Improving OJEU citation

Glossary

- CCMC: CEN and CENELEC Management Center
- CD: Committee Draft
- EC: European Commission
- EN: European Standard
- HAS: Harmonized Standard
- hEN: Harmonized European Standard
- FV: Formal Vote
- NSB/NC: National Standardization Body (CEN)/National Committee (CENELEC)
- OJ/OJEU: Official Journal / Official Journal of the European Union
- SRAHG: Standardization Request Ad-Hoc Group
- SREQ: Standardization Request
- TB: Technical Body
- TBO: Technical Body Officer
- TC: Technical Committee
- WD: Working Draft
- WG: Working Group
- WI/NWI: Work Item / New Work Item
- NR: Normative reference
- PM: Project Manager
- QC: Quality Check

Agenda

1. Processes for drafting Harmonized Standards
    1. For Homegrown hENs
    2. For hENs developed in parallel with ISO/IEC
2. The CCMC Quality Check
3. Best practices

Processes for drafting Harmonized Standards

Homegrown hENs

Innovative Process – homegrown hEN

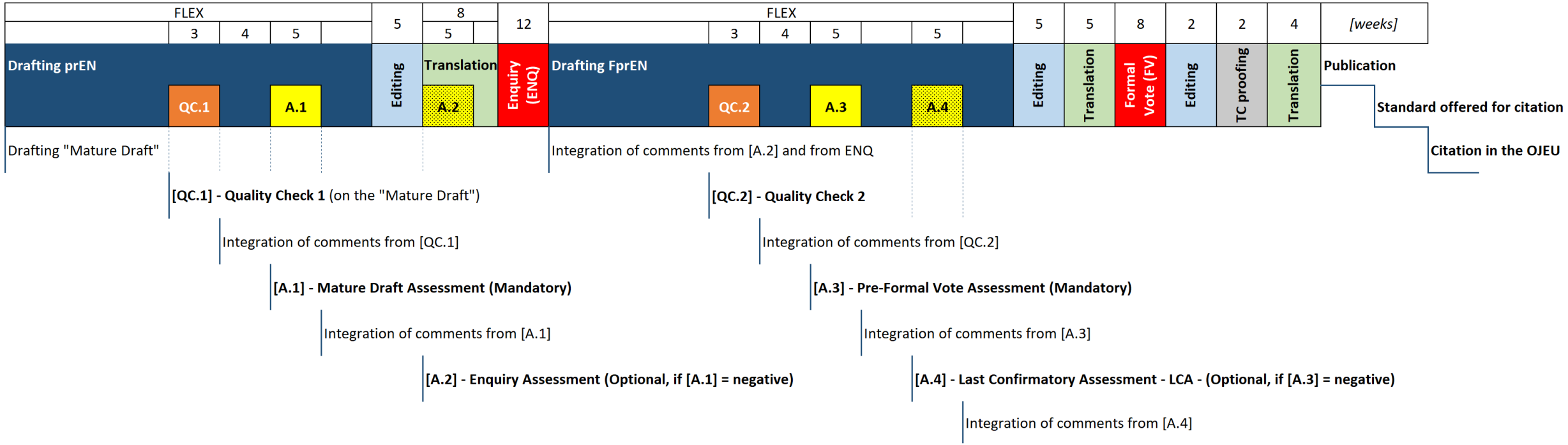
Target: To increase the number of "compliant" assessments and, in fine, the number of standards cited in the OJEU.

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
  - Uses Common checklist as support document

Innovative Process – homegrown hEN

▶ Workflow



Processes for drafting Harmonized Standards

hENs developed in parallel with ISO/IEC

Parallel Projects Process

Key factors for the International Standardization process:

- **Consensus-Building** at European and International level
- **Strong Communication and Coordination** between the European TC and the International TC (specific role for secretaries, convenors and TPM)

For Harmonized ENs

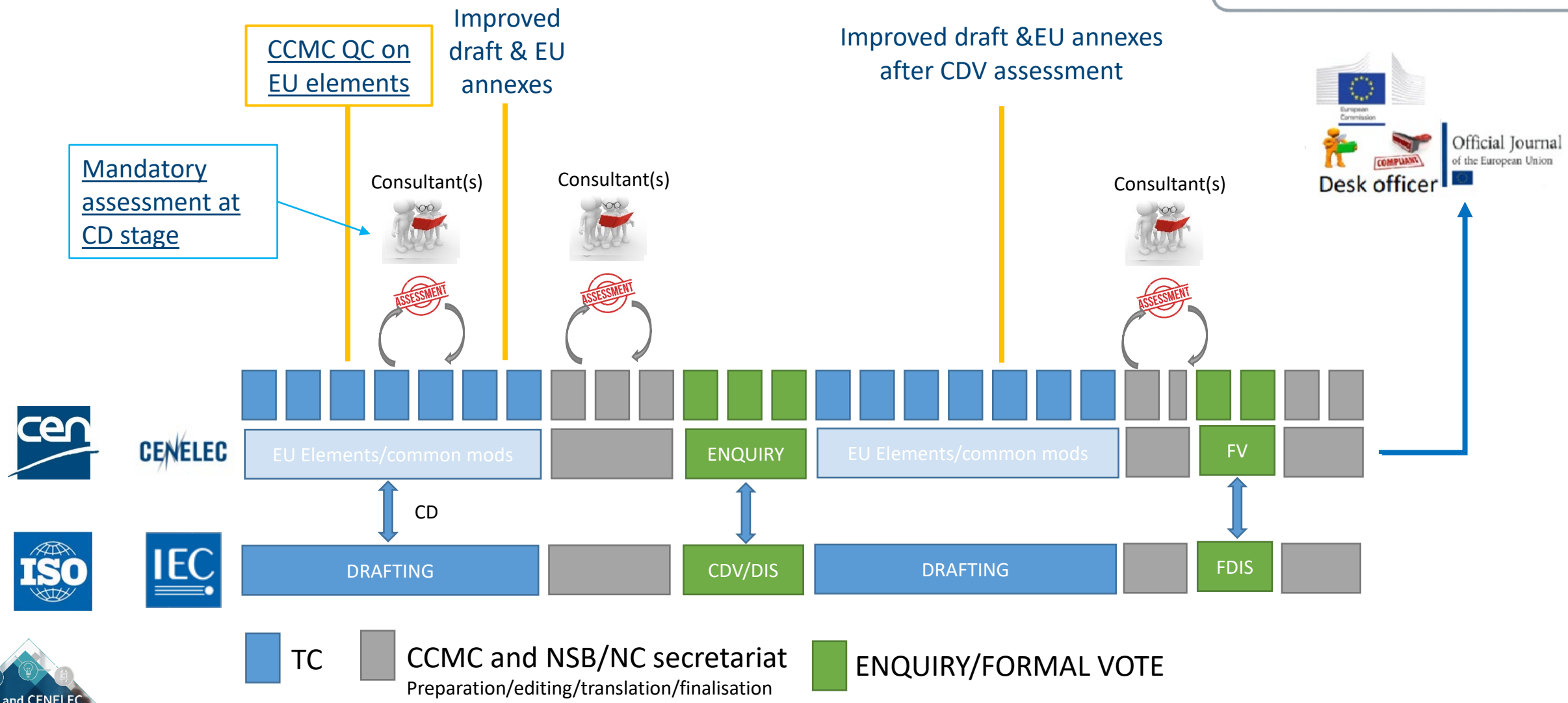
The same Standard applies Worldwide and provides presumption of conformity to the European Legislation

‘New’ Process for Parallel Projects (hENs)

Process intended to:

- Improve timely delivery for parallel ISO/IEC Harmonized Standards
- Avoid blocked draft Standards before Publication
- Minimize interference with International Projects timeframe

‘New’ Process for Parallel Projects (hENs)



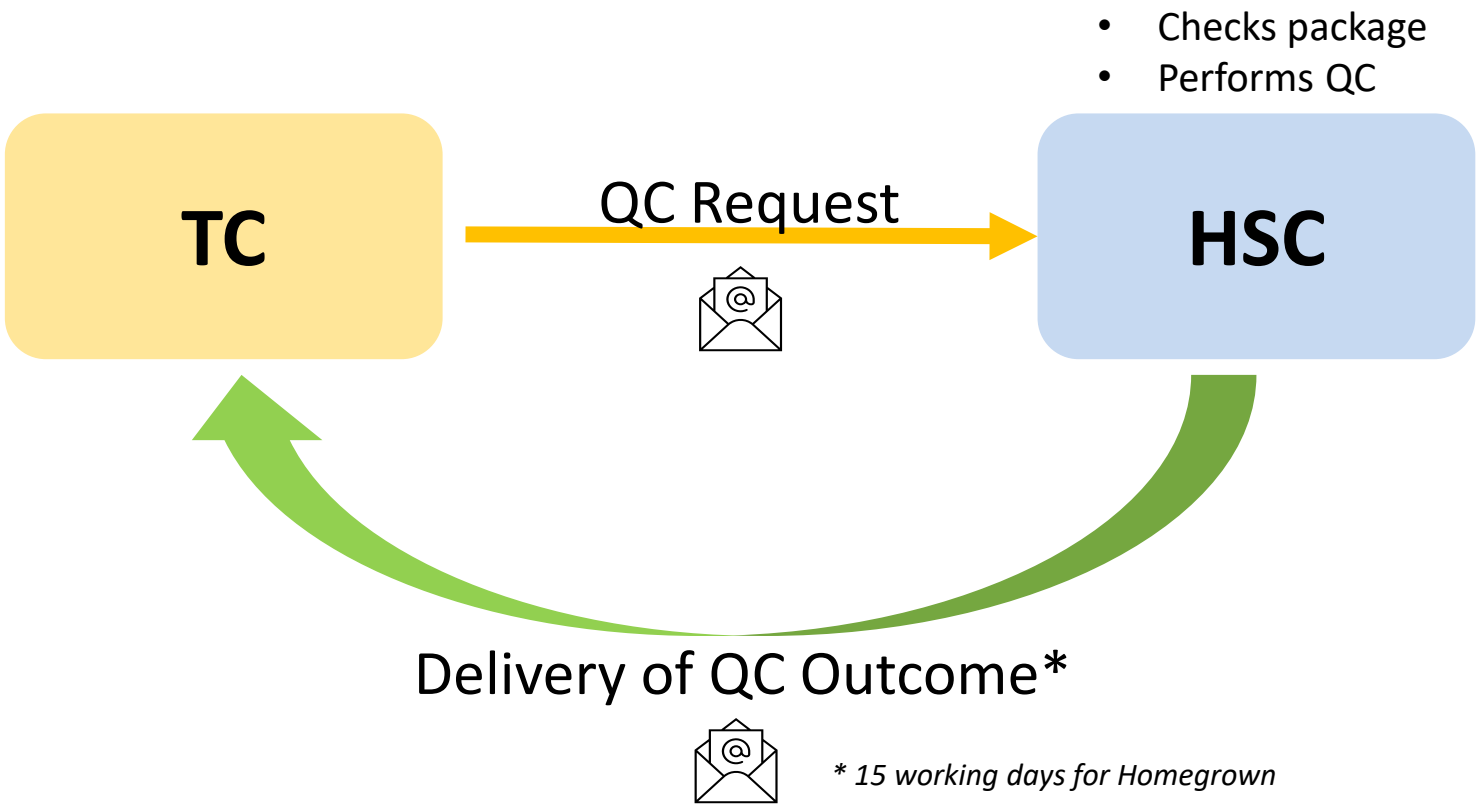
Key points for // development

- Start the process as early as possible
  - European TC invited to closely follow work at international level and to develop Annex Z in parallel with CD draft
- 'New' Process will only apply if:
  - CD available
  - European Elements available
- Communication is key
  - Ensure communication flows between CEN-CLC/TC (interaction with the HAS consultants) and ISO-IEC/TC (writing the standard)
- Common checklist not mandatory, but highly recommended when drafting European Annexes

The CCMC Quality Check

Quality Check Workflow

ALL communications done by email (hsc@cencenelec.eu)



Quality Check Procedure

- Quality Check only performed at:
  - Mature Draft stage (for Homegrown)
  - CD stage (for Parallel projects)
  - Pre-Formal Vote stage (for Homegrown)

- **NEW** Common Checklist for Harmonized Standards is the basis of the CCMC Quality Check (*not mandatory for parallel work*)

- Only Criteria linked to IR3, Normative References and Annex ZA/ZZ are checked

Common checklist

Checklist for standards in response to a standardization request and to be offered for citation in the OJEU

Scope

The present horizontal checklist is the basis for ESOs and their Technical bodies for self-assessment of standards under a standardization request (SReq)/mandate to ensure fulfilment of a SReq/mandate, EU legislation requirements and other possible European Commission (EC) criteria.

All CEN/CENELEC standards and deliverables shall follow the provisions of CEN, CENELEC Internal Regulations, part 3 "Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives — Part 2:2021, modified)"

The checklist is divided in three parts:

- **Part A**: It includes criteria for ESOs only
- **Part B.3**: It includes common criteria for EC/HAS and ESOs
- **Part C**: Administrative requirements for the HAS consultants

ESOs Technical Bodies need to complete Part A and B.3 when carrying out the self-assessment.
The Part B of this checklist covers the same content as in the HAS assessment report used by the HAS consultants when carrying out an assessment.

This checklist is applicable for all CEN and CENELEC sectors, except construction.
A dedicated checklist for the construction sector will be developed in cooperation with the European Commission.

NOTE: In very specific sectors, the applicable Standardisation Request may not require the Annex Z. In such cases, the criteria on Annex Z in Parts A and B of this checklist do not apply.

References

- CEN, CENELEC Internal Regulations, part 3 "Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives — Part 2:2021, modified)"
- EC Vademecum on European Standardisation (Part I, Part II and Part III)
- Guidance on normative references in harmonized standards (see CEN and CENELEC BOSS pages)

CEN Template

CENELEC Template

Mandatory checklist for Homegrown Standards!

General Documents required for QC/HAS Assessment

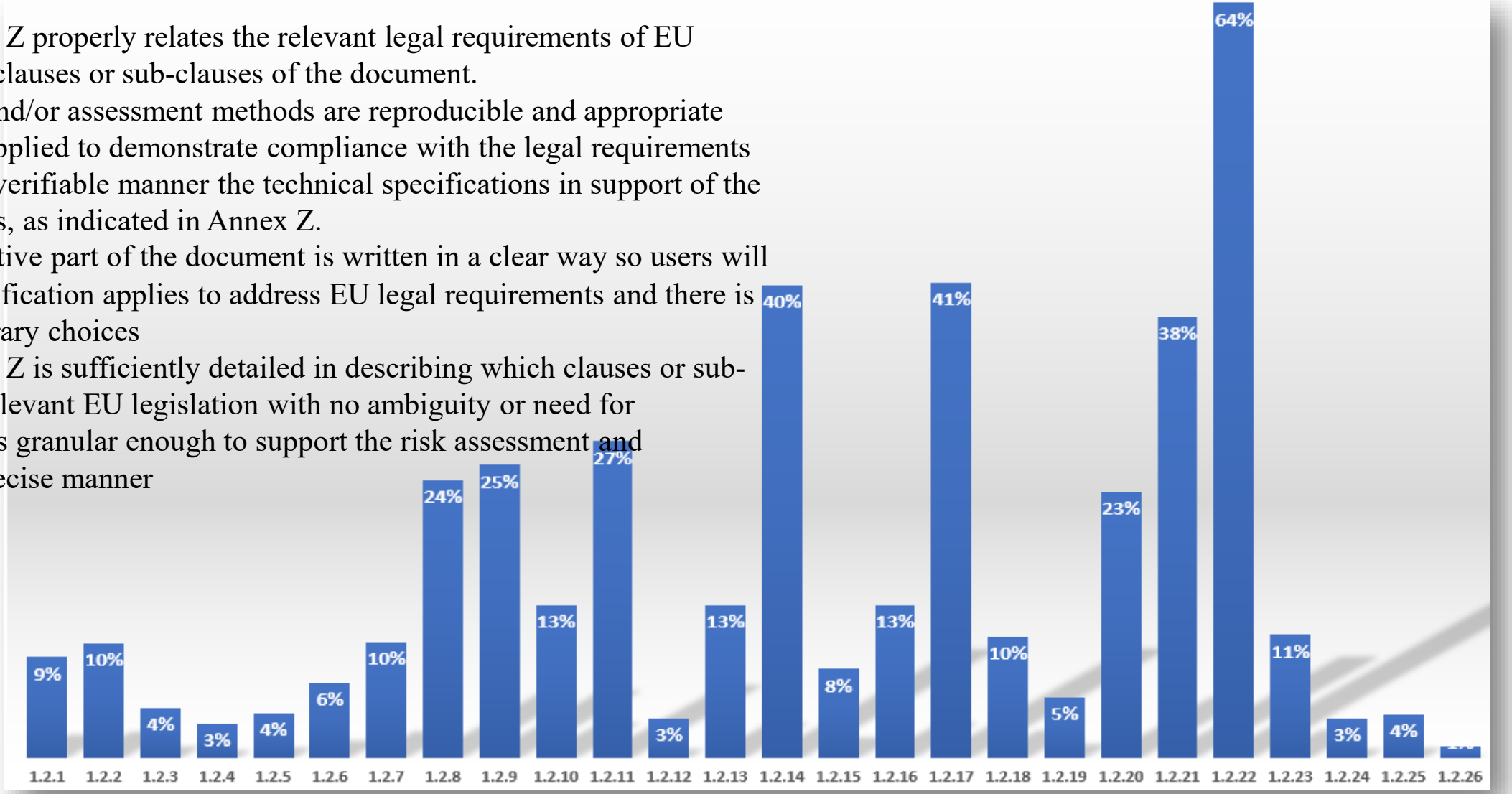
- Main Standard Text (including Annex ZA/ZZ)
- Common checklist
- HAS Consultant Template of Comments with TC replies (from previous stage)
- Risk Assessment (applicable for Low Voltage Directive)
- Optional supporting documents:
  - CCMC/TC Notes useful for assessment
  - Track-changes version
  - IEC/ISO standard text (for specific cases)
  - ...

Best practices (for drafting)

Main reasons for lack of compliance

(period: January 2024 - November 2025)

- 1.2.22 The Annex Z properly relates the relevant legal requirements of EU legislation to the clauses or sub-clauses of the document.
- 1.2.17 The tests and/or assessment methods are reproducible and appropriate and they can be applied to demonstrate compliance with the legal requirements in an objectively verifiable manner the technical specifications in support of the legal requirements, as indicated in Annex Z.
- 1.2.14 The normative part of the document is written in a clear way so users will know which specification applies to address EU legal requirements and there is no room for arbitrary choices
- 1.2.21 The Annex Z is sufficiently detailed in describing which clauses or sub-clauses support relevant EU legislation with no ambiguity or need for interpretation. It is granular enough to support the risk assessment and mitigation in a precise manner



Drafting principles

Clear and verifiable provisions

CEN-CENELEC Internal Regulations Part 3:2022 (E)

4 Objective of standardization

The objective of documents is to specify clear and unambiguous provisions in order to help international trade and communication. To achieve this objective, documents shall:

— be complete within the limits specified by their scope;

NOTE 1 When a document provides requirements or recommendations, these are either written explicitly, or made by reference to other documents (see Clause 10).

— be consistent, clear and accurate;

5.5 Verifiability

Requirements shall be objectively verifiable. Only those requirements that can be verified shall be included.

Phrases such as "sufficiently strong" or "of adequate strength" shall not be used because they are subjective statements.

Drafting principles

Avoid unclear requirements

9.1 General

Controlgear which does not rely upon the luminaire enclosure for protection against electric shock shall be sufficiently protected against accidental contact with hazardous live parts when installed as in normal use.

EXAMPLE Independent controlgear or built-in controlgear having an enclosure designed to be accessible under normal use, including when the luminaire is opened for light source replacement.

Annex A shall be used to establish whether any conductive part is a hazardous live part. However, Annex A is not applicable for SELV and PELV circuits where this is covered by 9.4 and 9.5.

Lacquer or enamel is not considered to be adequate protection or insulation for the purpose of protection against accidental contact with hazardous live parts.

Parts providing protection against accidental contact shall have adequate mechanical strength and shall not work loose in normal use.

Metals showing a great difference of electrochemical potential with respect to each other under moist conditions shall not be used in contact with each other.

Drafting principles

Define clear requirements

Information relating to the slicer itself

The slicing machine shall not exceed an emission sound pressure level of 70 dB(A) and the information shall be stated at the work station.

15.2 Insulation resistance

The insulation resistance of the sample is measured with an applied DC voltage of 500 $^{+50}_{0}$ V, the measurement being made 60 s ± 5 s after application of the voltage. The insulation resistance shall not be less than that specified in Table 3.

Table 3 – Minimum insulation resistance

Insulation to be tested	Insulation resistance MΩ
Functional	2
Basic	2
Supplementary	5
Reinforced	7

Normative references in hENs

Normative references can be hENs or non-hENs

Normative references **should be:**

- **dated**
- **active**
- **published when hEN is adopted**
- **EN/IEC/ISO**
- **Non-TRs/TSs**

Vademecum Part 3 (section 2.8.3): guidance on the use of normative references in hEN → **Reference document for EC**

Guidance on normative references in harmonized standards: guidance document with complete overview of the Normative References' rules for hENs

Normative references in hENs

Homegrown standards

Normative references **should be dated** in Clause 2 and **in body of standard**

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1011-4:2000[1], *Welding - Recommendations for welding of metallic materials - Part 4: Arc welding of aluminium and aluminium alloys*

EN 12644-1:2001+A1:2008, *Cranes - Information for us*

EN 60204-1:2018, *Safety of machinery - Electrical requirements (IEC 60204-1:2005, modified)*

EN ISO 4413:2010, *Hydraulic fluid power - General rules and safety requirements for systems and their components (ISO 4413:2010)*

EN ISO 10042:2018, *Welding - Arc-welded joints in imperfections (ISO 10042:2018)*

EN ISO 12100:2010, *Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)*

5.9.3 Electrical equipment

The electrical design and equipment shall comply with the requirements of EN 60204-1.

5.9.2 Hydraulic equipment

The hydraulic design and equipment shall comply with the requirements of EN ISO 4413.

Normative references in hENs

Homegrown standards

Normative references **should be dated** in Clause 2 and **in body of standard**

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EN 12644-1:2001+A1:2008, *Cranes - Information for use and testing - Part 1: Instructions*

EN 60204-1:2018, *Safety of machinery - Electrical requirements (IEC 60204-1:2005, modified)*

EN ISO 4413:2010, *Hydraulic fluid power - General rules components (ISO 4413:2010)*

EN ISO 10042:2018, *Welding - Arc-welded joints in al imperfections (ISO 10042:2018)*

EN ISO 12100:2010, *Safety of machinery - General principles reduction (ISO 12100:2010)*

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The hydraulic design and equipment shall comply with the requirements of EN ISO 4413:2010.

Normative references in hENs

Homegrown standards

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EN 12644-1:2001+A1:2008, *Cranes - Inform*

EN 60204-1:2018, *Safety of machinery* *requirements (IEC 60204-1:2005, modified)*

EN ISO 4413:2010, *Hydraulic fluid power - components (ISO 4413:2010)*

EN ISO 10042:2018, *Welding - Arc-welded imperfections (ISO 10042:2018)*

EN ISO 12100:2010, *Safety of machinery - reduction (ISO 12100:2010)*

Good practice: specify

5.9.3 Electrical equipment

The electrical design and equipment shall comply with the requirements of EN 60204-1:2006, Clause X.

5.9.2 Hydraulic equipment

The hydraulic design and equipment shall comply with the requirements of EN ISO 4413:2010, Clause X.

Key drafting reminders

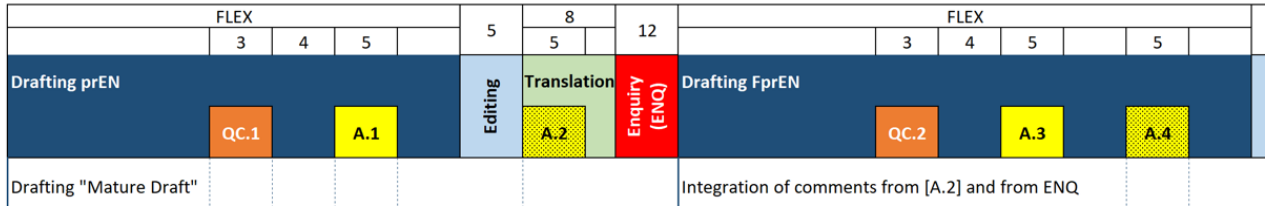
- Perform self assessment using Common checklist
- Draft **clear** and **verifiable provisions**

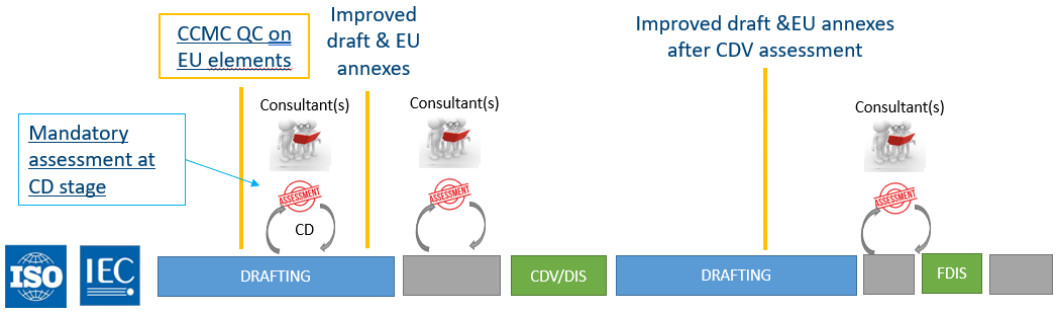
- Normative References :
  - should be **dated**, **active**, **published** when hEN is made available
  - Recommended to **refer to a specific clause** within the NR (to avoid issues with chains of NRs)

- Use CCMC guidance documents: do your homework ☺
  - CCMC guidance (CLC)

Key takeaways

- Processes :





- Start the process as early as possible
  - Annex Z (and needed supporting documents)
- Mandatory QC and assessment at Mature Draft stage
- Communication is key
  - Engage with HAS consultants, request a meeting after receiving an assessment report

Useful Links, CEN

- CEN webinar 'Drafting harmonized standards - IR3 rules, requirements and normative references'
- Webpage: Drafting European standards for citation in the OJEU
- Guidance document: Guidance on normative references in harmonized standards
- Webinar 'New process for harmonized standards under parallel development'
- Webinar 'Presentation of the new EC/HAS ESOs Common checklist'
- Webinar 'Innovative process for homegrown harmonised standards (hENs)'
- Webinar 'CEN Annex ZA - Updates related to the Table ZA.2' - Experts CEN

Useful Links, CENELEC

- CENELEC webinar 'Drafting harmonized standards - IR3 rules, requirements and normative references'
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Thank you

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