



European Standardization Organizations

Webinar

'Innovative Process for homegrown Harmonized Standards'

Frédéric MLANAO & Alberto SIMEONI



*We start
at
14:00*

Webinar moderator

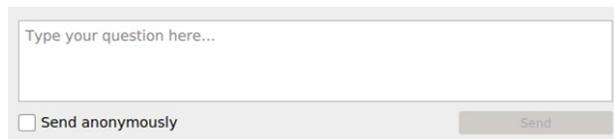


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Your speakers today



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Agenda

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

Glossary

- ▶ 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 developed based on:
 - ▶ The outcomes of the ESOs-EC Task Force on Timely European Standards
 - ▶ Discussions within Strategy 2030 Project 1 'Timely citation'
 - ▶ Discussions within CEN-CLC/BTWG 12 'Harmonized standards and the European regulatory framework' and CEN-CLC/BTWG 14 'Rules & Processes'

- ▶ Innovative process applies to homegrown hEN
 - ▶ Will be applied to NWIs launched for approval as of 2023-10-01

- ▶ Under discussion with ISO/IEC for parallel work
 - ▶ Current HAS process applies for parallel work

BT Decision - BT C135/2023 & D175/C112

BT,

- noting

- the persistent difficulties of having compliant assessments by the EC consultants on Harmonized standards (hENS) candidate for citation in the OJEU;
- the need to define an ad-hoc process for hENS subject to the EC consultants' assessment, since these hENS present challenges completely different from the development process of ordinary ENS;
- the outcomes of the ESOs-EC Task Force on Timely European Standards, which validated the Innovative process during its final meeting on 2023-07-07, and the discussions in S2030 P1 'Timely citation of hEN' team and CEN-CLC/BTWG 12 'Harmonized standards and the European regulatory framework';
- the principles, criteria and operational aspects of the Innovative process as in the Annexes to BT N 14488 and BT175/DG14002/DV;
- that the implementation of the changes to the necessary IT tools will not be completed by 1 October 2023, and that a two-step approach is necessary to allow the start of the new process as of 1 October 2023;
- the impact on the planning principles according to the Flexible standards process, as defined in BT 007/2021 & D167/006, and in particular the need to devote more time under Stage a (10.99-30.99);

- agreed with the principles, criteria and operational aspects of the innovative process for Homegrown hENs as defined in Annexes to BT N 14488 and BT175/DG14002/DV;
- decided that the process will be systematically applied to all homegrown NWIs for hENs (which are intended to be submitted to the EC consultants' assessment), which will be launched for approval as of 1 October 2023;
- invited CCMC to perform Quality Checks (QC) on Enquiry and Formal Vote drafts, on ongoing projects that did not reach stages 30.99 and 45.99, upon TBs request;
- awaiting the full implementation of necessary IT tools, recommended TBs to plan a duration of at least 50 weeks up to 30.99 (Stage a), and the remaining 18 weeks under Stage e, taking into account that a 9-month tolerance is still possible under Stage e;
- requested CCMC to initiate the necessary IT developments, organise, in due time, the necessary trainings to the Technical Bodies Officers and update BOSS pages accordingly;
- invited Members to instruct accordingly their Technical Bodies Officers as well as their national experts and delegates to ensure the successful implementation of the new process.

It applies to

It 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;

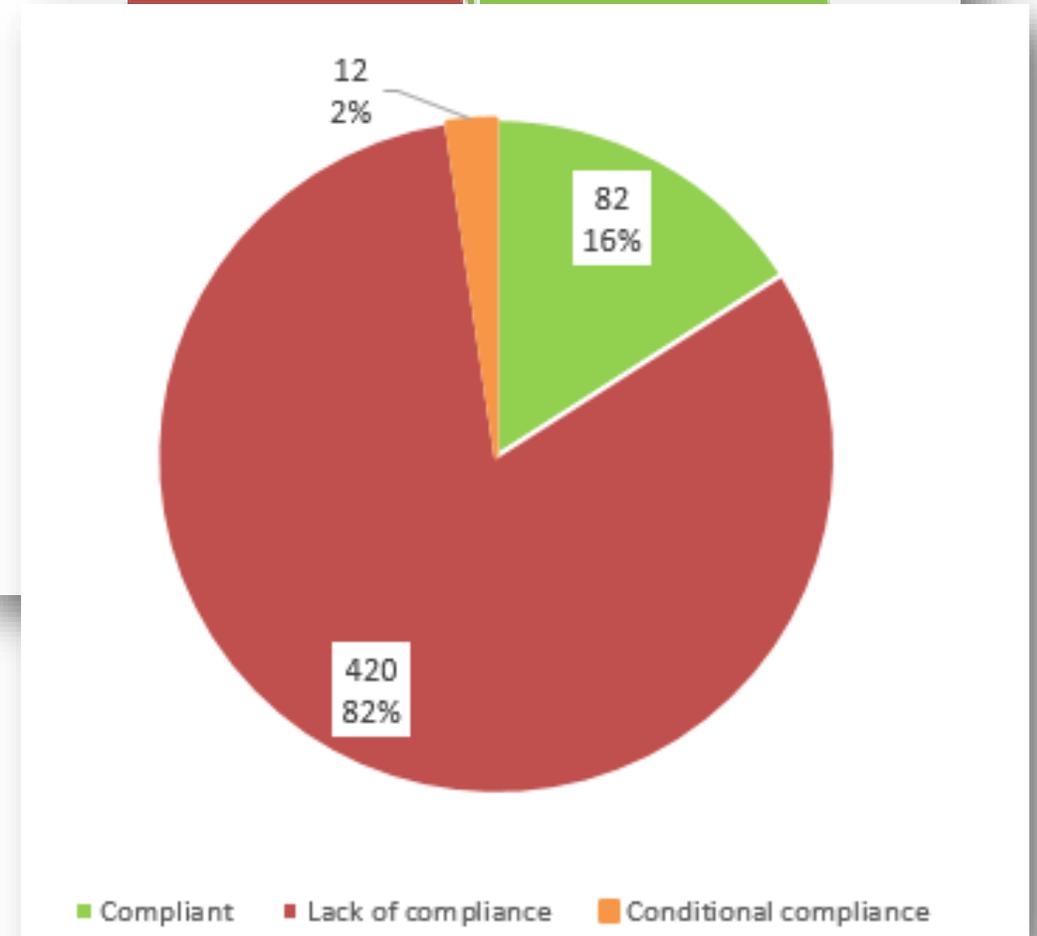
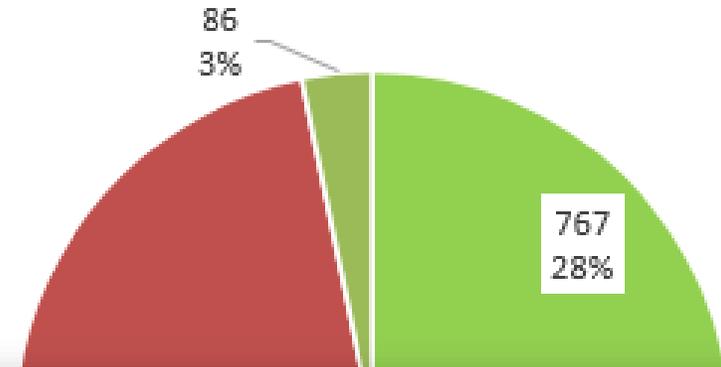
It does not apply to:

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

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



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 |

Why

- ▶ 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

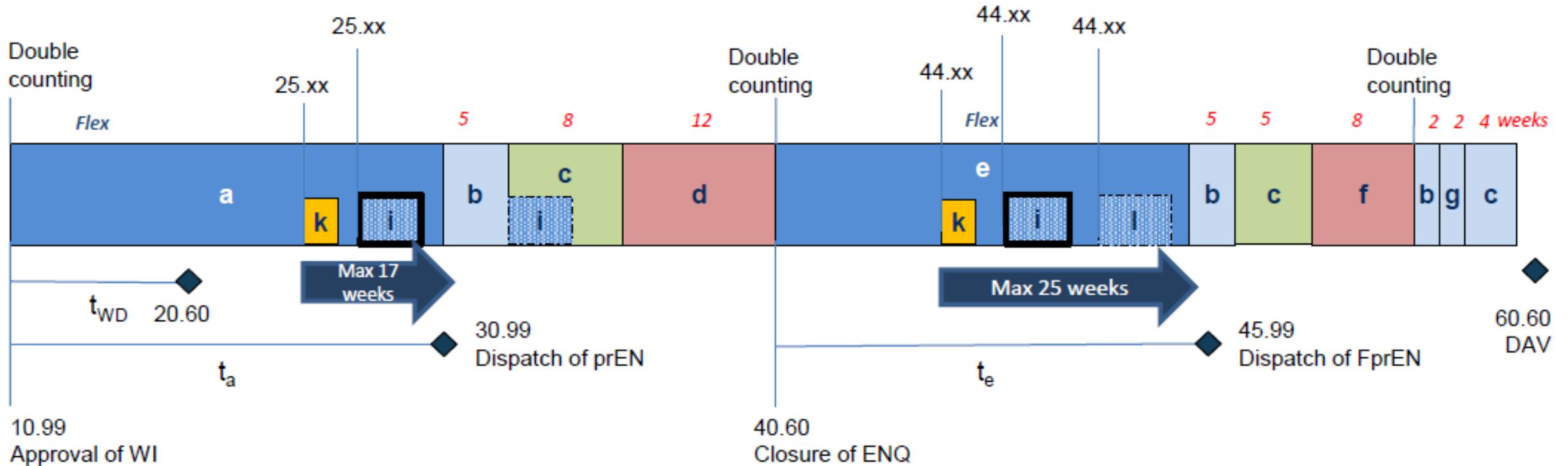
What

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”

What

Homegrown candidate hEN for citation



What

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

What

| | | | |
|---|---|---|----------------------------------|
| a | Drafting of prEN |  | Editing |
| b | Editing |  | Technical work |
| c | Translation and preparation of national publication |  | Voting |
| d | Enquiry |  | Mandatory assessment |
| e | Comments handling / preparation of FprEN |  | Confirmatory assessment Optional |
| f | Formal Vote |  | Translation |
| g | TC proofing |  | CCMC Quality check |
| h | Indicative Assessment (optional) | | |
| i | Assessment | | |
| j | solving negative assessment (if necessary) | | |
| k | CCMC Quality check | | |
| L | Last confirmatory assessment (LCA) | | |

How

How

Impact on planning (flex process)

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 generate the committee plan.

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

← 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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| | | | + 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

Preparing New Work Item – CEN-CLC/JTCs



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> | <u>1st WD (20.60)</u> | <u>ENQ (30.99)</u> | <u>FV (45.99)</u> |
| <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 |

Review of planning

Reminder: Completing in advance stage (a) will de facto extend the duration of stage (e) by the time saved before enquiry under stage (a).

Options to review the planning:

- ▶ To change the planning by using the 'one change' option. It does not require a formal TC decision but an agreement between TC leadership and the WG Convenor; the TB will be informed on the change. Same applies for CEN-CLC JTCs.
- ▶ **To ask for a tolerance.** It requires a TC decision in CEN and only a TC secretary request in CENELEC, as current practice. For JTCs a decision is required that shall be taken via either CIV or CIB depending on the organization holding the secretariat, i.e. respectively, a CENELEC or CEN Member.

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



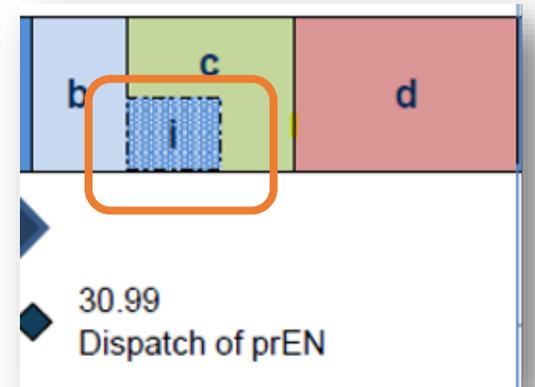
How

- ▶ 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.



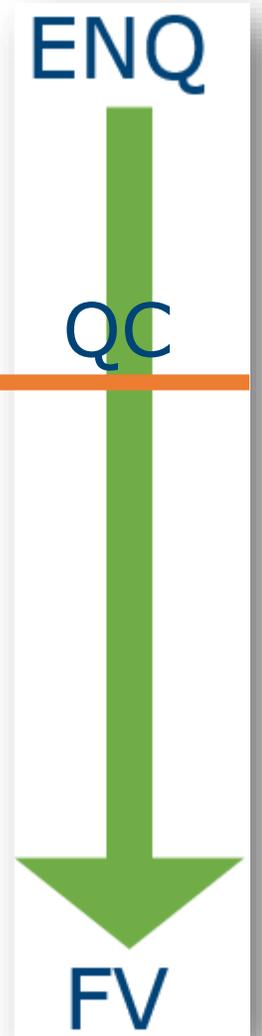
How: → ENQ

- ▶ 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.

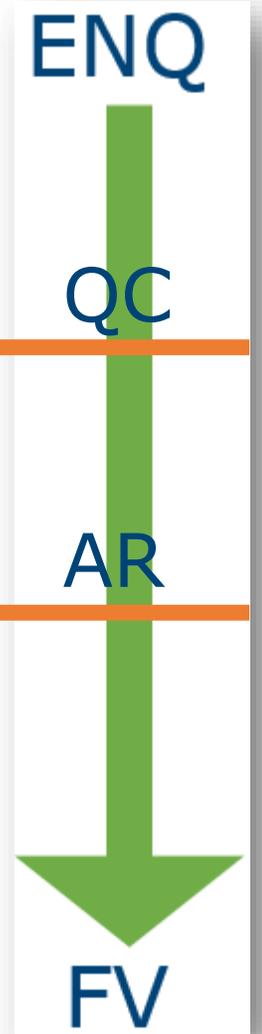
How: → FV

- ▶ 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 LoC.

Option 1: no LCA

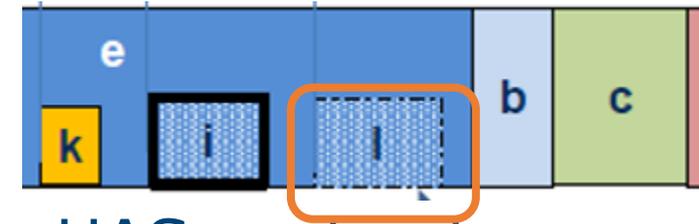


- ▶ Given the nature of comments, TB can address them **without requesting LCA**
- ▶ TB will proceed to FV
- ▶ TB delivers to CCMC through the **submission interface**:
 - ▶ Re-worked draft in track changes showing the changes in comparison with the version of the Formal Vote draft which received a Lack 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

Applying CCMC Quality Check on ongoing work items



- ▶ 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 available before Mature draft & Pre-FV assessment

Key take aways II

- ▶ 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'](#)



European Standardization Organizations

Thanks for your attention!

Upcoming webinars/events:

2023-10-03 - [Stakeholder Workshop "Timely European standards for a Green & Digital, Single & Global Market"](#)

2023-10-05 - [Webinar 'Implementing International Standards in Europe – The Frankfurt Agreement'](#)

2023-10-24 - [The Power of Standardization in Building the African and European Single Markets](#)

2023-10-26 - [Standards + Innovation Awards 2023](#)