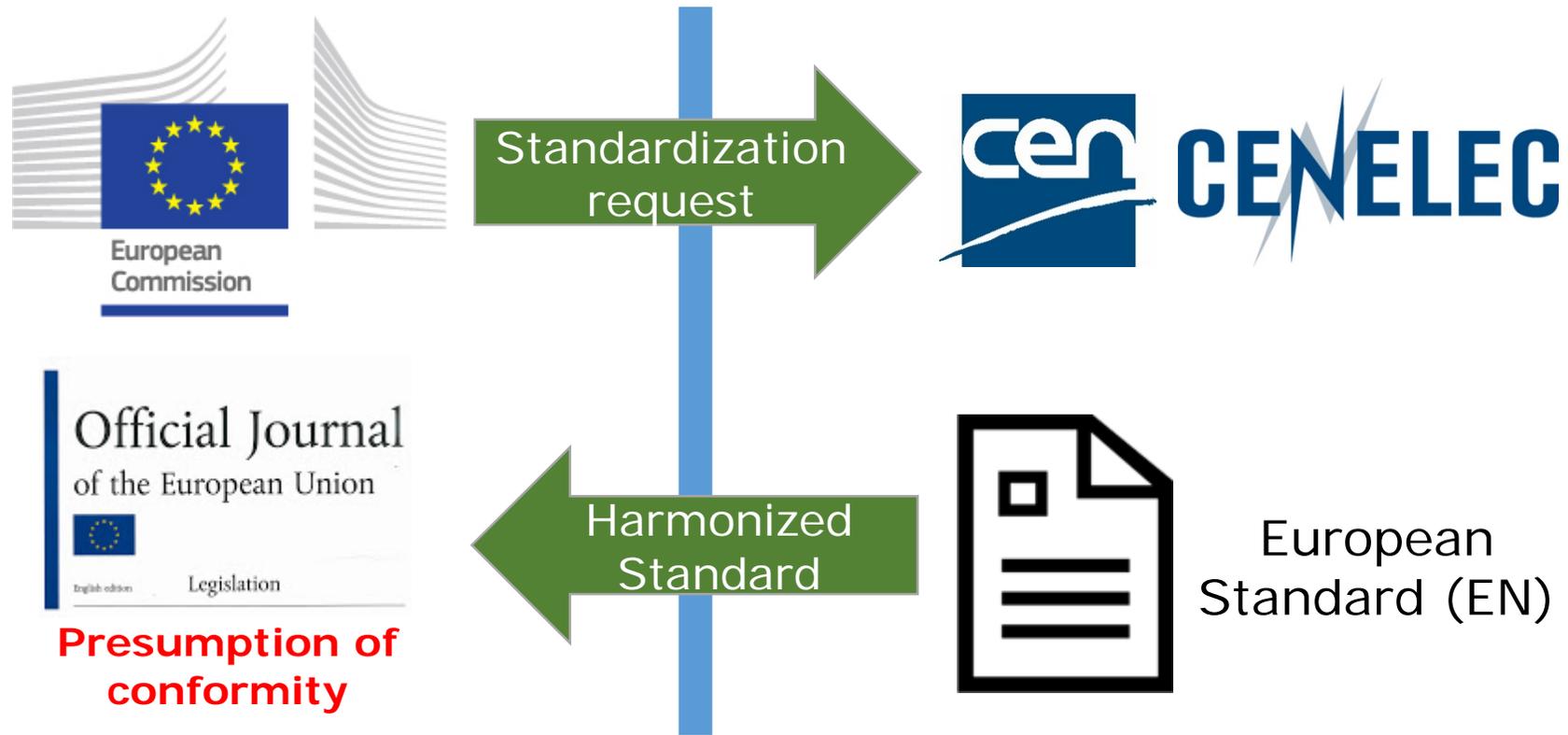
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4000 harmonized standards (hENs) listed in the Official Journal European Union

- **Standardization Request** a precondition for citation of harmonized standards in Official Journal of the European Union (OJEU)
- **Assessment** of compliance with legal requirements
- **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

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.

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 Union.

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

The European Commission changes 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

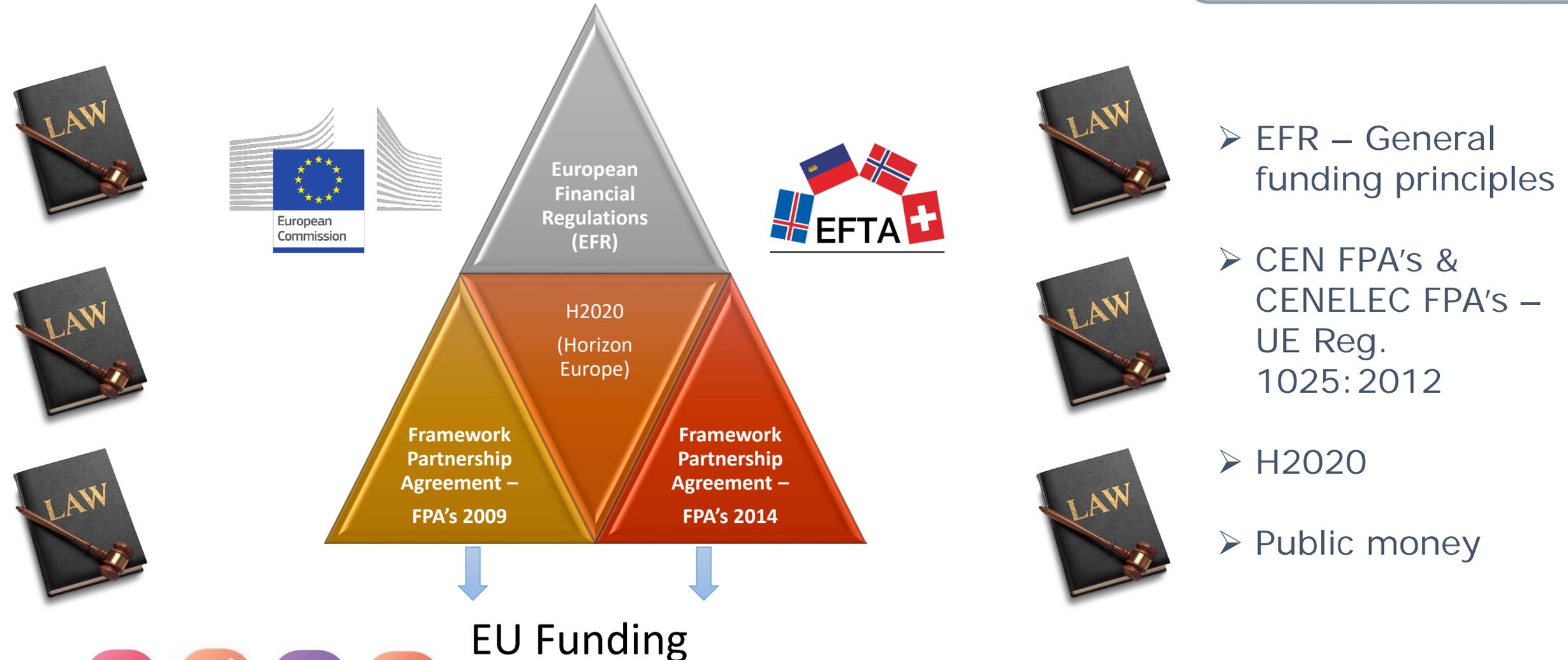
- **After** – standards are cited in the L series of the OJEU through a Commission Implementing Decision.

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>

5. Requesting funding for developing standards

Legal Framework



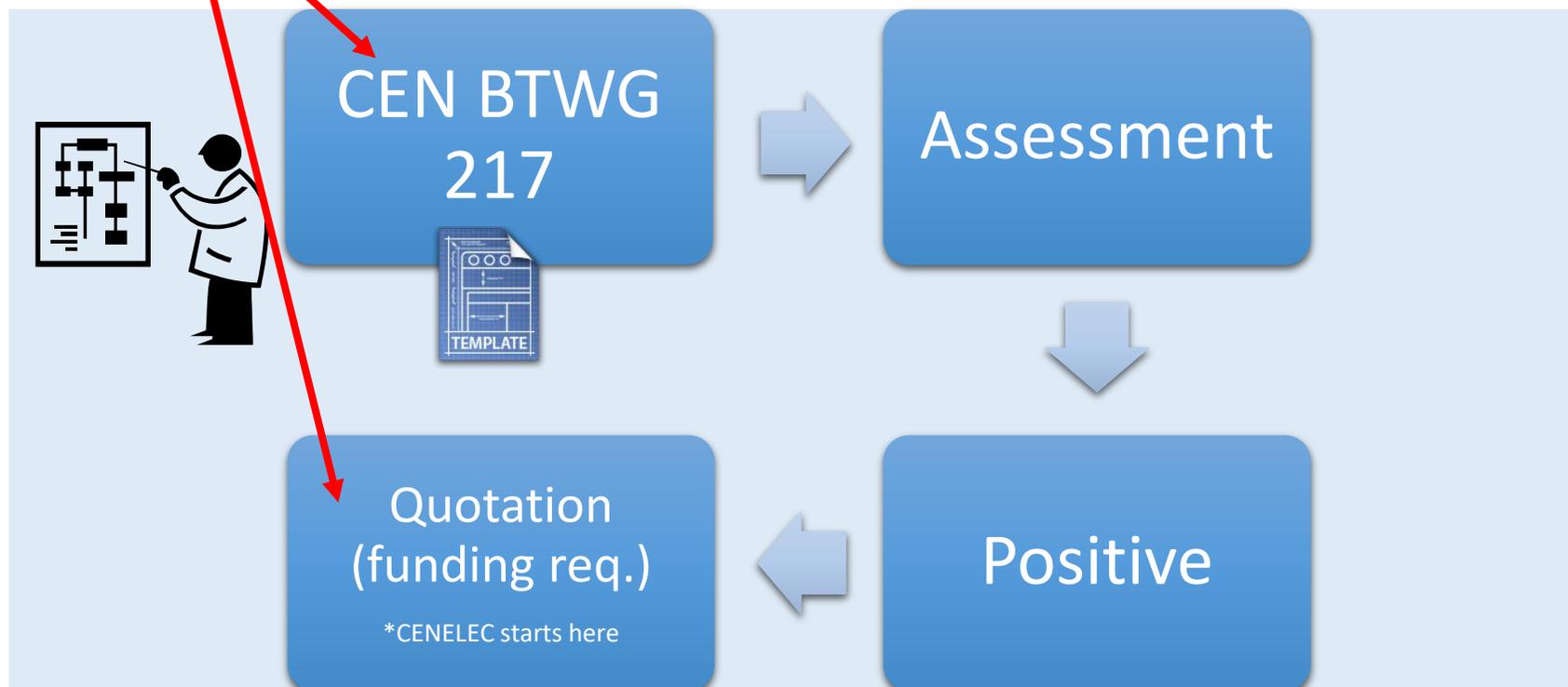
- EFR – General funding principles
- CEN FPA's & CENELEC FPA's – UE Reg. 1025:2012
- H2020
- Public money

- Standardization activities relevant for the European market (Prioritization of the BTWG 217)
- Standardization activities related to topics of possible interest of the European Commission!

Preparatory work to the funding req.



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

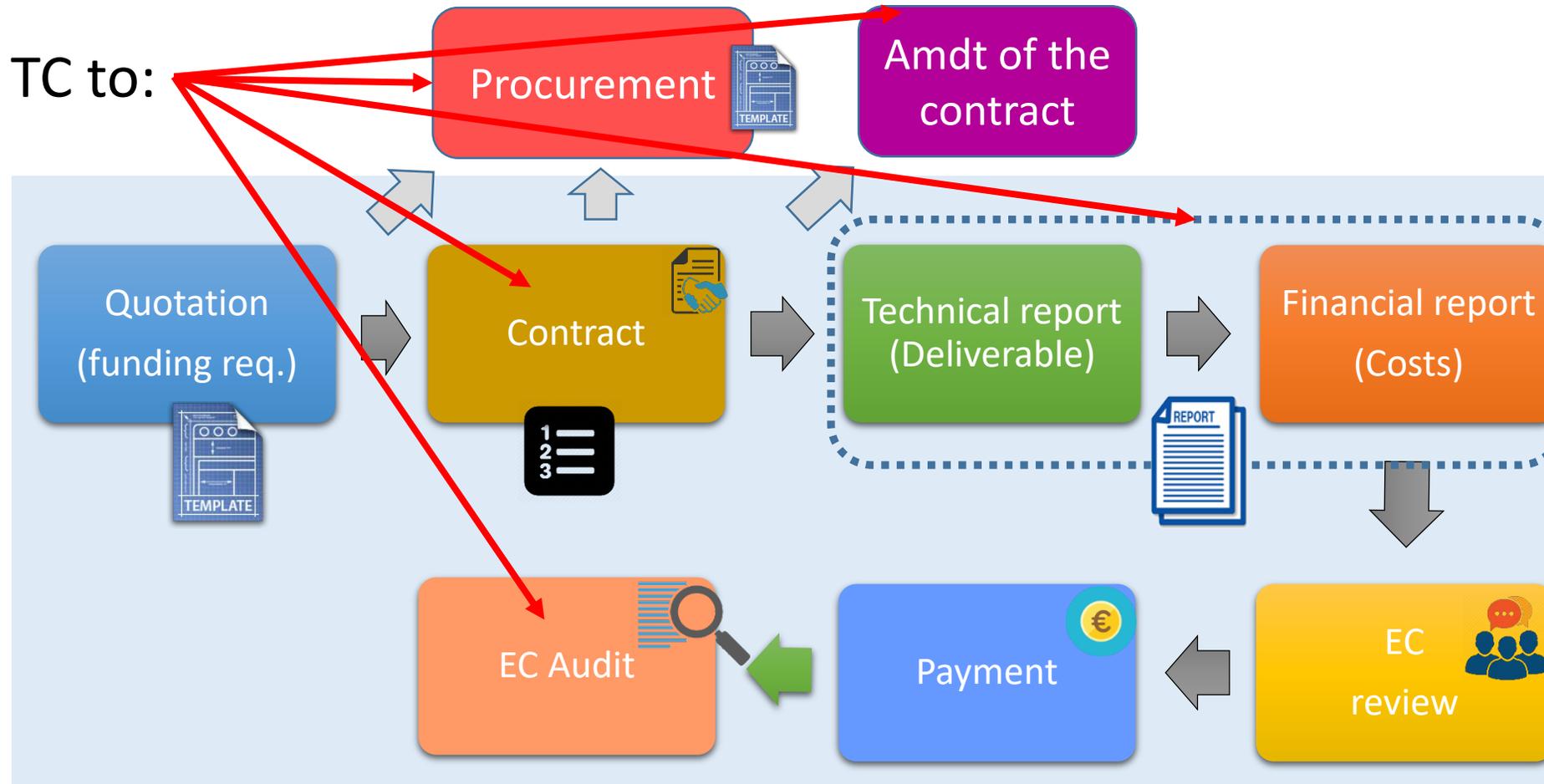


- Prioritization of contracts proposals
- BT members
- Assessment criteria

- 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)
- Audit → Max. 5 years later

Questions or doubts for quotations and contracts?



➤ Contact CCMC!



6. Recent Guidance documents



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- Best practices for improving effectiveness of working group meetings ([CEN](#)) ([CENELEC](#))
- Code of Conduct for delegates, experts and observers participating in the technical work of CEN/CENELEC ([CEN](#)) ([CENELEC](#))
- Matrix on Qualified support required to support development of (CEN) European standards to be offered for OJEU citation ([CEN](#))

Thank you! Questions?

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