European Standardization Organizations

Webinar ‘Drafting Harmonized Standards: IR3 rules, requirements and normative references’

We start at 11:30 CET

Presentation for CEN Technical Body Officers and standards drafters involved in drafting harmonized standards.

Webinar moderator

Els SOMERS
Project Manager
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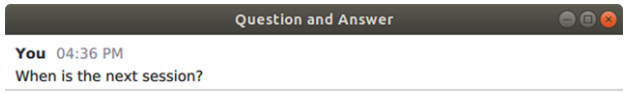
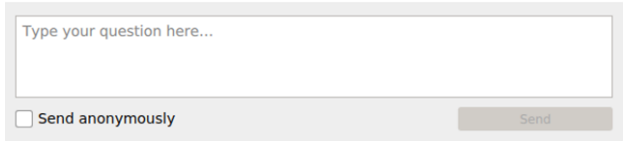
Get the most out of the webinar today

- You are muted
- Use the Q&A panel to submit your questions





- Talk about us on Twitter #training4standards @Standards4EU

Your speakers today

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Content

1. Introduction

2. IR-3 rules & requirements

3. Normative references

1 - Introduction

Objectives of the webinar

- Discuss specific drafting issues which have shown to potentially lead to lack of compliance HAS assessments.

- The webinar focuses on :
  - Specific drafting rules laid down in the 'CEN-CENELEC Internal Regulations - Part 3' (IR3)
  - The formulation of verifiable and unambiguous requirements
  - The neutrality principle
  - The use of normative references

Re-start of HAS assessment

- EY started processing HAS assessments mid-October 2022
- HAS assessment reports will be anonymous for **new assessments received** due to GDPR
- First assessment reports received, backlog is reducing

Webinar 're-start of the HAS assessment system'

- When: 2022-12-05

- Webinar goals:
  - Recap of the tasks and responsibilities of the HAS contractor and consultants,
  - Recap on the existing processes and flows,
  - Present the novelties of the HAS assessment system.

- Registration link

2 - IR-3 rules & requirements

IR-3 reminder

- IR-3 clause 4 – Objective of standardization :

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;

IR-3 reminder

- IR-3 clause 5.5 - Verifiability :

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.

IR-3 reminder

- IR-3 aspects of conformity assessment

All documents containing requirements for products, processes, services, persons, systems and bodies shall be written in accordance with the "neutrality principle" such that conformity can be assessed by a manufacturer or supplier (first party), a user or purchaser (second party), or an independent body (third party).

Drafting requirements

- Requirement to be clarified :

3.5.5
protective impedance
impedance connected between hazardous live parts and accessible conductive parts, of such value that the current, in normal use and under likely fault conditions, is limited to a safe value, and which is so constructed that its ability is maintained throughout the life of the equipment

MB/ NC[1]	Line number (e.g. 17)	Clause/ Subclause (e.g. 3.1)	Paragraph/ Figure/ Table/ (e.g. Table 1)	Type of comment[2]	Comments
1		3.5.3		Technical	What is the definition of a harmful electric shock. This may be explained in IEC 61140 , but still not clear in the sense of this standard. This standard only refers to 61140 in annex L .3.1 And based on the Explanation in 61140 it can still be open for different interpretations ? A harmful electric shock is what ? at what max, voltage , current ? energy of discharge ? different standard have different values here . So this not clear .
2		3.5.5		general	What is a safe level ? Same as above .

- → Lack of compliance assessment

Drafting requirements

- Requirement to be clarified :

8.2.5.5 Material of current-carrying parts

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.

HAS 12		8.2.5.5		EDIT	Metals showing great difference of electrochemical potential what is the definition of great difference? at what level is this required

- → Lack of compliance assessment

Drafting requirement

- Clear requirements :

7.2.2 Information relating to the slicer itself

— Detailed description of the slicing machine, of its fittings and of its protective devices (safeguards);

— comprehensive range of applications for which the slicing machine is intended;

— considering that a slicing machine does not exceed an emission sound pressure level of 70dB(A), the manufacturer shall state that the A-weighted emission sound pressure level at work stations does not exceed 70 dB(A);

— considering that hand-guided slicing machines (e.g. non-automatic slicing machines with carriage handle), do not exceed the vibration total value of 2,5 m/s^2 to which the hand-arm system is subjected, the manufacturer shall state that the vibration total value to which the hand-arm system is subjected, does not exceed 2,5 m/s^2;

- Compliant assessment, cited in the OJEU

Drafting requirement

- Clear requirement :

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

- Compliant assessment, cited in the OJEU

Neutrality principle

- Issue with neutrality principle

4.1 General

The sample size and representative device (or device configuration) shall be justified and stated for each applicable requirement. The manufacturer shall specifically ensure that test specimens shall be tested in the final finished form, after sterilization

- Clause redrafted according to neutrality principle

4.1 General

The sample size and representative device (or device configuration) shall be justified and stated for each applicable requirement. It shall be specifically ensured that test specimens shall be tested in the final finished form, after sterilization

Rules and requirements take aways

- **Clear** and **unambiguous** provisions shall be specified
- Requirements shall be **objectively verifiable**
- Clauses dealing with conformity assessment shall be written in a **neutral** way

3 - Normative References

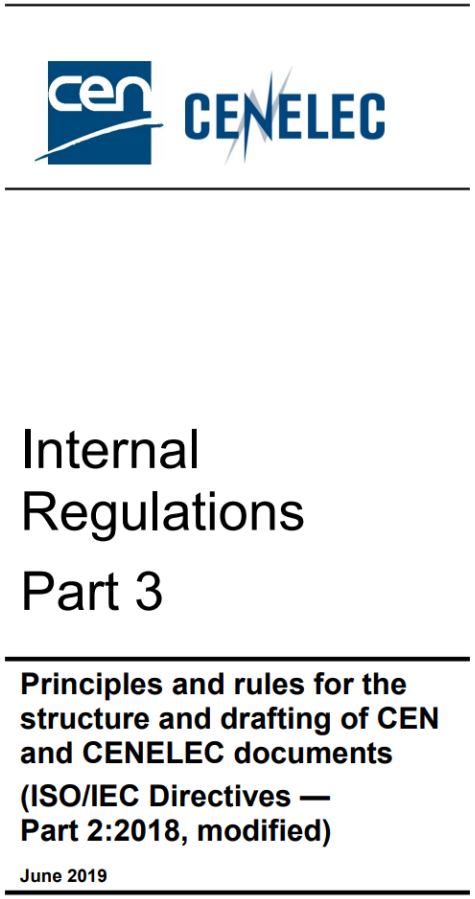
I. Normative references: general guidance

CEN-CENELEC IR-3: rules for normative references

Internal Regulations Part 3 (IR-3)

‘Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives — Part 2:2018, modified)’

→ CEN BOSS



Clause 2 ‘Normative references’

IR-3 Clause 15: Normative references

15 Normative references

15.1 Purpose or rationale

The Normative references clause lists, for information, those documents which are cited in the text in such a way that some or all of their content constitutes requirements of the document.

Information on how these references apply is found in the place where they are cited in the document, and not in the Normative references clause.

- **Informative:** a source of reference for the convenience of the user
- **How references apply**: in the body of the text!

Clause 2 ‘Normative references’

IR-3 Clause 10: Referencing

- Which normative references are permitted (10.2)
- Can be dated (10.5) or undated (10.4)

+ in which cases a dated/undated reference is allowed/mandatory

II. Normative references in hENs: EC requirements

Normative references in hENs

- Normative references can be hENs or non-hENs
- Normative references **should be:**
  - **dated**
  - **active**
  - **published when hEN is adopted**

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

- **Don't:** use normative references that are outdated/withdrawn; non-publicly available documents; draft standards; etc

Normative references in hENs

Is the normative reference included in clauses of hEN giving presumption of conformity?

YES → EC requirements and IR-3 apply

NO → IR-3 apply

European Commission

Normative references & legislation

EC position on normative references

- Normative references form an integral part of hENs → **normative references should be dated**
- Undated normative reference creates dynamic reference → difficult for EC to control its continued suitability to give presumption of conformity

European Commission

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**

  - **Example** of HAS consultant comment:

Clause/ Subclause (e.g. 3.1)	Paragraph/ Figure/ Table/ (e.g. Table 1)	Type of comment[2]	Comments	Proposed change	Observations of the
All		Ge	The standard has a good quality. The Annex ZA is correct. Unfortunately, the normative references are dated only in clause 2, while in the normative text undated references are used. This is not accepted by the EC, which requires dated normative references not only in clause 2 but also in the main text	Please, updated the normative text, using exclusively dated normative references.	

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 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 prin reduction (ISO 12100:2010)*

5.9.3 Electrical equipment

The electrical design and equipment shall comply with the requirements of EN 60204-1:2018.

5.9.2 Hydraulic equipment

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

Normative references in hENs

▶ Homegrown standards

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

Good practice: specify

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 - 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)*

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.

Normative references in hENs

Special attention when drafting **amendment of published hENs**

- TCs to review if normative references are dated and active in published hEN → **if not, date normative references in amendment**

Normative references

Replace Clause 2 with the following:

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.

ISO 3767-5:2016, *Tractors, machinery for agriculture and forestry, powered lawn and garden equipment — Symbols for operator controls and other displays — Part 5: Symbols for manual portable forestry machines*

ISO 3864-1:2011, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

ISO 5681:2020, *Equipment for crop protection — Vocabulary*

ISO 9357:1990, *Equipment for crop protection — Agricultural sprayers — Tank nominal volume and filling hole diameter*

ISO 11684:1995, *Tractors, machinery for agriculture and forestry, powered lawn and garden equipment — Safety signs and hazard pictorials — General principles*

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO 13857:2019, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs*

ISO 14982:1998, *Agricultural and forestry machinery — Electromagnetic compatibility — Test methods and acceptance criteria*

ISO 19732:2007, *Equipment for crop protection — Sprayer filters — Colour coding for identification*

ISO 19932-1:2013, *Equipment for crop protection — Knapsack sprayers — Part 1: Safety and environmental requirements*

ISO 19932-2:2013, *Equipment for crop protection — Knapsack sprayers — Part 2: Test methods*

ISO 22867:2011, *Forestry and gardening machinery — Vibration test code for portable hand-held machines with internal combustion engine — Vibration at the handles*

ISO 22868:2021, *Forestry and gardening machinery — Noise test code for portable hand-held machines with internal combustion engine — Engineering method (Grade 2 accuracy)*

IEC 61032:1997, *Protection of persons and equipment by enclosures — Probes for verification*

Normative references in hENs

Special attention when drafting **amendment of published hENs**

- **Modifying a normative reference in the body of the text**
  = modifying it also in Clause 2

Original standard:

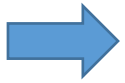
This test shall be carried out at the predicted mean contact force appropriate to the maximum design speed for the pantograph. The mean contact force shall fulfil the requirements of EN 50367:2012, 7.3, Table 6 for the designated speed.

Amendment:

13 Modification to 6.3, Validation of pantograph models

Replace in the fourth paragraph "EN 50367:2012" *by* "EN 50367:2020".

Replace the 13th paragraph by "For the calculation of Q, the frequencies with a measured apparent mass below 2 kg shall be excluded.".



2 Modification to Clause 2, Normative references

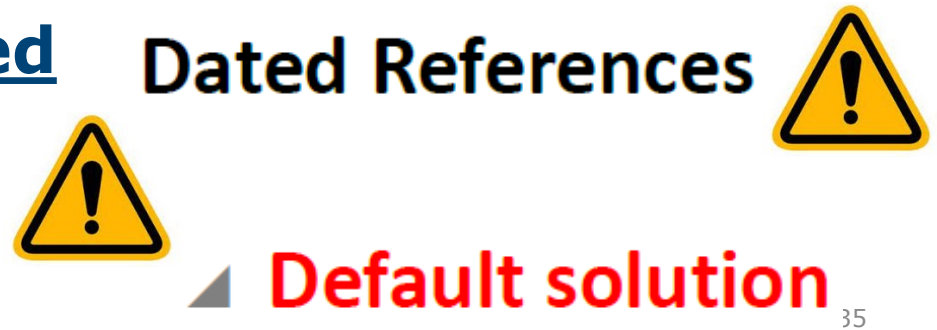
Replace "EN 50119:2009" *by* "EN 50119:2020".

Replace "EN 50367:2012, *Railway applications — Current collection systems — Technical criteria for the interaction between pantograph and overhead line (to achieve free access)*" *by* "EN 50367:2020, *Railway applications - Fixed installations and rolling stock - Criteria to achieve technical compatibility between pantographs and overhead contact line*".

Normative references in hENs

Undated references are possible when:

- Reference is informative
- Reference is normative but related to hEN clause that does not provide any legal effect (presumption of conformity)
  - Provision of justification
- **Exceptionally**, undated normative references to give presumption of conformity are possible if TCs provide very detailed justification → **not recommended**



Normative references in hENs

- EC view: at the time of adoption (DAV) of hEN → **latest edition of normative references** (Vademecum)
  - Use of prEN/FprEN as normative references in hEN **exceptionally** possible if being developed **at the same stage** (as a package)
  - **Use a long dash + footnote "Under preparation …"**

2 Normative references

The following documents are referred to in
constitutes requirements of this document.
undated references, the latest edition of the r

…. ISO 1234:—[2], lists the test methods for…

---

[2] Under preparation. Stage at the time of publication: ISO/DIS 1234:2014.

Dated reference to an enquiry or final draft (typically, the footnote is inserted the first time the reference appears)

EN 50059:—[1], *Electrostatic hand-held spraying equipment — Safety requirements — Hand-held spraying equipment for non-ignitable coating materials*

EN 50176:—[2], *Stationary electrostatic application equipment for ignitable liquid coating material — Safety requirements*

IR-3, 10.5, Example 2

Normative references in hENs

- EC view: at the time of adoption (DAV) of hEN → **latest edition of normative references** (Vademecum)
  - Use of prEN/FprEN as normative references in hEN **exceptionally** possible if being developed **at the same stage** (as a package)

At time of publication:

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 50059:2023, *Electrostatic hand-held spraying equipment — Safety requirements — Hand-held spraying equipment for non-ignitable coating materials*

EN 50176:2023, *Stationary electrostatic application equipment for ignitable liquid coating material — Safety requirements*

Normative references in hENs

- Normative references should be **EN/ISO/IEC published standards**
- Use of non-EN/ISO/IEC standards can only be included with EC agreement (exceptional):
  - Appropriate justification to be submitted to EC
  - TC decision is required
- **Attention**: non-EN/ISO/IEC standards can be used in clauses of hEN not giving presumption of conformity

Normative references in hENs

- Normative references should be **EN/ISO/IEC published standards**

ASME B31.3:2018, *Process piping*

NFPA 11:2021, *Standard for Low-, Medium-, and High-Expansion Foam*

NFPA 12:2018, *Standard on Carbon Dioxide Extinguishing Systems*

NFPA 13:2019, *Standard for the Installation of Sprinkler Systems*

NFPA 15:2017, *Standard for Water Spray Fixed Systems for Fire Protection*

NFPA 750:2019, *Standard on Water Mist Fire Protection Systems*

NFPA 2001:2018, *Standard on Clean Agent Fire Extinguishing Systems*

NFPA 2010:2020, *Standard for Fixed Aerosol Fire-Extinguishing Systems*

Normative references in hENs

- In Clause 2 of hEN do not refer to “all parts” (series of standards)

EN 795:2012, *Personal fall protection equipment — Anchor devices*

EN 818 (series), *Short link chain for lifting purposes — Safety*

EN 842:1996+A1:2008, *Safety of machinery — Visual danger signals - General requirements, design and testing*

EN 1005-2:2003+A1:2008, *Safety of machinery — Human physical performance — Part 2: Manual handling of machinery and component parts of machinery*

EN ISO 14118:2018, *Safety of machinery — Prevention of unexpected start-up (ISO 14118:2017)*

EN 1492 (series), *Textile slings — Safety*

EN 1837:1999+A1:2009, *Safety of machinery - Integral lighting of machines*

EN 12195-1:2010, *Load restraining on road vehicles — Safety — Part 1: Calculation of securing forces*

EN 12195-1:2010/AC:2014, *Load restraining on road vehicles — Safety — Part 1: Calculation of securing forces*

prEN 13155:2017, *Crane — Safety — Non-fixed load lifting attachments*

EN 13414 (series), *Steel wire rope slings — Safety*

EN 13557:2003+A2:2008, *Cranes - Controls and control stations*

HAS consultant comment:

2	EN 818 series	Ge	Also for standards published as series the normative reference shall be dated.	Please use exclusively dated references
2	EN 1492 series	Ge	See above	Please use exclusively dated references
2	EN 13414 series	Ge	See above	Please use exclusively dated references
2	EN 61496 series	Ge	See above	Please use exclusively dated references
2	EN 13856 series	Ge	See above	Please use exclusively dated references

Normative references in hENs

- Normative references
  - shall **not** be **Technical Reports**
  - should **not** be **Technical Specifications**

Parallel work with ISO

When developing EN ISO standard (VA)

- Normative references are listed in Clause 2 (reflecting references in the body of the standard)
- Same EU requirements apply
- Dated normative references are default solution
- Additional solutions are available

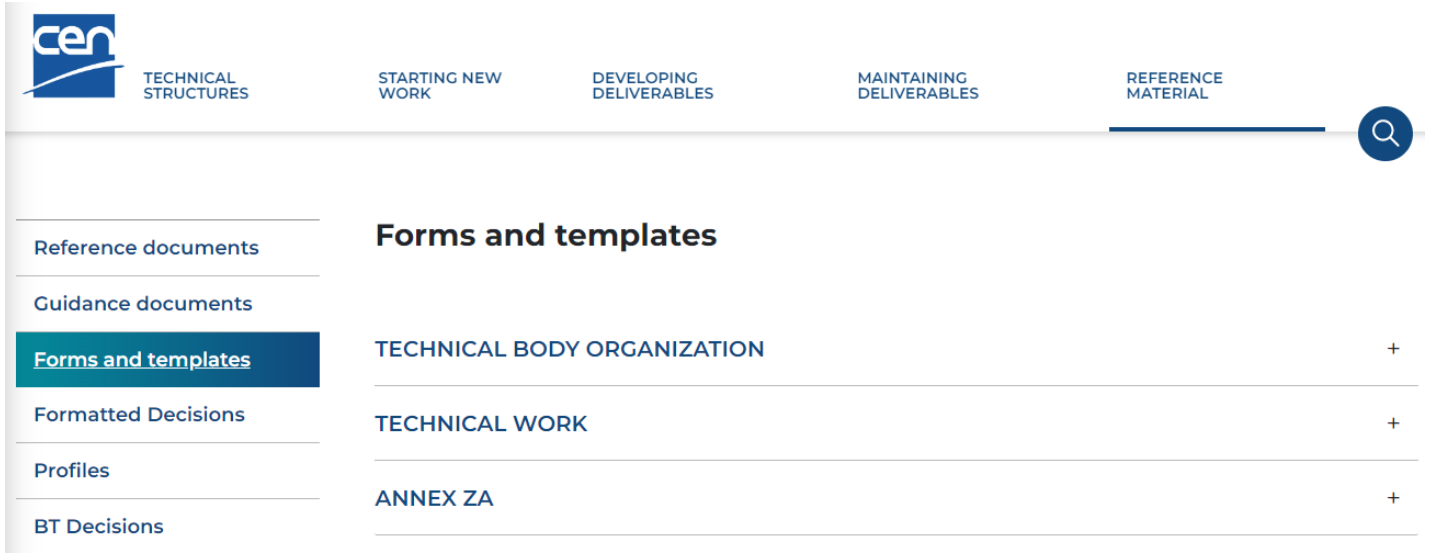
[CEN webinar 'Drafting harmonized standards - IR3 rules, requirements and normative references']

Key learning points

- Reference document on normative references: **IR-3**
- **Additional EC criteria** to be followed
- Normative references: common reason for lack of compliance assessment
- Default solution → **dated normative references in hENs**
- Normative references: **dated**, **active** and **published**
- Flexibility in case the reference is not linked with clauses giving presumption of conformity
- Special consideration when normative references and hEN are developed at the same time (same or different stages)

Where to find …

- Forms and templates
  - Checklist for hENs
  - Annex ZA templates



- Drafting European standards for citation in the OJEU
- Guidance on normative references in harmonized standards

European Standardization Organizations

Thank you for your participation!

Next webinars

2022-11-25 - Webinar 'Hearing for life – How can hearing protection support?'

2022-12-02- Workshop 'Trusted Chips: The Standardization Landscape & Opportunities for Europe

2022-12-05 – Webinar 're-start HAS assessment system'

2023-01-24 - Webinar 'Harmonized Healthcare Standards'