

**European Standardization Organizations** 

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

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

We start at

# Webinar moderator





# **Els SOMERS**

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

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# Your speakers today





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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



► 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 <u>link</u>



# 2 - IR-3 rules & requirements

# IR-3 reminder

### IR-3 clause 4 – Objective of standardization :

CEN-CENELEC Internal Regula	ations Part 3:2022 (E
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#### 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 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 <sup>1</sup>	Line number ( <u>e.g.</u> 17)	Clause/ Subclause ( <u>e.g.</u> 3.1)	Paragraph/ Figure/ Table/	Type of comment <sup>2</sup>	Comments
			( <u>c.g.</u> 17)	( <u>c.g.</u> 3.1)	( <u>e.g.</u> Table 1)		
		1		3.5.3		Technical	What is the definition of a harmful electric <u>shock.</u>
							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 <u>what ?</u> at what max, voltage , current ? energy of discharge ? different standard have different values here .
							So this not <u>clear .</u>
		2		3.5.5		general	What is a safe <u>level ?</u>
							Same as <u>above .</u>
$\blacktriangleright$	$\rightarrow$ Lack of compliance assessment						





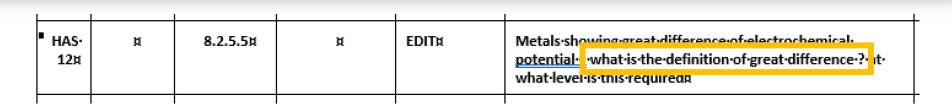
# Drafting requirements



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.



### $\blacktriangleright$ -> 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<sup>2</sup> 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<sup>2</sup>;

## Compliant assessment, cited in the OJEU





# Drafting requirement

### Clear requirement :

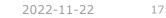
#### 15.2 Insulation resistance

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

#### Table 3 – Minimum insulation resistance

Insulation	Insulation resistance
to be tested	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



## **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)'
- → <u>CENELEC BOSS</u>

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)

July 2022



#### **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!



#### **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 can be hENs or non-hENs
- Normative references should be:
  - ► dated
  - ► active
  - published when hEN is adopted
- ► <u>Vademecum Part 3</u> (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; nonpublicly available documents; draft standards; etc







2022-11-22



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





**YES** → EC requirements and IR-3 apply

**NO**  $\rightarrow$  IR-3 apply





## **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





#### **Homegrown standards**

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

#### Normative references 2

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<sup>1</sup>, 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	5.9.3 Electrical equipment
EN 60204-1:2018, Safety of machinery - Electrical	The electrical design and equipment shall comply with the requirements of EN 60
EN ISO 4413:2010, Hydraulic fluid power - General rule	es and safety requirements for systems and their
components (100-1113:2010)	5.9.2 Hydraulic equipment
EN ISO 10042:2018, Welding - Arc-welded joints in	, , , ,
imperfections (ISO 10042:2018)	The hydraulic design and equipment shall comply with the requirements of EN ISO 4413.
EN ISO 12100:2010, Safety of machinery - General pl reduction (ISO 12100:2010)	nciples for design - Risk assessment and risk

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ΕN con



#### Homegrown standards

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

**Example** of HAS consultant comment:

Clause/ .ibclause	Paragraph/ Figure/ Table/	Type of comment <sup>2</sup>	Comments	Proposed change	Observations of the
e.g. 3.1)	(e.g. Table 1)				
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.	Please, updated the normative text, using exclusively dated normative references.	
			This is not accepted by the EC, which requires dated normative references not only in clause 2 but also in the main text		



#### 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 constitutes requirements of this document. For dated undated references, the latest edition of the referenced	references, only the edition cited applies. For
EN 1011-4:2000 <sup>1</sup> , Welding - Recommendations for weld aluminium and aluminium alloys	ding of metallic materials - Part 4: Arc welding of
EN 12644-1:2001+A1:2008, Cranes - Information for us	e and testing - Part 1: Instructions
EN 60204-1:2018, Safety of machinery - Electrical	5.9.3 Electrical equipment
EN ISO 4413:2010, Hydraulic fluid power - General rule	The electrical design and equipment shall comply with the requirements of EN 60204-1:2018.
components (150 4413:2010)	
EN ISO 10042:2018, Welding - Arc-welded joints in imperfections (ISO 10042:2018)	ai 5.9.2 Hydraulic equipment
Imperiections (180-10042.2010)	The hydraulic design and equipment shall comply with the requirements of EN ISO 4413:2010.
EN ISO 12100:2010, Safety of machinery - General pr reduction (ISO 12100:2010)	



#### 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<sup>1</sup>, Welding - Recommendations for welding of metallic materials - Part 4: Arc welding of aluminium and aluminium alloys



**Good practice: specify** 

EN 12644-1:2001+A1:2008, Cranes - Inforr EN 60204-1:2018, Safety of machinery	5.9.3 Electrical equipment
EN ISO 4413:2010, Hydraulic fluid power - L	The electrical design and equipment shall comply with the requirements of EN 60204-1:2006, Clause X.
components (130 4413:2010)	
EN ISO 10042:2018, Welding - Arc-welded imperfections (ISO 10042:2018)	5.9.2 Hydraulic equipment
EN ISO 12100:2010, Safety of machinery - reduction (ISO 12100:2010)	The hydraulic design and equipment shall comply with the requirements of EN ISO 4413:2010, Clause X.



# 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





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

Modifying a normative reference in the body of the text = modifying it 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".



**EN IEC standards** 

#### Normative references shall be dated through Annex ZA

#### 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60112:2003, Method for the determination of the proof and the comparative tracking indices of solid insulating materials

IEC 60423:2007, Conduit systems for cable management – Outside diameters of conduits for electrical installations and threads for conduits and fittings

IEC 60529:1989, Degrees of protection provided by enclosures (IP Code) IEC 60529:1989/AMD1:1999/AMD2:2013, Degrees of protection provided by enclosures (IP Code)

IEC 60695-2-11:2000<sup>2</sup>, Fire hazard testing – Part 2-11: Glowing/hot-wire based test methods – Glow-wire flammability test method for end-products

IEC 60695-10-2:20033, Fire hazard testing - Part 10-2: Abnormal heat - Ball pressure test

IEC 60981:2004, Extra-heavy duty rigid steel conduits

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

© CEN-CENELEC 61140:2001, Protection against electric shock – Common aspects for installation and equipment

Annex ZA (normative)

#### Normative references to international publications with their corresponding European publications

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: <u>www.cenelec.eu</u>.

Publication	<u>Year</u>	<u>Title</u>	EN/HD	<u>Year</u>
IEC 60112	2003	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003
EC 60423	2007	Conduit systems for cable management - Outside diameters of conduits for electrical installations and threads for conduits and fittings	EN 60423	2007
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
			+ corrigendum May 1993	1993
+ A1	1999		+ A1	2000
+ A2	2013		+ A2	2013
IEC 60695-2-11	2000	Fire hazard testing - Part 2–11: Glowing/hot-wire based test methods - Glow-wire flammability test method for end products	EN 60695-2-11	2014
IEC 60695-10-2	2003	Fire hazard testing - Part 10–2: Abnormal heat - Ball pressure test	EN 60695-10-2	2014
IEC 60981	2004	Extra-heavy duty electrical rigid steel conduits	-	-
IEC 61032	1997	Protection of persons and equipment by enclosures - Probes for verification	EN 61032	<b>1998</b> 35





#### EN IEC standards

Normative references shall be dated through Annex ZA

- ► IEC reference not dated, and European equivalent exists
  - => Date the European equivalent

Publication	Year	<u>Title</u>	EN/HD	Year
IEC 60112	-	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	<mark>2003</mark>



► IEC reference not dated, but no European equivalent exists

=> Date the IEC reference + footnote "Dated as no European equivalent exists"

IEC 62873-2 2016<sup>3</sup> Residual current operated circuit-breakers for household and similar use – Part 2: Residual current devices (RDCs) – Vocabulary



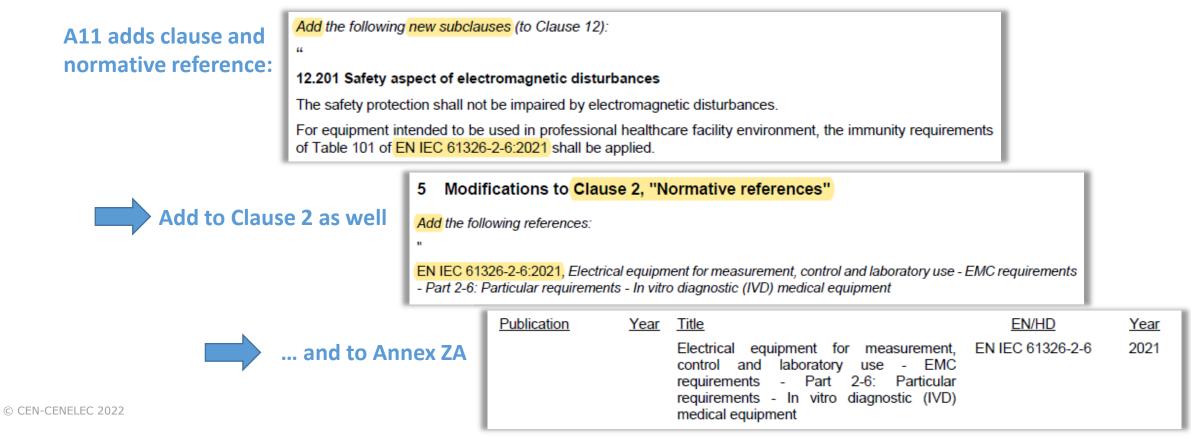
<sup>3</sup> Dated as no European equivalent exists.



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#### Special attention when drafting **Common Modifications**

Common Modification which modifies/adds/deletes a normative reference in the body of the text, e.g.:





#### 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)
- ► Exceptionally, undated normative references to give presumption of conformity are possible if TCs provide very detailed justification → <u>not recommended</u>





### Default solution



► 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 ..."

			ISO 1234:— <sup>2</sup> , lists the test methods for	Dated reference to an enquiry or final draft (typically, the footnote is inserted
Publication	Year	Title		the first time the reference appears)
IEC 61000-4-19	-		1234:2014.	
IEC 61543	<mark>—</mark> 1		rated protective devices EN 61543 —² old and similar use.	IR-3, 10.5, Example 2



► 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:

Publication	Year	Title	EN / HD	Year
IEC 61000-4-19	-	Electromagnetic compatibility (EMC) – Part 4- 19: Testing and measurement techniques – Test for immunity to conducted, differential mode disturbances and signalling in the frequency range 2 kHz to 150 kHz at a.c. power ports	EN 61000-4-19	2014
IEC 61543	2023	Residual current-operated protective devices (rcds) for household and similar use. Electromagnetic compatibility.	EN 61543	<mark>20</mark> 23



- 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

Attention: non-EN/ISO/IEC standards can be used in clauses of hEN not giving presumption of conformity



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







In Clause 2 (homegrown) or Annex ZA do not refer to "all parts" (series of standards)
Annex ZA do not refer to "all parts"



#### HAS consultant comment:

er 7)	Clause/ Subclause ( <u>e.g.</u> 3.1)	Paragraph/ Figure/ Table/ ( <u>e.g.</u> Table 1)	Type of comment <sup>2</sup>	Comments
36	2 Normative references and annex ZA	2 Normative ge and annex		-Some standards listed are outdated -Series of standards are not individually listed and dated. -Some normative references in the body of the standard do not cope with those listed in 2 Normative references or the annex ZA. For details see the commented annex ZA added to the assessment report.

#### Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their conter 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.

NOTE 1 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/H applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available her www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60034-1 (mod) -	2010 -	Rotating electrical machines - Part 1: Rating and performance	EN 60034-1 + corr. October	2010 2010
IEC 60072	series	Dimensions and output series for rotating electrical machines	-	-
IEC 60034-5	2000	Rotating electrical machines – Part 11: Thermal protection	EN 60034-11	2001
+ AMD1	2006		+ A1	2007
IEC 60034-11	2004	Rotating electrical machines – Part 11: Thermal protection	EN 60034-11	2004
IEC 60068-2-27	1987	Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock	EN 60068-2-27	2009
IEC 60068-2-31	2008 1990	Environmental testing - Part 2-31: Tests. Test Ec: Rough handling shocks, primarily for equipment type specimens	EN 60068-2-31	2008
IEC 60073	2002	Basic and safety principles for man-machine interface, marking and identification - Coding principles for indicators and actuators	EN 60073	2002
IEC 60309-1 + AMD1 + AMD2	1999 2005 2012	Plugs, socket-outlets and couplers for industrial purposes - Part 1: General requirements	EN 60309-1 + A1 + A2	1999 2007 2012
IEC 60332	Series	Tests on electric and optical fibre cables under fire conditions	EN 60332	Series



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



# 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 to 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 C

- Checklist for hENs
- ► <u>Annex ZA</u> template
- Annex ZZ templates

CENELEC	ECHNICAL STRUCTURES HOMEGROWN DELIVERABLES	FRANKFURT AGREEMENT DELIVERABLES	REFERENCE MATERIAL
Reference documents	Forms and templates		
Guidance documents Forms and templates			Expand/Collapse All
	TECHNICAL BODY ORGANIZATION		+
	TECHNICAL WORK		+
	ANNEX ZZ		+
	TECHNICAL BOARD		+

#### Drafting EN IEC standards for citation in the OJEU



#### **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 <u>Webinar 'Re-start HAS assessment system'</u>
- 2023-01-24 Webinar 'Harmonized Healthcare Standards'