

## Guidance on normative references in harmonized standards

### **Background**

The ruling of several EU court cases (e.g. James Elliott, Global Garden case) had consequences on the European Commission's (EC) internal processes and on formal EC requirements for harmonized standards (hENs). As a result, the EC is asking CEN and CENELEC, for legal certainty purposes, to date the normative references in harmonized standards (hENs) when they are included in clauses linked to essential requirements of the EU legislation providing presumption of conformity.

Normative references are one of the main issues leading to lack of compliance assessment for all sectors (see Annex 1), particularly undated normative references. In practice, this means that the HAS consultant/EC desk officer, when assessing harmonized standards, will verify if the normative references are dated and active (in case they are linked with clauses giving presumption of conformity). Additionally, the use of withdrawn or not yet published normative references will also lead to lack of compliance assessment or rejection for citation. Based on HAS assessment reports/EC rejection letters, there are other issues related to normative references that have contributed to lack of compliance assessments/rejections.

Hence, the goal of this document is to provide some practical guidance on the use of normative references when drafting hENs intended to be cited in the OJEU or referenced in EU legislation or delegated acts.

### **Current rules**

[Internal Regulations Part 3:2019](#) (IR 3) provide the following elements, concerning the purpose and or rationale on the use of 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.***

#### **15.2 Normative or informative?**

*The Normative references clause is an informative element.*

*The list of references it contains is given for the convenience of the user, who can then **consult the place where they are cited in the document to understand and assess how they apply.***

#### **15.5.3 Referencing**

*Only references cited in the text in such a way that some or all of their content constitutes requirements of the document shall be listed in the Normative references clause.*

*Table 3 provides the verbal forms and expressions that make a citation normative. When citing other documents, avoid using potentially ambiguous expressions, where it is unclear whether a requirement or a recommendation is being expressed. For example, the expressions "see ..." and "refer to ..." should only be used informatively.*

*References listed may be dated or undated see ed. See [Section 10.4 'Referencing – Undated references'](#) and [Section 10.5 'Referencing – Dated references'](#) in IR 3.*

## Normative references guidance for hENs

### 1) CEN and CENELEC harmonized standards<sup>1</sup> or EN ISO harmonized standards under VA

When drafting homegrown harmonized standards and parallel harmonized standards under Vienna Agreement (VA), Technical Bodies need to consider the instructions below on the use of normative references in hENs. Additionally, the European Commission Staff working document '[Vademecum on European standardization in support of Union legislation and policies – Part III Guidelines for the execution of standardization requests](#)' also provides guidance on normative references (see section 2.8.3).

**If the normative reference is included in clauses of the standard that are linked with Essential Requirements (ER) of the EU legislation proving presumption of conformity**, the following applies:

1. Normative references can be either harmonized standards or non-harmonized standards.
2. Normative references should in principle be dated.

*Note: very exceptionally, if the Technical Committee provides a detailed justification, the normative reference could be undated, but the default solution should be to date normative references in hENs.*

3. Normative references should be dated in Clause 2 and in the whole text of the standard.

3.1. For EN ISO harmonized standards, if clause 2 and/or the body of the standard contain undated normative references, the dating of normative references takes place in Table ZA.2 (see decision BT 027/2021, and the related '[Guidance document on the use of Table ZA.2 to date undated Normative references in EN ISO standards](#)').

4. When the hEN is adopted by ESOs (adoption is meant DAV), the hEN should only include dated and active normative references and shall not include prENs/FprENs normative references.

*Note 1: active refers to a standard with a Stage-code starting from 60.60 (DAV) and before 99.60 (withdrawal effective).*

*Note 2: very exceptionally, if the Technical Committee wishes to deviate from the recommendation to include dated and/or active normative references, a detailed justification must be provided, but the default solution should be dated and active.*

5. During the development of hEN, normative references can be draft standards (prENs or FprENs) under the following condition:

5.1. the normative references and hENs are being developed exactly at the same time and stage (as a package) and they are submitted together to CCMC for ENQ or FV stages.

*Note 1: if a final draft hEN is submitted to FV stage, it should not include a prEN as normative reference.*

*Note 2: if a draft standard is circulated at drafting stage or submitted to ENQ, it can include prEN or FprEN as normative references.*

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<sup>1</sup> Developed by a CEN and/or a CENELEC Technical Body only (not under the Vienna or the Frankfurt agreements)

*Note 3: see some examples in the Annex 2 to this document.*

6. Normative references should be EN/ISO/IEC standards. In general, the EC does not agree with the inclusion of non-EN/ISO/IEC standards. The use of non-EN/ISO/IEC standards can only be included with the EC agreement. In these cases, a request with appropriate justification need to be submitted to the EC.

*Note 1: the EC requests that national standards are not used in hEN (E.g. ASTM, ANSI, SAE). Technical Committees are invited to coordinate with CCMC to clarify with HAS consultants/EC the exceptional use of national standards.*

*Note 2: the EC accepts the use of standards developed by international standards organizations for specific sectors (e.g. ITU, IEEE, WHO, UIC, 3GPP).*

7. Technical Reports (TR) shall not be used as normative references and Technical Specification (TS) should be avoided as Normative References in harmonized standards. TR are just informative documents that cannot include requirements. TS do not carry the obligation of withdrawal of national conflicting standards.

*Note: the use of TS as normative references should be considered exceptional. A request with appropriate justification should be submitted to the EC.*

8. hENs that have been formally rejected by the EC for OJEU citation or are subject to a formal objection can only be referenced in a draft hEN under the following conditions:

- 8.1. TC provide a justification or

- 8.2. The hEN under development refers to a specific clause of another rejected hEN and that clause does not have any issue of compliance with EU legislation.

*Note: If the hEN under development normatively refers to an hEN that was rejected by the EC for citation, this may lead to a non-citation.*

9. Normative references can be hENs intended to be offered for OJEU citation or hENs that were offered to the EC for citation but did not receive any reply yet on whether they can be cited.
10. When drafting an amendment of a hEN, TCs should review if the relevant normative references in this hEN are dated and active. If not, the TC should consider updating the normative references in the amendment, i.e., ensure that the last version of the normative reference is used and dated (to avoid undated or withdrawn normative references).
11. When there is a need to use a series of standards as normative references, all the parts should be listed and dated in clause 2 and in text of the standards.
12. Good practice: when possible, the hEN should refer to a specific clause of the normative reference instead of referring to the whole document. Additionally, if in this specific clause of the normative reference there are no additional normative references, the normative reference loop is closed.

## 2) Parallel EN IEC harmonized standards under FA

When drafting parallel harmonized standards EN IEC under the Frankfurt Agreement (FA), Technical Bodies need to consider the instructions below on the use of normative references in hENs. Additionally, the European Commission Staff working document '[Vademecum on European standardization in support of Union legislation and policies – Part III Guidelines for the execution of standardization requests](#)' also provides guidance on normative references (see section 2.8.3).

**If the normative reference is included in clauses of the standard that are linked with Essential Requirements (ER) of the EU legislation providing presumption of conformity, the following applies:**

- 1) Normative references can be either harmonized standards or non-harmonized standards.
- 2) Normative references can be undated in Clause 2 and body of the EN IEC standard but shall be dated in the last column of Annex ZA 'Normative references to international publications with their corresponding European publications'. The dating in the last column of Annex ZA also concerns the related amendments.
- 3) If the IEC publication includes a normative reference that does not have a corresponding European publication, then the last active version of the normative reference shall be dated in the second column of Annex ZA. The third and fourth columns shall be empty.
- 4) When the EN IEC harmonized standard is adopted by CENELEC (adoption is meant DAV), the harmonized standard should only include in the Annex ZA normative references that are dated and active and shall not include prENs/FprENs normative references in the Annex ZA.

*Note 1: active refers to a standard with a Stage-code starting from 60.60 (DAV) and before 99.60 (withdrawal effective).*

*Note 2: very exceptionally, if the Technical Committee wishes to deviate from the recommendation to include dated and/or active normative references, a detailed justification must be provided, but the default solution should always be dated and active.*

- 5) Normative references should be EN/ISO/IEC standards. In general, the EC does not agree with the inclusion of non-EN/ISO/IEC standards. The use of non-EN/ISO/IEC standards can only be included with the EC agreement. In these cases, a request with appropriate justification needs to be submitted to the EC.

*Note 1: the EC requests that national standards are not used in harmonized standards (E.g. ASTM, ANSI, SAE). Technical Committees are invited to coordinate with CCMC to clarify with HAS consultants/EC the exceptional use of national standards.*

*Note 2: the EC accepts the use of standards developed by international standards organizations for specific sectors (e.g. ITU, IEEE, WHO, UIC, 3GPP).*

- 6) Technical Reports (TR) shall not be used as normative references and Technical Specification (TS) should be avoided as Normative References in harmonized standards. TR are just informative documents that cannot include requirements. TS do not carry the obligation of withdrawal of national conflicting standards.

*Note: the use of TS as normative references should be considered exceptional. A request with appropriate justification should be submitted to the EC.*

- 7) Normative references can be EN IEC harmonized standards, including their amendments, intended to be offered for OJEU citation or EN IEC harmonized standards that were offered to the EC for citation but did not receive any reply yet on whether they can be cited.

- 8) hENs that have been formally rejected by the EC for OJEU citation or are subject to a formal objection can only be referenced in a draft hEN under the following conditions:

- a. TC provide a justification or
- b. The hEN under development refers to a specific clause of another rejected hEN and that clause does not have any issue of compliance with EU legislation.

- 9) When an amendment of a parallel project is being developed, Technical Bodies should review the normative references of the main standard and the coherence of the normative references of the amendment through the use of the Annex ZA. Alternatively, this review could be done via A11 (in case it is created in parallel).
- 10) When there is a need to use a series of standards as normative references, all the parts should be listed and dated in the Annex ZA.

## Annex 1 - Overview of critical findings leading to lack of compliance for all sectors for the period 2020/07-2021/10

### Overview of Critical findings

#### Part A: Summary of assessments

A total of 1093 assessment have been performed on the full assessment template and are considered in this analysis.

AR ref.	Critical findings	Frequency of finding at CD	% at CD	Frequency of finding at ENQ	% at ENQ	Frequency of finding at FV	% at FV	Frequency of finding at PUB	% at PUB	Total Full Assessments
A- 1.2.1.	Terminology	25	2,29%	35	3,20%	15	1,37%	4	0,37%	1093
A- 1.2.2.	Foreword	8	0,73%	32	2,93%	14	1,28%	1	0,09%	1093
A- 1.2.3.	Scope covers products not considered by the relevant legal requirements	9	0,82%	20	1,83%	16	1,46%	3	0,27%	1093
A- 1.2.4.	The Scope sets requirements or covers aspects which cannot be subject to harmonised standards	8	0,73%	17	1,56%	4	0,37%	9	0,82%	1093
A- 1.2.5.	Scope excludes products or aspects that are expected to be covered by the standard	18	1,65%	33	3,02%	11	1,01%	5	0,46%	1093
A- 1.2.6.	Normative references that are essential for the assessment or harmonised elements are not available	45	4,12%	97	8,87%	14	1,28%	1	0,09%	1093
A- 1.2.7.	Document contains undated normative references without proper justification	62	5,67%	96	8,78%	63	5,76%	36	3,29%	1093
A- 1.2.8.	Too long chains of normative references	2	0,18%	17	1,56%	4	0,37%	0	0,00%	1093
A- 1.2.9.	Normative references need updating or reconsideration	47	4,30%	86	7,87%	46	4,21%	13	1,19%	1093
A- 1.2.10.	align with or contradict relevant EU legislation	50	4,57%	112	10,25%	63	5,76%	12	1,10%	1093
A- 1.2.11.	Technical content of the document unsuitably repeats legal requirements as part of its normative requirements	13	1,19%	23	2,10%	20	1,83%	8	0,73%	1093
A- 1.2.12.	Absence of reproducible tests or assessment methods	48	4,39%	93	8,51%	37	3,39%	12	1,10%	1093
A- 1.2.13.	Neutrality principle is not respected: the document contains clauses imposing requirements or obligations on or between certain economic operators	11	1,01%	36	3,29%	15	1,37%	5	0,46%	1093
A- 1.2.14.	Neutrality principle is not respected in requirements for verifications, sampling and testing	10	0,91%	15	1,37%	3	0,27%	1	0,09%	1093
A- 1.2.15.	Risk assessment or identification of relevant risks is missing or not complete	25	2,29%	26	2,38%	17	1,56%	19	1,74%	1093
A- 1.2.16.	The Annex Z is not sufficiently detailed	56	5,12%	156	14,27%	68	6,22%	27	2,47%	1093
A- 1.2.17.	The Annex Z does not properly refer to the relevant legal requirements	67	6,13%	174	15,92%	96	8,78%	26	2,38%	1093
A- 1.2.18.	The document is not aligned with the guidance documents or checklist	26	2,38%	43	3,93%	24	2,20%	8	0,73%	1093
A- 1.2.19.	Other comments	72	6,59%	182	16,65%	110	10,06%	30	2,74%	1093

## Annex 2 - Examples on guidance on normative references in homegrown hENs

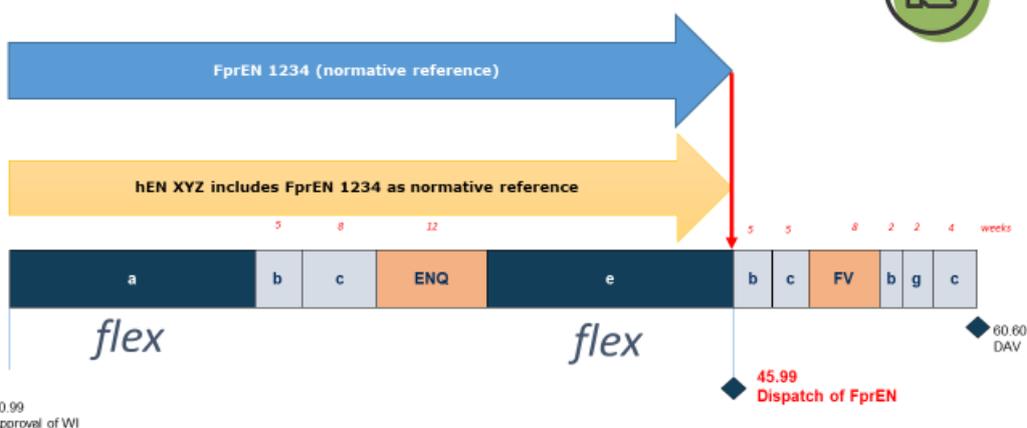
### Example 1

#### Guidance on normative references in hENs

3. Use of prEN/FprEN as normative references in hEN is **exceptionally** possible if being developed **at the same stage** (as a package)

#### Example 1:

Harmonized standards:  
hEN XYZ  
Normative reference in  
hEN XYZ: EN 1234



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10.99  
Approval of WI

### Example 2

#### Guidance on normative references in hENs

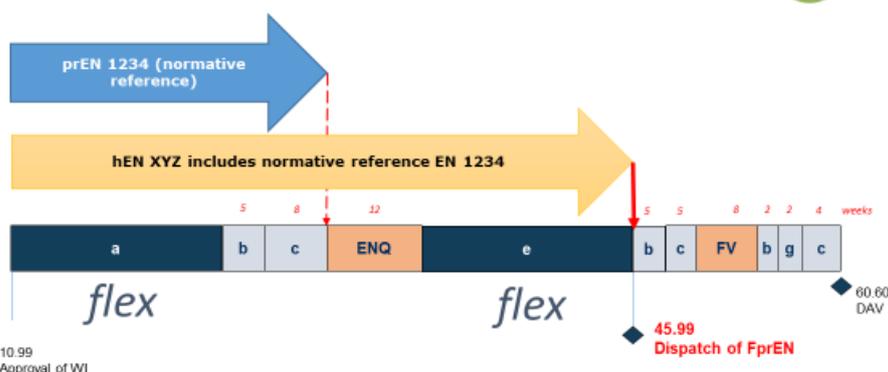
4. Special consideration when normative reference and hEN being developed at the same time, but **different stages**

#### Example 2:

Harmonized standards:  
hEN XYZ  
Normative reference in  
hEN XYZ: EN 1234

**Option 1:** Use published normative reference

**Option 2:** align development of documents



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### Example 3

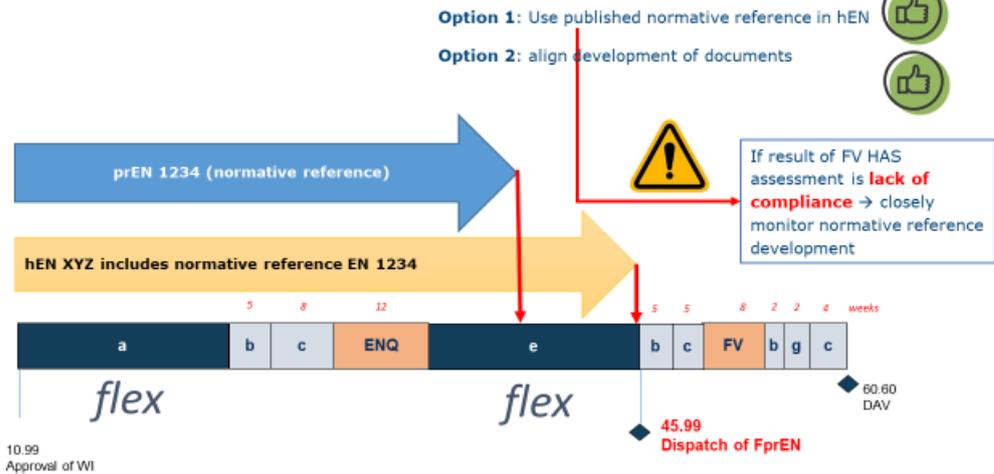
## Guidance on normative references in hENs

4. Special consideration when normative reference and hEN being developed at the same time, but **different stages**

#### Example 3:

Harmonized standards:  
hEN XYZ

Normative reference in  
hEN XYZ: EN 1234



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### Example 4

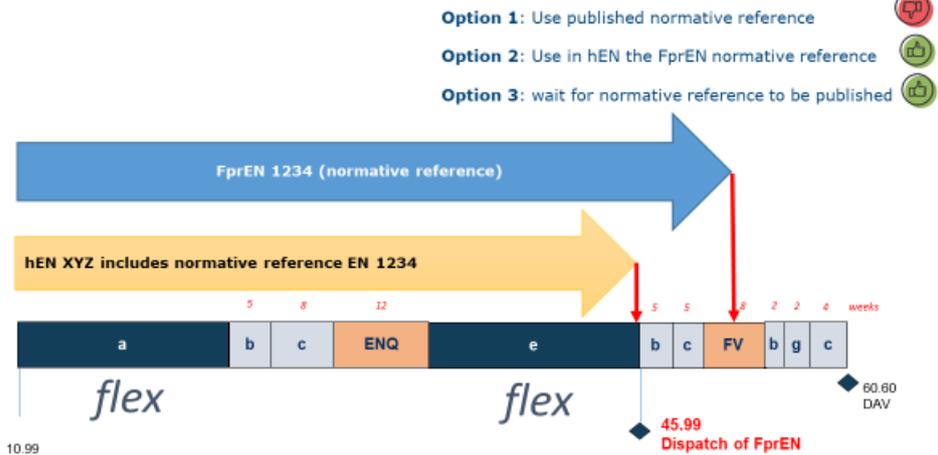
## Guidance on normative references in hENs

4. Special consideration when normative reference and hEN being developed at the same time, but **different stages**

#### Example 4:

Harmonized standards:  
hEN XYZ

Normative reference in  
hEN XYZ: EN 1234



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