

European Standardization Organizations

Webinar

'Innovative Process for homegrown Harmonized Standards'

Frédéric MLANAO - Alberto SIMEONI

Anda BANEIA – Mauro SOARES



*We start
at
14:00*

A yellow sticky note with a red pushpin at the top right corner, containing the text 'We start at 14:00' in a black, handwritten-style font.

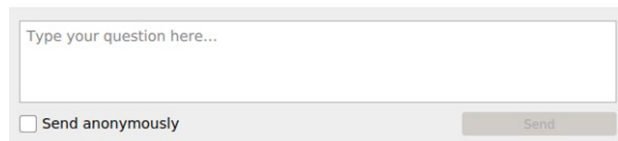


Els SOMERS
Project Manager
Policy & Partnerships
CEN-CENELEC
esomers@cencenelec.eu

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Your speakers today



Frédéric MLANAO

Account Manager

Harmonized Standards Compliance
Standardization

CEN-CENELEC

fmlanao@cencenelec.eu



Anda BANEAE

Project Manager

Harmonized Standards Compliance
Standardization

CEN-CENELEC

abanea@cencenelec.eu



Alberto SIMEONI

Account Manager

Technical Boards • Standardization

CEN-CENELEC

asimeoni@cencenelec.eu



Mauro SOARES

Project Manager

Harmonized Standards Compliance
Standardization

CEN-CENELEC

msoares@cencenelec.eu

Agenda

1. Introduction
2. Why
3. What
4. How
5. Key take aways

- ▶ hEN: Harmonized European Standard
- ▶ TB: Technical Body
- ▶ TBO: Technical Body Officer
- ▶ CCMC: CEN and CENELEC Management Center
- ▶ QC: Quality Check
- ▶ LoC: Lack of compliance assessment
- ▶ EY: Ernst and Young, HAS contractor
- ▶ EC: European Commission
- ▶ ESO: European Standardization Organization
- ▶ WG: Working Group
- ▶ NWI: New Work Item
- ▶ VHK Consultants: Consultants for DG ENERGY (EcoDesign)

Introduction

Innovative process applies to Homegrown hENs

- ▶ **which are intended to be submitted to the EC consultants' assessment, ie. HAS consultants (DG GROW) and VHK consultants managed by DG ENERGY (ie. Eco-design)**
- ▶ And launched for NWI approval as of 1 October 2023;

It does not apply to:

- ▶ Any homegrown hEN, for which the NWIP was launched for approval before 1 October 2023
- ▶ Any homegrown hEN which is NOT intended for submission to the consultants

Two steps approach implementation

- ▶ IT tools need to be updated to fully support innovative process

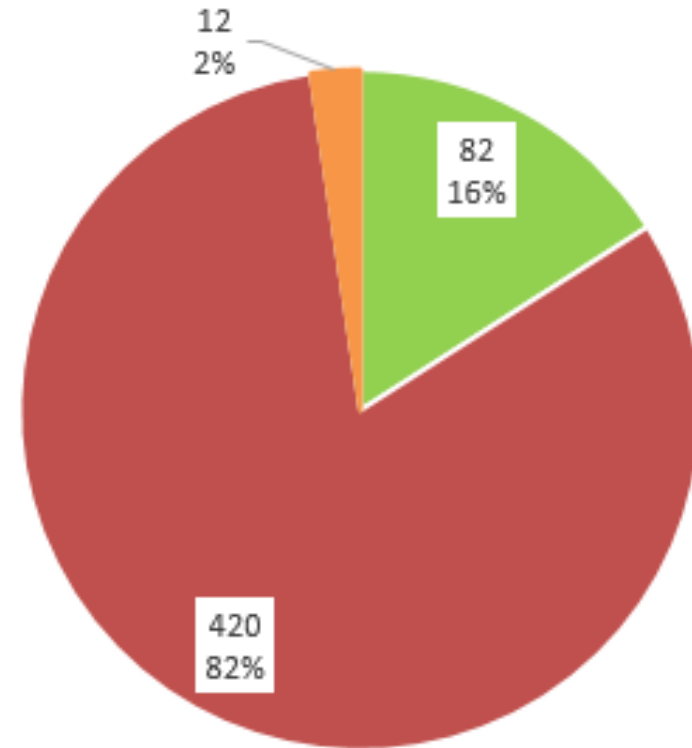
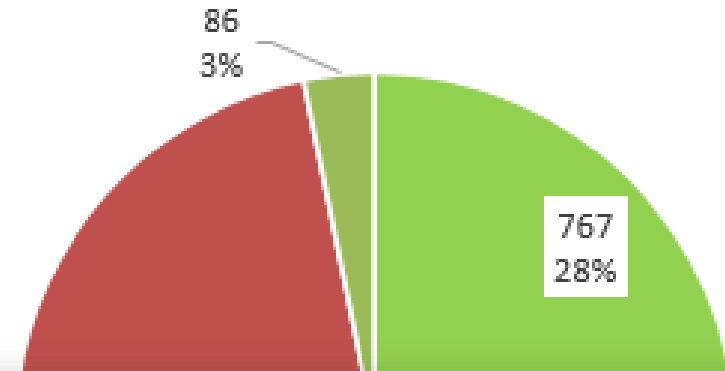
Under discussion with ISO/IEC for parallel work

- ▶ Current HAS process applies for parallel work

Why

Why the innovative process

- ▶ Challenging to get a compliant assessment
- ▶ During previous HAS contract: average around 30% 'compliant outcome' for all stages
- ▶ Since January 2023 under the new HAS contract: average of 16% 'compliant outcome' for all stages
- ▶ Substantial change needed



- ▶ The objective of the innovative process is to improve the timely delivery of compliant harmonized Standards by
 - ▶ shifting the focus and the efforts at the beginning of the development process, i.e. introducing the concept of “Mature draft” and “Pre-FV assessment”
 - ▶ introducing the new CCMC Quality Check (QC).

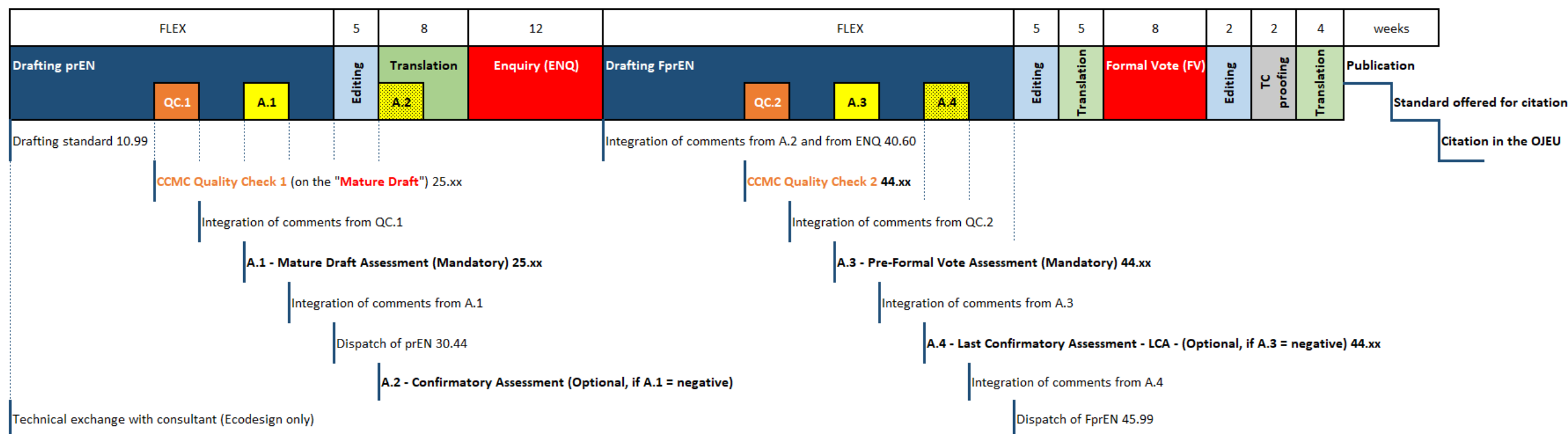
- ▶ Again: this innovative process applies only to hEN which are submitted to the EC consultants’ assessment.

What

Innovative process based on 2 main pillars:

- ▶ Mature draft concept
 - ▶ Draft ready for ENQ
 - ▶ Mature draft assessment mandatory
 - ▶ Optional FWD assessment **not possible** anymore (while FWD circulation still possible)
- ▶ CCMC Quality Check
 - ▶ help Technical Bodies identify elements in the draft, or the related Annexes, that could potentially lead to a lack of compliance assessment
 - ▶ Will use Common checklist as support document
 - ▶ Replaces “Harmonized Standards checklist”

Homegrown candidate hEN for citation



Mature draft

- Quality check: **3 weeks**
- TC to consider and revise: 4 weeks (6 weeks in holiday period)
- CCMC to submit the draft to HAS assessment
- HAS assessment: **5 weeks**
- TC to consider and revise: 5 weeks

Total up to 17 weeks = Less than 4 months

Pre-FV draft

- Quality check: **3 weeks**
- TC to consider and revise: 4 weeks (6 weeks in holiday period)
- CCMC to submit the draft to HAS assessment
- HAS assessment: **5 weeks**
- TC to consider and revise: 5 weeks (5 same as today)

Total 17 weeks = Less than 4 months

LCA draft

- CCMC to submit the draft to HAS assessment
- HAS assessment: **5 weeks**
- TC to consider and revise: 3 weeks (4 weeks in holiday period)

Total 8 weeks = Less than 2 months

Total up to 25 weeks = Less than 6 months

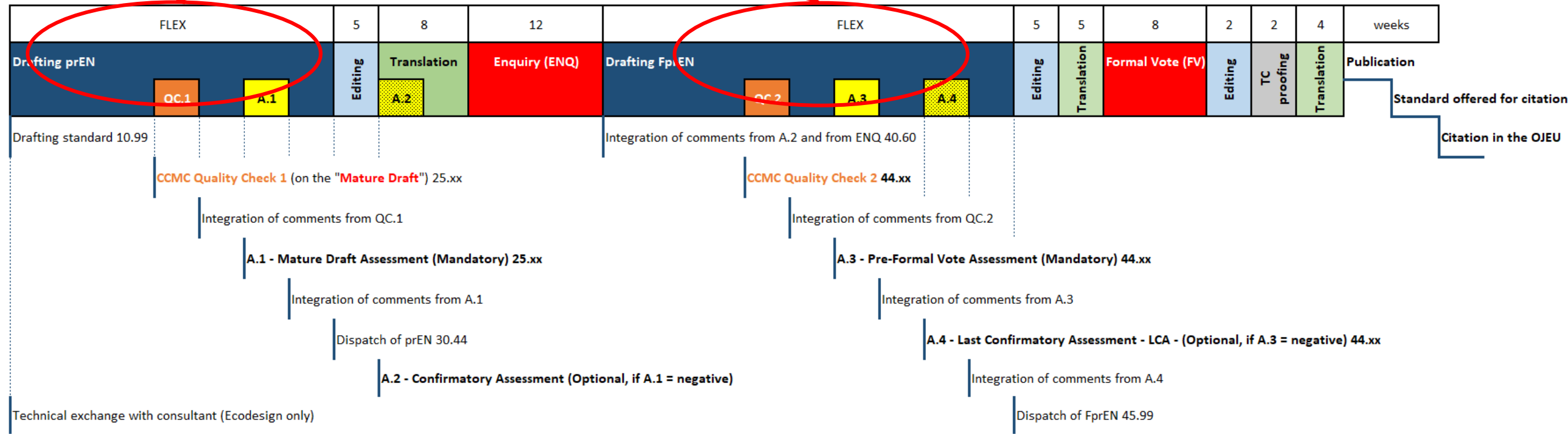
How

How

Impact on planning (flex process)

Principles of flex planning

Max 68 weeks

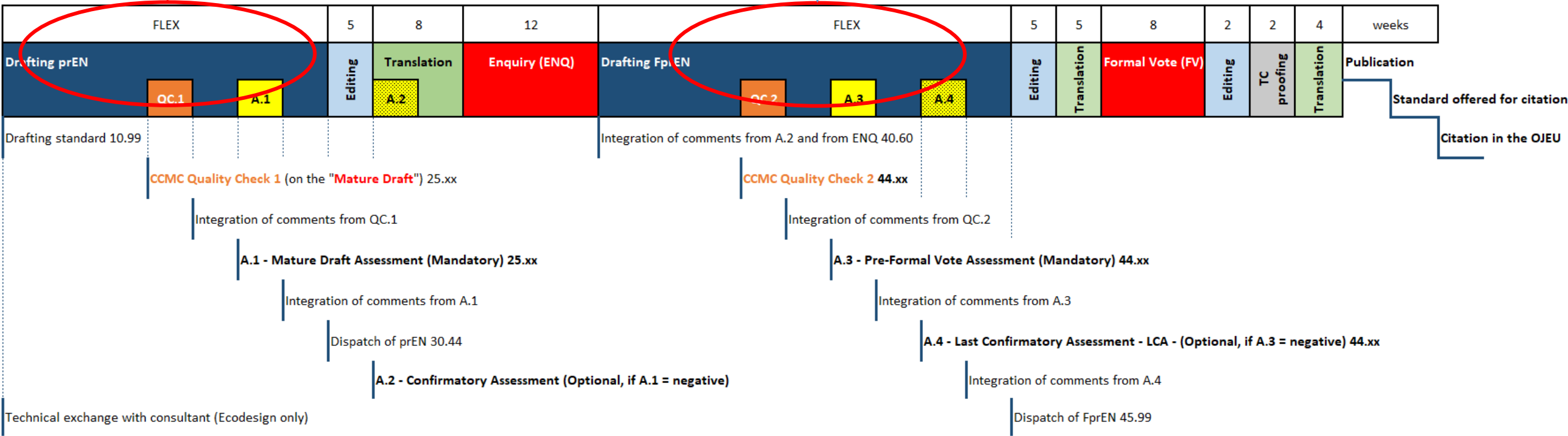


BT recommendation for main standards

50 weeks

18 weeks

+ Tolerance 39 weeks



Creation of a Work Item - CEN

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

Stage Code	Stage	Target date	
10.99	Decision on WI Proposal	2020-03-04	+ 17 weeks
20.60	Circulation of 1st WD	2020-07-01	+ 17 weeks
30.99	Dispatch ENQ draft to CMC	2020-10-28 	+ 13 weeks
40.20	Submission to Enquiry	2021-01-27	+ 12 weeks
40.60	Closure of Enquiry	2021-04-21	+ 34 weeks
45.99	Dispatch FV draft to CMC	2021-12-15 	+ 8 weeks
50.20	Submission to Formal Vote	2022-02-09	+ 8 weeks
50.60	Closure of Formal Vote	2022-04-06	+ 4 weeks
60.55	DOR/Ratification	2022-05-04	+ 4 weeks
60.60	DAV/Definitive text available	2022-06-01	

Project start date: 

Please enter the start date of the project and push on the button 'Calculate target' dates to committee plan.

Remark: the dates may still be manually changed after the simulation but cannot go beyond

← Editable

Default target dates are proposed by the system, but they can be edited.

← Editable

Creation of a Work Item - CEN

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45.99	Dispatch FV draft to CMC	2021-12-15	+ 8 weeks
50.20	Submission to Formal Vote	2022-02-09	+ 8 weeks
50.60	Closure of Formal Vote	2022-04-06	+ 4 weeks
60.55	DOR/Ratification	2022-05-04	+ 4 weeks
60.60	DAV/Definitive text available	2022-06-01	

Project start date:

BT recommends to set 50 weeks for stage (a)
+25
+25

← Editable

Default target dates are proposed by the system, but they can be edited.

By default time for stage (e) will be +18

← Editable

Express the target dates through a duration in the NWIP form:

- (1 WD_TARGET: BT decision + N weeks)
- ENQ_TARGET: BT decision + N weeks
- FV_TARGET: ENQ + N weeks

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.			
Project start date (10.99)	1 st WD (20.60)	ENQ (30.99)	FV (45.99)
<u>yyyy/mm/dd</u>	Date will be added by CCMC. It is half the number of weeks planned for ENQ (30.99)	yyyy/mm/dd 10.99 + 50 weeks	yyyy/mm/dd 40.60 + 18 weeks



Duration for 1WD is half of duration for 30.99. It could be indicated or will be deduced by 30.99

Express the target dates through a duration in the NWIP form:

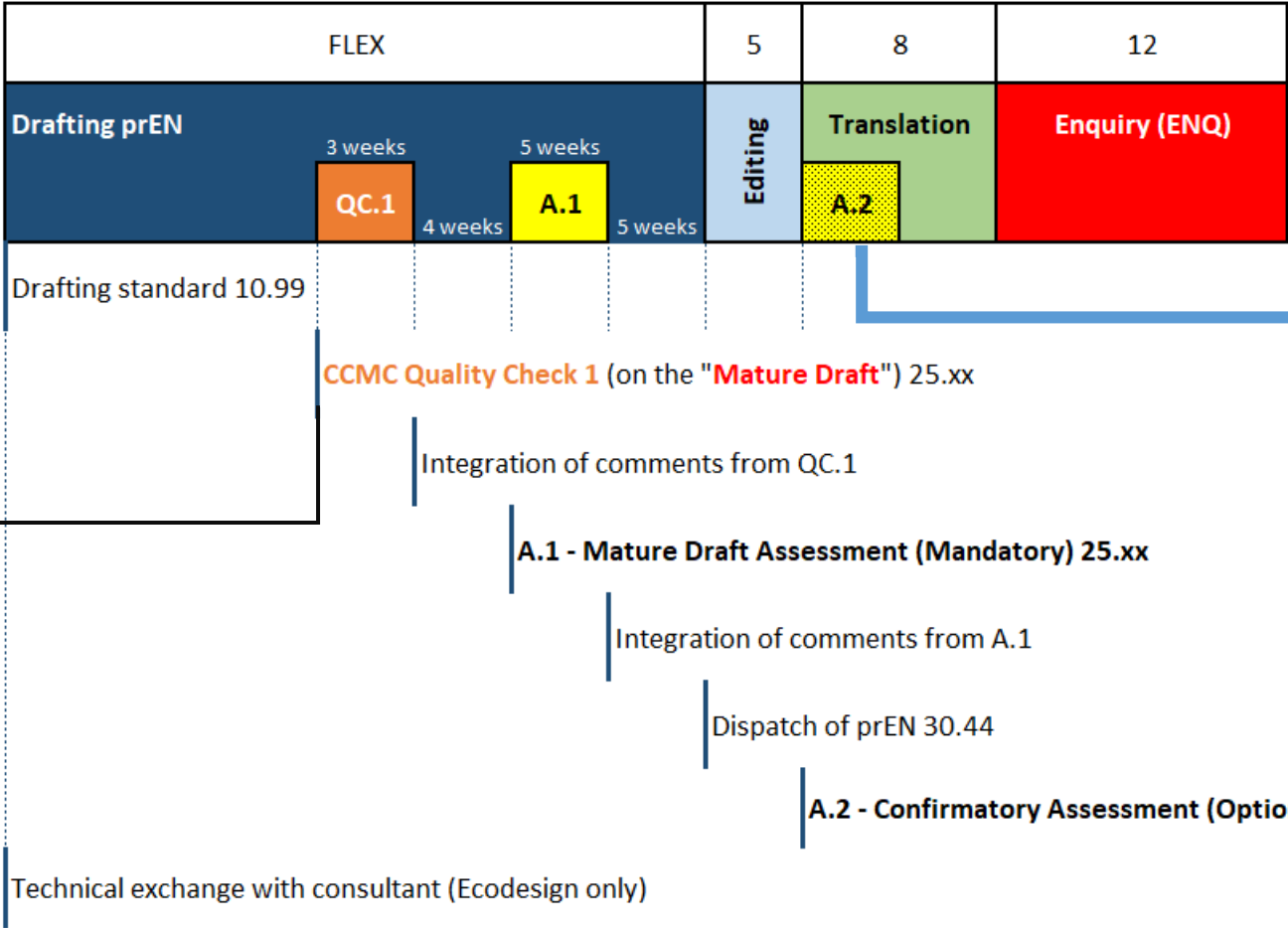
<u>Project start date (10.99)</u>	<u>Dispatch of 1st WD (20.60)</u>	<u>Dispatch of ENQ (30.99)</u>	<u>Dispatch of FV draft (45.99)</u>
<u>yyyy-mm-dd</u>	It is half the number of weeks planned for ENQ (30.99) For CEN/TC: automatically calculated via Working Area For JTC: date will be added by CCMC	<u>yyyy-mm-dd</u> For JTC only: to indicate the duration in weeks from <u>10.99</u> 10.99 + 50 weeks	<u>yyyy/mm/dd</u> For JTC only: to indicate the duration in weeks from <u>40.60</u> 40.60 + 18 weeks

With CEN WI lead

With CENELEC WI lead

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.			
<u>Project start date (10.99)</u>	1 st WD (20.60)	ENQ (30.99)	FV (45.99)
<u>yyyy/mm/dd</u>	Date will be added by CCMC. It is half the number of weeks planned for ENQ (30.99)	<u>yyyy/mm/dd</u> 10.99 + 50 weeks	<u>yyyy/mm/dd</u> 40.60 + 18 weeks

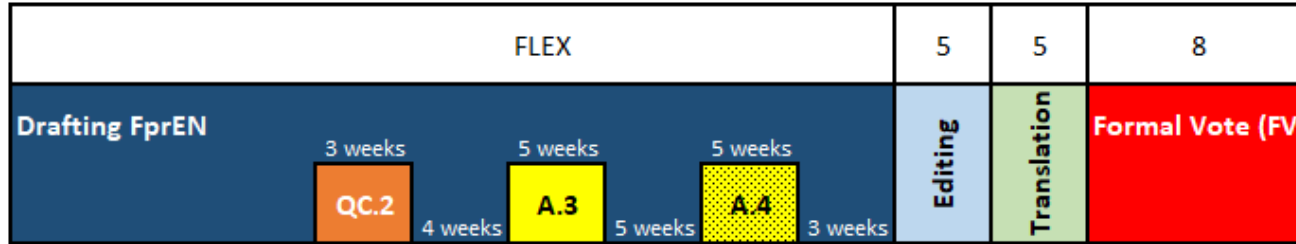
Innovative process impact on timeframe



TC to plan WG meetings to address comments.

In case of **Lack of Compliance** outcome in the A.2 Enquiry Confirmatory Assessment, TC should submit the request for a 9 months tolerance.

Innovative process impact on timeframe



Integration of comments from A.2 and from ENQ 40.60

CCMC Quality Check 2 44.xx

Integration of comments from QC.2

A.3 - Pre-Formal Vote Assessment (Mandatory) 44.xx

Integration of comments from A.3

A.4 - Last Confirmatory Assessment - LCA - (Optional, if A.3 = negative) 44.xx

Integration of comments from A.4

Dispatch of FprEN 45.99

Use the tolerance!

How?

New Common Checklist

- ▶ **Goal:**
 - ▶ support Technical Bodies in drafting hEN
 - ▶ Increase HAS assessment 'Compliant'
 - ▶ Have a common checklist used by ESOs and EC/HAS
 - ▶ TBs will use same document as HAS consultants

- ▶ **Mandatory** as of 2023-10-01
- ▶ Mandatory for homegrown draft hEN
- ▶ Strongly recommended for drafting of hEN under VA and FA (with ISO or IEC lead)
- ▶ [CEN BOSS](#) – [CENELEC BOSS](#)

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

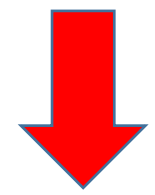
- ▶ Checks that checklist is filled out
- ▶ Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?



ENQ/FV procedure could start

Checklist not submitted?



CCMC will reject hEN submission

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)

TC secretary

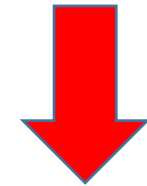
- ▶ Checks that checklist is filled out
- ▶ Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?



ENQ/FV procedure could start

Checklist not submitted?



CCMC will reject hEN submission

How?

CCMC Quality Check

EY critical findings (August 2022 to May 2023)

AR ref.	Critical findings (CEN/CLC only)	Frequency of finding	% of finding	Total # of Assessments (n)
A- 1.2.1.	Terminology	25	7%	354
A- 1.2.2.	Foreword	22	6%	354
A- 1.2.3.	Scope covers products not considered by the relevant legal requirements	17	5%	354
A- 1.2.4.	The Scope sets requirements or covers aspects which cannot be subject to harmonised standards	7	2%	354
A- 1.2.5.	Scope excludes products or aspects that are expected to be covered by the standard	27	8%	354
A- 1.2.6.	Normative references that are essential for the assessment of harmonised elements are not available	28	8%	354
A- 1.2.7.	Document contains undated normative references without proper justification	77	22%	354
A- 1.2.8.	Too long chains of normative references	9	3%	354
A- 1.2.9.	Normative references need updating or reconsideration	71	20%	354
A- 1.2.10.	Technical content of the document contains requirements that do not align with or contradict relevant EU legislation	102	29%	354
A- 1.2.11.	Technical content of the document unsuitably repeats legal requirements as part of its normative requirements	33	9%	354
A- 1.2.12.	Absence of reproducible tests or assessment methods	64	18%	354
A- 1.2.13.	Neutrality principle is not respected: the document contains clauses imposing requirements or obligations on or between certain economic operators	32	9%	354
A- 1.2.14.	Neutrality principle is not respected in requirements for verifications, sampling and testing	34	10%	354
A- 1.2.15.	Risk assessment or identification of relevant risks is missing or not complete	33	9%	354
A- 1.2.16.	The Annex Z is not sufficiently detailed	71	20%	354
A- 1.2.17.	The Annex Z does not properly refer to the relevant legal requirements	119	34%	354
A- 1.2.18.	The document is not aligned with the guidance documents or checklist	23	6%	354
A- 1.2.19.	Other comments	118	33%	354

- ▶ Quality Check only performed at:
 - ▶ Mature Draft stage
 - ▶ Pre-Formal Vote stage
- ▶ NEW Common Checklist for Harmonized Standards is the basis of the CCMC Quality Check
- ▶ Only Criteria linked to IR3, Normative References and Annex ZA/ZZ are checked

- ▶ New Common checklist elements checked by CCMC Quality Check:
 - ▶ Normative References
 - ▶ Annex ZA/ZZ
 - ▶ Foreword
 - ▶ Scope
 - ▶ Terminology
 - ▶ Neutrality Principle
 - ▶ Ambiguities within the text
 - ▶ Personal Data and Other

▶ Normative References

- ▶ They have a big impact in the outcome of the HAS Assessment
- ▶ To improve the chances of compliance the Normative References should be:
 - ▶ Dated
 - ▶ Active, Published and not subject to Formal objection
 - ▶ Normatively referred to within the text giving presumption of conformity (linked to the Annex ZA/ZZ)
 - ▶ Follow the rules of the [Guidance on Normative References in Harmonized Standards](#) and [CEN-CENELEC EC Internal Regulations – Part 3](#)

▶ Annex ZA/ZZ

- ▶ It has a big impact in the outcome of the HAS Assessment
- ▶ To improve the chances of compliance the Annex ZA/ZZ should:
 - ▶ Follow the correct template depending on each sector (for each Directive/Regulation covered by the Harmonized Standard one Annex ZA/ZZ should be stated)
 - ▶ Cover only clauses drafted as requirements, supporting the presumption of conformity
 - ▶ Follow best practices (e.g.: place in order the Essential Requirements from the Directive/Regulation)

▶ Foreword, Scope and Terminology

- ▶ To improve the chances of compliance both Foreword, Scope and Terminology should:
 - ▶ Be consistent with the relevant EU legislation
 - ▶ Not set requirements/recommendation/permission in their text

▶ Neutrality Principle

- ▶ To improve the chances of compliance the body of the text should:
 - ▶ Not contain clauses imposing requirements or obligations on/between certain economic operators
 - ▶ Not contain 1st, 2nd and 3rd – party testing obligations

- ▶ **Ambiguity, Personal Data, Other**
 - ▶ To improve the chances of compliance the body of the text should:
 - ▶ Contain clear and unambiguous sentences
 - ▶ Not contain personal information (In case of doubts please contact dataprivacy@cencenelec.eu)
 - ▶ Follow [CEN-CENELEC EC Internal Regulations – Part 3](#)

How

The steps in detail

▶ 4 assessments possible per work item:

1. Mature draft (mandatory)
2. ENQ confirmatory (will take place only if the first assessment is LOC)
3. Pre FV (mandatory, if the draft does not skip FV)
4. Last Confirmatory Assessment (LCA, optional) - should become exceptional!

How

- ▶ Mature draft, together with filled-in Common Checklist and Annexes shall be sent to CCMC for QC: hsc@cencenelec.eu
- ▶ CCMC QC shall be performed in 15 working days (3 weeks)
- ▶ CCMC shares by email the outcome of the QC with TBO
- ▶ TB has 4 weeks to consider CCMC QC comments, **shall address comments related to IR-3, Annex Z and Normative References (NR)**.
 - ▶ TB shall justify, through the QC checklist, the QC comments not addressed



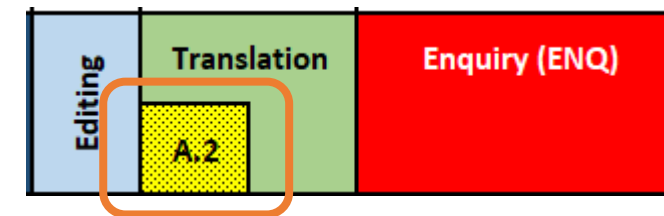
How

- ▶ TB sends to CCMC by email (hsc@cencenelec.eu) updated draft and Annexes, together with filled-in Common Checklist, for Mature draft assessment request (AR).
- ▶ CCMC will request the Mature draft assessment to the HAS contractor.
- ▶ TB secretary will receive an email that includes the assessment report when the latter is available.



How: → ENQ

- ▶ If Mature draft assessment is compliant:
 - ▶ TB delivers to CCMC the draft for ENQ through the **submission interface**
- ▶ If Mature draft lack of compliance (LoC):
 - ▶ TB can call a meeting with HAS consultant if deemed necessary
 - ▶ TB addresses comments from HAS assessment
 - ▶ TB delivers to CCMC through the **submission interface**:
 - ▶ Updated draft (and Annexes)
 - ▶ Filled-in Common Checklist
 - ▶ Filled-in table of comments from previous assessment
 - ▶ Supporting documents (Annexes, ...)
 - ▶ When launching translation, CCMC will request the **ENQ confirmatory assessment** to the HAS contractor.



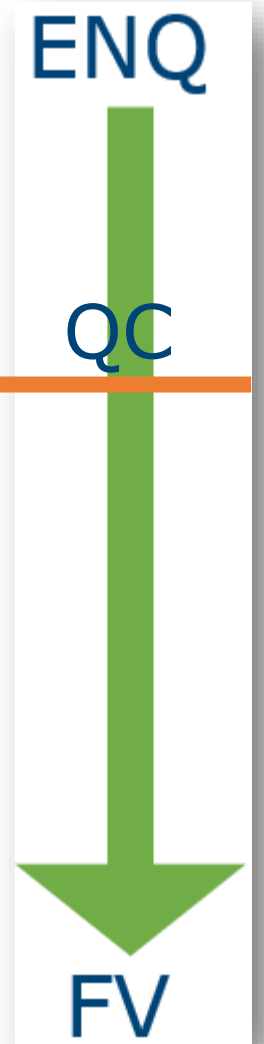
How: → ENQ

- ▶ TB secretary will receive an email that includes the assessment report when the latter is available.
- ▶ ENQ won't be delayed in case of LoC at ENQ confirmatory assessment

- ▶ Possibility to skip FV if:
 - ▶ ENQ Vote positive
 - ▶ One of the previous assessments is 'Compliant' or 'Conditional compliance' (or the LoC at ENQ confirmatory assessment could be resolved)
 - ▶ No technical changes are made
 - ▶ TB decides by simple majority to skip the Formal Vote and proceed to publication.

How: → FV

- ▶ After ENQ, TB will consider ENQ comments and HAS consultant report. The draft together with Annexes (pre FV draft) will be revised
- ▶ Pre FV draft, together with filled-in Common Checklist and Annexes shall be sent to CCMC for QC: hsc@cencenelec.eu
- ▶ CCMC QC shall be performed in 15 working days (3 weeks)
- ▶ CCMC shares by email the outcome of the QC with TBO
- ▶ TB has 4 weeks to consider CCMC QC comments, **shall address comments related to IR-3, Annex Z and Normative References (NR).**
 - ▶ TB shall justify, through the QC checklist, the QC comments not addressed



How: → FV

- ▶ TB sends to CCMC by email (hsc@cencenelec.eu) updated draft and Annexes, together with filled-in Common Checklist, for Pre FV draft assessment request (AR).
- ▶ CCMC will request the Pre FV draft assessment to the HAS contractor.
- ▶ TB secretary will receive an email that includes the assessment report when the latter is available.



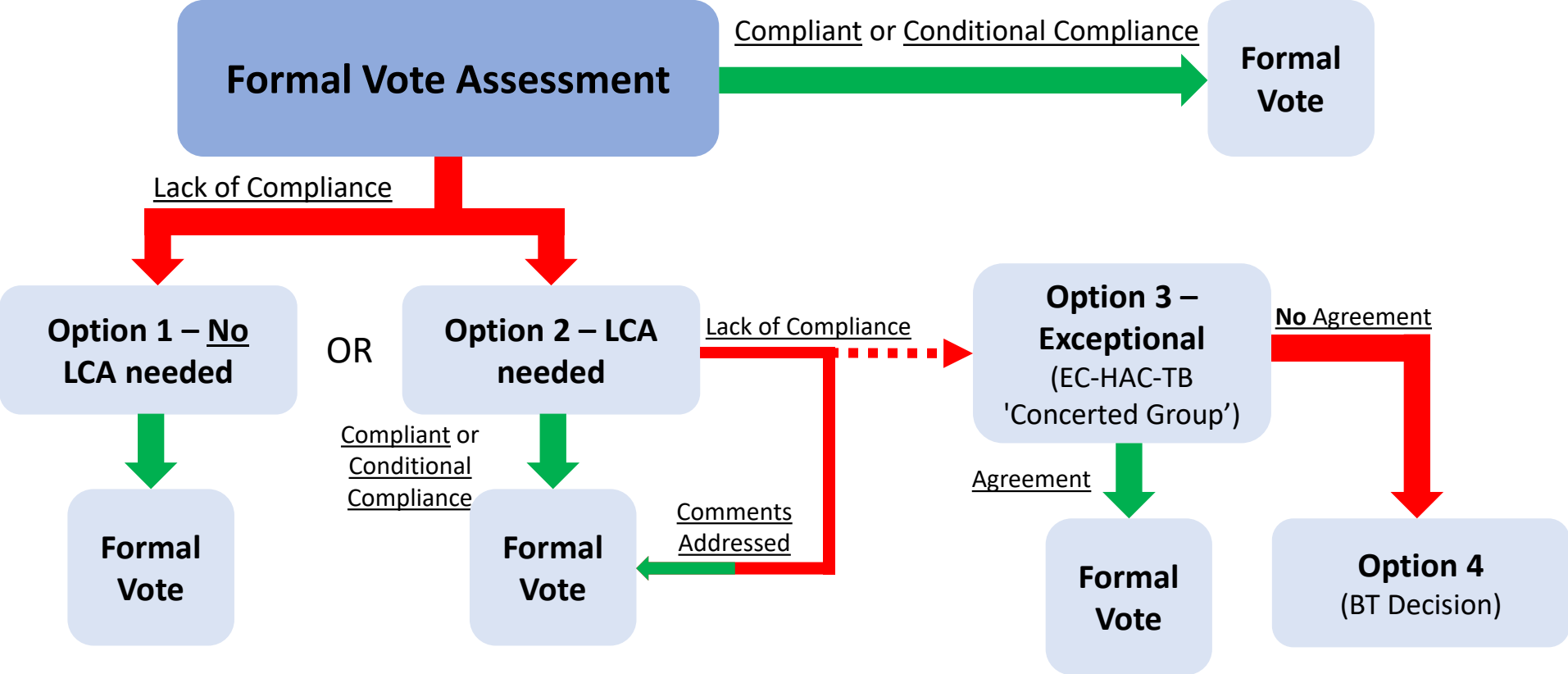
How: → FV

- ▶ If Pre FV draft assessment is compliant:
 - ▶ TB delivers to CCMC the draft for FV through the **submission interface**

- ▶ If Pre FV draft lack of compliance (LoC):
 - ▶ Standard development process **put on hold**
 - ▶ TB shall do its utmost to resolve any issues and ensure that the CCMC Project Manager/Editor is properly informed
 - ▶ TB can call a meeting with HAS consultant if deemed necessary

- ▶ Different options possible in case of LoC:
 - ▶ Within 7 weeks after reception of the assessment, the TB Secretariat informs CCMC by email on the chosen way forward

Way forward following Pre FV assessment



Way forward following Pre FV LoC.

Option 1: no LCA

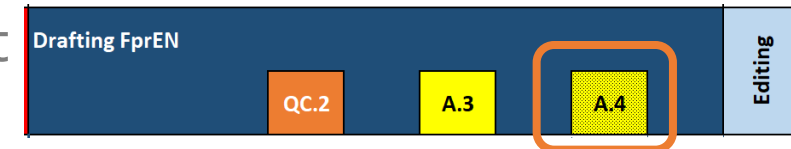


- ▶ Given the nature of comments, TB can address them **without requesting LCA**
- ▶ TB will proceed to FV
- ▶ TB delivers to CCMC through the **submission interface**:
 - ▶ Re-worked draft in track changes showing the changes in comparison with the version of the Formal Vote draft which received a Lack of Compliance assessment.
 - ▶ Filled-in Common Checklist
 - ▶ Filled-in table of comments from previous assessment
 - ▶ Supporting documents (Annexes, ...)

Way forward following Pre FV LoC.

Option 2: LCA needed

- ▶ TB revises the draft and delivers to CCMC through the **submission interface**:
 - ▶ Re-worked draft in track changes showing the changes in comparison with the version of the Formal Vote draft which received a Lack of Compliance assessment.
 - ▶ Filled-in Common Checklist
 - ▶ Filled-in table of comments from previous assessment
 - ▶ Supporting documents (Annexes, ...)
- ▶ CCMC will request the last confirmatory assessment to HAS contractor
- ▶ If compliant assessment: FV ballot will resume
- ▶ If the LCA assessment outcome is 'Lack of compliance'
 - ▶ the TB needs to agree on the way forward, i.e. to
 - ▶ revise the FprEN to address the final comments of the HAS consultant,
 - ▶ or proceed with Option 3 or Option 4 (see below) within 7 weeks in total



Way forward following Pre FV LoC. Option 3 (exceptional)



- ▶ Should the comments resolution meeting between the HAS Consultant and the TB not succeed to solve all the HAS Consultant's comments, a meeting between the HAS Consultant, EC and TB could be organized by CCMC (EC-HAS-TB 'Concerted Group')
- ▶ If remaining comments resolved, TB delivers to CCMC through the **submission interface** for FV:
 - ▶ Re-worked draft in track changes showing the changes in comparison with the version of the Formal Vote draft which received a Lack of Compliance assessment.
 - ▶ Supporting documents (Annexes, ...)
- ▶ If remaining comments not resolved, TB should proceed with Option 4

Way forward following Pre FV LoC.

Option 4



- ▶ When assessment issues could not be resolved by TB, a proposal on the way forward is circulated to BT for approval:
 - ▶ Option 4a: Unlink the EN temporarily from legislation, i.e. remove any link to legislation and Annex Z, and initiate an amendment or revision of the EN in order to resolve the lack of compliance assessment.
 - ▶ Option 4b: Unlink the EN permanently from legislation, i.e. remove any link to legislation and Annex Z. In this case, the EC will need to be informed.
 - ▶ Option 4c: Abandon the project. In this case, the EC will need to be informed.

Measures for ongoing projects

- ▶ To have an impact on ongoing work, and thus to already improve the timely delivery of compliant hENs, **TBs are invited** to request a CCMC QC on ENQ and FV drafts before the projects are submitted to Enquiry (30.99) and FV (45.99).
- ▶ The request, together with the filled-in Common Checklist and all supporting documents, are to be sent **only by email** to hsc@cencenelec.eu .
- ▶ CCMC will perform Quality Checks (QC) within 15 working days (3 weeks)

Key take aways

Key take aways I

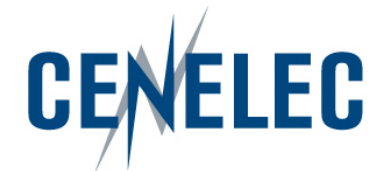
- ▶ Two different processes for homegrown EN and homegrown hEN!!
- ▶ Process mandatory for homegrown hEN, launched for approval as of 2023-10-01
- ▶ Process agreed with the EC (also DG Energy)
- ▶ Max 4 assessments, but different timing and purposes
- ▶ Quality check performed before Mature draft & Pre-FV assessment

- ▶ Combination of CCMC QC and assessments at the right timing should help TBs to reach compliance
- ▶ Two-step approach: manual exchange of documents until IT tools are updated
- ▶ NWI form:
 - ▶ foresee enough time up to ENQ (50 weeks recommended)
 - ▶ use 39-week tolerance for time up to FV
- ▶ BTs will monitor the success of this new process
- ▶ New process for hEN in parallel with IEC and ISO currently under scrutiny

- ▶ Webinar drafting guidance: [CEN](#) – [CENELEC](#)
- ▶ Guidance document on normative references:
 - ▶ [CEN BOSS](#) – [CENELEC BOSS](#)
- ▶ [Webinar 'Presentation of the new EC/HAS ESOs Common checklist'](#)

Feedback poll





European Standardization Organizations

Thanks for your attention!

Upcoming webinars/events:

2024-01-18 - Webinar [for CEN TBOs - TS & TR new process](#)

2024-01-18 - Webinar for [CENELEC TBOs - New process for the approval of NWI, including TS & TR](#)

2024-01-26 - Webinar ['The role of standardization in climate change adaptation'](#)