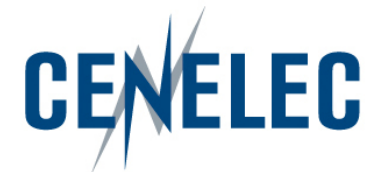


INFORMATION FOR TECHNICAL BODY OFFICERS

CEN & CENELEC Technical Body Officers Seminar

8 December 2021



INFORMATION FOR TECHNICAL BODY OFFICERS

Welcome to the Technical Body Officers Seminar

Cinzia Missiroli

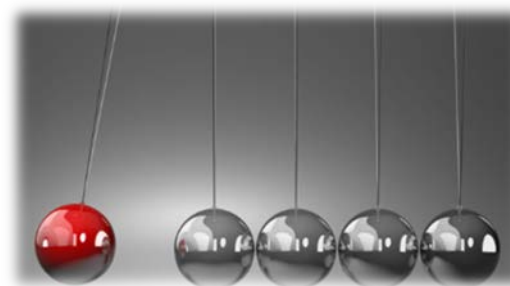


Why is this seminar important?

Standardization system principles



Latest developments and Impact on technical work

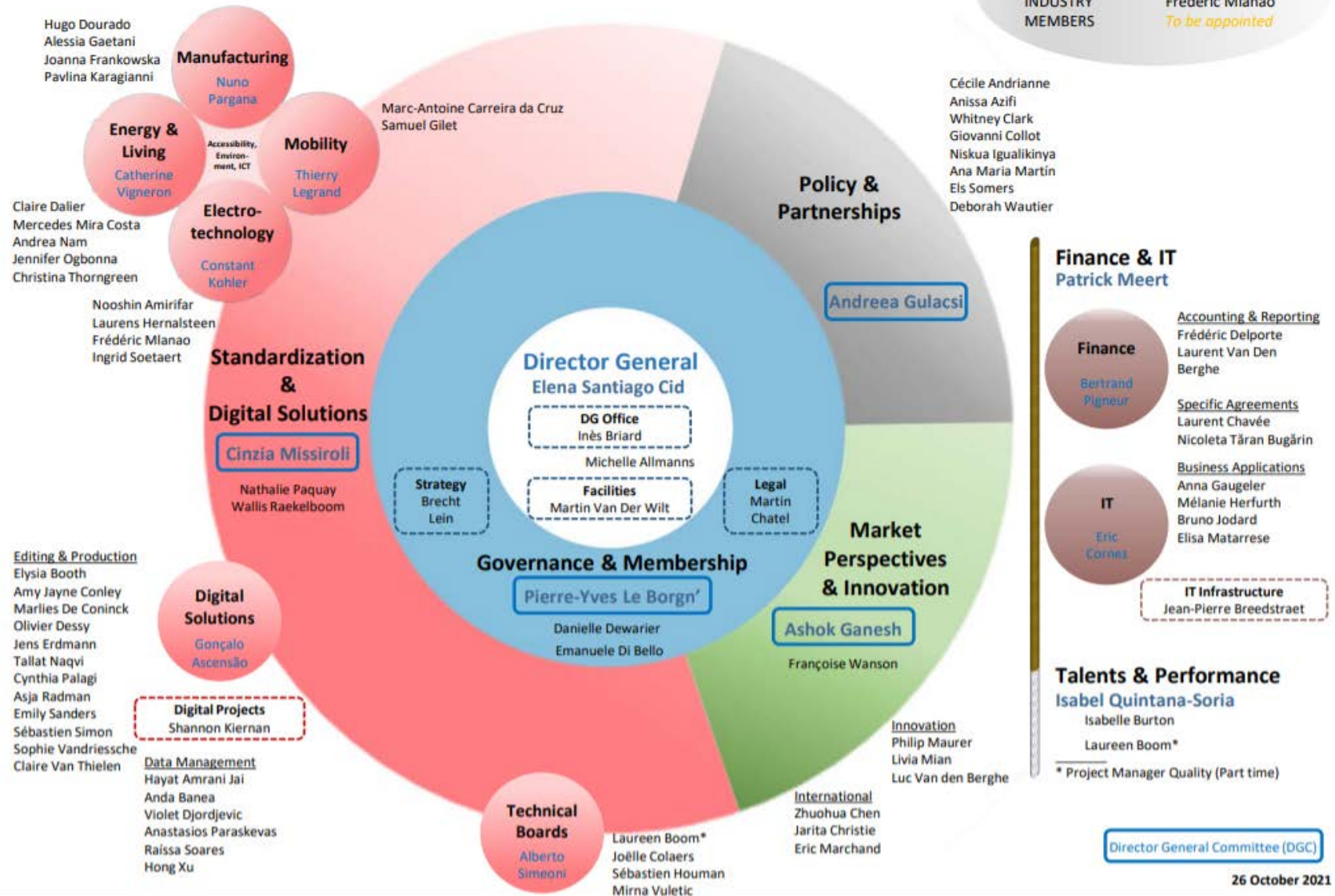


Meeting CCMC

CEN-CENELEC Management Centre



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



TBO Seminar Agenda

09:00	09:10	Welcome
CEN and CENELEC Internal regulations		
09:10	10:20	Novelties in rules and processes <ul style="list-style-type: none">• What's new since 2020• What's coming next
10:20	10:35	Questions and Answers
10:35	10:50	Coffee break
Standardization in support of EU policies and legislation		
10:50	12:10	Drafting standards for citation
12:10	12:30	Questions and Answers
12:30	13:10	Lunch
Sharing knowledge in managing TCs		
13:10	14:10	Best practices for TC secretaries <ul style="list-style-type: none">• Drafting resolutions and decisions with examples• Collecting comments in view of the finalization of the standards
14:10	14:20	Questions and Answers
14:20	14:30	Closing address

TBO Seminar Agenda

- ▶ Pre-recorded sessions available for you:
- ▶ **Integrating Research & Innovation with Standardization**
- ▶ **Adoption of standards by 3rd countries and overview of modes of partnership**
- ▶ **Digital Transformation: key initiatives**

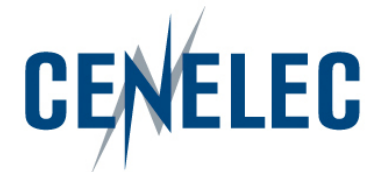
Have a fruitful day !

Ask as many questions as you like!

Cinzia Missiroli

► Director Standardization & Digital Solutions
cmissiroli@cencenelec.eu





INFORMATION FOR TECHNICAL BODY OFFICERS

Novelties in rules and processes

Alberto SIMEONI



What's new since 2020?

▶ CEN-CENELEC

▶ CEN-only

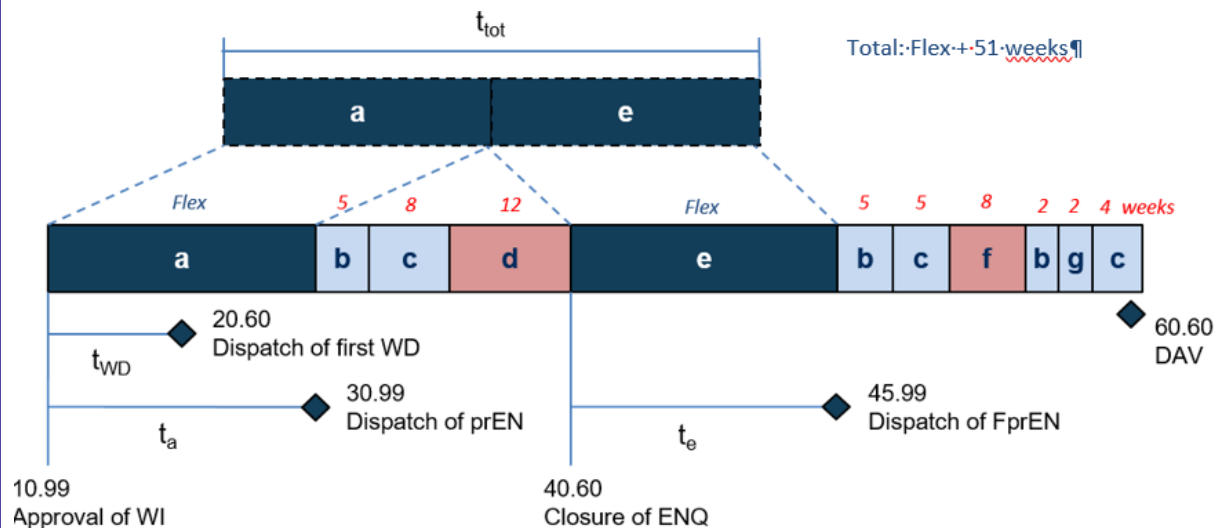
▶ CENELEC-only



Alberto SIMEONI

Account Manager Technical Boards

Flexible standards development process



► Since 1 April 2020, in view of optimizing the development process of Standards and their time to market, a new *Flexible standards development process* has been implemented, where the TCs are empowered to autonomously plan and organize their work within a maximum timeframe.

► To support the TC Officers, two webinars were given beforehand – if you missed them, you still have the possibility to listen to the recordings:

- *Flexible process* – [CEN BOSS](#) [incl. [RECORDINGS](#)]
- *Flexible process* – [CENELEC BOSS](#) [incl. [RECORDING](#)]

Flexible standards development process



19. Please provide the target dates for the below key stages.

19.1 – For ENs

This section applies only to WIs for homegrown CEN standards (excluding ISO adoptions), WIs under VA with CEN lead only and homegrown standards developed by a CEN-CLC/JTC (with CEN lead). This section does not apply to the adoption of PWIs. For JTCs also add the durations in week.

<u>Project start date (10.99)</u>	<u>Dispatch of 1st WD (20.60)</u>	<u>Dispatch of ENQ (30.99)</u>	<u>Dispatch of FV draft (45.99)</u>
yyyy-mm-dd	It is half the number of weeks planned for ENQ (30.99) For CEN/TC: automatically calculated via Working Area For JTC: date will be added by CCMC	yyyy-mm-dd For JTC only: to indicate the duration in weeks from 10.99 10.99 + X weeks	yyyy/mm/dd For JTC only: to indicate the duration in weeks from 40.60 40.60 + X weeks

CEN

Proposed target dates and corresponding duration in weeks – This section applies only to WIs for homegrown CLC standards (including homegrown amendments to IEC standards) and homegrown standards developed by a CEN-CLC/JTC with CLC lead.

CENELEC

<u>Project start date (10.99)</u>	<u>1st WD (20.60)</u>	<u>ENQ (30.99)</u>	<u>FV (45.99)</u>
yyyy/mm/dd	Date will be added by CCMC. It is half the number of weeks planned for ENQ (30.99)	yyyy/mm/dd 10.99 + X weeks	yyyy/mm/dd 40.60 + X weeks

Repartition of time under 30.99

► CENELEC

Duration planned for 30.99	34 weeks	Over 34 weeks	Under 34 weeks	
Number of work items	23	28	60	
%	21%	25%	54%	100%



79%

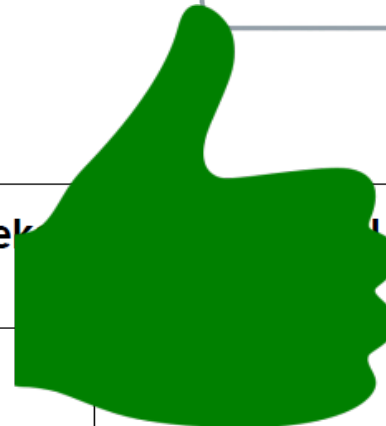
► CEN

Duration planned for 30.99	34 weeks	Over 34 weeks	Under 34 weeks	Grand Total
Number of work items	535	114	95	744
%	72%	15%	13%	100%

Repartition of time under 45.99

► CENELEC

Duration planned for 45.99	34 weeks	Over 34 weeks	Under 34 weeks	Grand Total
Number of work items	24	6	81	111
%	22%	5%	73%	100%



3.2 Implementation of Flexible process – Alberto Simeoni

17 October 2021

78%

► CEN

Duration planned for 45.99	34 weeks	Over 34 weeks	Under 34 weeks	Grand Total
Number of work items	584	71	88	743
%	78%	10%	12%	100%

Simplification of the governance at technical level

- ▶ Delegation of responsibilities from the Technical Board to the Technical Bodies will be increased
 - ▶ E.g. decision on liaison organizations within TC
- ▶ Further deployment of digital tools (e.g. Projex-online working area) for TBOs → reduce manual interventions from CCMC

CEN/BT C011/2021 and CENELEC D168/C009

Removal of links to legislation

▶ TC requests to remove the link to legislation from a draft EN covered by a mandate or Standardization Request

→ BT decision required

- ▶ In CEN – weighted vote
- ▶ In CENELEC – regular consultation

▶ CCMC informs EC when a standard cited in OJEU is superseded

CEN/BT 008/2020 and CLC/BT D164/006, applicable from 2020-02-05

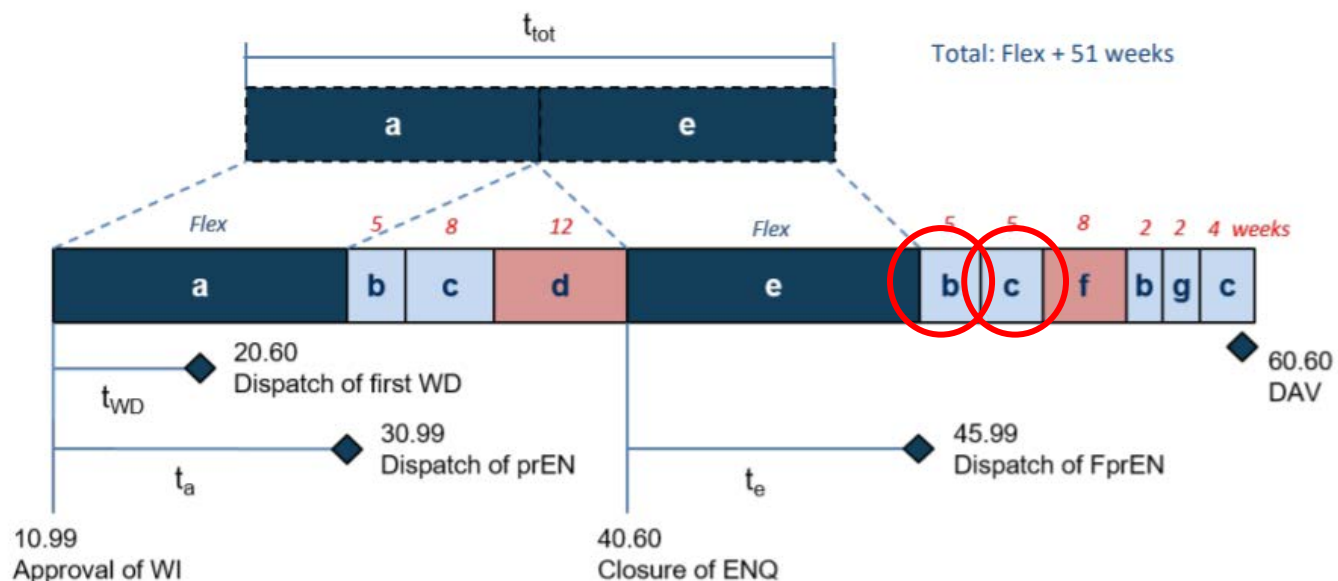
Changes in the process

- ▶ a **5-week translation** period *prior to Formal Vote* for homegrown ENs and ENs under Vienna Agreement with CEN lead, instead of having it *during* Formal Vote

CEN/BT 025/2020 and CLC/BT D165/007, applicable from 2020-05-19

- ▶ The **5-week-editing period** for draft homegrown standards received at CCMC for Formal Vote, has been reintroduced

CEN/BT 040/2020 and CLC/BT D166/001, applicable from 2020-09-30



Harmonized Standards Checklist



- ▶ When drafting Harmonized Standards, Technical Bodies shall check their compliance against the **checklist**
- ▶ **Technical Body secretary shall ensure that the checklist is filled out and submitted to CCMC with the draft candidate Harmonized Standards and their supporting documents/justifications where relevant**
- ▶ if the completed checklist, or relevant supporting documents/justifications, is not submitted, the draft Harmonized Standards received for Enquiry or Formal Vote is rejected
- ▶ Guidance available on [CEN](#) and [CENELEC BOSS](#)

CEN/BT C089/2021 & CLC/BT D168/C108, applicable from 2021-05-19

CEN-CLC/JTCs - Creation

Clarification of rules for creating CEN-CLC/JTCs (IR2:2020):

- vote according to [IR 2 Clause 6.1.4](#), *both* in CEN and CENELEC,
- **12 weeks** consultation by **correspondence**,
- at least **5 countries** committed to participate.

→ In case of divergent outcome in CEN and CENELEC, the proposal for creation of JTC is brought to BTs Common session.

CEN/BT C006/2020 & CLC/BT D164/C004, applicable from 2020-02-05

CEN-CLC/JTCs - Reporting to BTs

- ▶ Reports shall be circulated to both BTs
 - ▶ CEN BT for information &
 - ▶ CENELEC BT for decision
- ▶ Dedicated template for CEN-CLC/JTCs is available on [CEN](#) and [CENELEC BOSS](#).

CEN/BT 026/2020 and CLC/BT D165/008, applicable from 2020-05-19

- ▶ A Business Plan for a CEN-CLC/JTC is **optional**.
- ▶ **if** a Business plan is **developed**, it **shall** be **approved** by both CEN and CENELEC BTs.
- ▶ *Decision ref: CEN/BT 028/2020 and CLC/BT D165/010, applicable from 2020-05-19*

CEN-CLC/JTCs - Technical changes after FV prior to Publication



In case **exceptional** technical changes are needed after Formal Vote prior to the Publication of a deliverable developed by a CEN-CLC/JTC

- ▶ the BT Member/Permanent Delegate of the NSB/NC holding the secretariat of the JTC shall send a request for exceptional technical changes preventing a deficient standard to be published to the VP Technical of the organisation having the WI lead and to Director Standardization
- ▶ a BT document is circulated for decision to the organization having the WI lead.

CEN/BT 027/2020 and CLC/BT D165/009, applicable from 2020-05-19

To ensure the proper handling of 'anomalous' deliverables, e.g. taking the form of a database or software, currently not covered by rules

- ▶ The Technical Body submits a request with supporting justification, to BT (the project is on hold)
 - ▶ The Joint Commercial Advisory Group and DITSAG Task Form is consulted before the BT takes a decision
 - ▶ CCMC follows up and uploads the files as necessary, and provides information on the validity of the digital content in line with the JCAG and DITSAG TF 'Digital content' advice
- ▶ *D167/009 and CEN/BT 002/2021*

Feedback mechanism for stakeholders

- ▶ As of 1 July 2021, the following sentences are added in the foreword of ENs, TRs and TSs, to inform customers on how to provide feedback on published documents:
 - ▶ **CEN documents:** "Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website."
 - ▶ **CENELEC documents:** "Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CENELEC website."
 - ▶ Documents from a **CEN-CENELEC** group: "Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites."

EN IEC 60974-10:2021 (E)

◀ European foreword

The text of document 26/695/FDIS, future edition 4 of IEC 60974-10, prepared by IEC/TC 26 "Electric welding" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60974-10:2021.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2022-08-10
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2024-11-10

This document supersedes EN 60974-10:2014 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a Standardization Request given to CENELEC by the European Commission and the European Free Trade Association.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

What's new since 2020?

▶ CEN-CENELEC

▶ **CEN-only**

▶ CENELEC-only



Joelle COLAERS

Project Manager Technical Boards

REMINDER!

- ▲ **All work items** should be **allocated to a Working Group**
- ▲ In line with **BT 060/2007** (extract):
 - ▲ preparing European Standards and other CEN publications is a task that can only be allocated to a CEN/TC Working Group;
 - ▲ **CEN/TC Secretaries to check** the work programme of their TC and ensure that any work item is allocated to a Working Group, except in particular, well-identified cases e.g. projects under the Vienna Agreement, ISO lead

Managing sub-groups of TC/WGs - CEN Documents Platform



- ▲ 4th Level Group may **not** be formally created in CEN Documents
- ▲ Working Groups may create **temporary subgroups** for specific purposes (to disband upon completion of tasks)
- ▲ Creating a new WG should be considered before creating a subgroup
- ▲ For transparency, the parent WG shall create a **sub-folder** under the members' upload area for each subgroup and make available all working documents and members' list
- ▲ The WG agrees on the sub-group membership which is strictly **restricted to members of the WG**
- ▲ The subgroup shall report to the parent WG

Decision ref: CEN/BT 016/2021, taken on 2021-07-08

CEN/TC new delegated decision

- ▲ Registration/adoption of an ISO/TS as CEN ISO/TS or of an ISO/TR as CEN ISO/TR under Vienna Agreement
- ▲ Shall be taken as part of the **New Work Item Proposal** with a clear justification under Section 3
- ▲ No longer any need for BT approval

Decision ref: CEN/BT 017/2021, taken on 2021-07-08

CIB - Duration

- ▲ Recommended **timeframe**: 4 weeks,
 - ▲ Except e.g. Adoption of NWI and Activation of PWI (2months)
- ▲ **TC Secretary**, in consultation with TC Chair/WG Convenor can
 - ▲ Shorten the timeframe to 2 weeks, with **justification** and no objection from any NSB
 - ▲ Extend the timeframe, also upon request of NSBs with **justification**

Decision ref: CEN/BT 037/2020, taken on 2020-09-29

CIB – Reference document



- ▲ **CIB** shall be accompanied by a reference **(N-)document** for completeness and clarity
 - ▲ e.g. NWIP form or draft decision
 - ▲ CIB Guidance has been updated on [CEN BOSS](#)

Decision ref: CEN/BT C094/2021, taken on 2021-05-19

Initiation of amendments and revisions of ENs



- ▲ TC decision shall be taken:
 - ▲ by correspondence
 - ▲ 2-month CIB
 - ▲ based on a **completed NWIP form**
- ▲ the NWI for initiating amendments or revisions **not modifying the scope of ENs** shall be taken **by simple majority vote**
- ▲ the NWI for initiating amendments or revisions **modifying the scope of ENs** shall be taken **by weighted vote**

- ▲ the 5-members rule applies

Decision ref: CEN/ BT 018/2021, taken on 2021-07-09

Revised NWIP form

- ▲ Improvement of the NWI proposal form to clarify some parts, e.g.: target dates for Flex process
- ▲ Addition of United Nations Sustainable Development Goals (SDGs)
- ▲ Only form generated from Projex-Online Working Area for drafting the decision for the NWIP ballot
- ▲ Implementation date: **2022-01-10**

Decision reference: CEN/BT 022/2021 taken on 2021-10-21

Recordings available on CEN website as of 2021-12-17

What's new since 2020?

▶ CEN-CENELEC

▶ CEN-only

▶ **CENELEC-only**



Mirna VULETIC

Project Manager Technical Boards

Principles of (de-)ratification

- **Default Ratification:** 5 weeks after closure of FV (=T) → project **automatically** ratified & implementation dates planned
 - The 5-week-period is used for finalization, TC proofing and clearing of small issues.
- **After Formal Vote**, events might occur that would justify not to implement the voted text as such. Those events shall be **managed by exception**:
 - **Project is stopped *prior* to ratification (T+5)** → **ratification on hold** & project 'parked' in a specific stage code until a (BT) decision is taken or a solution is found on how to proceed;
 - **Project is stopped *after* ratification (T+5)** → **project is ratified** – however DAV will not be triggered until CCMC makes the document available
 - Any issues preventing the publication by CCMC (DAV) shall be submitted by TC to CCMC timely (<T+8)** to allow a decision by the BT on the way forward no later than T+12
 - Should no such elements timely be raised – with the exception of an appeal – implementation will go its normal route.
- Projects not ratified and parked in the above-mentioned specific stage code will be reported to BT on a monthly basis

D164/016 taken on 2020-02-06

TC Report to BT

In line with CLC/BT decision D158/021, the TC Secretary shall send a report to CCMC within 8 weeks after the TC meeting.

- **whenever the TC report is not in the right format or does not contain clear and appropriate information** → CCMC shall send it back to the TC Secretary for improvement, with the relevant Permanent Delegate in copy
- A TC report is considered as 'received' by CCMC only when all elements are available for its processing to BT.

The template to be used by a TC for reporting to BT is available on the [CENELEC BOSS](#).

Decision ref: BT D164/019, applicable from: 2020-02-06

Review of TC liaisons & observership

- To ensure transparency and a clear view of existing liaisons and alike between CEN, CENELEC and/or ETSI Technical Bodies
- **'Review of liaisons'** item added to the **templates 'TC meeting agenda'** and **'TC report to BT'**, not only covering liaisons with Technical Bodies but also any other observership where relevant.
- CENELEC Technical Bodies should
 - systematically report on their liaisons and observers by
 - identifying the Technical Body or organization in liaison
 - incoming and outgoing liaison officers
 - the mode of cooperation
 - the specific field of cooperation
 - the envisaged duration of the liaison;
 - ensure that appropriate reporting is performed by the liaison officers.

Decision ref: BT D166/008, applicable from 2020-10-01

CIV - Best practice

When the Committee Internal Voting (CIV) is used, the **Technical Body secretary** shall

- **create and link the supporting document to a CIV** (uploaded on Collaboration platform);
- have the **questions** from the CIV **copied in this attached document**.

Minimum timeframe for CIV is 4 weeks.

More information and guidance relating to the use of CIV can be found on the [CENELEC BOSS](#)

Decision ref: CLC/BT D167/002, applicable from 2021-02-16

Extension of TC proofing period during holidays

TC proofing period extended by 2 additional weeks during the holiday period

→ the deadline of all proofing requests from CCMC sent to TCs from **15 June until 15 August** and in **December** will be extended by 2 more weeks.

This BT decision has been implemented since 15 June 2021 and will be evaluated one year after its implementation.

Decision ref: CLC/BT D168/004, from 2021-05-27

Information on interested TBs in a document

Possibility to indicate other potentially interested TCs when developing WI

TB Secretaries to provide information in the European Foreword

In future the information will be included in the 'LT letter' (pending IT development)

Decision ref: D169/002, from 2021-10-20

Revised NWIP form

Improvement of the NWI proposal form to clarify some parts, e.g.: target dates for Flex process

Addition of United Nations Sustainable Development Goals (SDGs)

Addition of potentially impacted stakeholders when developing standards

Recordings available on CLC website as of 2021-12-17

implementation date: **2022-01-10**

Decision ref: D169/003, from 2021-10-20

This document could be of interest to			
The following CEN and/or CENELEC (joint) technical bodies:			
Other technical bodies are requested to indicate their interest, if any, in this work item to the TC/SC secretary.			
Functions concerned			
<input type="checkbox"/> EMC	<input type="checkbox"/> Environment	<input type="checkbox"/> Quality Assurance	<input type="checkbox"/> Safety
<input type="checkbox"/> Accessibility	<input type="checkbox"/> Research & Innovation		
Specific Stakeholder Groups			
<input type="checkbox"/> SME	<input type="checkbox"/> Consumers	<input type="checkbox"/> Environmental	<input type="checkbox"/> Social/labour
How will these Stakeholders benefit from or be impacted by the proposed deliverable?			
stakeholders_benefit			
Please select any United Nations Sustainable Development Goals (SDGs) that this work item contributes to. For more information, please visit the dedicated section on the CEN-CENELEC website.			
<input type="checkbox"/> GOAL 1: No Poverty	<input type="checkbox"/> GOAL 2: Zero Hunger	<input type="checkbox"/> GOAL 3: Good Health and Well-being	<input type="checkbox"/> GOAL 4: Quality Education
<input type="checkbox"/> GOAL 5: Gender Equality	<input type="checkbox"/> GOAL 6: Clean Water and Sanitation	<input type="checkbox"/> GOAL 7: Affordable and Clean Energy	<input type="checkbox"/> GOAL 8: Decent Work and Economic Growth
<input type="checkbox"/> GOAL 9: Industry, Innovation and Infrastructure	<input type="checkbox"/> GOAL 10: Reduced Inequalities	<input type="checkbox"/> GOAL 11: Sustainable Cities and Communities	<input type="checkbox"/> GOAL 12: Responsible Consumption and Production
<input type="checkbox"/> GOAL 13: Climate Action	<input type="checkbox"/> GOAL 14: Life Below Water	<input type="checkbox"/> GOAL 15: Life on Land	<input type="checkbox"/> GOAL 16: Peace, Justice and Strong Institutions
<input type="checkbox"/> GOAL 17: Partnerships to achieve the Goal	<input type="checkbox"/> None of the above		
Rationale for the selected SDG(s)- (optional):			
Intellectual Property Rights (IPR)			
<input type="checkbox"/> there is no knowledge of items covered by IPR(s), for instance patents, copyright, trademark, etc			
<input type="checkbox"/> items covered by IPR(s), for instance patents, copyright, trademark, etc have been identified:			
IPR_identified			
RELATION TO OTHER ORGANISATIONS OR PROJECTS			
IEC RELATIONS			
<input type="checkbox"/>	To be offered to IEC under the Frankfurt agreement	Justification for not offering	FA_justification_not_offering
Project based on			
<input type="checkbox"/>	No document from another organization	<input type="checkbox"/>	An IEC or ISO/IEC document (not covered by a parallel procedure)
<input type="checkbox"/>	A document from (other than IEC or ISO/IEC)	<input type="checkbox"/>	A document from (other than IEC or ISO/IEC)
Adoption type	<input type="checkbox"/> Identical	<input type="checkbox"/>	Doc/project reference
	<input type="checkbox"/> Non-Identical	<input type="checkbox"/>	source_reference
<input type="checkbox"/>	A draft or outline is attached		
<input type="checkbox"/>		<input type="checkbox"/>	Publication date
		<input type="checkbox"/>	source_reference_pub
Linked to European Research and Innovation Project			
<input type="checkbox"/>	YES	Project RI_project_code	Project acronym RI_project_acronym
		code	
	Project Title	RI_project_title	
PROJECT MANAGEMENT			
Proposed target dates and corresponding duration in weeks – This section applies only to WIs for homegrown CLC standards (including homegrown amendments to IEC standards) and homegrown standards developed by a CEN-CLC/JTC with CLC lead.			

Participation of liaison/partner organization in TBs

1st delegated decision from BT to Technical Body in the frame of Simplification!

Process :

- ▲ **CCMC** to **assess**, within **1 week**, the request from the interested European organization (including Partner organizations) to participate in CENELEC Technical Bodies as a Liaison organization;
 - ▲ **TB Secretary** to **submit** a draft decision by correspondence via a **4-week CIV** within the concerned Technical Body, using the **draft decision template**;
- the participation is approved by the CENELEC Technical Body if the following conditions are met:
- ▲ **simple majority** and **absence of sustained opposition against the applicant**, that has to be provided in writing by the opposer;
 - ▲ **TB Secretary** to **communicate** the decision to **CCMC** (partners@cencenelec.eu)

Mandatory CIV!

Decision ref: D169/004, from 2021-10-20

Matrix of responsibilities for the development of hENs

- ▲ **Scope:** detail the tasks for TBOs, Convenors and experts, responsible for the development of harmonized standards
- ▲ **Objective:** facilitate citation of standards
- ▲ The [Matrix](#) concentrates on **EN IEC standards only**
- ▲ CENELEC Technical body Officers to start applying the Matrix
- ▲ invited TBO's to provide **feedback on possible improvements** by **end January 2022** in view of its mandatory use as of 1 March 2022

Decision ref: D169/006, from 2021-10-20

What's coming next

- ▶ Implementation of further measures for the Simplification of the Governance
- ▶ New edition of IR2 to be published in January 2022
 - ▶ Main changes:
 - ▶ Clarification on Joint advisory and coordination groups (Annex G)
 - ▶ Addition of 'System Committees' in the function of CLC/SRs
 - ▶ Clarification of the start of standstill
 - ▶ Clarification and renumbering of clause 6.1.4
 - ▶ Clarification of A-deviations in Annex E
 - ▶ Improvement of Annex A.2 'CWA'
- ▶ New edition of IR3 under drafting

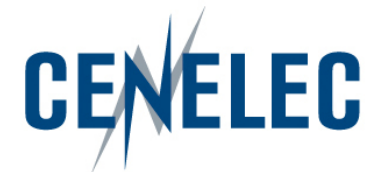
What's coming next

- ▶ CEN/TC WG consultations via the CEN eBalloting Portal
 - ▶ To facilitate consultation among WG experts → recommendations to the parent body
 - ▶ For collecting written advice and contributions not for **WG vote**
 - ▶ ad-hoc webinars for TBOs and experts will be organized

Decision CEN/BT C196/2021

Break





INFORMATION FOR TECHNICAL BODY OFFICERS

Drafting standards for citation in OJEU

Joanna Frankowska and Constant Kohler



Drafting standards for citation in OJEU

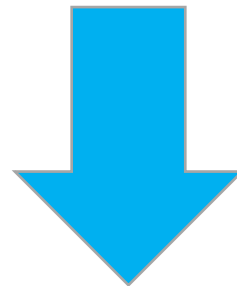
1. Standardization Requests
2. HAS assessment system update including resolution of Lack of compliance assessments
3. Elaboration of harmonised standards
4. Citation of harmonised standards in OJEU

Standardization Requests

1. Standardization Requests

At European Commission request

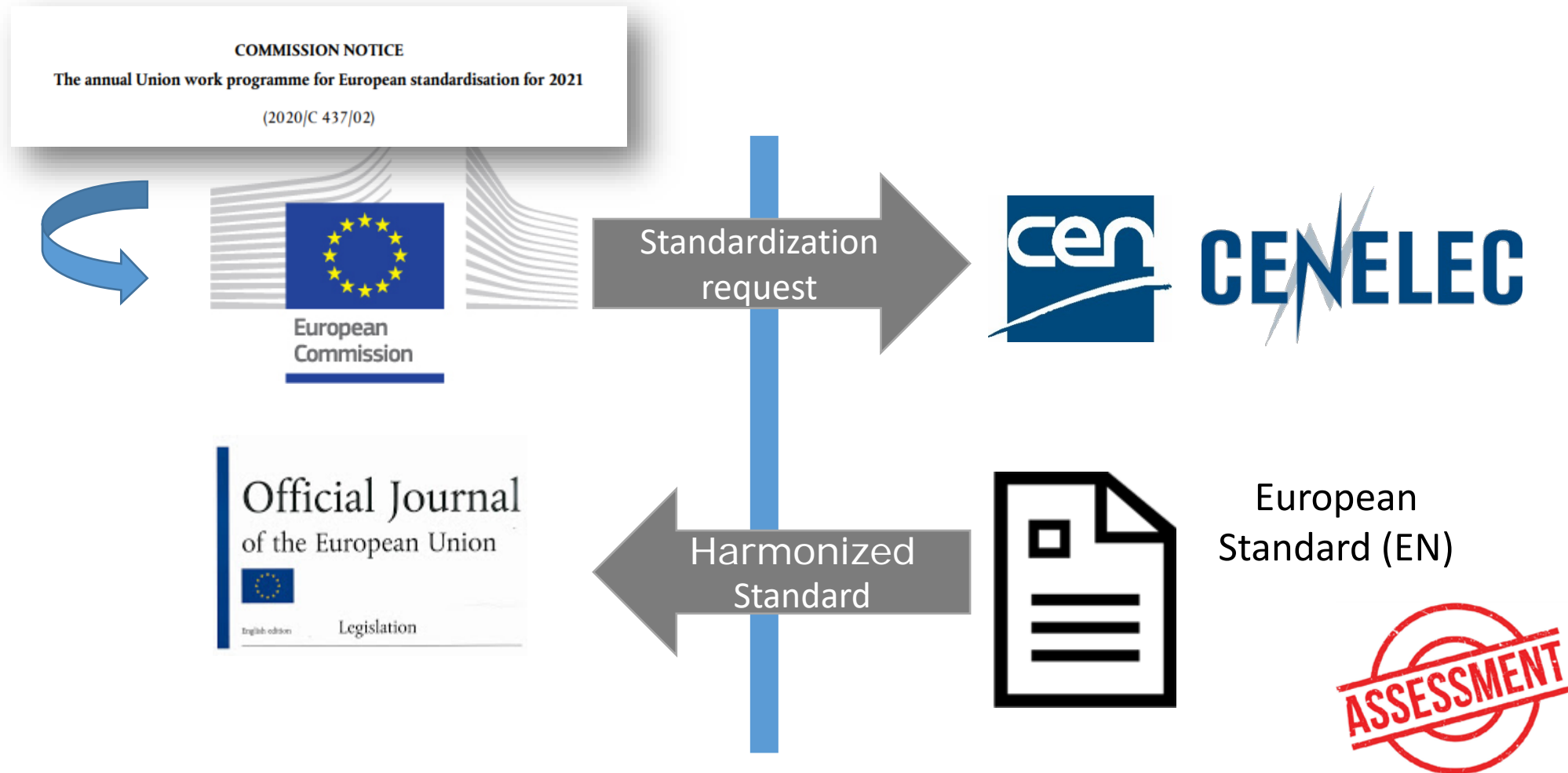
Standardization Request = Commission Implementing Decision



Regulation 1025/2012

CEN and CENELEC develop Harmonized Standards in support of EU legislation and/or policies

1. Standardization Requests



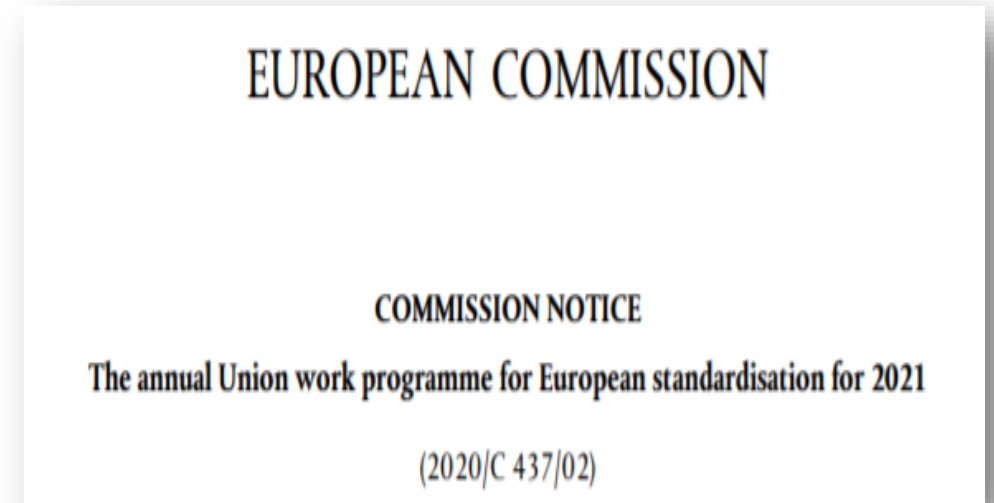
Standardization Request a **precondition** for citation of harmonized standards in OJEU

1. Standardization Requests - initiation

Development process described in [EC Vademecum on European standardization \(Part II\)](#)

Regulation 1025/2012 (art 8) - Annual Union Work Programme

- ▶ Identify strategic priorities for European standardisation
- ▶ **First** reference to upcoming standardization requests



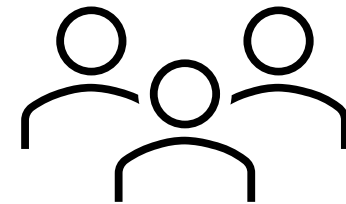
[Preliminary Draft of 2022 Annual Union Work Programme](#)

1. Standardization Requests – consultation - SRAHG

Consultation of stakeholders (e.g. CEN and CENELEC) and Members States

-> CEN and CENELEC establish **Standardization Request Ad Hoc Groups (SRAHG)** consisting of representatives of the concerned:

- CEN/BT Members and CENELEC Permanent Delegates
- Experts nominated by CEN/BT Members and CENELEC Permanent Delegates
- Partner Organizations;
- Technical Body(ies)
- Sector Forum and/or Coordination Group(s)
- ISO/IEC
- EC
- CCMC



1. Standardization Requests - SRAHG

Standardization Request Ad Hoc Group - role

► This consultation is a key step



► Group established for any new draft SReq that **ensures coordination** and input from all relevant stakeholders (incl. TCs) during the drafting and approval of Standardization Requests → group advises the Technical Boards

1. Standardization Requests – approval and specificities

- ▶ Voted by Members States (Committee on Standards)
- ▶ Submitted to CEN and/or CENELEC for **acceptance/rejection** (1 month art. 10)
- ▶ Have an **expiry** date
- ▶ If work item is not in the Standardization Request (Annex) → **no OJEU citation**
- ▶ Standardization Request can be revised → **full approval process**
- ▶ All Standardization Requests are **available** → [database](#)

1. Standardization Requests – content

Article 1

Requested standardisation activities

1. The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are requested to revise the existing harmonised standards listed in Table 1 of Annex I to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/745 for medical devices by the deadlines set in that Annex.
2. CEN and Cenelec are requested to revise the existing standards listed in Table 1 of Annex II to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices by the deadlines set in that Annex.

Deadline for adoption of a hEN

List of hEN

ANNEX I
List of existing standards to be revised and list of new standards to be drafted as referred to in Article 1(1)

Table 1: List of existing harmonised standards to be revised and deadlines for the adoption of the revised harmonised standards

Reference information		Deadline for the adoption
1.	EN 285:2015 Sterilization - Steam sterilizers - Large sterilizers	27 May 2024
2.	EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	27 May 2024

1. Standardization Requests – content

ANNEX III

Requirements for the standards referred to in Article 1

Part A. General requirements

1. Legal requirements to be supported by the harmonised standards

The harmonised standards shall support application of relevant safety and performance requirements for medical devices and *in vitro* diagnostic medical devices for human use and system and process requirements for economic operators and sponsors of clinical investigations and performance studies set out in Regulations (EU) 2017/745 and (EU) 2017/746.

The harmonised standards shall provide detailed technical, scientific, processual or methodological specifications of safety and performance requirements with the purpose of allowing compliance with relevant requirements of Regulations (EU) 2017/745 and (EU) 2017/746. Where appropriate, the harmonised standards shall include methods to verify compliance with such specifications.



Annex with general and specific requirements for hENs !

Part B. Specific requirements

1. Requirements for all harmonised standards listed in Annexes I and II

The harmonised standards shall ensure safety and effectiveness of devices and a high level of protection of health and safety of patients, users or others persons. They shall reflect the generally acknowledged state of the art.

2. Requirements for certain specific standards listed in Annexes I and II

2.1 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (EN ISO 10993-7:2008+AC:2009) and Part 17: Establishment of allowable limits for leachable substances (EN ISO 10993-17:2009)

In the standard EN ISO 10993-7:2008+AC:2009, the method of calculation of residue limits for ethylene oxide sterilant laid down in point 4.3.1 of that standard shall be modified in such a way as to take into account also patients with a weight lower/higher

HAS assessment system update

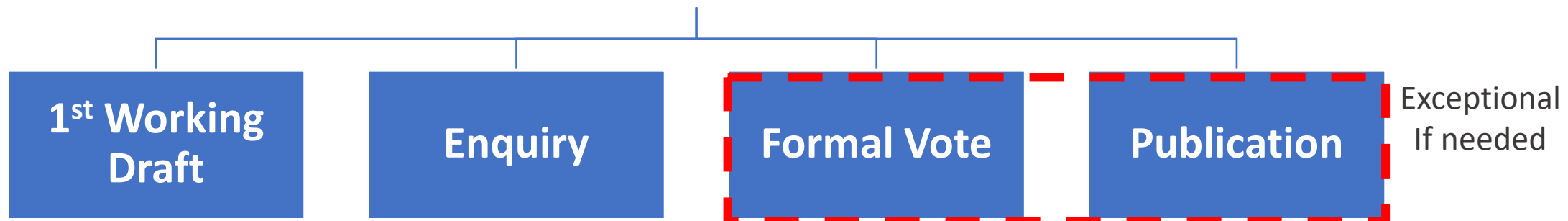
2. HAS assessment system update – HAS Contractor tasks

- ▶ **HAS Contractor = Ernst & Young (EY)**
- ▶ HAS contract duration: 1 April 2018 until 31 March 2022
 - ▶ New contract: expected early 2022
- ▶ HAS contractor manages the pool of harmonized standards consultants 'HAS Consultants'
- ▶ Assessment outcome: **'Compliant'** or **'Lack of compliance'**
- ▶ Tasks HAS consultants:
 - ▶ 'Compliance assessment' of the documents drafted by the ESO's
 - ▶ 'Communication' to the technical bodies of the ESO's to give advice to contribute to compliance of the drafted documents with the EC's standardization requests → **Meetings***

*Meetings with HAS consultants have temporarily stopped due to budget limitations of HAS project

2. HAS assessment system update – Interaction with standards development

When can assessments be requested?



► Duration assessments:


- Normally 5 weeks after notification to HAS CONTRACTOR (EY)

- ▲ HAS budget limitations: **EC is prioritizing FV and PUB assessments**
- ▲ Temporary measure until new contract is in place

2. HAS assessment system

FWD HAS assessment

Assessments: DRAFTING STAGE (indicative)

- ▶ TC secretary submits to CCMC the first working draft (FWD)
 - ▶ Transmission notice
 - ▶ CCMC Project Manager submits request to EY 
 - ▶ First draft of informative Annex Z
 - ▶ For parallel work: CD-text

▶ Assessment report available on LIVELINK

▶ Lack of compliance → possible meeting*
 *meetings have been temporarily stopped

Electronic Transmission Notice		
TC Name	[provide TC name]	
TC Title	[provide TC title]	
Secretariat:	[NC]	[provide TC Secretary name and email address]
[In case WG Convenor and project leader should receive a copy of the draft for TC proofing after Formal Vote, provide name(s) and email address(es)]		

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:

Deliverable	EN <input type="checkbox"/>	HD <input type="checkbox"/>	Amdt <input type="checkbox"/>	TS <input type="checkbox"/>	TR <input type="checkbox"/>	AC <input type="checkbox"/>
Milestone	1 st Working Draft <input type="checkbox"/>	draft for ENQ <input type="checkbox"/>	draft for FV <input type="checkbox"/>	2nd ENQ <input type="checkbox"/> [provide TC decision, number, and date]	2nd FV <input type="checkbox"/> [provide BT decision, number, and date]	TS/TR vote <input type="checkbox"/>
Publication <input type="checkbox"/> [In case of decision to skip FV following ENQ, provide TC decision, number, and date]						


GENERAL				
The text is sent in the following Reference language version in PDF and revisable Word format (only one Reference language permitted).				
	ENGLISH	FRENCH	GERMAN	Comments
Provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reference version	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
WORD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PDF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

TO BE FILLED IN IN CASE OF HARMONIZED STANDARD ONLY					
Standardization request	Related Directive/policy	New Approach OJEU citation	Assessment required by		
			HAS	EC	Other
[SREQ_1]	[DIR_1]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> [specify method]
[SREQ_2]	[DIR_2]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> [specify method]
[SREQ_3]	[DIR_3]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> [specify method]

TO BE FILLED IN IN CASE THIS IS A 1 st WORKING DOCUMENT:
<input type="checkbox"/> document is to be submitted to HAS Consultant for indicative assessment

2. HAS assessment system update - ENQ HAS assessment

Assessments: ENQUIRY STAGE

- ▶ Technical Body secretary submits to CCMC :
 - informative Annex Z (for parallel work with ISO no need to submit to CCMC but secretary ensures that Annex is included in ISO text)
 - normative Annex ZA on normative references (for // work with IEC only)
 - checklist for hENs (for // work – **recommended**) 
- ▶ CCMC editor requests assessment at start of translation
- ▶ Assessment report available on LIVELINK
- ▶ Dealing with the outcome:
 - **Compliant** → if all criteria are met: possibility to skip FV
 - **Lack of compliance:**
 - Launch of ENQ is not delayed
 - TC **meeting*** with HAS consultant to solve the issues

*meetings have been temporarily stopped

2. HAS assessment system update - FV HAS assessment



Assessments: FORMAL VOTE stage

- ▶ Technical Body secretary submits
 - informative Annex Z (for parallel work with ISO no need to submit to CCMC but secretary ensures that Annex is included in ISO text)
 - normative Annex ZA on normative references (for // work with IEC only)
 - Checklist for hENs (for // work – **recommended**) NEW
 - ENQ HAS assessment report → last column 'observations of the secretariat' completed to indicate how consultant comments have been addressed

MB/NC ¹	Line number ¹ (e.g.-17) ¹	Clause/Subclause ¹ (e.g.-3.1) ¹	Paragraph/Figure/Table ¹ (e.g.-Table-1) ¹	Type of comment ²	Comments ³	Proposed change ³	Observations of the secretariat ⁴
JJ1		7.2.2		Te	The technical text in the DIS made rightly reference to Annex A of ISO 7960 for the operating conditions of building site saws during noise emission measurement. Unfortunately, in the FDIS this text has been replaced by a mere reference to clause 7.2.2 of Part 1. Consequently, a manufacturer using Part 10 is not going to know which operating conditions he has to use.	Reintegrate in 7.2.2 the DIS text relating to Annex A of ISO 7960 i.e. replace the current text of 7.2.2 by: "This sub-clause of ISO 19085-1:2017 applies with the following additions: - → Operating conditions shall comply with A.2.b) in Annex A of ISO 7960:1995 - → Measurement surface, number of microphone positions and measuring distance shall comply with	We fully agree with this comment. It was not the intention during DIS/CRM to delete so much of 7.2.2 – but it happened. We had no technical reason. It was a mistake, as you can see also in the fact, that Annex E (for machines not in ISO 7960) is marked as "does not apply". We will change 7.2.2 to: 7.2.2.Noise emission measurement This subclause of ISO 19085-1:2017 applies with the following additions.

- ▶ CCMC editor requests assessment at start of translation
- ▶ Assessment report available on LIVELINK

2. HAS assessment system update – additional documentation



TC can include additional document in the request for a HAS assessment, e.g.:

- Risk assessment / Explanation / clarification regarding a hEN or a product covered by a hEN;
- Detailed justifications, e.g. **very exceptionally** when use of normative reference undated or withdrawn (**not recommended**).
- Reports / notes from the calls / meetings with a HAS consultant

Document must be in **PDF**

In practice: TC Secretary provides document to CCMC **in usual package** submitted for procedure:

- via e-trans for parallel work with ISO – FWD
- @ CCMC PM email for parallel work with IEC - FWD
- via e-trans for CEN homegrown - FWD, ENQ or FV
- at production@cencenelec.eu for CENELEC homegrown
- @ CCMC PM email and Consultants@cencenelec.eu for parallel work with ISO/IEC - ENQ, FV
- @ CCMC PM email for parallel work with ISO/IEC –PUB

Document must be clearly named with 'to include in request for assessment'

2. Resolving a non-compliant assessment prior to FV

Homegrowns

Decision BT C045/2018 and D159/C071, in case of a 'Lack of Compliance' at FV stage:

- ▶ **FV is suspended for maximum 12 weeks** after the reception of the assessment
- ▶ Technical Body Secretariat and BT member/PD of the NSB/NC holding the secretariat shall be informed
- ▶ Technical Body to decide on the way forward within **7 weeks**

Parallel work with ISO

HAS assessment is made before FV as well and FV is suspended in case of 'Lack of Compliance' -> deadlines as for homegrown hENs apply (**new**)

2. Resolving a non-compliant assessment prior to FV

TCs to follow the procedure:

- 1) TC prepares the following documents:
 - a) **HAS Assessment report with the last column** 'Observations of the secretariat' **filled** to indicate how the TC is addressing the comments from consultant
 - b) **Re-worked draft in track changes** showing the changes made by TC in comparison with the version of FV draft which received a Lack of Compliance assessment
- 2) TC assesses whether a HAS consultant needs to be contacted* to resolve an assessment. In case of minor comments leading to a lack of compliance assessment a meeting may not be necessary.
- 3) If necessary, TC to organise a **meeting*** with HAS consultant to solve the assessment. Prior to the **meeting***: TC provides to consultant the documents as listed in 1)

*meetings have been temporarily stopped

2. Resolving a non-compliant assessment prior to FV

4 a) CEN or CLC TC (and ISO TC**) leadership concludes whether the assessment is **resolved**:

- ▶ CEN or CLC TC Secretary provides the documentation as indicated in 1) a and b as well as Consultant's feedback (if any)* to CCMC PM(, to ISO TPM and ISO Committee Manager**)
- ▶ CCMC PM registers in CEN database "HAS Assessment resolved" (and informs ISO TPM and ISO Arrangements (cooperation.agreements@iso.org))
- ▶ ISO/TC Committee Manager submits the documentation on the [ISO submission interface**](#))
- ▶ CCMC provides documentation to the EC when a hEN is offered

*Meetings with the HAS consultants are temporarily stopped

**for // work between CEN and ISO

2. Resolving a non-compliant assessment prior to FV

4.b) In case an assessment is **not resolved** ->

project leader, WGs and TCs leadership in CEN or CENELEC (and ISO)** in consultation with CCMC PM (and ISO TPM)** decide on a way forward.

If useful, a CEN or CLC TC Secretary organises **a call** to discuss the matter with the participation of these persons or most of them

**for // work between CEN and ISO

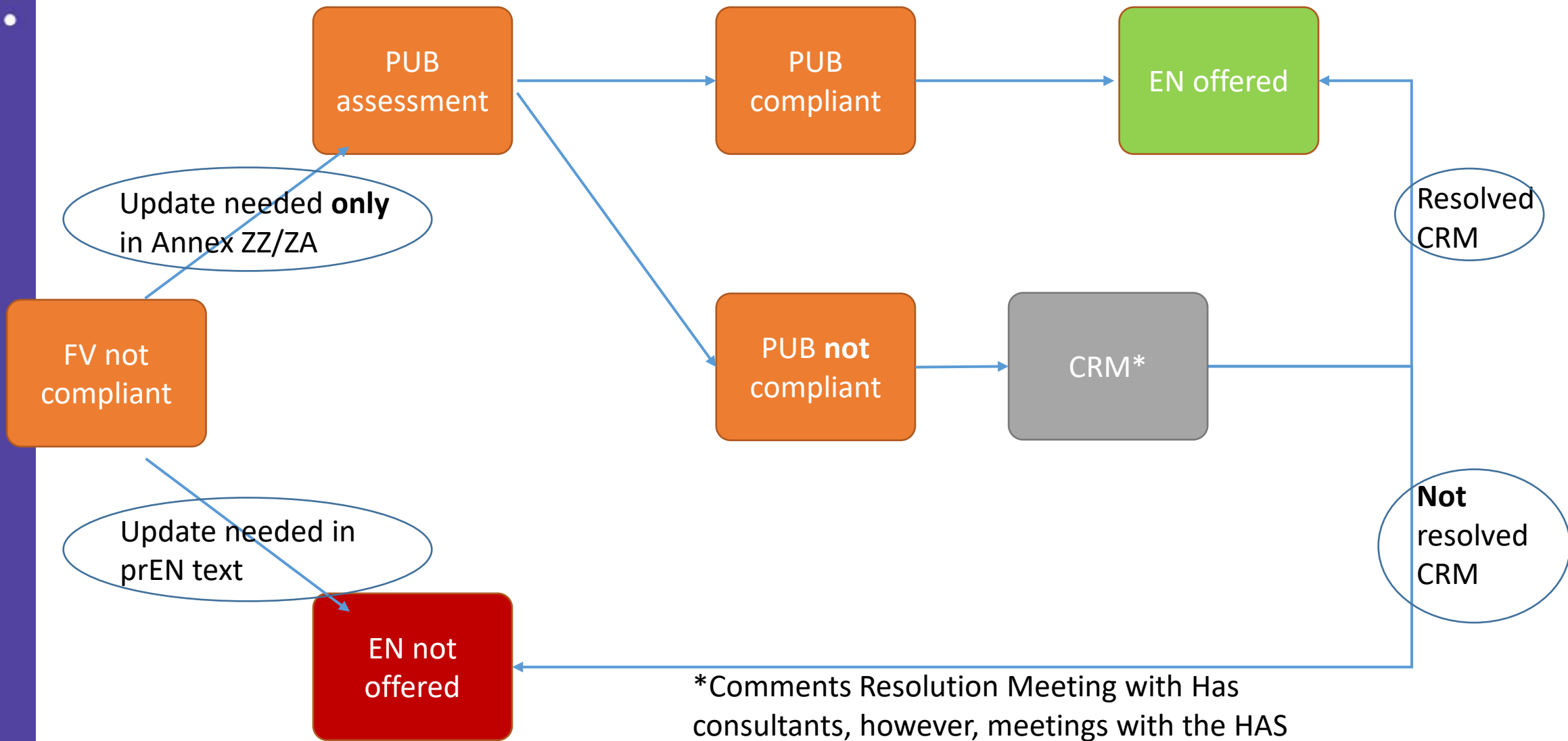
Resolving a non-compliant assessment prior to FV

4.b) In case an assessment is **not resolved** the options are as follows:

- ▶ proceed to FV (with possibility to ask a PUB assessment after a vote, if necessary);
- ▶ removal of the link to the EU legislation so that a non-harmonised standard is published (TC decision and BT decision are required);
- ▶ cancellation of a project (TC decision and BT decision are required). After BT approval a new project with a new work item can be launched
- ▶ **decoupling from Vienna Agreement****

**for // work with ISO

Lack of compliance FV assessment (EN IEC)



Elaboration of harmonised standards

3. hEN development process

Harmonized standards (hEN) are developed in the same way as any other EN in CEN and CENELEC – **but with additional considerations:**

Mandatory for hEN:

All harmonized standards **shall** include an informative Annex Z, demonstrating the relationship between the clauses of the standard and the regulatory requirements. For standards developed under the Frankfurt Agreement, a normative Annex ZA ‘normative references’ shall be included as well.

Consultant assessments:

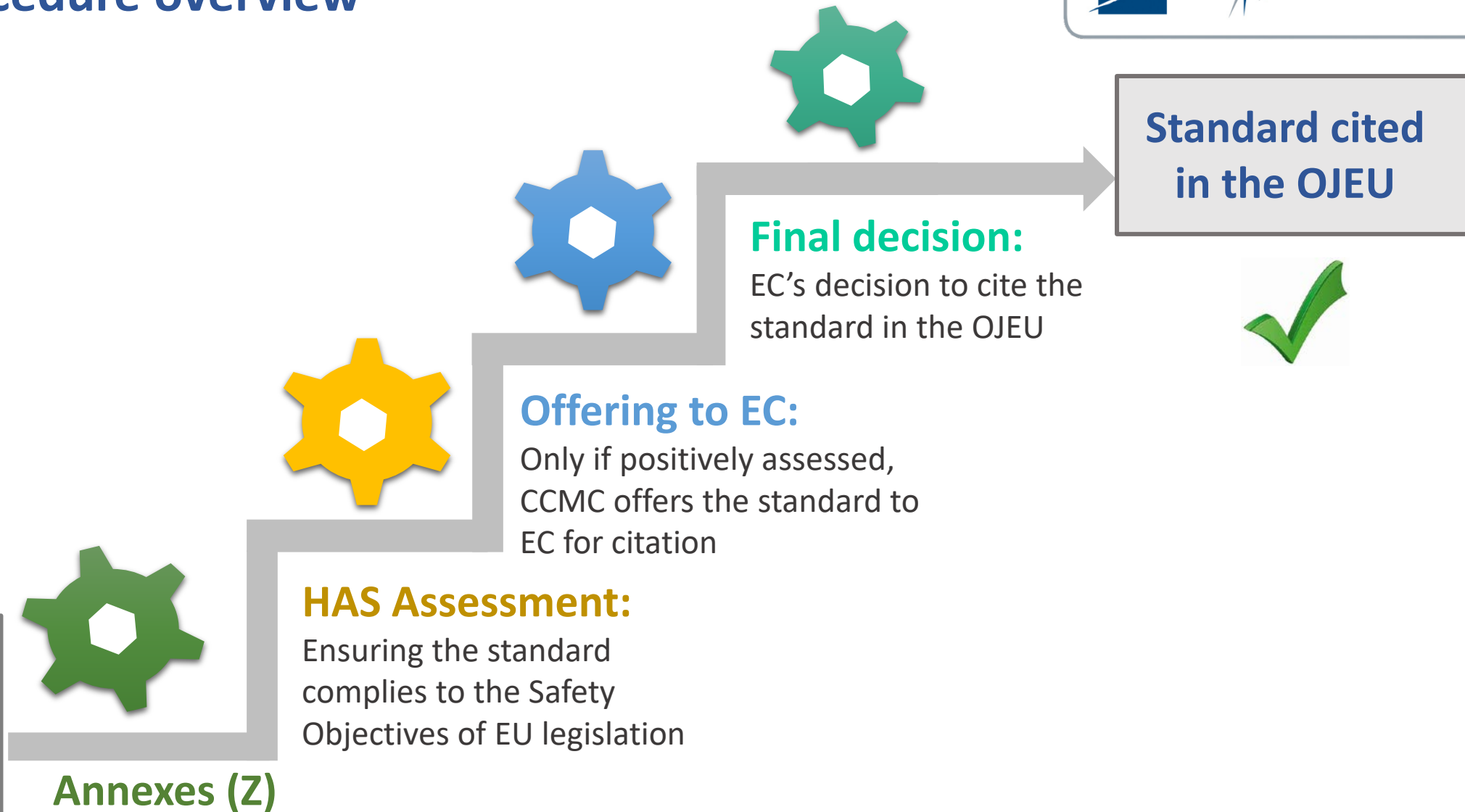
The HAS consultants assess the compliance of a standard with directive’s (and standardization request) requirements, via communicating with and delivering assessments to the TCs - they work on behalf of the EC.



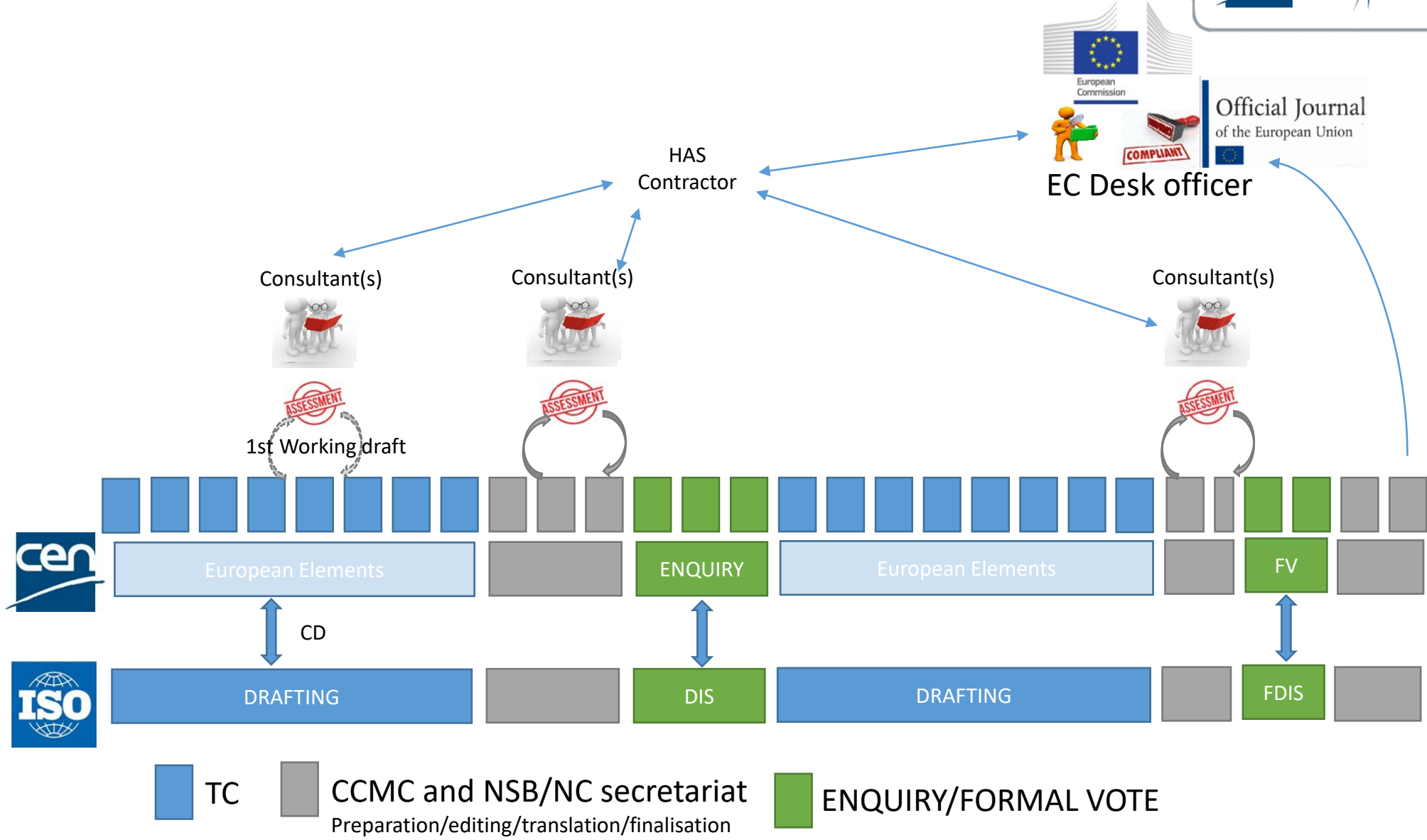
‘Compliant assessment’ or ‘HAS assessment resolved’ on EN is needed to have the EN “offered” (by CEN-CENELEC) to the European Commission and then cited in the OJEU (European Commission decision)!

□ Procedure overview

**hEN standard
developed in the
support of
legislation**



International dimension



Normative references in harmonised standards

- ▶ Normative references, when harmonised standard is adopted (DAV), should be:
 - ▶ **dated**
 - ▶ **active**
 - ▶ **published**
- ▶ Vademecum Part 3 (section 2.8.3): guidance on the use of normative references in hEN → Reference document for EC
- ▶ Normative reference to a standard that has **not been cited** in the OJEU is **possible unless** the referenced standard has been **formally rejected** by EC – details to be discussed

Normative references in harmonised standards

- ▶ In principle, the EC **does not accept** the references to the the **non-CEN/CENELEC/ISO/IEC documents**
- ▶ Reference to “**all parts**” (series of standards) in general **will not be accepted** - not precise enough, equals undated normative reference;
- ▶ **IMPORTANT:** In case these rules are not applied and no valid, detailed justification provided **upfront** -> lack of compliance assessment and non-citation in the Official Journal of the European Union
- ▶ More details - CEN-CENELEC webinar on hEN for machinery (2021-10-28) – link [here](#)

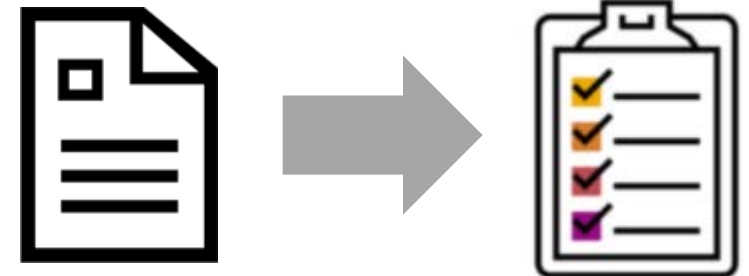
In terms of standards' contents...

- In case the parallel EN/IS is not compliant, it does not mean that the standard is not adequate for the market... It simply means that the EN/IS has not met the specific European requirements for **compliance**:
 - ✓ • Concise and clear **scope**
 - ✓ • Objectively-verifiable **requirements** and **test methods** (e.g. avoid that a same clause addresses (for instance) safety, EMC and radio requirements)
 - ✓ • **Normative references** must be dated
 - ✓ • **Neutrality** principle: the standard shall not contain clauses imposing requirements or obligations on or between certain economic operators
 - ✓ • Annex ZA (CEN) and Annex ZZ (CENELEC)
 - ✓ • Comply with **sector specific rules**... see dedicated Webinars and Trainings



Checklist for hENs: main principles

- 1) When drafting homegrown hENs, harmonized standards under VA (CEN lead) or European Common modifications (CENELEC) → **Technical Bodies shall check their compliance against a dedicated checklist**
- 2) TC secretary in CEN and Technical body secretary/ Reporting Secretariat in CENELEC → **ensure checklist is filled out and submitted to CCMC with the draft hEN and supporting documents** (where relevant)
- 3) During the ENQ and FV procedures: **CCMC will reject, as of 2021-10-01, the submission of draft hEN if the completed checklist and relevant documents were not submitted**



Checklist for hENs

► [CEN](#) and [CENELEC](#) BOSS pages guidance on hENs published

< European Standard (EN)

European Standards (EN)

- > Drafting of European Standards up to Enquiry stage
- > Enquiry
- > Formal Vote
- > Finalization and implementation of European Standards
- > European standards for citation in the OJEU
- > HAS assessment process

Drafting European standards for citation in the OJEU

This page provides guidance to Technical Bodies and Working Groups (WGs) on horizontal aspects to be considered when preparing harmonized European standards in support of EU harmonization legislation intended to be cited in the Official Journal of the European Union (OJEU). Information on the HAS process and how to interact with the HAS consultants can be found on the page [HAS assessment process](#). Regulation (EU) No 1025/2012 on European standardization defines a harmonized standard as "a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation".

1 PREPARATION OF NEW WORK ITEM

The starting point for the development of a harmonized standard is to assess whether it is in the scope of the relevant EU harmonization legislation and whether the standard is covered by a standardization request or mandate which was accepted by the Technical Boards.

- [Forms & Templates](#) +
- [Related decisions](#) +
- [Reference document](#) +
- [Internal Regulations](#) +

v2021-04-14

Checklist – Items to be considered when drafting standards answering a Standardisation Request and to be offered for citation in the OJEU

This checklist was prepared following the format of Internal Regulations CEN/CENELEC Part 3 – Annex A "Checklist for writers and editors of document". All CEN/CENELEC standards and deliverables shall follow the provisions of IR 3.

This checklist is applicable for all sectors, except construction.

This checklist shall be fulfilled before dispatch for:

1. the First Working Draft for optional assessment (if any),
2. the draft for Enquiry,
3. the final draft for Formal vote,
4. In case of lack of compliance assessment, a new optional assessment after Formal vote (PUB assessment).

The Technical Committee secretary in CEN and the Technical body secretary / Reporting Secretariat in CENELEC are responsible for ensuring that the checklist below is filled out and submitted to CCMC with the draft candidate harmonized standards and their supporting documents/justifications where relevant. In CEN, the matrix of responsibilities shall be followed (see decision BT C081/2018).

It is strongly recommended to use of the checklist for the drafting of harmonized standards in support of EU Legislation under VA and FA (with ISO or IEC lead).

	Check the following questions – if you answer yes to all the questions, the draft is probably ready for submission to CCMC (and HAS Consultant assessment).	Check
General	Is this draft standard listed in a Standardisation Request / covered by a Mandate? Is this reflected in Projex-online database? <i>NB: This information is normally already provided in the NWIP form. NB: If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (revised) Standardisation Request. This is not applicable if the standard is covered by an open Mandate (e.g. M/396 Machinery)</i>	<input type="checkbox"/> <input type="checkbox"/>

European foreword	If the HAS assessment was performed (i.e. optional assessment at First Working Draft (FWD) stage or assessment at Enquiry stage), has the WG answered <u>all</u> comments from the HAS Consultant(s)? <i>NB: The last column of the HAS Assessment Report ('Observations of the secretariat') at previous stage shall be filled in with the information on how the comments have been addressed.</i>	<input type="checkbox"/>
	If the text deals with requirements that are not linked to essential requirements of EU legislation, are these requirements in separate clauses, so that in Annex Z only the clauses covering essential requirements are identified?	<input type="checkbox"/>
Scope	If the standard is a revision, are the significant changes with respect to the previous edition precisely defined? <i>NB: The list of the significant changes with respect to the previous edition is an important element of the useful information to the standard users. It should not be too vague. NB: When the list of significant technical changes is extensive, it may be included in an informative annex. A reference to that annex shall be included in the foreword, preferably after the generic sentence that refers to the superseded document.</i>	<input type="checkbox"/>
	Does it include the following sentences "The standard has been prepared under a standardisation request given to CEN/CENELEC by the European Commission and the European Free Trade Association and support essential requirements of EU Directive / Regulation. For relationship with EU Directive / Regulation, see informative Annex Z, which is an integral part of this document."? <i>NB: Annex ZA in CEN and Annex ZZ in CENELEC.</i>	<input type="checkbox"/>
Normative reference	Is the scope concise and clear? Is it worded as a series of statements of fact? Are the title, <u>scope</u> and annex Z consistent regarding exclusion / content covered by the standard? <i>NB: The scope of the standard could be broader than the relationship between this standard and the requirements of the EU legislation. NB: The scope shall not include requirements, <u>permission</u> or <u>recommendation</u> (in line with IR 3).</i>	<input type="checkbox"/> <input type="checkbox"/>
	Are the standards listed in the Normative references Clause 2 normatively referenced within the text (i.e. are they cited in the text in such a way that some or all of their content constitutes requirements of the document, for instance with a "shall"). <i>NB: See IR 3 with the preferred verbal form to be used to express a requirement.</i> Are the normative references dated in Clause 2 and in all clauses of the draft standard?	<input type="checkbox"/> <input type="checkbox"/> Yes <input type="checkbox"/> No

Checklist for hENs: ENQ/FV process (CEN)

WG

- ▶ WG drafts hENs
- ▶ WG Qualified support checks that the draft hEN fulfils requirements to be cited
- ▶ WG Qualified support ensures that checklist is filled out
- ▶ WG Qualified support/convenor submits to TC secretary:
 - 1) **Draft hEN**
 - 2) **Checklist filled out**
 - 3) **ENQ HAS assessment report with last column filled on how consultant comments were addressed** (applicable for FV only)

TC secretary

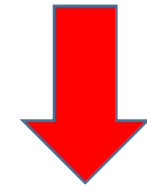
- ▶ Checks that checklist is filled out
- ▶ Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?



ENQ/FV procedure could start

Checklist not submitted?



CCMC will reject hEN submission

CEN: [matrix responsibilities](#) to be followed (decision BT C08172018)

Checklist for hENs: ENQ/FV process (CENELEC)



WG

- ▶ WG drafts hENs
- ▶ WG ensures that following docs are submitted to TC secretary:
 - 1) **Draft hEN**
 - 2) **Checklist filled out**
 - 3) **ENQ HAS assessment report with last column filled on how consultant comments were addressed** (applicable for FV only)

CENELEC: **matrix of responsibilities** under discussion

TC secretary

- ▶ Checks that checklist is filled out
- ▶ Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?

Checklist not submitted?

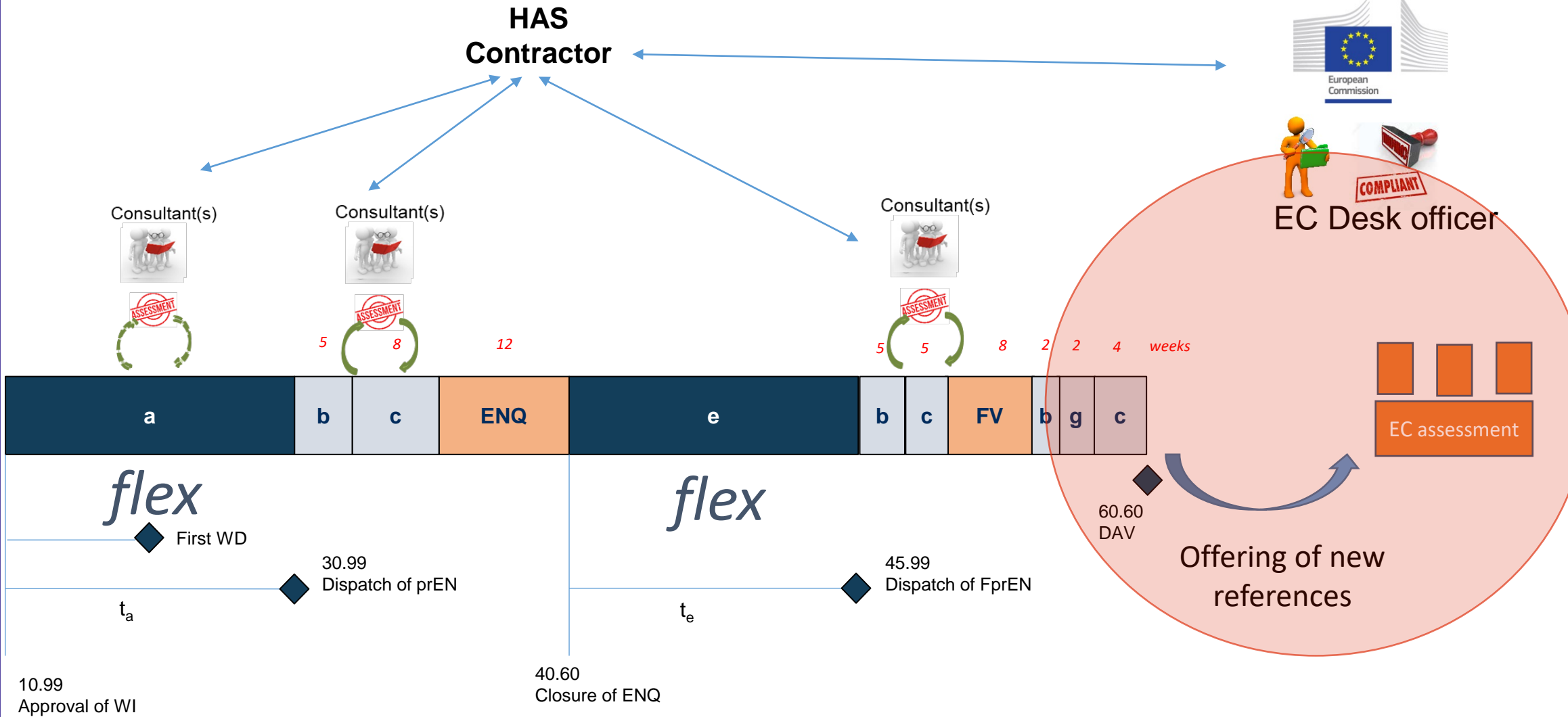
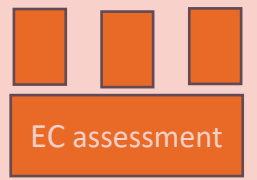


ENQ/FV procedure could start

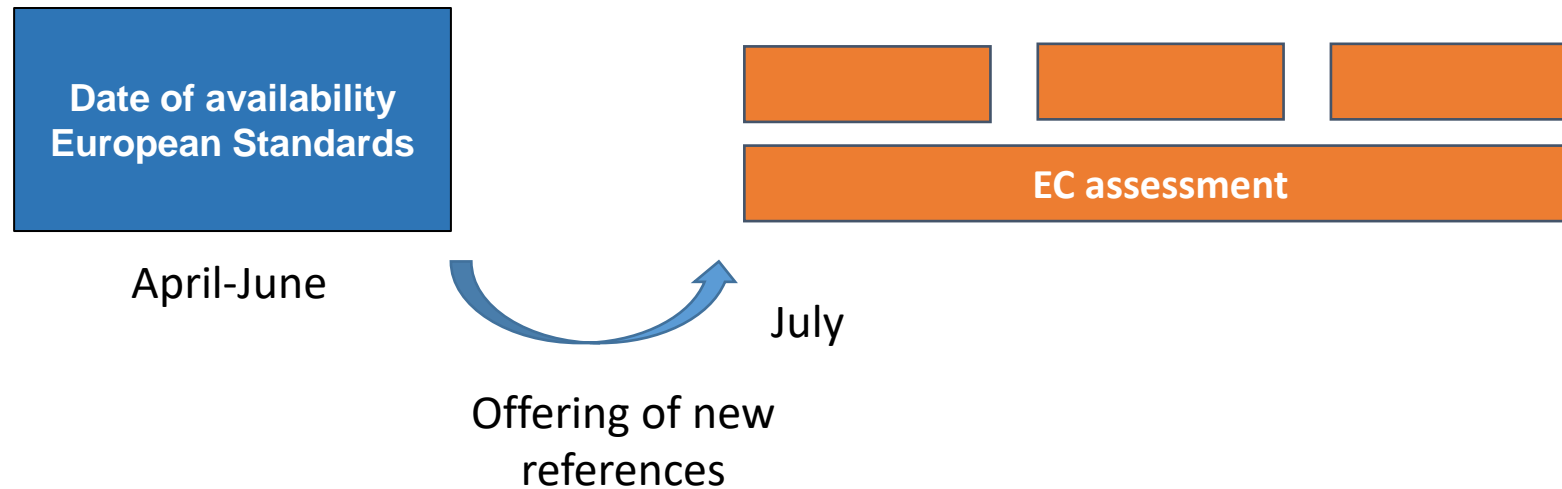
CCMC will reject hEN submission

Citation of harmonized standards in the OJEU

Citation of hENs in the OJEU – the process

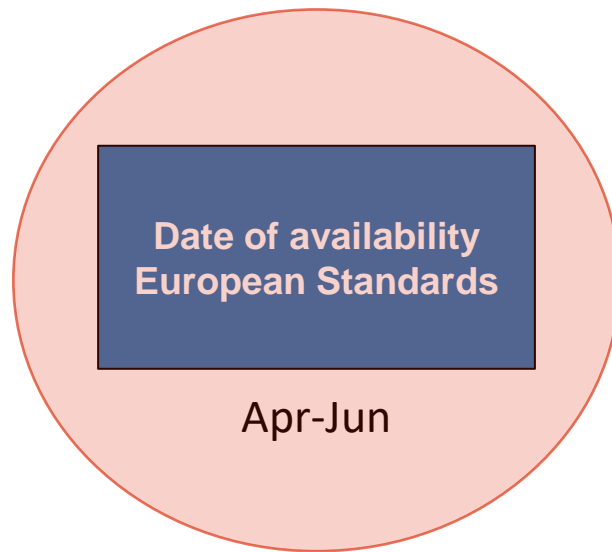


The process step by step



- ▶ Every Quarter CEN and CENELEC offer references to EC;
- ▶ e.g. DAV between April-June → offered in July

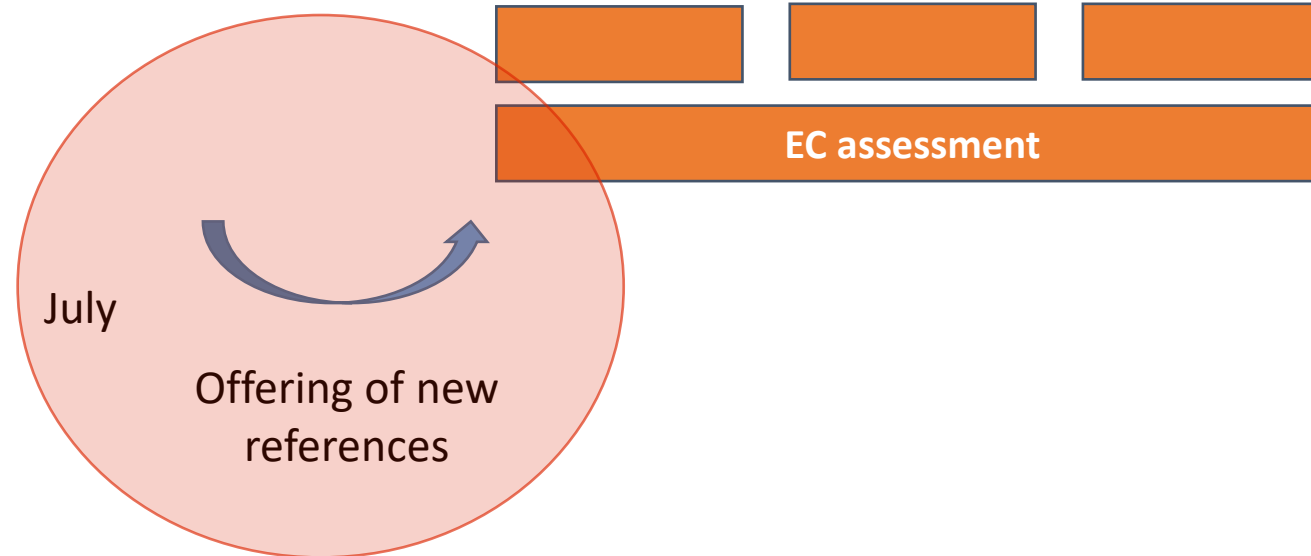
Before end of Quarter



Quarter	Period
Q1	Jan-Mar
Q2	Apr-Jun
Q3	Jul-Sep
Q4	Oct-Dec

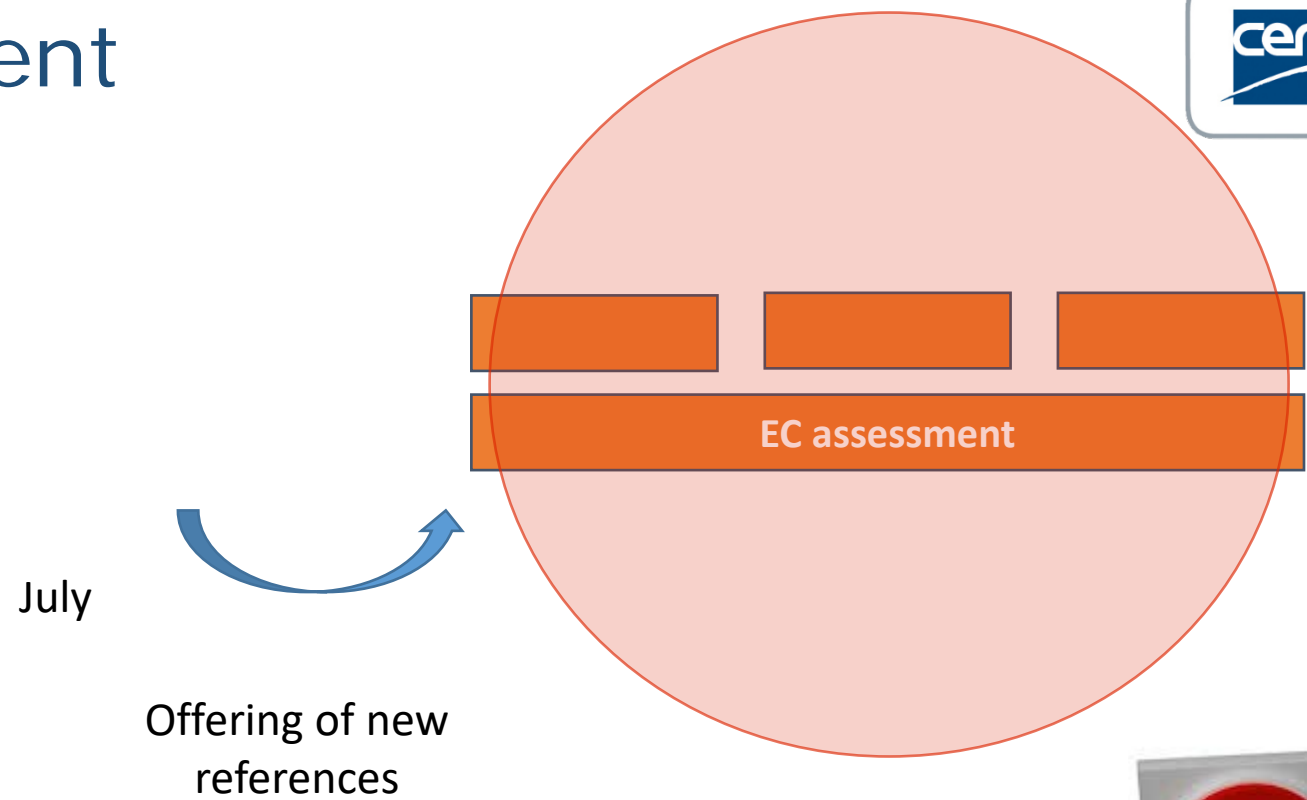
- ▶ CCMC identifies new references;
- ▶ Validation of compliance with HAS assessment (if relevant);
- ▶ Creation of the new lists to be offered (different Directives/Legislation);
- ▶ Pre-notification of references sent to EC;

Quarterly offering



- ▶ Lists which have been validated by CCMC;
- ▶ Formal letter sent to EC;
- ▶ References are provided to EC;

EC assessment



- ▶ 10 weeks deadline to provide feedback;
- ▶ Possible outcomes are:
 - ▶ Acceptance – leading to citation in OJEU
 - ▶ Rejection – reply to CEN and CENELEC

Outcome of EC assessment

Citation in OJEU in the L series
info available in

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

- ▶ CEN and CENELEC are informed

Outcome of EC assessment

Citation in OJEU in the L series – e.g. Low Voltage

22.6.2021

EN

Official Journal of the European Union

L 222/45

ANNEX I

Annex I to Implementing Decision (EU) 2019/1956 is amended as follows:

- (1) row 11 is deleted;
- (2) the following row 11a is inserted:

'11a.	EN 60335-2-85:2003 Household and similar electrical appliances – Safety -Part 2-85: Particular requirements for fabric steamers EN 60335-2-85:2003/A1:2008 EN 60335-2-85:2003/A11:2018 EN 60335-2-85:2003/A2:2020'
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Outcome of EC assessment

Citation in OJEU in the L series – e.g. Toys

31.5.2021

EN

Official Journal of the European Union

L 190/99

ANNEX I

No	Reference of the standard									
1.	EN 71-1:2014+A1:2018 Safety of toys — Part 1: Mechanical and physical properties									
2.	EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability									
3.	EN 71-3:2019 Safety of toys - Part 3: Migration of certain elements									
4.	EN 71-4:2013 Safety of toys — Part 4: Experimental sets for chemistry and related activities									
5.	EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets									
6.	EN 71-7:2014+A3:2020 Safety of toys — Part 7: Finger paints — Requirements and test methods									
7.	EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use									
8.	<p>EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances</p> <p>Informative note: The limit values in point a) of Table 2 of clause 4.2 of standard ‘EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances’ are lower than the limit values to be complied with set in point 8 of part III of Annex II to Directive 2009/48/EC. In particular those values are as follows:</p> <table border="1"> <thead> <tr> <th>Substance</th> <th>Standard EN 71-12:2016</th> <th>Directive 2009/48/EC</th> </tr> </thead> <tbody> <tr> <td>N-nitrosamines</td> <td>0,01 mg/kg</td> <td>0,05 mg/kg</td> </tr> <tr> <td>N-nitrosatable</td> <td>0,1 mg/kg</td> <td>1 mg/kg</td> </tr> </tbody> </table>	Substance	Standard EN 71-12:2016	Directive 2009/48/EC	N-nitrosamines	0,01 mg/kg	0,05 mg/kg	N-nitrosatable	0,1 mg/kg	1 mg/kg
Substance	Standard EN 71-12:2016	Directive 2009/48/EC								
N-nitrosamines	0,01 mg/kg	0,05 mg/kg								
N-nitrosatable	0,1 mg/kg	1 mg/kg								

Outcome of EC assessment

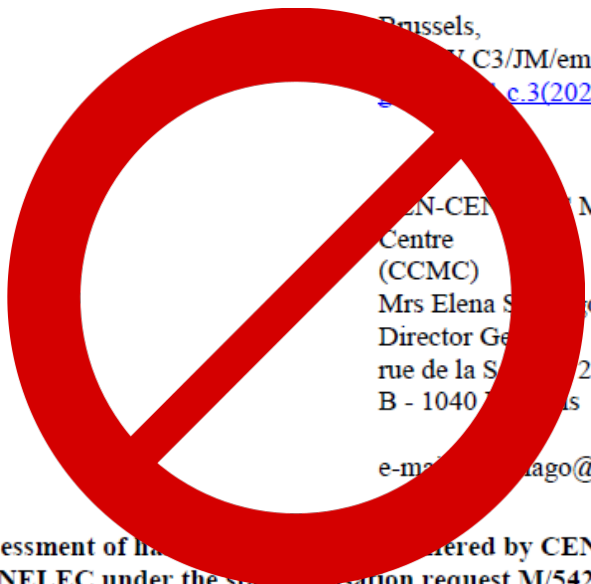
Rejection of citation

Ref. Ares(2021)1761531 - 11/03/2021



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP
AND SMES
Industrial Transformation and Advanced Value Chains
The Director

Brussels,
C3/JM/em
[c.3\(2021\)1790929](#)



CEN-CENELEC Management
Centre
(CCMC)
Mrs Elena Sordo Cid
Director General
rue de la Solenne 23
B - 1040 Brussels
e-mail: elena.sordo@cencenelec.eu

Subject: Assessment of the standard M/542, C(2015) 8736 final of 15.12.2015 in support of Directive 2013/53/EU related to recreational craft

Date of withdrawal of references to standards from the OJEU

- ▶ In the EC Decisions on OJEU publications, a specific annex lists the withdrawn references and the respective withdrawal dates

Article 2

The references of harmonised standards for machinery drafted in support of Directive 2006/42/EC listed in **Annex III** to this Decision are hereby withdrawn from the *Official Journal of the European Union* as from the dates set out in that Annex.

ANNEX III

No	Reference of standard	Date of withdrawal
1.	EN 1037:1995+A1:2008 Safety of machinery — Prevention of unexpected start-up	19 September 2020
2.	EN 474-1:2006+A4:2013 Earth-moving machinery — Safety — Part 1: General requirements Notice: This publication does not concern clause 5.8.1 Visibility — Operator's field of view of this standard, the application of which does not confer a presumption of conformity to the essential health and safety requirements 1.2.2 and 3.2.1 of Annex I to Directive 2006/42/EC.	19 September 2020

- ▶ Date of withdrawal from the OJEU is not equal to the DoW set in the superseding standard => no automatic alignment between the two dates
- ▶ As a default date of withdrawal from OJEU, EC intends to use the 18 months transition period normally used for legislation

Thank you! Questions?

Joanna Frankowska Jfrankowska@cencenelec.eu

Constant Kohler CKohler@cencenelec.eu

www.cencenelec.eu

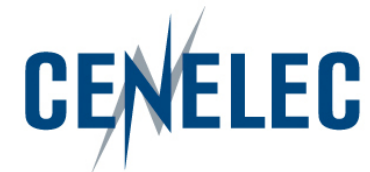
Follow us



Lunch Break

We are back at 13:10 CET





INFORMATION FOR TECHNICAL BODY OFFICERS

Best practices for TC Secretaries

Raíssa Soares & Gonçalo Ascensão

Structure

- ▶ Drafting decisions and providing them to CCMC
- ▶ Finalization of the deliverables – important elements
- ▶ CEN-CENELEC patent policy

Drafting decisions and providing them to CCMC

To-do list before a TC plenary

- ▶ Download formatted decisions (CEN boss & CLC boss)
- ▶ Copy all relevant decisions on a word file and allocate numbers
- ▶ **ALREADY** have a rough draft with good explanations
- ▶ **READ** if the decision is duly filled in, precise and in English!!
- ▶ Ensure it makes sense to people who are not a part of the TC (and to yourself after some time)
- ▶ Separate technical and process decisions

What can data service do?

- ▶ Help with decisions TC secretaries cannot register via Projex Working Area
- ▶ Decisions which are not automatic (BT 013/2018)
- ▶ Provide/manage access of liaison, affiliates, partners and EU institutions to technical committees (observers)
- ▶ Register WIs for edition 2 under VA — Joint collaboration with ISO (Revisions, amendments and corrigenda)
- ▶ Monitor registration of IEC parallel projects

What data service does not do:

- ▶ Decisions which can be registered on Projex Working Area (except in case of issues or for CENELEC - manual data handling by dataservice)
- ▶ Register national experts to ISO/TCs in case of liaisons (done by NSBs/NCs and ISO helpdesk)
- ▶ Provide access to non-TC structures (done by itsupport@cencenelec.eu)

What should you do as a TC secretary?

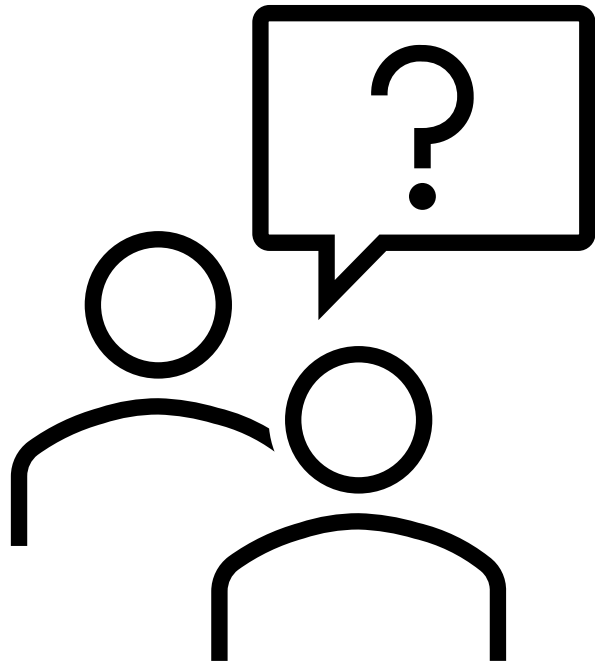


CEN

After the plenary, go through the BT 013/2018:

- ▶ See which decision you should register in working area
- ▶ Register them (If you can't – contact dataservice)
- ▶ Send the meeting minutes & unregistered decisions to dataservice

When in doubt — contact the PM



- ▶ What should be done for given action?
- ▶ What should be submitted?
- ▶ Where can I submit it?

Good practices — CEN

- ▶ After the meeting in **one** email:
 - ▶ Send meeting minutes to dataservice (to be saved in the archives);
 - ▶ Inform which decisions have been submitted via Projex Working Area;
 - ▶ Inform any difficulties you faced (if any!)

- ▶ Ensure decisions are clearly explained and justified with unique decision number and dates

- ▶ Even in case of a CIB!!

- ▶ Ensure only 1 action per decision

Formatted Decisions — CEN

Related to TC Organisation

- ▶ Appointment of the Chairperson of a Technical Committee & Checklist
- ▶ Appointment of the Vice-Chairperson of a Technical Committee (twinning arrangement)
- ▶ Approval of the revised business plan of a Technical Committee
- ▶ Confirmation of the Business Plan of a Technical Committee
- ▶ Participation of a liaison or partner organization in a Technical Committee - Approval
- ▶ Participation of a liaison or partner organization in a Technical Committee – Cancellation
- ▶ Appointment of a Working Group Convenor
- ▶ Approval of co-operation within a Technical Committee
- ▶ Final title and scope of a Technical Committee

All can be found in [CEN BOSS](#)

Formatted Decisions — CEN

Related to Technical Work

- Activation of preliminary WI number
- Adoption of a Preliminary Work Item
- Approval of a package of ENs & Checklist
- Approval of a package of ENs not belonging to the work programme of the same TC
- Change of deliverable for work items neither mandated nor covered by a Specific Agreement & Checklist
- Deletion of work items neither mandated nor covered by a Specific Agreement and possible release of their standstill
- Derogation from standstill on an EN & Checklist
- Derogation from standstill on a work item & Checklist
- Extension of dow for future ENs not yet made available to the CEN Members for final vote
- Future of ENs after Enquiry
- Merging of work items (within the frame of an approved Business Plan) & Checklist
- Negative result on a first Formal Vote (for WIs mandated or under Specific Agreement) - Decision on the future of the WI
- Negative result on a first Formal Vote (for WIs neither mandated nor covered by a Specific Agreement) - Decision on the future of the WI
- Normative references in European Standards to documents other than CEN, CENELEC, ETSI ISO or IEC documents
- Review of a CEN/TS - Decision to keep as a CEN/TS
- Review of a CEN/TS - Decision to withdraw the CEN/TS
- Splitting of work items (within the frame of an approved Business Plan)
- Transfer of WI(s) to ISO (ISO Lead)
- Tolerance request for the development of ENs, CEN/TRs and CEN/TSSs
- A-deviation - Result of the verification of a notification of A-deviation(s)
- Change of deliverable or deletion of work item for work mandated or covered by an Order Voucher
- Review of EN - Confirmation of EN
- Review of EN - Withdrawal of EN

All can be found in [CEN BOSS](#)

Delegated Decisions — CEN

Related to the Technical work

- Activation of preliminary Work Item number
- Approval of a package of ENs
- Approval of a package of ENs not belonging to the work programme of the same TC
- Change of deliverable for work items neither mandated nor covered by a Specific Agreement
- Deletion of work items neither mandated nor covered by a Specific Agreement and possible release of their standstill
- Derogation from standstill on an EN
- Derogation from standstill on a Work Item
- Extension of DOW for future ENs not yet made available to the CEN Members for final vote
- Future of ENs after Enquiry
- Merging of work items (within the frame of an approved Business Plan)
- Negative result on a first Formal Vote (for WI mandated or under Specific Agreement) - Decision on the future of the work item
- Negative result on a first Formal Vote (for WI neither mandated nor covered by a Specific Agreement) - Decision on the future of the work item
- Normative references in European Standards to documents other than CEN, CENELEC, ETSI ISO or IEC documents
- Splitting of work items
- Transfer of work item(s) to ISO (ISO Lead)
- Tolerance request for the development of ENs, CEN/TRs and CEN/TSs

Related to TC organization

- Appointment of the Chairperson of a TC
- Appointment of the Vice-Chairperson of a TC
- Approval of the revised business plan of a TC
- Confirmation of the Business Plan of a TC
- Participation of a Liaison or Partner organization in a TC - Approval
- Participation of a Liaison or Partner organization in a TC - Cancellation

List can be found in [CEN BOSS](#)

Decisions via working area — CEN

- ▲ Adoption of NWI
- ▲ Adoption of PWI
- ▲ Activation of PWI
- ▲ Splitting of a WI
- ▲ Merging of a WI
- ▲ Tolerance request
- ▲ Decision to launch a FV
- ▲ Decision to launch a 2nd ENQ
- ▲ Decision after a negative first vote
- ▲ Decision to skip FV
- ▲ Decision to launch the Enquiry
- ▲ Deletion of a WI
- ▲ Change the title and/or scope
- ▲ Change of deliverable for a WI
- ▲ Change of track for a WI
- ▲ Confirmation of published EN
- ▲ Confirmation of published CEN/TS
- ▲ Withdrawal of published EN
- ▲ Withdrawal of published TS or TR
- ▲ Reference to other normative documents
- ▲ Extension of DOW to be included in future EN
- ▲ Activation of one-change option (does not require a TC decision)

Other Decisions — CEN

Decisions related to TC internal organization

- ▶ Creation of a Working Group
- ▶ Disbandment of a Working Group
- ▶ Change of title of a Working Group

Good example when drafting a decision — CEN

► Use of the formatted templates

Decision number taken by CEN/TC number on CCYY-MM-DD

Subject : CEN/TC number– Creation of WG number and title

CEN/TC number,

- Considering the CEN/CENELEC Internal Regulations – Part 2, subclause 2.5 concerning working groups;

Decides to create WG number, title, scope and secretariat.

The decision is taken by *unanimity or simple majority with N positive votes, N negative vote(s) and N abstention(s).*

► Use of the formatted templates

Decision CEN/TC 600 44/2021 taken on 2021-11-11

Subject: CEN/TC 600 - Decision to skip the Formal Vote

CEN/TC 600 - Title


- considering the results of the Enquiry ballot;
- considering the table of decisions and the formal written proposals as distributed after the comments decision meeting;
- considering the CEN/CENELEC Internal Regulations - Part 2, clause 11.2.3;
- considering Decisions BT 34/2002, BT 42/2003 and related document BT N 6962 concerning timeframes for the development of ENs;
- considering Decision BT 35/2014 to associate a vote to the CEN Enquiry and to allow Technical Bodies to decide to skip the Formal Vote;
- considering Decision 49/2014 to allow Technical Bodies to decide to skip the Formal Vote through a TC decision based on simple majority only;

decides to skip the Formal Vote and proceed with the publication of WI 00600611 - EN ISO 600:2020/prA1 – Title (ISO 600:2020/DAmD 1:2021) *(In this case the TC must not finalize the publication, this will be done by CCMC. Instead the TC must notify CCMC of its intention to skip Formal Vote by posting only an electronic transmission notice onto eTrans.)*

The decision was taken by unanimity.

► Respect only one action per decision

Reference: Activation preliminary work item EN

Committee: CEN/TC  **Type:** CIB-ActivPWI (Activation of a Preliminary Work Item)

Status: Closed

Opening date: 2021-09-10 **Closing date:** 2021-11-10

Opened on: 2021-09-10 00:04 **Voting closed on:** 2021-11-11 00:03

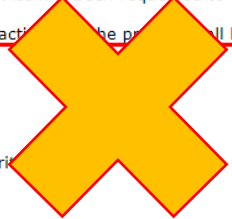
Title: The CEN/TC preliminary work item 006002356 – Title has reached the end of the 3 years preliminary stage (project started 18th June 2018).
Therefore the work item is been requested to become active.

In addition to the activation of the preliminary work item, the project will be split into the two following parts:

- Title – Part 1
- Title – Part 2

Method: Weighted Majority

Secretariat:



Separate CIB for the decision to Split the PWI

Common issues with submissions via Working Area



► Upon the creation of a revision (or a new project that will supersede one or more projects), missing information regarding supersession information:

Section 1 - Complete type of deliverable and item description

1. Deliverable

EN

TS

TR

2. This item corresponds to

A new project

An amendment to an EN

The revision of an EN

The conversion of a CEN/TS into an EN

The conversion of an ENV into an EN

The revision of a CEN/TS

A new TR

The revision of a CEN/TR

3. Explain the purpose and give a justification for this proposal ⓘ

→ The information must be added upon creation.
more than one project can be added to be superseded

If missed, please inform dataservice@cencenelec.eu as soon as possible to add the information.

- ISO documents can be created to revise a homegrown:
 - > Select the EN to be revised
 - > In field 13 or 14 input ISO's document information

Common issues with submissions via Working Area

► Parallel projects (joint collaboration with ISO) and adoptions:

Section 6 - Complete Vienna Agreement or links with documents from other organizations

13. Vienna Agreement

No or expected CEN lead ⓘ

Yes - Parallel ISO lead

ISO project reference ⓘ

ISO project ID ⓘ

ISO TC ⓘ

PARALLEL PROJECT
JOINT COLLABORATION WITH ISO



Field 13 is for parallel projects (joint collaboration with ISO)



Field 14 is for the adoption of a published ISO document

14. The project is based in

No document from another organization

An ISO document (not covered by a parallel procedure)

Identical

Non-identical

ISO project reference Issue year ⓘ ISO project ID ⓘ

A document from another organization

Identical

Non-identical

Organization name ⓘ Document reference ⓘ Issue year ⓘ

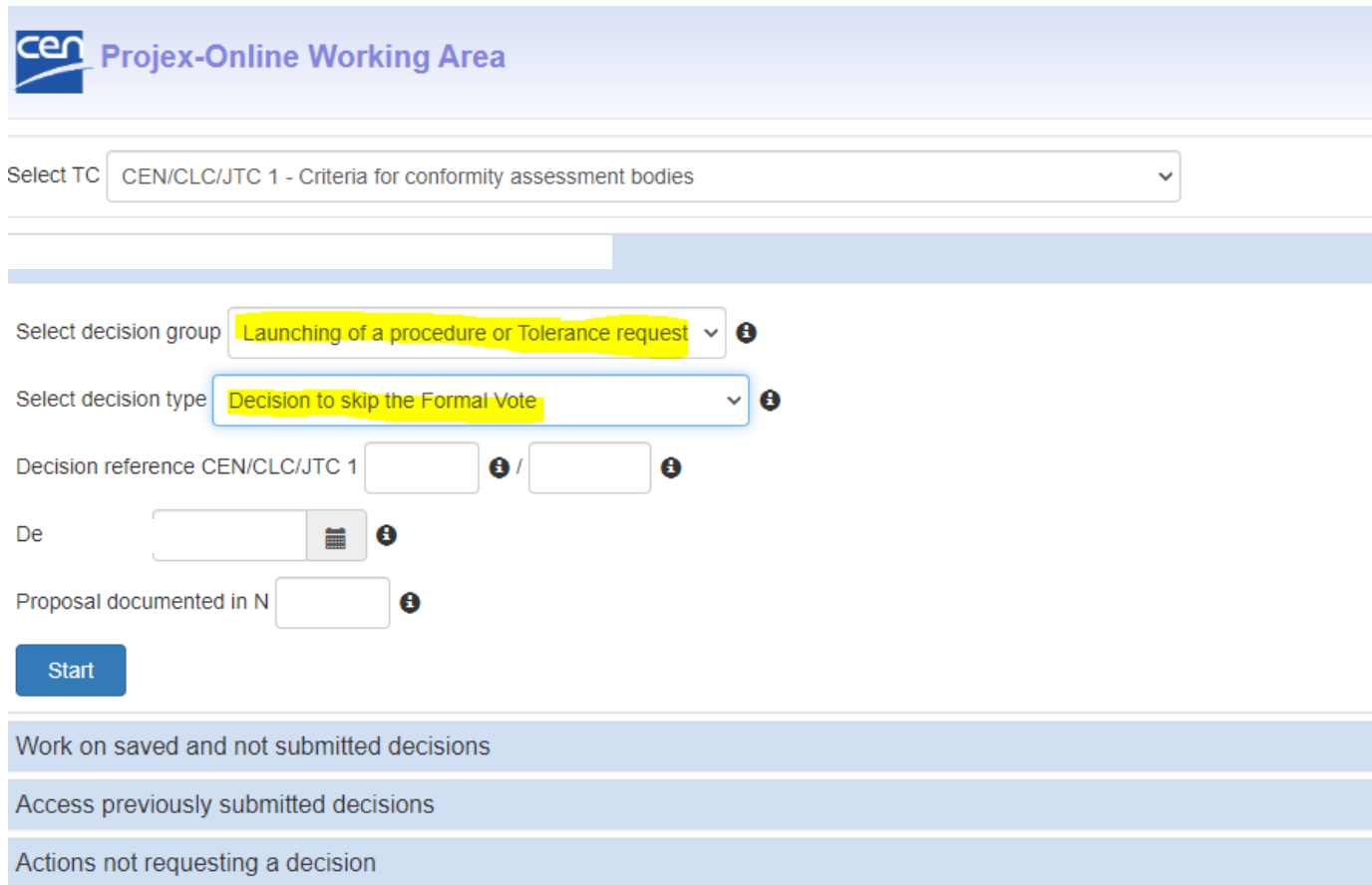
ADOPTIONS
OF
PUBLISHED ISO DOCUMENTS

Encoding the **correct information** in the **correct field** ensures:

- ✓ A smoother procedure (no manual data correction)
- ✓ Prevents errors in the lifespan of projects under VA

Common issues with submissions via Working Area

► Decisions to Skip FV:



The screenshot shows the 'Projex-Online Working Area' interface. It includes a dropdown menu for 'Select TC' with the value 'CEN/CLC/JTC 1 - Criteria for conformity assessment bodies'. Below this are two more dropdown menus: 'Select decision group' with the value 'Launching of a procedure or Tolerance request' and 'Select decision type' with the value 'Decision to skip the Formal Vote'. There are also input fields for 'Decision reference CEN/CLC/JTC 1', 'De', and 'Proposal documented in N', each with an information icon. A blue 'Start' button is located below the input fields. At the bottom, there are three blue bars with the text: 'Work on saved and not submitted decisions', 'Access previously submitted decisions', and 'Actions not requesting a decision'.

✓ Decisions to Skip FV should be submitted via Projex Working Area and will be further processed by dataservice upon reception.



For ISO parallel projects (joint collaboration), the decision to Skip FV is needed (only adoptions are exempted).

CENELEC

- ▶ After the meeting in one email:
 - ▶ Send meeting minutes to data services (to save in the archives)
 - ▶ TC report
 - ▶ And difficulties/questions you face (if any!)
- ▶ Ensure decisions are clearly explained and justified
- ▶ Even in case of a CIV!!
- ▶ Every action – 1 decision
- ▶ For parallel WIs with IEC → Follow closely and at an early stage the work at IEC level → Timely prepare European elements for CD assessment and/or CMs.

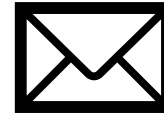
Good practices — CENELEC TC Report to BT



- ▶ Ensure decisions are clearly explained and justified
- ▶ New [template](#) for TC report to BT

Other Decisions/Requests — CENELEC

- ▶ Creation of a Working Group
- ▶ Disbandment of a Working Group
- ▶ Changing Working Group Title
- ▶ Appointment of Working Group Convenor
- ▶ Tolerance request
- ▶ Activation of the one-change option
- ▶ NWIP
- ▶ Skip Formal Vote



dataservice@cenelec.eu

Good example for drafting a request — CENELEC

CLC/TC **number**— Creation of **WG number and title**

- Considering the CEN/CENELEC Internal Regulations – Part 2, subclause 2.5 concerning working groups;

Requests to create WG number, title, scope and secretariat.

Good examples for drafting NWIP — CENELEC

► NWIP — Dates for flexible WIs

Dates provided in the form should be correct and compliant to the rules of the [flexible development of standards](#).

PROJECT MANAGMENT					
Proposed target dates					
1 st WD (20.60)	2020-01-27	ENQ (30.99)	2020-02-17	FV (45.99)	2020-11-17
	BT approval + 3 weeks		BT approval + 6 weeks	(EN/HD ONLY)	12 weeks
Drafting Body					

➔ Dates + Number of weeks

PROJECT MANAGMENT					
Proposed target dates					
1 st WD (20.60)	BT approval + 3 weeks	ENQ (30.99)	BT approval + 6 weeks	FV (45.99)	12 weeks
				(EN/HD ONLY)	

➔ Number of weeks

[Flexible Timeframe Calculator](#)

Reminder: The date for the circulation of the 1st WD (20.60) is a fixed date. It is always half the time for the circulation of the draft for the Enquiry (30.99).

Good examples for drafting NWIP — CENELEC

► NWIP — Information regarding offering to IEC

Provide accurate and short justification regarding the reason of not offering to IEC:

RELATION TO OTHER ORGANISATIONS OR PROJECTS	
IEC RELATIONS	
<input type="checkbox"/> To be offered to IEC under the Frankfurt agreement	Justification for not offering Not applicable because the project will introduce the CMs in according to LVD essential requirements

Good examples for drafting NWIP — CENELEC

- ▶ NWIP — Information regarding members endorsing the work

Mandatory to have at least 5 members endorsing the work.

If this information is missing, the request will not proceed to BT approval.

Commitment	
<input checked="" type="checkbox"/> at least five NCs are committed to participate in the work (proposal cannot be usually approved without the commitment of 5 NCs)	List of NC DE, GB, IT, NL, DK, TK, CH, FR

Finalization of deliverables

Technical changes after FV

- ▶ ***Decision CEN BT 34/2018 & CENELEC BT D160/005***
 - ▶ confirmed the principle that after Formal Vote and during TC proofing **only editorial comments are to be implemented**, while technical comments are to be taken into consideration for the next review of the standard;
 - ▶ confirmed that Technical Bodies **shall provide a quality document for Enquiry and Formal Vote**

Changes after Formal Vote

- ▶ No editorial or technical changes allowed after submission of documents to FV!! (with two exceptions)

As per CEN BT 036/2019 and CENELEC BT D163/029

- ▶ **Exception 1:** Obvious editorial errors and errors introduced by CCMC in preparation of draft FV

‘**Obvious editorial error**’ is an editorial error that is recognised as such immediately and without any doubt, both by the CCMC editor and the TC Secretary.

Absence of the aforementioned condition disqualifies the requested changes for direct editorial correction

► **Exception 2:** Technical changes aiming to correct errors and thus avoiding a deficient standard

According to decision BT 48/2014 & D149/017

Request by the BT member holding the secretariat with justification (for minor changes)



BT approval —→ CCMC implements changes —→ Publication

Other comments

- ▶ Retained for next review
- ▶ Recorded by CCMC as 'noted for future consideration' using the commenting form

TC proofing

- ▶ 2 weeks each for CCMC editing and TC proofing (exceptions in CENELEC for holiday periods)
CENELEC BT D168/004
- ▶ If no response obtained – CCMC moves to next step
- ▶ Exceptional cases – extension by 1 week!
- ▶ If problems persist – BTs to be contacted

- ▶ Principles defined in [CEN-CENELEC Guide 8](#) - CEN-CENELEC Guidelines for Implementation of the Common Policy on Patents
- ▶ Encouragement for experts to disclose all essential patents
- ▶ Patents included in the standard:
 - ▶ A- Patents that are **essential** for the standard
 - ▶ B- Patents of which **licensing conditions** are **declared**
- ▶ Information and forms available in CEN and CENELEC BOSS



INFORMATION FOR TECHNICAL BODY OFFICERS

Thank you!

www.cencenelec.eu

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