

# Understanding the standardization process

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#### CONTENT



- Role and responsibilities of TCs and WGs
- From New Work Item to Publication
  - Focus: Enquiry procedure associated with Formal Vote
- Frankfurt Agreement day-to-day management
- Developing ENs intended to be cited in OJEU
- Information and guidance documents









## Role and responsibilities of TCs and WGs



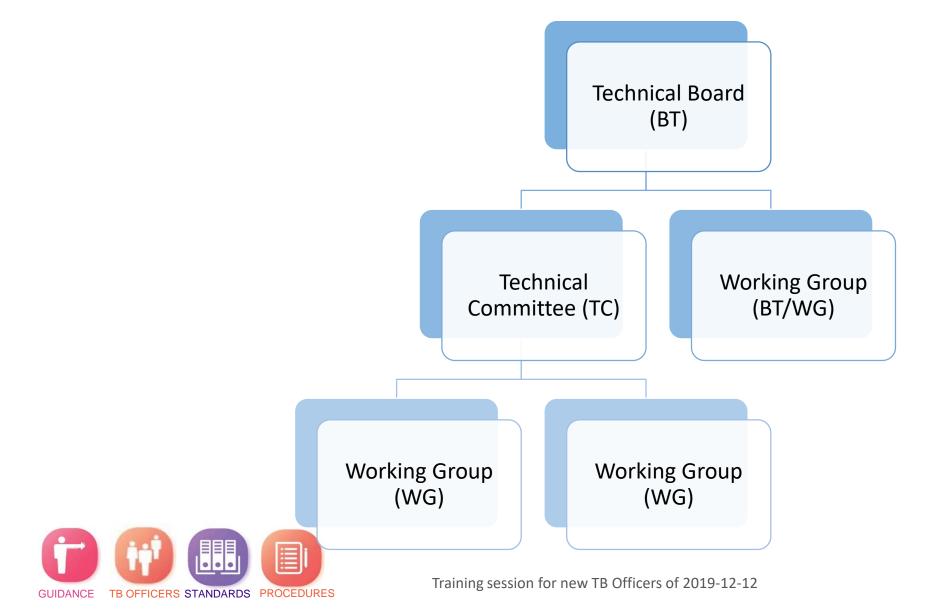






### The three-decision layers at technical level





### The three-decision layers at technical level



# **Technical Board** BT









### Technical Board



#### Composition

**Chairperson: CENELEC Vice President Technical** 

**Secretariat: CCMC** 

**Permanent Delegate: 1 per NC** 

Observers: ANEC, ECOS, CECED, European Commission...

#### Working

By correspondence (4 weeks) + 3 meetings/year









### Technical Board



#### Responsibilities

- Advises and decides on technical matters
  - organization, procedures, coordination, overlaps, etc.
- Monitoring of work programmes
- **Examines and decides on new projects (New Work Items)**
- **Approval/Rejection of Standardization Requests (SReqs)**
- Undertakes any task with regard to technical work as requested by the AG or CA
- 'Management by exception' principle







### The three-decision layers at technical level



# **Technical Committees** TC









### Technical Committees



#### Responsibilities

- **Established by CLC/BT**
- Precise title, scope and business plan
- **Responsible of drafting deliverables**
- **Support CCMC during the negotiations on standardization request**
- Timely execution of standardization request deliverables

#### Composition

- **Chairperson and Secretary**
- National Delegations (national position, voting right)
- **European Partners (observers, no voting right)**







### Technical Committees - Chairperson



#### Chairperson

- Neutral
- Appointed by CLC/BT
- Presides meetings and manages consensus
- Interface with CCMC (strategic directions, specific issues, external relationships,...)
- Ensures coordination and info exchange with other committees







### Technical Committees - Secretary



#### **Secretary**

- Appointed by NC holding the secretariat
- Ensures that TC works efficiently and agreed timetables are kept
- Prepares and distributes documents (agenda, reports, actions, decisions, etc.)
- Manages documents distribution via Collaboration Tool
- Is aware of CLC/BT decisions related to technical work and provide inputs when needed
- Coordinate and exchange with other committees
- Liaises with CEN-CENELEC Management Centre (CCMC)
- Ensures coordination and info exchange with other committees
- In case of Standardization Requests responsible for preparing reports









### Technical Committees - Composition



#### **National delegations**















### Technical Committees - Composition



**Secretariat:** Allocated by BT (to a Member)

**Chair:** Appointed by BT

**CENELEC** Technical Committee

**CEN-CENELEC Guide 25** 

'The concept of Partnership with **European organisations and other** stakeholders'

#### **CENELEC** Members

Max. 3 delegates - Vote

**European Partners (including Annex III)** 

Observer – No vote

ISO/IEC

Observer – No vote

**European Commission/EFTA** 

Observer - No vote

Liaison officers from other TCs

Observer – No vote









Observer – No vote

**Affiliates** 

Partner St. Bodies

© CENELEC 2019

### Technical Committees - Meeting



#### General

 Recommendation to have every 2<sup>nd</sup> plenary meeting is held in Brussels (CEN-CENELEC Meeting Centre)

#### Before the meeting

- TC secretary
  - circulates agenda (2 months before) and documents for discussion (4 weeks before) → templates available on <u>CLC BOSS</u>
  - uploads documents on Collaboration Tool
  - TC Work programme available on Projex online (excel or word version)
  - 'ERAS' attendance list to be used (meeting attendance)



### Technical Committees - Meeting



#### After the meeting

- TC secretary
  - issues report (template available on CLC BOSS)
  - to be sent back to CCMC (dataservice@cencenelec.eu) within 6 weeks incl. corrections to database, WG info, NWI form, ...
- CCMC
  - issues a cover sheet to TC report highlighting elements for which a BT decision is needed (scope, questions of principles, new work item requests, etc.)
  - If needed: put additional info on non-technical issue added
  - sends report to BT (usually through dispatch by correspondence)





### The three-decision layers at technical level



# **Working Groups** WG









## Working Groups (3)



#### Working Group(s)

- **Established by TC**
- Short term task
- Individual experts appointed by the NCs

#### **Working Group Convenor**

- Seeks support from the parent body (if needed)
- **Ensures that WG experts knows rules and procedures**
- Responsible for sending drafts to the TC
- Actively progresses work and reports regularly to the TC











### Smooth and efficient meeting



#### BT decision D160/003

- Efficient and smooth cooperation between TC (WG) experts, delegates and observers contributing to the development of standards is fundamental:
- Code of Conduct for experts participating in CEN and CLC (technical work) here
- Best practices for improving effectiveness of WG meetings here





### From Work Item to publication



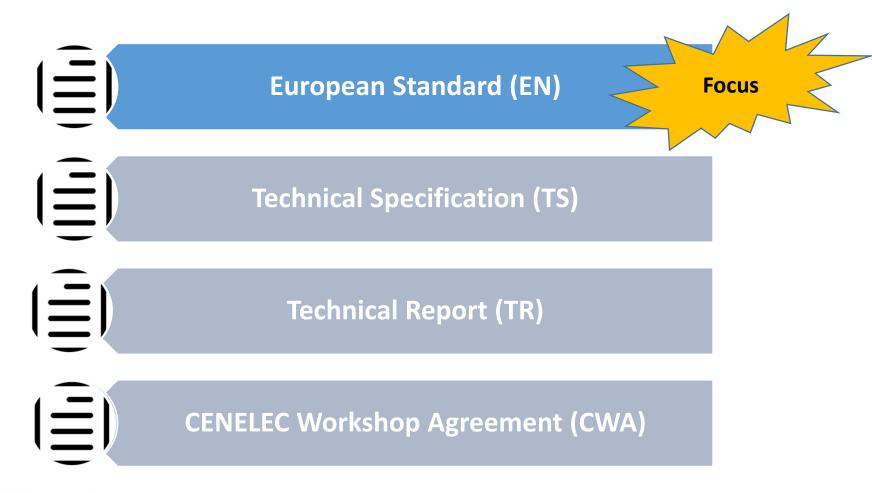






### Deliverables developed by TCs













### How are standards made?



Proposal - evaluation and decision

Drafting and consensus building

**Public enquiry** 

**Consideration of comments** 

Approval of the standard

**Publication** 





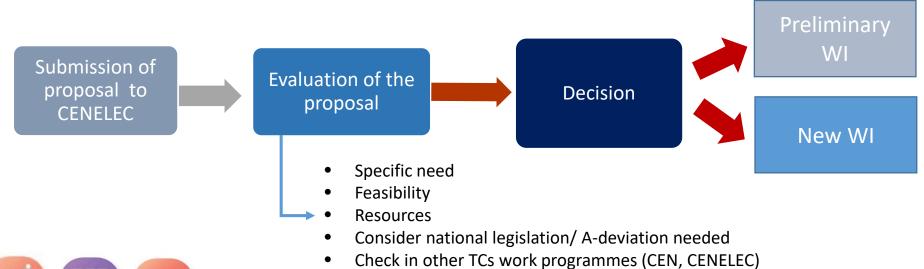


### Proposal - Evaluation and decision



#### **Proposals may originate from:**

- Existing Technical Committees
- European Commission or Agency
- National Committees (NCs)
- CENELEC Partner Organizations



## New project



#### **New Work Item**

Template mandatory with a justification for not offering it to IEC!!

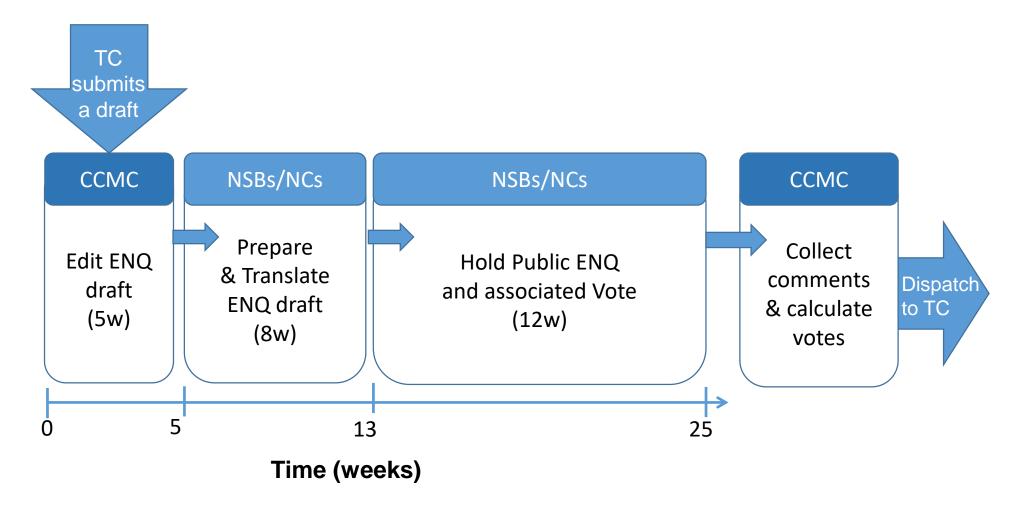
- Precise information needed (e.g. superseding EN(s), link with IEC, possible a-deviation(s), link with EU regulation, ...)
- TC decision: 5 members committed to actively participate
- Filled in template to be sent to <u>dataservice@cencenelec.eu</u>
- BT decision (by correspondence)
- If approved → standstill
- WI in TC work programme → timeframe to be respected!
   → alerts sent by CCMC to TCs



CENI	ELEC	Ne	w Wor	k Item	Propos	al			
		TC N	lame		TC_I	NAME			
		TC T	TC Title			TC_TITLE			
		Secr	etariat:	NC	Date	of proposal:	Y	YYY-N	IM-DD
			INFO	RMATION	ON THE V	ORK ITEM			
Title									
English	Tile_en								
French (Optional)	000002001								
German (Optional)	Tile de								
Scope Scope									
This proposal relates to the creation of a new project in the committee's work programme (stage 10.99) the creation of a preliminary project in the committee's work programme (stage 00.60) The activation of a project currently registered as a Preliminary Work Item in the committee's work programme PWI PWI_NR									
Deliverab	le								
■ Euro	pean Standard		Harmoniz	ation Docu	ment 🔲	Technical Spec	fication		Technical Rep
This item	corresponds to								
	project	ive a iu	Amendme			w version (revision	) [	] Co	onversion TS to
	Explain the purpose and give a justification for this proposal purpose_justification								

### Public Enquiry











### Consideration of comments



Possibility to use the CLC TC Committee Internal Voting (CIV) to take Analysis of decisions to skip the vote comments and voting results Skip Formal Vote Keep Formal Vote If: - Simple Majority; Analysis of comments and voting results 71% positive weighted votes; Positive consultant assessment TC Decision Simple majority Formal Vote Draft **Publication** Decision TC finalises the final draft and dispatches it to CCMC No technical changes allowed with regard to ENQ draft



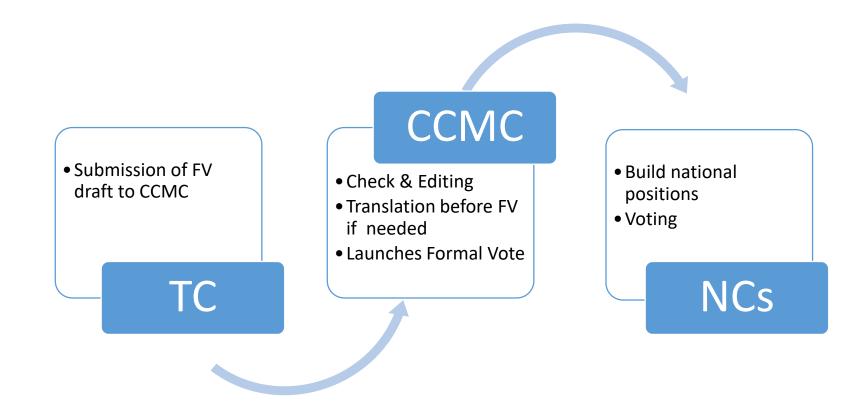






### Approval of the standard





71% positive votes (weighted) → approved European Standard









### Approval of the standard



Member country	Weighting	Member country	Weighting
France	29	Switzerland	10
Germany	29	Serbia	7
Italy	29	Croatia	7
United Kingdom	29	Denmark	7
Turkey	29	Finland	7
Poland	27	Ireland	7
Spain	27	Lithuania	7
Romania	14	Norway	7
Netherlands	13	Slovakia	7
Belgium	12	Cyprus	4
Czech Republic	12	Estonia	4
Greece	12	Latvia	4
Hungary	12	Luxembourg	4
Portugal	12	Slovenia	4
Austria	10	FYROM	4
Bulgaria	10	Iceland	3
Sweden	10	Malta	3
		TOTAL	412





Vote simulation tool available on CENELEC website: here

### Publication



#### CCMC

- Finalizes and publishes the EN
- **Provides EN to National Committees for national publication**
- **Provide titles to European Commission (if harmonized standard)**

#### **Members**

- Publish as national standard
- **Withdraw** conflicting standard(s)
- May translate into national language







## Amendments, corrigenda & maintenance



#### **Amendments**

- Modification/addition to or deletion of specific parts of the text
- Only the amended text will be voted upon
- If amended → NWI request needed → Track: Enquiry (+ vote)

#### Corrigenda

- TC rationale needed
- Corrects mistakes that lead to incorrect/unsafe use of EN
- TC to contact CCMC Publication unit

#### Maintenance

- **Process initiated by CCMC (alerts sent)**
- TC to ensure that EN content is still valid 5 years after publication
- If revision → NWI request needed → Track: Enquiry (+ vote)









## Drafting, Editing and Publishing of a European Deliverable







### Key points



- Useful tools to get you started
  - Internal Regulations Pt 3
  - Webinars
  - STD.dot template
- Timeframe
  - who does what? When?
- Document exchange and collaboration
  - What to expect from CCMC
  - What the editor expects from you









### Getting started



CEN/TC XXX

Date: 20XX-XX

pren xxxxx: xxxx

Secretariat: XXX

Introductory element — Main element — Complementary element

Einführendes Element — Haupt-Element — Ergänzendes Element Élément introductif — Élément central — Élément complémentaire

ICS:

CCMC will prepare and attach the official title page.

- Simple template
  - ▲ Find on CENELEC BOSS
- ▲ Ready-styled
- ▲ Contains all elements
  - Styles
  - ▲ Headings
  - ▲ Content layout









#### Drafter checklist



#### Annex A (informative)

#### Checklist for writers and editors of documents

The following checklist is a tool to help writers and editors of documents.

Task	Assessment	Done 🗹	Comments
Structure	Check table of contents:		
	Is the top-level structure logical?		
	Is the subdivision consistent?		
	Hanging paragraphs:		
	Check for and remove any hanging paragraphs.		
Use of plain	Is the text clear and concise?		
anguage	Are the sentences short? (check punctuation)		
Title	Is the title organized going from the more general to the more particular?		
	Does the title unintentionally limit the scope of the document?		
	Is it as clear and concise as possible?		
	Make sure that the title does not contain more than three elements.		
	If there are several parts, are the titles aligned?		
Foreword	Is the document a revision? If so, insert a revision statement including any amendments and technical corrigenda and a list of changes with respect to previous edition.		
	Are there any other organizations involved in the drafting that should be mentioned?		
Introduction	Is it purely informative?		
	Does it describe the content or give information on why the document is needed?		
Scope	Does it describe what the document does?		
	Does it state where it is applicable?		
	Does it only contain statements of fact?		
Normative references	Normative references clause: are all the references cited in the text actually normative?		
	Are the references dated or undated?		
	Are the references used ISO and IEC standards? If not, do suitable ISO and IEC standards exist which could be used instead?		
	Are the normative references publicly available?		
	References cited in a normative manner in the text: are all such references listed in Clause 2?		
Terms and	Are the terms listed used in the document?		
definitions	Do suitable terms exist in the terminology databases?		
	<ul> <li>http://www.electropedia.org/</li> <li>http://www.iso.org/obp</li> </ul>		
	Are the definitions correctly drafted?		

# Internal Regulations Pt 3 – Annex A

All potential issues & drafting requirements covered

Follows the structure of a European Standard

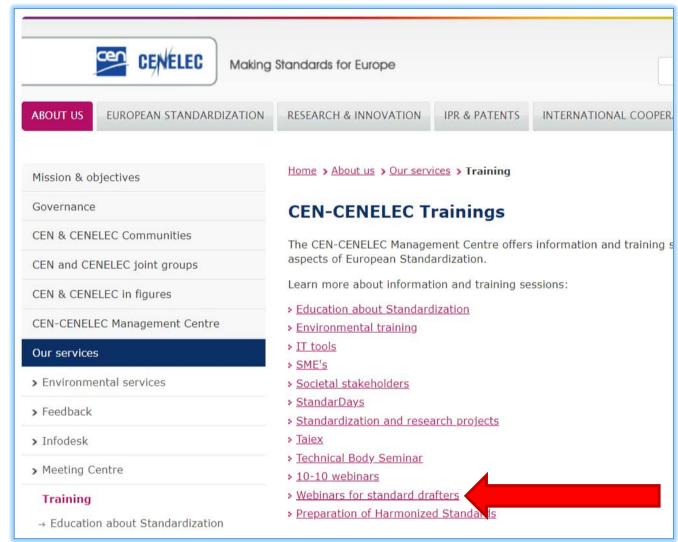
Training session for new TB Officers of 2019-12-12

Task	Assessment	Done  ☑	Comments
Figures	Does each figure have a concise title?		
	Is each figure numbered correctly?		
	Is there a key if necessary?		
	Are all figures cross-referenced in the text?		
Graphical symbols	Are symbols used taken from the ISO and IEC databases?		
	If not, contact IEC TC 3, IEC SC 3C and ISO/TC 145 in order to register a standardized symbol.		
Tables	Does each table have a concise title?		
	Is each table numbered correctly?		
	Are all tables cross-referenced in the text?		
Annexes	Is there a reference to each annex in the main part of the text?		
	Is their status (normative or informative) correct? Is this made clear in the main part of the text?		
Bibliography	Is it formatted consistently?		
	Are all the entries correct and complete?		
	Are any of them normative references that should be listed in Clause 2?		
	Are any of the listed documents duplicated in Clause 2?		
Drafting of provisions	Make sure that "shall", "should" or "may" are not used in the foreword, Scope or notes.		
	Make sure that "shall", is not used in the Introduction.		
	Are "may" and "can" used correctly?		
	Is "must" used anywhere in the document? Is "must" used correctly to mean external constraints?		
	Make sure that no requirements specifying compliance with national/legal regulations are included.		
Potential legal	Copyrights		
problems	Trademarks		
	Patents		
Conformity assessment	Are there potential conformity assessment issues?		
Cross-references	Are all cross-references correct?		
Common problems	Are symbols for variable quantities correctly formatted in the text and mathematical formulae?		
	Is a comma on the line used as the decimal sign?		
Other issues			

#### Webinars and online trainings



- CENCENELEC.eu
  - Accessible to all
- 10-10 webinars
- Webinars for standards drafters











### Webinars and online trainings



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- CENCENELEC.eu
  - Accessible to all
- 10-10 webinars
- Webinars for standards drafters

Home > About us > Our services > Training > Webinars for standard drafters



Two webinars are organized in 2018 for the drafters of CEN & CENELEC standards. Both webinars aim primarily Technical Body Secretaries and TC Working Group convenors.

Through these webinars we will achieve a common understanding of the drafting rules and the related procedures. This is also an ideal opportunity for CCMC editors to better understand TCs' expectations and strengthen working relationships with Technical Bodies.

#### Check our 2018 calendar of webinars for standard drafters

17 SEPTEMBER 2018 - 10:00 TO 11:00 (CEST)

#### Webinar for standard drafters - Checklist for writers and editors of documents

- > Discover the scope of this webinar
- Download the <u>Powerpoint presentation</u> (PDF format)
- Download the <u>Questions & Answers</u> raised (PDF format)
- Listen to the video recording SOON AVAILABLE

6 NOVEMBER 2018 - 10:00 TO 11:00 (CET)

#### Webinar for standard drafters - Conformity assessment

- > Discover the scope of this webinar
- Download the Powerpoint presentation (PDF format) SOON AVAILABLE
- Download the Questions & Answers raised (PDF format) SOON AVAILABLE
- > Listen to the video recording soon available SOON AVAILABLE

#### Past webinars presentations and Questions & Answers:

- 2016 webinars
- 2017 webinars





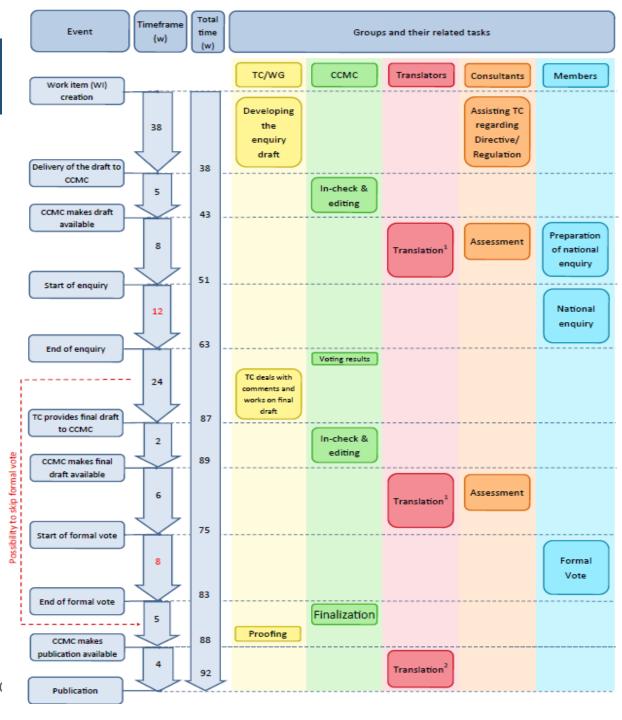


# Document exchange and collaboration

#### ENQUIRY

- In-depth edit (5 weeks)
- Translation (8 weeks)
- Formal Vote (can skip)
  - In-depth edit (2 weeks)
  - Translation
- Publication
  - Light edit & comments (2 weeks)
  - TC proofing (2 weeks 3 for exceptional cases)
  - Translation (4 weeks)





# Enquiry (ENQ) & Formal Vote (FV)



#### **Electronic Transmission Notice**



All documents submitted to CCMC shall comply with the CEN-CENELEC Internal Regulations Part 3
"Rules for the structure and drafting of CEN-CENELEC Publications"

Reference Number :		
Work Item Number:		
Title:		
Sending date:		
With reference to the above, find in attachment, the electronic files appertaining to the following procedure:		
Stage 20.60 (first working draft)		
□ COCOR Vote		
☐ Enquiry ☐ 2 <sup>na</sup> Enquiry		
Formal Vote 2 <sup>nd</sup> FV Reference of CENTC decision to launch FV (for CEN ENs only):		
□ Vote on Technical Specification		
□ Vote on Technical Report		
□ 3 month UAP □ Reference of decision to launch UAP (For CEN only):		
Publication In case of decision to skip FV following ENQ. Reference of CENTC decision (For CEN only):		
□ Corrigendum		
The text is sent in the following ONE Reference language version in PDE and revisable Word format:		

#### Via email:

- Word (.doc/.docx) and PDF files
- Transmission notice

- Figure files (not compulsory, but <u>VERY</u> useful!)
- Anything we need to know? Comments!

#### COMMENTS:

FROM:

Name: Technical Body:	

# Enquiry stage (ENQ)

### In-depth edit (5 weeks)

- Full, thorough edit (Internal Regulations Pt 3):
  - No hanging paragraphs
  - Normative references (incl. dating, if necessary)
  - No requirements, recommendations or permissions in:
    - Scope/Introduction (requirements)
    - Notes
  - Annexes Z (if applicable)
  - Cross-references

Translation (8 weeks) + consultant











**NO NEWS** 

**GOOD NEWS!** 

# Formal Vote stage (FV)

### In-depth edit (2 weeks)

- Use ENQ text when drafting your FV!
- Edit as per ENQ

#### **Translation:**

- Default no translation
- IF CANDIDATE AND HARMONIZED 6 weeks + assessment
- IF DKE/AFNOR REQUEST TRANS. DURING ENQ 6 weeks













### Editing (2 weeks)

- Light editing only editorial changes + formatting
- Comments handling only editorial comments accepted
  - What is a technical change?
    - Changes the scope of a requirement
    - Adds a requirement
    - Removes a requirement

      Some fundamental chocolate requirements of product and exposure necessary for the scenario to certai in wrappings are This refersin papalstic and tinded and interpolated and interpolate



003

Accepted.

Mg to be replaced by Mw



- Comments at FV (D163/029)
  - Editorial or technical changes to the drafts after their submission to Formal Vote is not accepted  $\rightarrow$  Only 2 kinds of comments (and corrections) acceptable:
    - Obvious editorial error & errors introduced by CCMC in the preparation of the draft
    - All other comments retained for next review!
- Applicable as of 2019-12-01
- Technical change aiming to correct errors and thus avoiding a deficient standard, according to Decision BT 48/2014 & D149/017  $\rightarrow$  Upon request of the TC secretary and following BT approval, these changes will be introduced by CCMC before publication  $\rightarrow$  only limited technical changes !!









- TC proofing (D163/029)
  - CCMC to send the final draft not only to TC secretaries but also to WG convenor (provided that the necessary emails are available in our database)
  - Reduced from **3 to 2 weeks**, BUT extendable to 3 upon request of TC
  - Not to wait for TC reply after 2 (3) weeks: in case of no response, CCMC shall proceed to the finalization, i.e. translation or immediate publication, and inform the TC secretary and secretariat accordingly (in line with D157/016);
- Provisions will be applied to drafts that are submitted to CCMC for the editorial preparation for FV from 2019-12-09









#### YOUR DEADLINE = 2019-

#### In case of no response, we shall assume that you agree to the immediate publication.

Dear [TC NAME],

The above mentioned standard is now ready for publication.

As responsible Secretary you are now invited to check this document in its totality, before the above mentioned deadline.

The project has been finalised for publication.

Enclosed is the following material:

- a clean version (EN :201X) of the document, in word format (without title page) and pdf format, as we intend to publish it;
- the voting results from the approval procedure.
- the comments from the approval procedure, including remarks for your attention.

It is our understanding that your confirmation is an acknowledgement that no further modifications will be brought to the text and that the document, as presented, can be published.

Should you be unable to meet the above mentioned deadline, please let me know as soon as possible

With kind Regards,

Amy Jayne CONLEY



#### TC Proofing (2 weeks)

- Comments file with editor response ([TC]\_[WI]vote1\_res)
- Clean PDF as we intend to publish (ENXXX{201X}e.pdf)
- Marked-up document with all changes (ENXXX{201X}e stm)

#### Your role:

- Check ALL comments
- Check the WHOLE standard
- Reply to editor comments in comments file









#### Translation (4 weeks)

- DKE and AFNOR German and French
- No translation for Technical Reports
  - -> straight to Publication

# **Publication**

Always on Friday (as is the launch of enquiries and votes)











# **Frankfurt Agreement Day-to-day management**







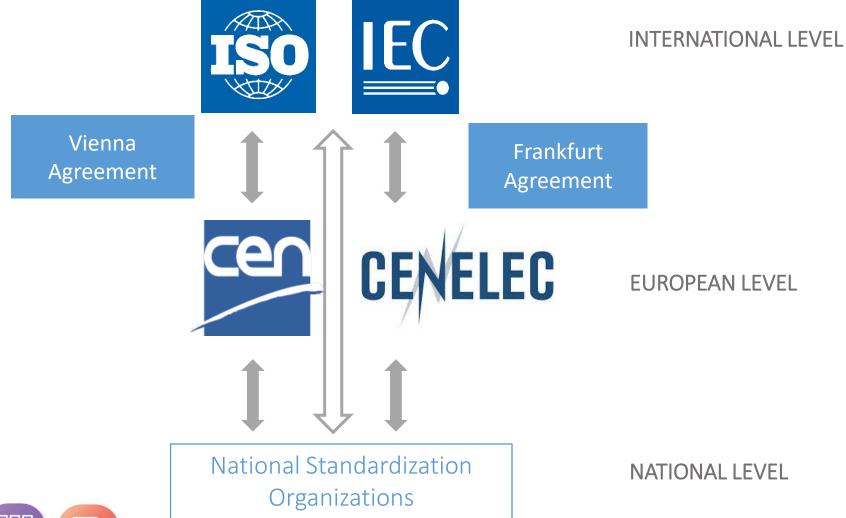






# International dimension - Frankfurt Agreement











### International dimension



### **Primacy of International standards**

- Commitment to primarily undertake the work at IEC level
- Expedite publication and common adoption of International Standards
- Rational use of available resources/avoid duplication
- Accelerate standards preparation process in response to market demands
- Include mechanisms to cater for particular needs that may arise from European stakeholders

#### Supporting the European Market, using global standards









### International dimension





#### Global network of 173 countries

covering 99% of world population and electricity generation and directly impacting 20% of international trade

- → Product safety and quality
- → Interoperable ecosystems
- → Technical source for laws and regulations
- → Independent, neutral, inclusive (one country, one vote)
- → Technical Barriers to Trade (TBT) Agreement











# International dimension Added value of CENELEC to IEC standards





1 region = one standard in stead of 34

- → Status of EN
- → Standstill
- → Obligation to implement

30% CENELEC portfolio = harmonized standards

C E Presumption of conformity



Access to European Market of 600 Million consumers using global standards

# Facts and figures



#### What?

Agreement on common planning of new work and parallel voting between IFC and CFNFLFC

#### When?

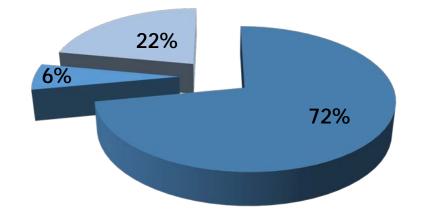
- 1996 Signature **Dresden Agreement**
- 2016 Signature Frankfurt Agreement

#### 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

Only European Standards (no TS, no TR, no Guides) are covered by the Frankfurt Agreement



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





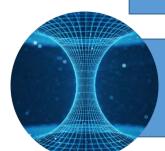




# Frankfurt Agreement 4 pillars







Parallel voting on draft International Standards



**Publication Requirements** 



Conversion of European Standards into International Standards





# Common planning of New Work Items



#### Work initiated in IEC

### (New work (NP) or result of review (RR))

- When not 'exempted'
  - Assigned to mirroring CLC Technical Committee or Reporting Secretariat
  - Registered in CLC database with timescales
  - Information e.g. on legislative aspects  $\rightarrow$  feedback to IEC
  - Parallel adoption process starts in CENELEC
- When 'exempted'
  - No 'European adoption' but national adoption possible
  - Standstill may apply  $\rightarrow$  to be **used 'as such'** in Europe, no competing standards







# Common planning of New Work Items



# Work initiated in CENELEC (NWI)

Before initiating:

Assess situation at IEC on overlaps, the possibility the IEC TC timely initiates the work

- On approval of a New Work Item for a European standard at CENELEC
  - Default\*: the New Work Item is offered to IFC
  - The CLC/TC starts the work IEC starts a NWIP on the WI
  - If IEC NWIP accepted → CLC hands over work
  - \* For specific reasons, the CLC Technical Board (BT) can decide not to offer







# Parallel voting on draft international standards



It is important to start parallel work from the earliest stages!! From CDV on systematic parallel voting procedure in CENELEC

CENELEC IEC Start work (NP – RR) Start parallel work CD Consult TC on CD **COMMON MODIFICATIONS** parallel vote on CDV **COMMON MODIFICATIONS** (parallel vote on FDIS) (FDIS) **COMMON MODIFICATIONS International standard EN IEC & EN IEC A1x** 





# Parallel voting on draft international standards





>75% IEC standards follow // CLC procedures 80% IEC standards -> European Standards

> 80% of all European Standards (consolidated main and amendments) are identical to or based on IEC standards











# Parallel voting on draft international standards





Why not 100%?

#### By CLC BT decision some IEC Standards are

- Permanently exempted
- Temporarily exempted from parallel procedures
  - for a specific version
  - for adoption after IEC publication
- Exempted to be used as such in Europe (standstill)
  - **Databases**
  - Standard referred to in international legislation
  - PCB, electronics,...







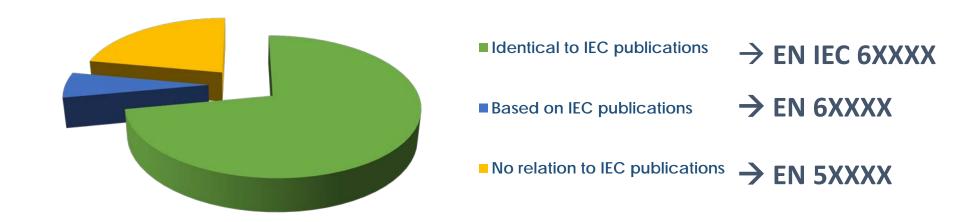


# Publication requirements



**Application of ISO/IEC Guide 21** 

From 2018 on: EN IEC-referencing











## Conversion of European Standards into International Standards



- CENELEC deliverables of European origin ('homegrown standards') offered to IEC
- European common Modifications to IEC based standards
- If IEC Technical Body takes them on board:
  - IEC text identical to CENELEC text = 'Boomerang case'
    - No parallel voting
    - Once IEC published: corrigendum to EN (numbering)
  - IEC text different from CENELEC text → parallel vote









# Developing ENs intended to be cited in OJEU



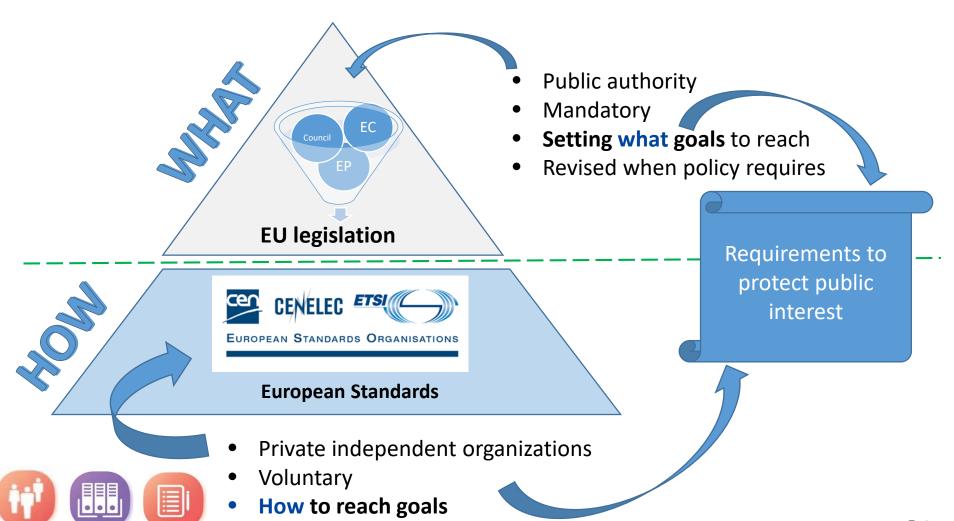




# EU legislation and European standards

TB OFFICERS STANDARDS PROCEDURES

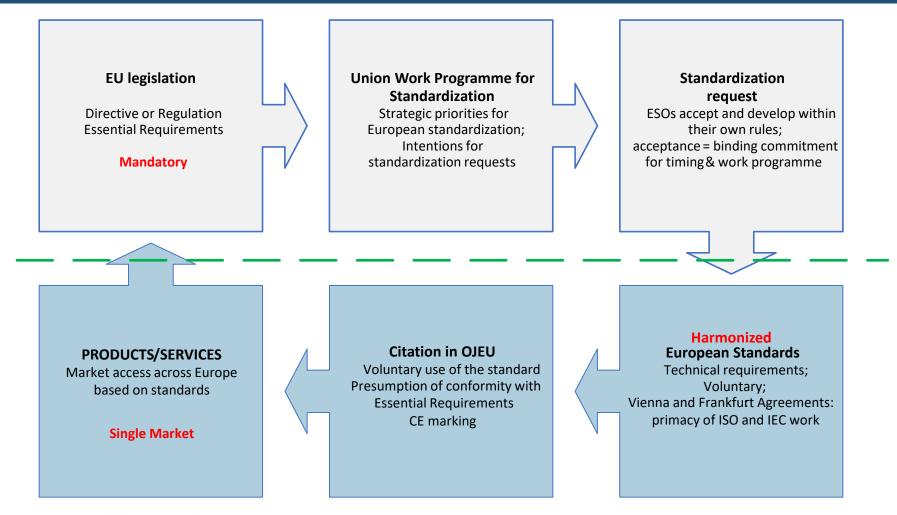




State of the art; 5-year review cycle

## Harmonized standards process defined in Reg. 1025/2012













## EU legislation



#### **EU** legislation

**Directive or Regulation Essential Requirements** 

**Mandatory** 

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

- ▲ Low voltage equipment (2014/35/EU)
- ▲ Electromagnetic compatibility (2014/30/EU)
- Equipment and protective systems in Explosive Atmosphere (94/9/EC)
- ▲ Rail (2008/57/EC)
- ▲ Machinery (2006/42/EC)
- Medical devices (93/42/EEC and 98/79/EC → 2017/745/EU and ) 2017/746/EU)
- ✓ Standards can be developed in support of the legislation through the New Legislative Framework (New Approach)









# EU legislation



# **EU** legislation

**Directive or Regulation Essential Requirements** 

**Mandatory** 

### **New Approach Directives**

- Define essential requirements (e.g. heath and safety)
- Indicate WHAT shall be achieved without specifying **HOW**
- Transposed in Member States

#### Reference to standards

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









# Standardization Request



#### Standardization request

ESOs accept and develop within their own rules; acceptance = binding commitment for timing & work programme

Refer to the legislation / Requested standardisation activities policy Work programme of requested deliverables; Establishment of the work programme responsible technical bodies; timeframe. Agreement on the work programme EC to be informed/consulted of any changes in the WP Reporting Annual reporting Clear and precise description of Harmonised standards relationship between hEN and EU legislation **Validity** Requirements of the hENs Harmonised standards and ANNEXES deadlines for adoption









### Harmonized standards



#### Harmonized

#### **European Standards**

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

### ▲ Regulation 1025/2012 - Article 10.5

The Commission together with the European standardization organizations shall assess the compliance of the documents drafted by the European standardization organizations with its initial request.

- Exact Coverage of applicable legal requirements
  - Essential requirements/Safety Objectives
  - Other requirements in Standardization Request 5SME, Annex III, ...)
- Compliance with formal requirements
  - VADEMECUM
  - Verification document (Ares(2016)6548298 22/11/2016)









### Harmonized standards



#### **Harmonized**

#### **European Standards**

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

- ▲ EC Vademecum on European Standardization art. 7.2
- ESOs 'Self-assessment'
- Independent Experts **HAS Consultants**

**(>2018/04/01)** 

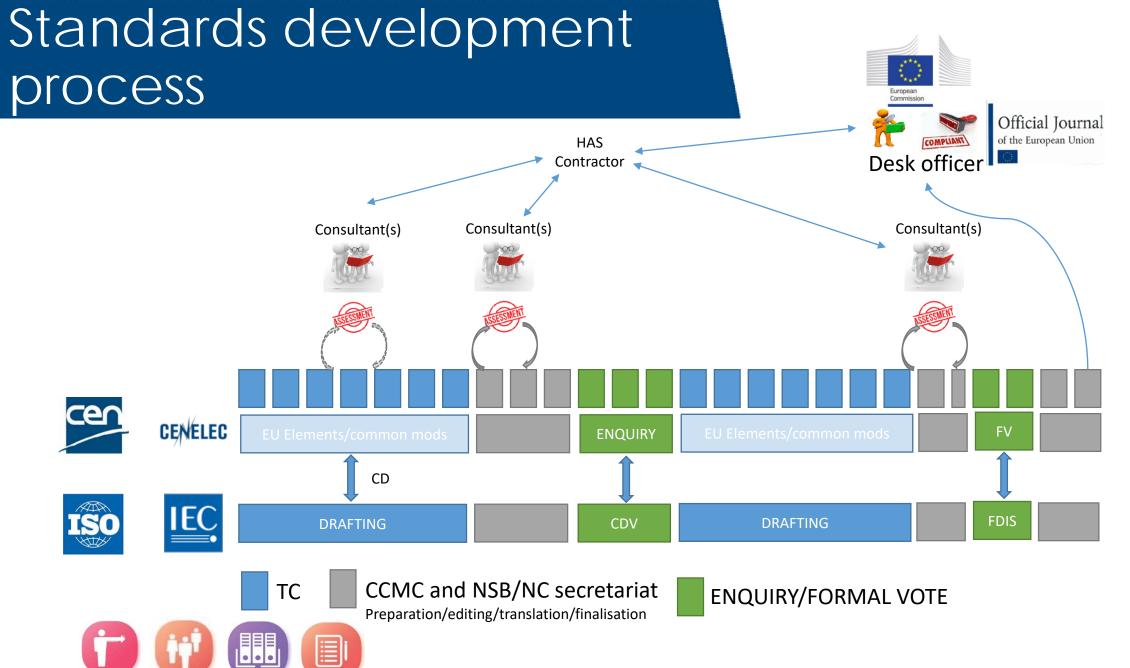
Commission's service active role during standardization process











TB OFFICERS STANDARDS PROCEDURES

### Harmonized standards



#### Harmonized

#### **European Standards**

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

### Harmonised standards developed under usual CENELEC procedures

#### Consultant assessment

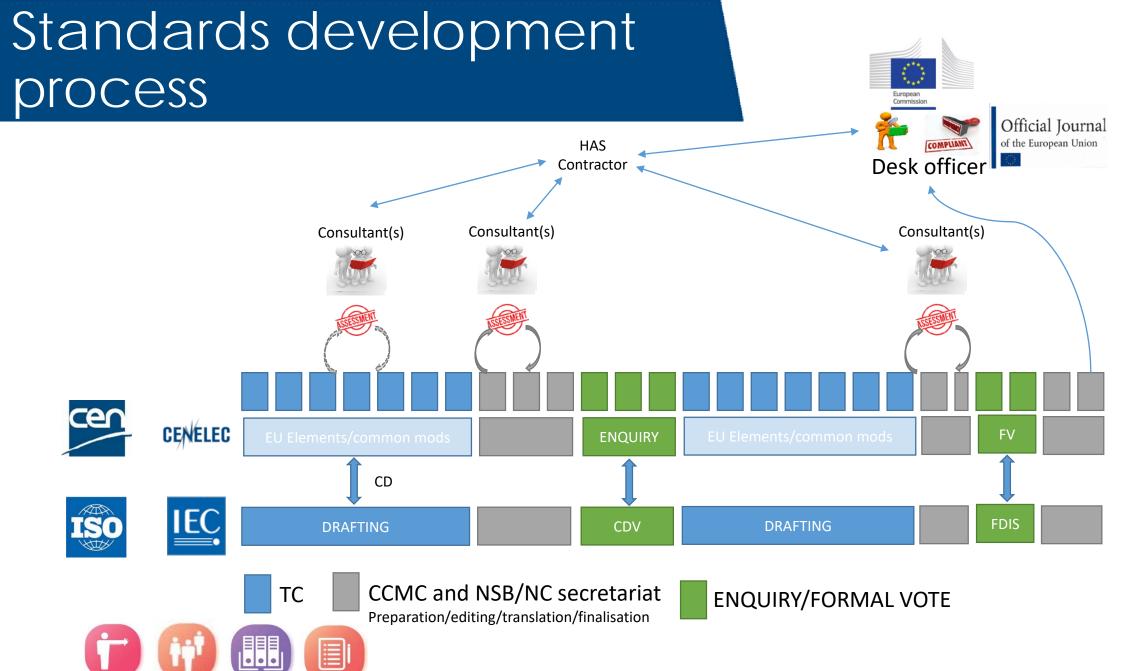
- Homegrown: Formal assessment before ENQ and FV on the standard's coverage of the essential requirements of the legislation
- ✓ IEC-CLC parallel work: Formal assessment during CDV and during FDIS on the standard's coverage of the essential requirements of the legislation
- Possibility of indicative assessment throughout the EN development process
- 'Compliant' assessment required for publication of the reference in the OJFU











TB OFFICERS STANDARDS PROCEDURES

### Harmonized standards



#### **Harmonized**

#### **European Standards**

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

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









### Harmonized standards - Annex ZZ



#### 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



#### Annex ZZA (informative)

#### 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



#### Citation in OJEU

Voluntary use of the standard Presumption of conformity with **Essential Requirements CE** marking

### **Regulation 1025/2012 – Article 10.6**

'Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the Official Journal of the European Union or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation.'









#### Citation in OJEU

Voluntary use of the standard Presumption of conformity with **Essential Requirements CE** marking

### EC Vademecum on European Standardization – art. 7.3

- Before publication under under Article 10(6)
  - access to the results of a compliance assessment
  - information indicating how these results were implemented
  - the Commission to decide, without delay, whether publication of the references in the Official Journal can be done.

It is the Commission's prerogative whether or not to accept the assessment results when it applies Article 10(6).











#### Citation in OJEU

Voluntary use of the standard Presumption of conformity with **Essential Requirements CE** marking

- ✓ Only when listed in the OJEU → presumption of conformity for Essential Requirements covered by the hEN
- ✓ Application of hEN remains voluntary → other means to show conformity are allowed
- Final responsibility to reference Harmonized Standards in the OJEU **European Commission - not CEN and CENELEC**
- ✓ The lists of hENs are published in the OJEU and continuously updated: http://ec.europa.eu/growth/index\_en.htm
- ✓ Specific process applies → Joint Assessment of the Harmonized Standard Verification and publication of the reference











#### **Citation in OJEU**

Voluntary use of the standard Presumption of conformity with **Essential Requirements** CE marking

Cene	Sound and television broadcast receivers and associated equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55013:2001 and its amendments	22/04/2016
Cenelec	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1:2000 + A1:2001 + A2:2002 Note 2.1	Date expired (01/09/2009)
	EN 55014-1:2006/A1:2009 CISPR 14-1:2005/A1:2008	Note 3	Date expired (01/05/2012)
	EN 55014-1:2006/A2:2011 CISPR 14-1:2005/A2:2011	Note 3	Date expired (16/08/2014)
Cene	EN 55014-2:1997  Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard	EN 55104:1995 <u>Note 2.1</u>	Date expired (01/01/2001)











## Information and guidance documents



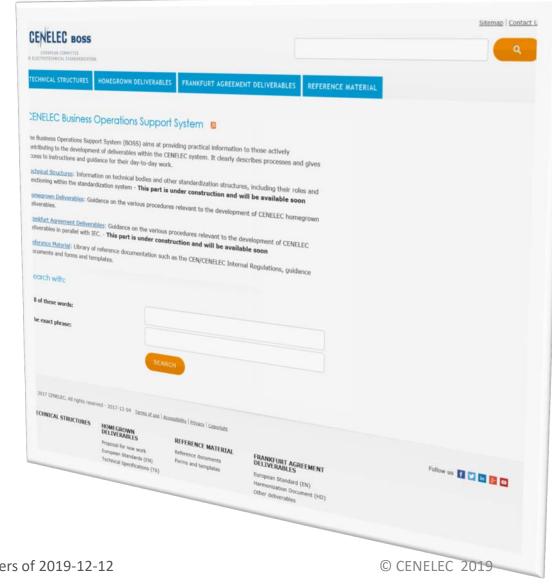




## Business Operations Support System - BOSS



- Source of stable information from CENELEC to **CENELEC/TC** secretaries, chairs, experts.
- Quick and easy access to navigate- internet tool with public access from main CENELEC website
- **CEN-CENELEC Internal Regulations are on the BOSS** 
  - Part 2: Common Rules for Standardization Work
  - Part 3: Rules for the structure and drafting of **CEN/CENELEC Publications**











## Business Operations Support System - BOSS



### Forms and templates

#### TECHNICAL BODY ORGANIZATION

- > Meeting agenda
- > Terms of Reference NEW!
- > TC Business Plan
- > TC report to BT
- > SC report to TC
- > BTTF report to BT
- > Registration form TC meeting
- > Registration form BTTF meeting
- Registration form (BT)WG meeting

#### **TECHNICAL WORK**

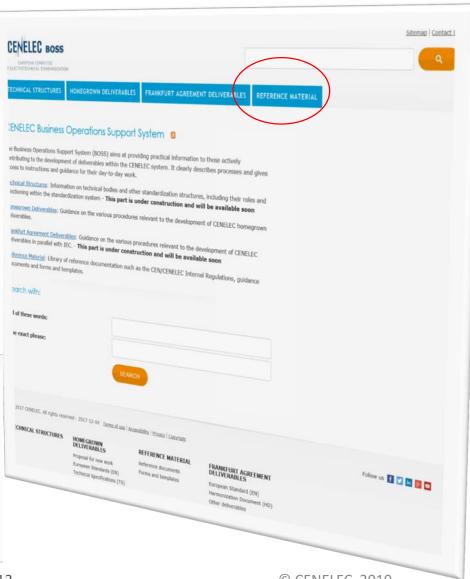
- > Commenting template
- > HAS Consultants meeting attendance Guide
- > HAS Consultants meeting attendance Request form
- > IPR- Exploitation Rights License Agreement
- > IPR Attendance list
- > IPR Patents declaration
- IPR WS exploitation
- > NWI form
- > New Field of Technical Activity
- > Standard template
- > SSO Opinion on draft ENs
- > Transmission Notice
- > Vilamoura Notification of a new national project
- > Vilamoura Notification of a revision of a national standard

### **ANNEX ZZ**

- > Generic template (EN FR DE)
- > Ecodesign (EN FR DE)
- > EMCD (<u>EN</u> <u>FR</u> <u>DE</u>)
- > LVD (EN FR DE)
- > RED EMC (EN FR (not available) DE)
- > RED Safety (EN FR (not available) DE)
- > Medical Devices (EN FR and DE not available)
- > Machinery (EN FR and DE not available)
- > IVDR (EN FR and DE not available)

### **TECHNICAL BOARD**

- > NC template for BT documents
- > Reply to BT consultation (NCs) general NEW!
- > Reply to BT vote on Standardization Requests (NCs)
- > Reply to BT consultation Partners
- > Comments on draft Standardization Requests
- > Candidature for (re)allocation of TC/SC/JTC secretariat
- > Candidature for (re)allocation of SR secretariat



### BT Newsletter



- Source of stable information from CENELEC to **CENELEC/TC** secretaries, chairs, experts
- Quick and easy access to navigate- internet tool with public access from main CENELEC website
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  - Part 2: Common Rules for Standardization Work
  - Part 3: Rules for the structure and drafting of **CEN/CENELEC Publications**
- Forms and templates













### Useful information









### General information available



- Websites:
  - www.cenelec.eu
  - www.cencenelec.eu
- CEN-CENELEC Newsletter: 'On the spot'
- Social Media: <u>Facebook</u>, <u>Twitter</u>, <u>LinkedIn</u>
- <u>CEN-CENELEC</u> and <u>CENELEC</u> Guides
- Members <u>list</u>
- <u>10-10 webinars</u>



## Information available - Contact points



- TC reports to BT, NWI requests: <a href="mailto:dataservice@cencenelec.eu">dataservice@cencenelec.eu</a>
- Texts for procedures: <u>production@cencenelec.eu</u>
- Liaisons with European federations: <u>Partners@cencenelec.eu</u>
- Support on research projects: <u>research@cencenelec.eu</u>
- For anything else, contact your project manager ©





# Thank you! Questions?

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www.cenelec.eu

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In the lobby on this floor







