



EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

CENELEC webinar on LVD topics

18 November 2021

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Objectives of the webinar

- Support the increase of LVD standards cited in the OJEU
- Focus on processes, contents, requirements



Today's programme



Introduction & Practicalities	Ingrid Soetaert (CEN-CENELEC)
Opening of the webinar and aim of the session	Nadine Petermann (DKE - Convenor of CEN-CLC/BTWG 143-1)
Role of CEN-CLC/BTWG 143-1 'LVD and the legal framework'	
HAS system	Federico Musso (European Commission, DG GROW/H.3)
OJEU referencing	
Specificities of LVD	Alexis Basiaux (European Commission, DG GROW/H.2)
Interaction between EC, EY, and TCs: process for successful harmonization	Frédéric Mlanao (CEN-CENELEC)
Preparing standards for citation in the OJEU	Nooshin Amirifar (CEN-CENELEC)
Break	
Safety related risk assessment and risk reduction for low voltage equipment	Giovanni Cassinelli (Secretary CLC/TC 23E)
Normative references in standards	Nuno Pargana (CEN-CENELEC)
Use conditions in standards	Jos Remy (Convenor CEN-CLC/BTWG 15 'Reasonably foreseeable use')
Conclusions and way forward	Ingrid Soetaert (CEN-CENELEC)
Closing	Constant Kohler (CEN-CENELEC)



EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

CENELEC webinar on LVD CLC/BTWG 143-1 **LVD standardization** in the **EU regulatory framework**

Nadine Petermann
18th November 2021

Nadine Petermann



Head of International Affairs DKE
DE Permanent Delegate in CENELEC BT
Convenor of BTWG 143-1 'LVD
standardization in the EU regulatory
framework'

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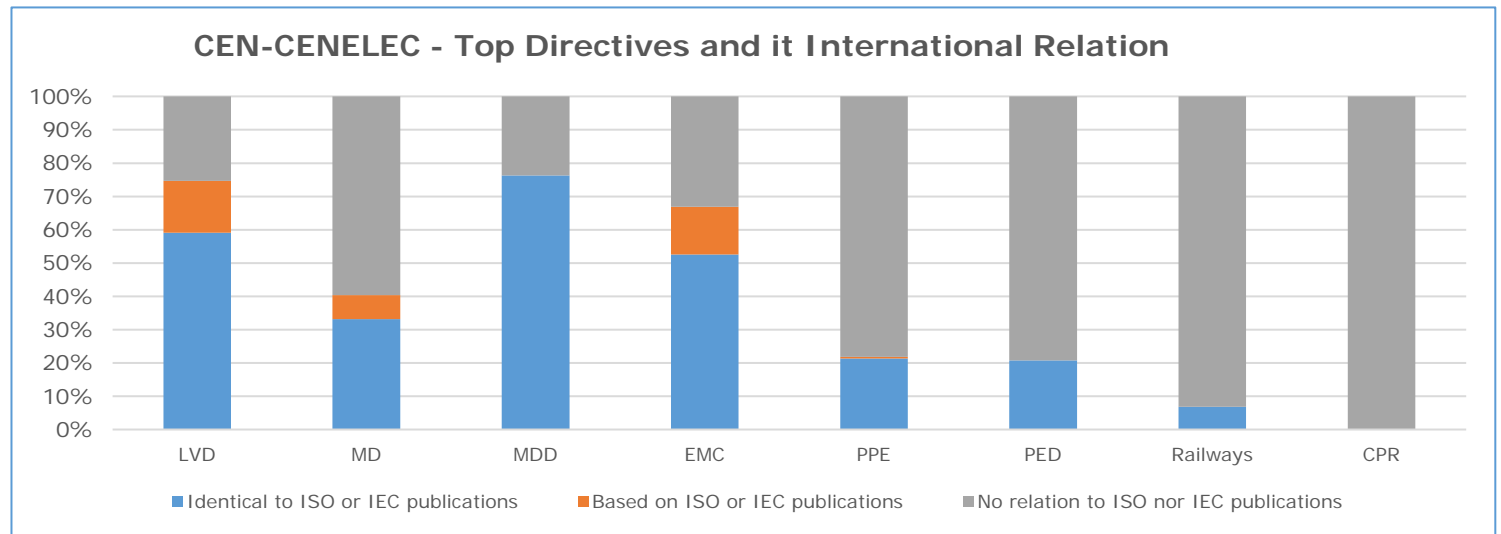
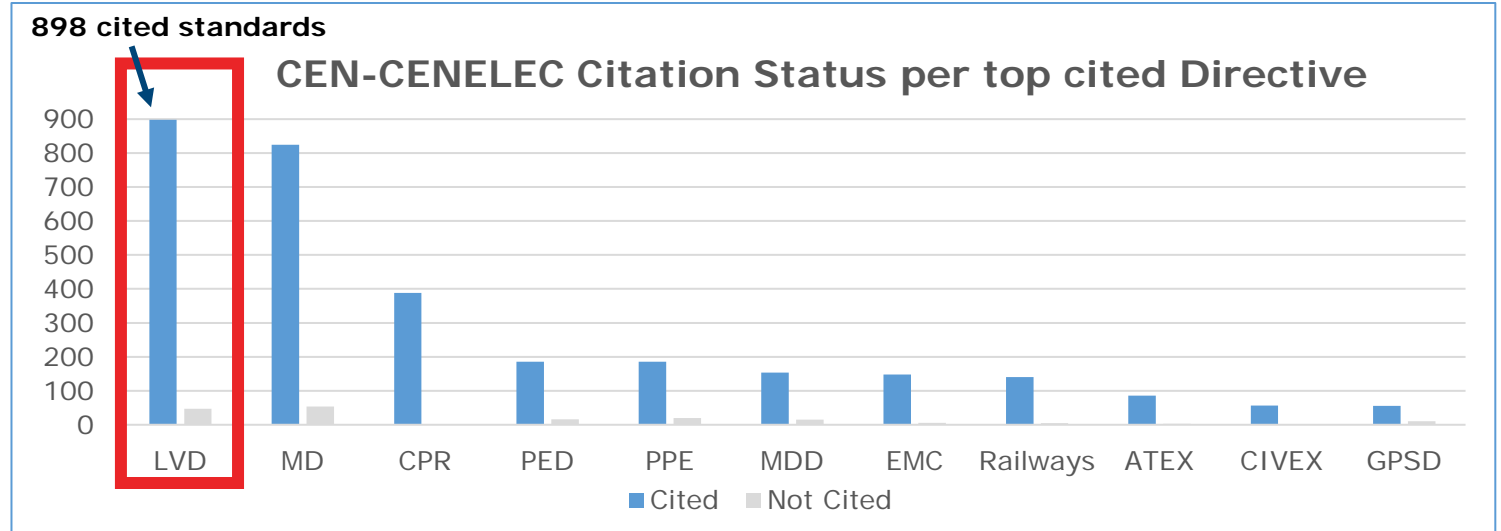
- ▶ The objective of this BTWG is
 - to address horizontal issues in relation to standardization surrounding LVD Directive 2014/35/EU and its possible review
 - To offer a platform to prepare and mirror the LVD working party and LVD ADCO
 - Coordinate on matters related to LVD work programme regarding its assessment and acceptance for citation in the OJEU
 - Maintain the CENELEC Guide 32 Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment

- ▶ Members are nominated experts from **NCs, CENELEC, IEC TBs** affected by LVD and **CENELEC partner organizations**

Impact of BTWG 143-1 for CENELEC



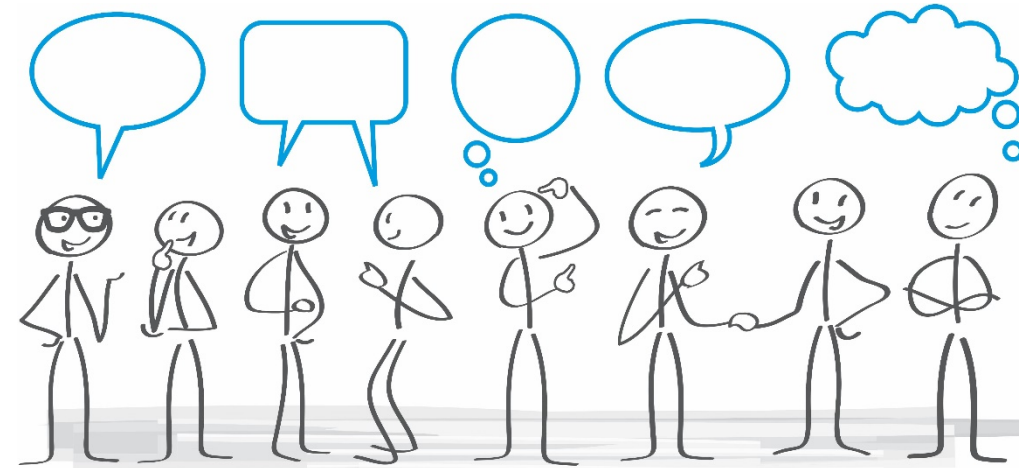
- ▶ most standards supporting legislation are cited in OJEU under the LVD
- ▶ The overall objective is to adopt fully IEC standards that meet EC requirement



Source: https://www.cenelec.eu/stats/CEN_CENELEC_in_figures_quarter.htm

The benefit for Technical Bodies

- ▶ Provide advice on LVD issues e.g.
 - ▶ discuss diverging 'horizontal' views between HAS Consultant and TC
 - ▶ issues on topics being cover or excluded from LVD
 - ▶ issues with non-citation/formal objections of hENs
- ▶ Provide trainings, guidance material, case studies
- ▶ TBs can share their expertise with the BTWG 143-1
 - ▶ TBs have direct impact on input to the work of the LVD Working Party



Source: trueeffelpix / stock.adobe.com

Thank you for your attention!

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The process and the roles for the OJEU-citation of harmonised standards

CEN-CENELEC's Webinar

“Harmonised European standards under the
Low Voltage Directive (LVD)”

18 November 2021

Regulation (EU) No 1025/2012 and James Elliott ruling of the EUCJ

- *Compliance of standards drafted by ESOs must be assessed by COM jointly with ESOs (Art. 10(5) of **Standardisation Regulation**) with the standardisation request (mandate)*
- *The **James Elliott judgment** of 27.10.2016: harmonised standards are considered a measure of EU law after citation in OJEU. Since their development is entrusted to private organisations (the ESOs), it follows that this assignment must be a “controlled delegation” in which the Commission plays a fundamental role => Articles 10(1), 10(5) and 10(6) of the Regulation must be fully applied.*

Previous system of consultants

- *Previously, assessment of conformity was delegated to ESOs: COM paid full cost of New Approach Consultants (NAC), but they were contracted and managed by CEN/CENELEC. NACs went beyond assessment tasks, participating to the drafting work in the TCs.*
- *After Elliott ruling, COM services started to verify and assess conformity of standards themselves and often disagreed with the assessments of NACs => significant amount of standards not cited in the OJEU.*

Introduction of the new system of HAS Consultants

- *To comply with its legal obligation as per Art. 10(5) of the Regulation, COM needed technical assistance => decision to discontinue NAC system and replace it with a new system, directly managed by COM.*
- *The system of Harmonised Standards (HAS) Consultants replaced the NACs on 01.04.2018. HAS Consultants to work closely with, and on behalf of, COM's sectoral Units.*
- *Assessment of documents to be done according to criteria set by COM, on the basis of initial standardisation requests and legislation.*

How the HAS Consultants system works

- *COM and consultants must keep distance from drafting and from consensus building process of ESOs, and must be clear of conflicts of interest.*
- *Results of assessments are not binding for COM.*
- *The horizontal Standardisation Unit in DG GROW coordinates the HAS Consultants work and provides guidance and periodical trainings on horizontal aspects, to ensure consistency.*
- *Coordination on sector-specific elements is provided by COM's sectoral Units, when necessary.*

Main guidance documents for HAS Consultants

- *GROW's Standardisation Unit has developed the Assessment Report template.*
- *Main guidance documents: European Vademecum, OJ-Checklist from 2016, CEN-CENELEC's Internal Regulations Part 3, sectoral checklists (when existing), other training material (presentations, etc.)*

Previous system of OJEU referencing

- *Lists of harmonised standards providing presumption of conformity with the essential requirements of a specific Directive/Regulation were published in the C series of the OJEU, already in the form of a consolidated list.*
- *New standards were included in the list, and those standards that were meant to be withdrawn were simply no longer included.*
- *The act used to publish references was a Commission Communication; decision was decentralised (taken at sectorial Unit level)*

Reasons for changing publication system

- *The main reason for the new system lies in the jurisprudence of the EUCJ on harmonised standards*
- *In particular, the James Elliott ruling and the Global Garden ruling were relevant:*
 - **James Elliott:** harmonised standards, though voluntary, are “by their nature measures implementing or applying an act of EU law” once referenced in the OJEU
 - **Global Garden:** important to have legal certainty when publishing and repealing references in the OJEU. To set starting and ending dates for the legal effect is exclusive competence of Commission

Commission Communication on Harmonised Standards

- *In its Communication on harmonised standards COM(2018) 764 of 22.11.2018, the Commission announced the review of its internal decision making process for publishing the references to harmonised standards in the OJEU.*
- *As of 1st December 2018, the publication of references to standards happens via Commission Implementing Decisions, adopted by written procedure by the College of Commissioners and published in the L series of the OJEU; the L series is used for legally binding acts (while the C series is used for information and communication).*
- *For legal legitimacy, the adoption of these Decisions is no longer decentralized within COM. All adopted Decisions are published in DG GROW's web-site, and are available in all languages.*

Publication Decisions under the new system

- *In the Decisions, there are different Annexes for publication, publication with restriction and withdrawal. In several sectors, only new standards (or withdrawn standards) are listed: no consolidated lists annexed to the Decisions (in some other sectors we are moving towards consolidated lists annexed to the Decisions)*
- *For publication Decisions which do not contain a consolidated list, DG GROW publishes summary lists on its web-site (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en) after each publication*
- *To increase user-friendliness, the summary lists are provided in two formats, .pdf and .xls*

Overview of publication in the L series of the OJEU

- *In 2018: 1 publication Decision (1 new reference)*
- *In 2019: 15 publication Decisions (157 new references in total)*
- *In 2020: 19 publication Decisions (215 new references in total)*
- *In 2021 (so far): 27 publication Decisions (214 new references in total) – 8 more publication Decisions (including for LVD) currently in the pipeline for adoption, for a total of 87 new references*

- *Overall speed of publication is steadily improving*

- *Backlog of pending standards fully cancelled in almost all sectors (exceptions: GPSD, Eco-design)*

Date of withdrawal of references to standards from the OJEU

- *The Global Garden ruling has confirmed that it is COM's exclusive competence to terminate the legal effect of harmonised standards by withdrawing the references from the OJEU*
- *In the new publication Decisions, a specific annex lists the withdrawn references and the respective withdrawal dates*
- *Date of withdrawal from the OJEU has nothing to do with the DoW set in the superseding standard => no automatic alignment between the two dates*
- *As a default date of withdrawal from OJEU, COM intends to use the 18 months transition period normally used for legislation - motivated exceptions (longer or shorter periods) are possible*

Thank you for your attention!

Questions?

Federico Musso

European Commission

DG GROW/H.3 (the Standards Policy Unit)

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CEN-CENELEC Webinar on LVD Specificities of standards

Low Voltage Directive 2014/35/EU

DG GROW.H2

Outcome of the Evaluation (1)

- Effectiveness
 - Internal market and Health & Safety
 - Facilitate trade within EU
 - Harmonised Standards are useful tools for compliance and market access
 - Room for improvement: Market Surveillance (including enforcement for e-commerce), Conformity assessment procedures for riskier products.
- Efficiency
 - The Directive is regarded as efficient with benefits outweighing the costs.
 - Room for improvement: costs for marking and documentation, and standards

Outcome of the Evaluation (2)

- Relevance
 - Safety objective met (as it is a key issue for the competitiveness)
 - Helps prevent diverging regulations between MS
 - RED → reduction of LVD Scope
 - No clear indication of the benefits to remove the lower voltage limits
- Coherence
 - Interplay with RED and MD → coming from other Directives (not from LVD)
 - New Machinery Regulation provides clarity on the interplay with the LVD and the RED
- EU added value
 - the impact of the Directive is more directly attributable to the activities of the standardisation bodies, market surveillance authorities and businesses that interpret and apply systems and processes that support and enable the Directive

Conclusion

- The Directive is relevant, effective, efficient, coherent, and has EU added value.
- Specific improvements have been identified to make the directive future proof, which are mainly outside the remit of the LVD (e.g. market surveillance).
- No revision for the moment.

LVD Guidelines

- Guidelines are not a legal text.
- Gives explanation on various elements of the directive and its application.
- COM drafted the guidelines in collaboration with stakeholders such as national authorities, industry bodies and standardisation bodies.
- For the time being the guidelines are not intended to be updated.

Publications of standards

- Latest publication
 - 22 June 2021 OJ L 222/40: Commission Implementing Decision 2021/1015 amending Implementing Decision 2019/1956
 - Covered Q3 2020
- Next publication
 - XX YYYY ZZZZ OJ L XXX/XX: Commission Implementing Decision ZZZZ/XXXX amending Implementing Decision 2019/1956
 - It will cover standards proposed in Q4 2020, Q1 2021 and Q2 2021.
- Q3 2021 batch of proposed standards was received 28 October 2021
 - COM Assessment is ongoing

Findings on Non-Compliance

- Annex ZA – undated, misdated or missing references
- Annex ZZ – missing or too generalistic (improvements have been seen in this regard)
- Standards that apply to other mandates/directives
 - If standards have received a negative assessment for which the comments were not addressed by CCMC and a positive assessment under LVD. (most recent examples with EMCD)
- Proposal for publication of part 2 standard referring to a part 1 which has received a non-compliance assessment.

Some insight

- Annex ZA
 - Dated and up-to-date normative references shall clearly be identified in the ZA annex.
- Annex ZZ
 - The parts of the standard related to the essential requirements of the LVD shall clearly be identified in the ZZ annex (in accordance with the agreed template).
- Risk Assessment
 - Draws the link between the safety aspects (related to low voltage equipment) identified by the CEN guide and their coverage within the standards assessed. Allows to identify potential gaps.
- Checklist
 - The existing documents in the hand of ESOs are enough to draft compliant standards: the Vademecum, the blue guide, the IR3, the COM email dated 2018, the CEN guide 32, and the requirements engineering.

Thank you



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EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

Webinar on LVD issues Process for successful harmonization

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Presenters



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The harmonization procedure

Standards development process

Harmonized standards (hEN) are developed in the same way as any other EN in CENELEC – **but with additional considerations:**

❑ Mandatory for hEN:

All harmonized standards **shall** include an informative Annex ZZ (CENELEC), demonstrating the relationship between the clauses of the standard and the regulatory requirements.

For standards developed under the Frankfurt Agreement, a normative Annex ZA ‘normative references’ shall be included as well.

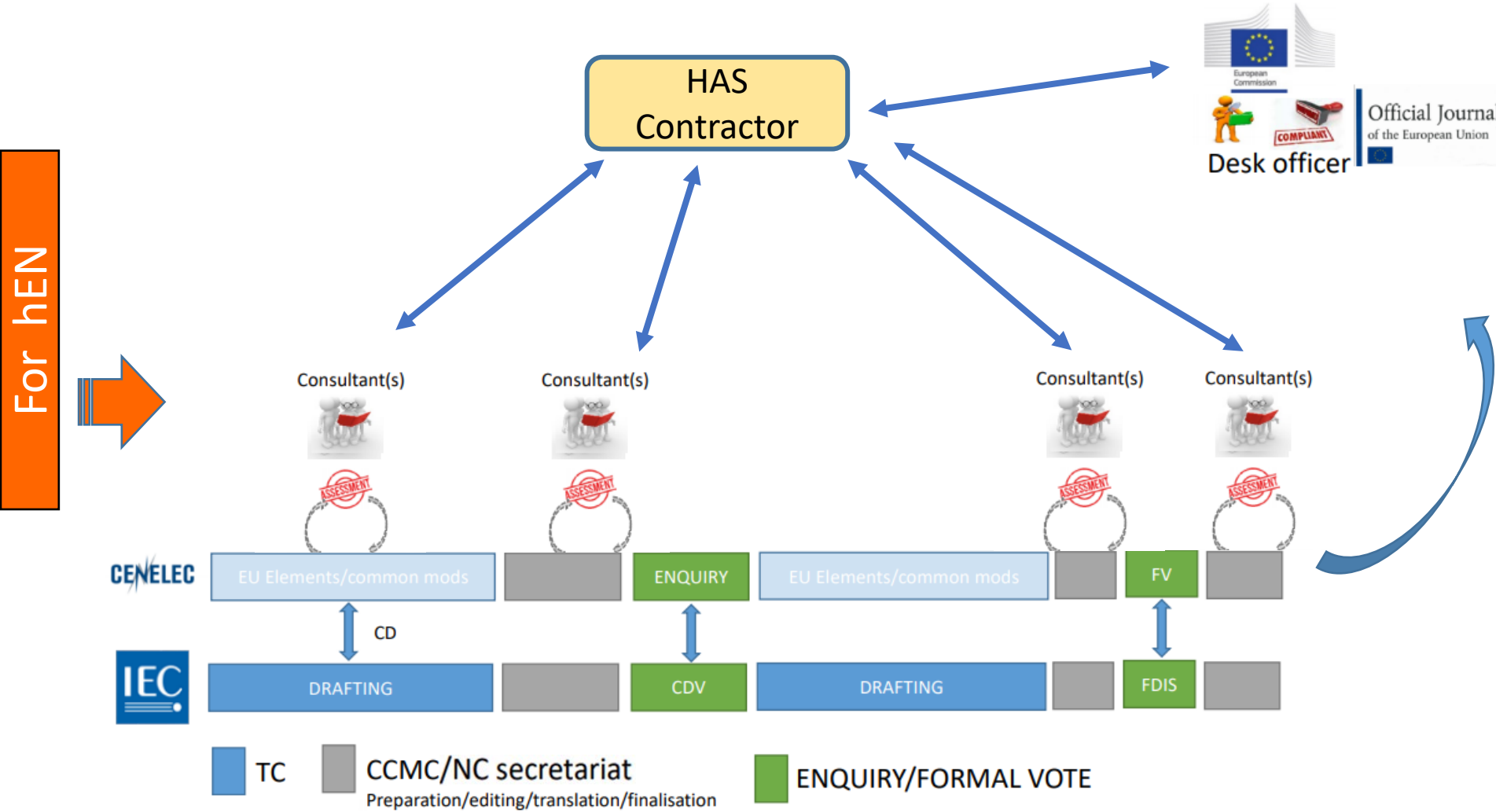
❑ Consultant assessments:

The HAS consultants assess the compliance of a standard with directive’s (and standardization request) requirements, via communicating with and delivering assessments to the TCs - they work on behalf of the EC.

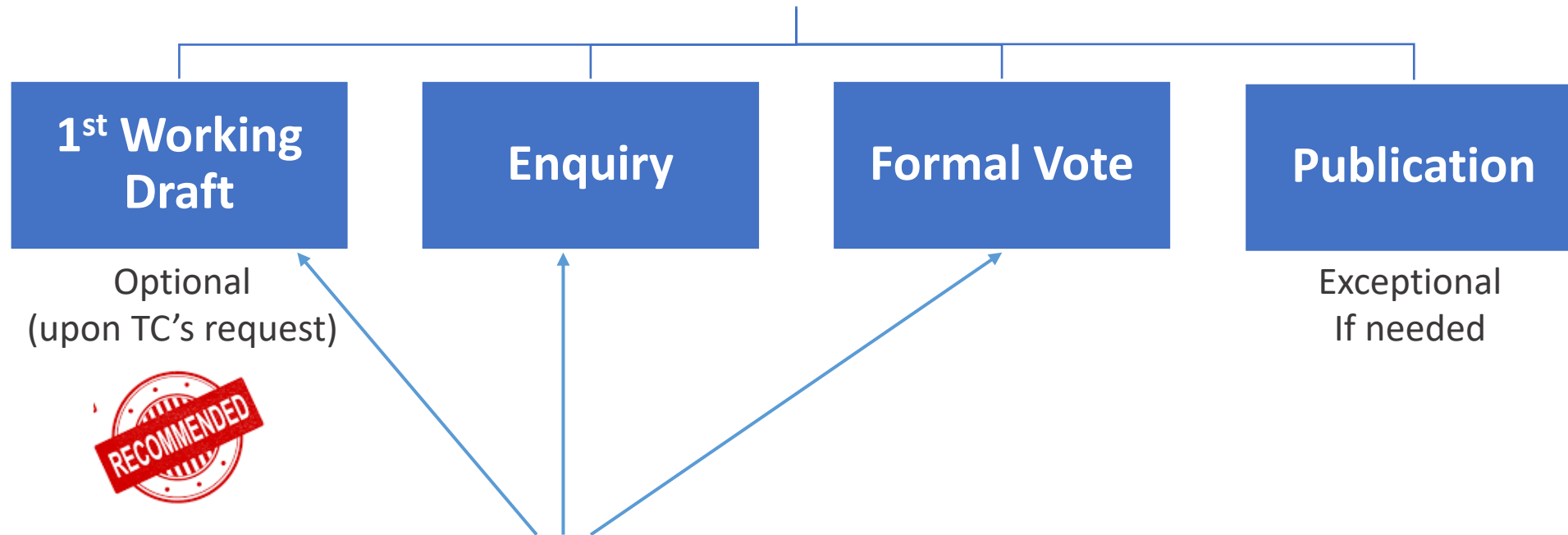


‘Compliant assessment’ on EN is needed to have the EN “offered” (by CEN-CENELEC) to the European Commission and then cited in the OJEU (European Commission decision)!

Standards development process



When can assessment be requested?

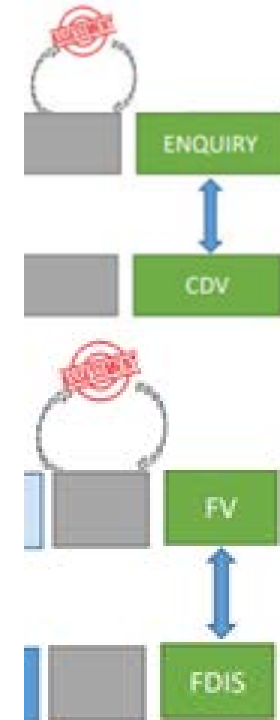


**At any of above stages assessment can be requested.
However, only 1 assessment per stage !**

Assessment request: EN IEC under FA

When the assessment should be requested by CCMC ?

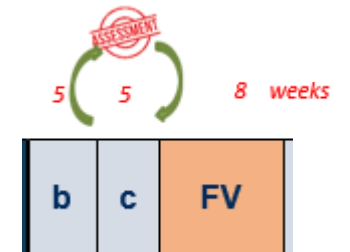
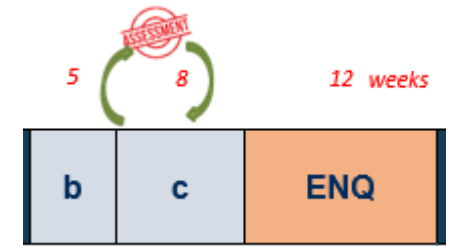
- ❑ **CD** : upon TC request
- ❑ **// CDV** : when CDV notification received (with standard text), CCMC asks EU elements to TC. Assessment requested before CDV/Enquiry starts.
- ❑ **// FDIS** : when FDIS notification received, CCMC asks EU elements to TC. Assessment requested before FDIS/Formal Vote starts.
- ❑ **PUB** : exceptional, in case of need



Assessment request: Homegrown EN

When the assessment should be requested by CCMC ?

- ❑ **FWD** : upon TC request
- ❑ **ENQ** : assessment requested when translation starts.
- ❑ **FV** : assessment requested when translation starts. Report shall be available when FV starts. FV starts only if compliant assessment.

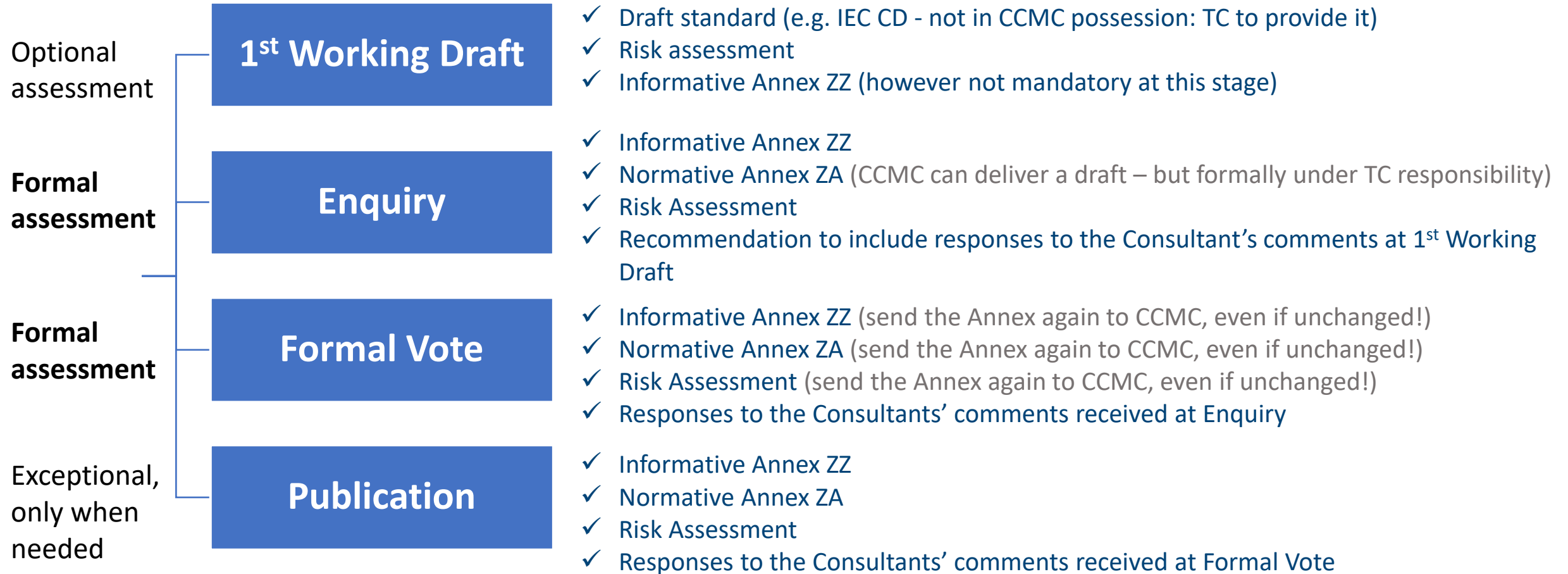


*

b= editing
c= translation

Assessment requests: EN IEC under FA

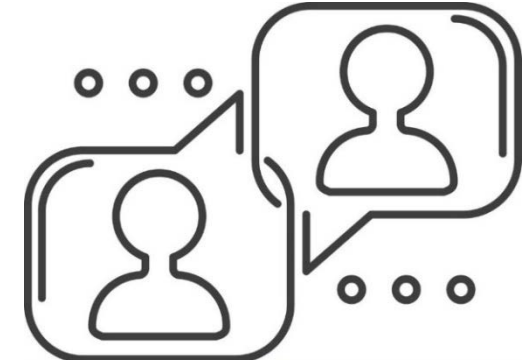
What TC needs to deliver to CCMC?



Assessment results

Duration of assessment process

- 5 weeks** maximum after notification to HAS Contractor
- Results are uploaded on **LiveLink** available to TC secretaries



Communicate with HAS consultant?

- The TC can contact directly the HAS consultant (via email) before and/or after the assessment is delivered for further discussions
- Exception: for meetings with the duration > 4 hours, TC secretary or PM shall make the request using the link www.ey.com/be/HASmeetingrequests.
- Since April 2021, the communication with HAS consultant is temporarily suspended by the EC
- EC is looking for solutions to resume the normal communication process



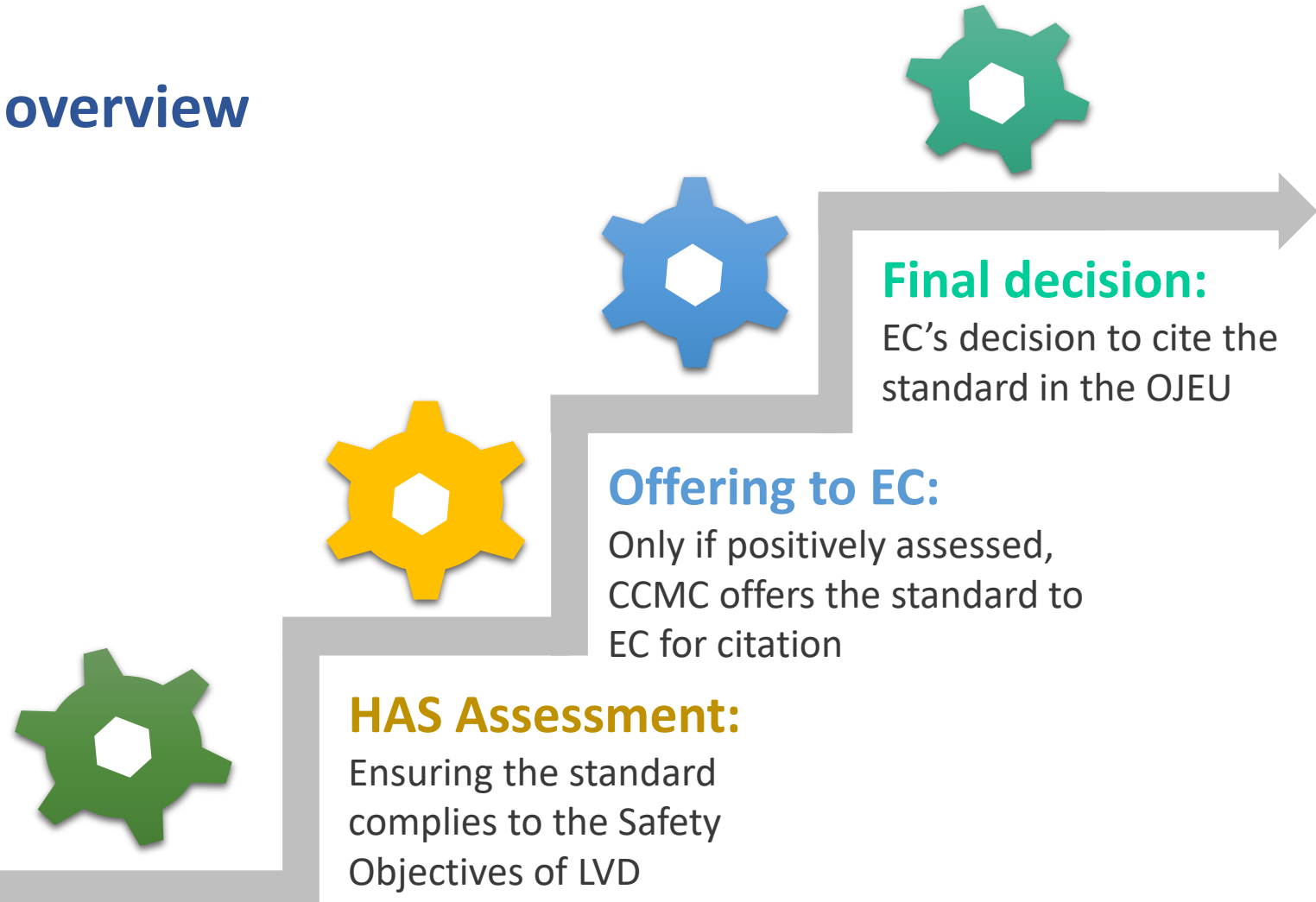
**Always inform
your CCMC
PM!**

Citation of a harmonized standard in the OJEU



□ Procedure overview

hEN standard developed in the support of legislation



Annexes:
TC to provide additional European elements

HAS Assessment:
Ensuring the standard complies to the Safety Objectives of LVD

Offering to EC:
Only if positively assessed, CCMC offers the standard to EC for citation

Final decision:
EC's decision to cite the standard in the OJEU

Standard cited in the OJEU



Post-assessment

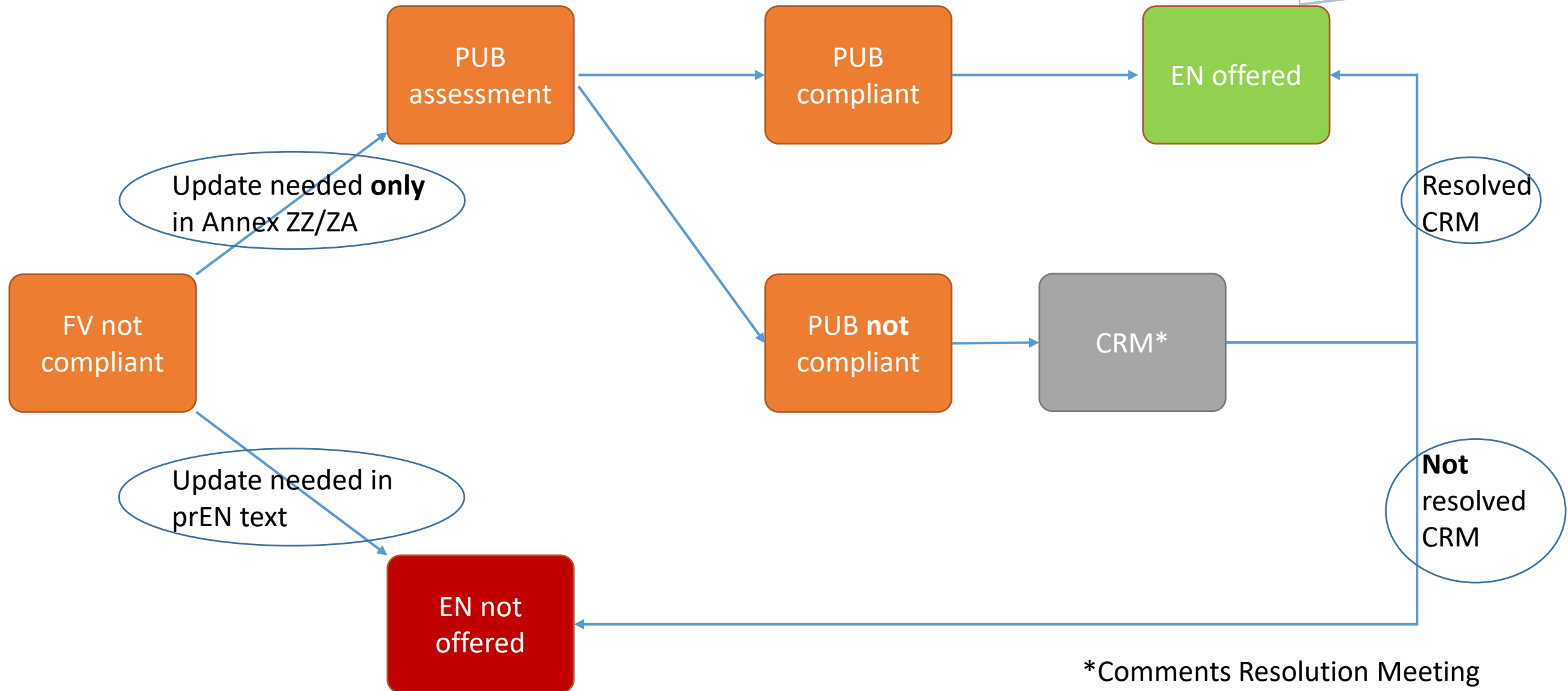
Key points!

Principles for a successful assessment

- ❑ **Start the process as early as possible!**
i.e. with the assessment request of the first working draft: the consultant would flag compliance issues early in the process
- ❑ **Systematically provide feedback!**
TC shall provide feedback by responding, in writing, to the HAS consultant's comments (column: observations from the secretariat)
- ❑ **Communication is the key!**
 - ✓ Ensure communication flows between CLC/TC (interaction with the HAS consultants) and IEC/TC (writing the standard)
 - ✓ Ensure communication flows with HAS Consultant: After the submission of the assessment by CCMC, TCs are encouraged to engage with HAS consultants



Negative FV assessment (EN IEC)

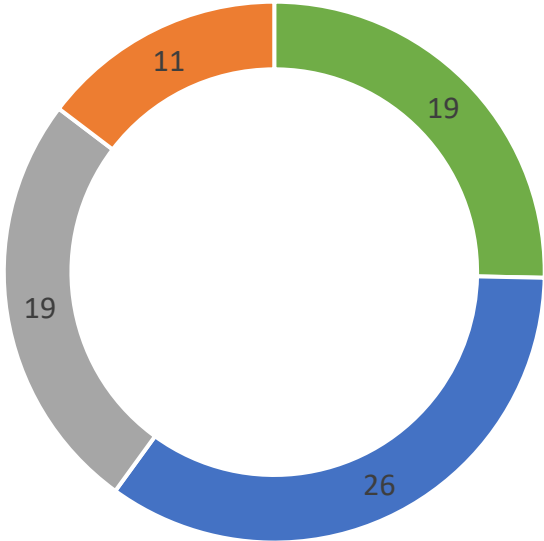


*Comments Resolution Meeting

Overview of requests from July 2020 to November 2021

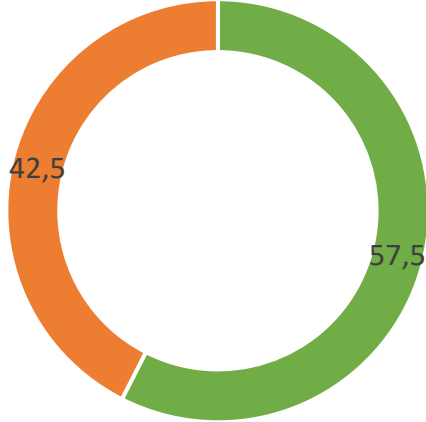


Assessment outcome at last stage



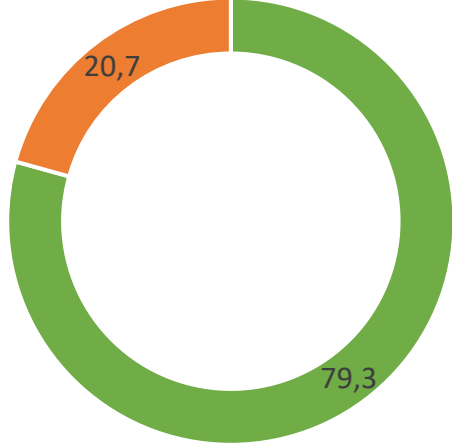
- Compliant
- Compliant, with minor or limited number of changes not affecting compliance
- Lack of compliance, minor or limited number of changes required
- Lack of compliance, redrafting required

Compliance rate (%)



- Compliant
- Lack of compliance

Compliance rate after resolution (%)



- Compliant
- Lack of compliance

(* data provided by EY)

Critical findings

- ▶ Template used by the HAS consultant in the formal Assessment Report

1.2 Critical findings leading to a Lack of compliance - Tick relevant boxes for the Critical findings that have been found in the document (and provide details in 1.3 'Additional information on the critical findings', Part B and template of comments)

- 1.2.1 The terminology (including definitions of terms) is not in line or consistent with relevant EU legislation
- 1.2.2 The Foreword or the introduction contains inappropriate information not belonging there or misleads document users on its role and scope as a harmonised standard (e.g. contains requirements, legal or technical interpretations, information outside of the scope of a document)
- 1.2.3 The Scope covers products not considered by the relevant legal requirements of EU legislation or standardisation request and organisation/subdivision of technical content or Annex Z mislead users of a document on its support on EU legislation
- 1.2.4 The Scope sets requirements or covers aspects which cannot be subject to harmonised standards on the basis of relevant EU legislations or standardisation request
- 1.2.5 The Scope excludes products or aspects that are expected to be covered by the standard according to its title or Annex Z in order to support relevant EU legislation or standardisation Request. This means that there is not consistence between the title, the scope and Annex Z; as a result, products that are expected to be covered are excluded.
- 1.2.6 One or several Normative references that are essential for the assessment of harmonised elements are not available at the time of the assessment
- 1.2.7 The document contains undated normative references without proper justification (and assessment) or the justification is not acceptable
- 1.2.8 The document contains too long chains of normative references that are needed to comply with or to follow (in the case of CPR) when applying the harmonised part of the document
- 1.2.9 The normative references need updating or reconsideration, i.e.
 - one or more do not reflect the state of the art and have an impact on compliance with EU legislation,
 - one or more normative references, in particular references to other harmonised standards should be informative (to avoid later contradictions because of different update cycles of referring and referenced documents)
- 1.2.10 The technical content of the document contains requirements that do not align with or contradict relevant EU legislation (e.g. are out of scope from supporting proper or any legal requirements, fails to specify 'technical solutions', allows users of a document to decide on the specification)
- 1.2.11 The technical content of the document unsuitably repeats legal requirements as part of its normative requirements (e.g. without any added value or modifying them, suggesting that only some legal requirements are valid)

Overview of critical findings (07/2020 to 11/2021)

Part A: Summary of assessments

A total of 154 assessment have been performed on the full assessment template and are considered in this analysis.

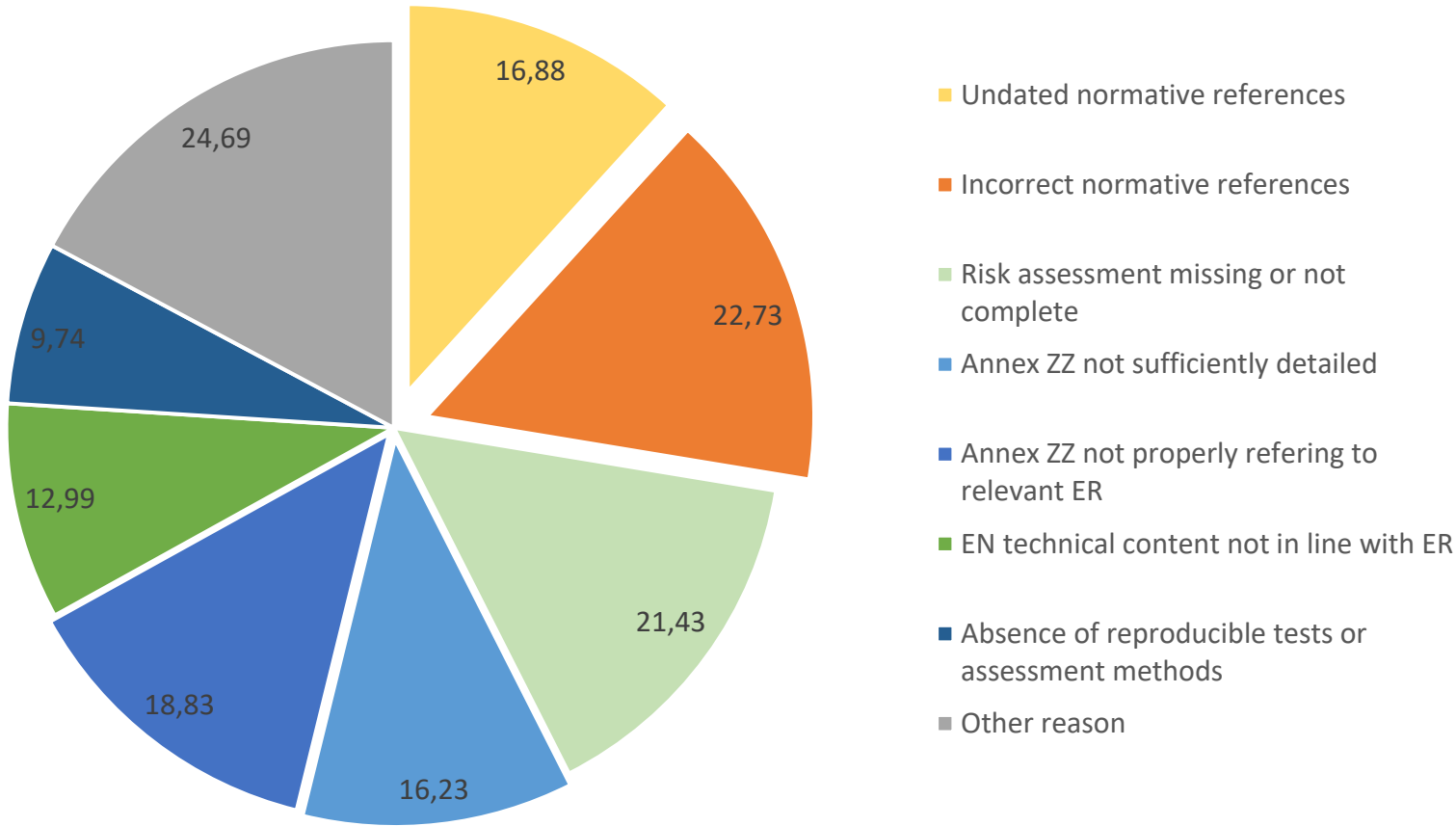
AR ref.	Critical findings	Frequency of finding	Total Assessments	Proportion
A- 1.2.1.	Terminology	1	154	0,65%
A- 1.2.2.	Foreword	2	154	1,30%
A- 1.2.3.	Scope covers products not considered by the relevant legal requirements	5	154	3,25%
A- 1.2.4.	The Scope sets requirements or covers aspects which cannot be subject to harmonised standards	1	154	0,65%
A- 1.2.5.	Scope excludes products or aspects that are expected to be covered by the standard	3	154	1,95%
A- 1.2.6.	Normative references that are essential for the assessment of harmonised elements are not available	2	154	1,30%
A- 1.2.7.	Document contains undated normative references without proper justification	26	154	16,88%
A- 1.2.8.	Too long chains of normative references	0	154	0,00%
A- 1.2.9.	Normative references need updating or reconsideration	35	154	22,73%
A- 1.2.10.	Technical content of the document contains requirements that do not align with or contradict relevant EU legislation	20	154	12,99%
A- 1.2.11.	Technical content of the document unsuitably repeats legal requirements as part of its normative requirements	3	154	1,95%
A- 1.2.12.	Absence of reproducible tests or assessment methods	15	154	9,74%
A- 1.2.13.	Neutrality principle is not respected: the document contains clauses imposing requirements or obligations on or between certain economic operators	5	154	3,25%
A- 1.2.14.	Neutrality principle is not respected in requirements for verifications, sampling and testing	7	154	4,55%
A- 1.2.15.	Risk assessment or identification of relevant risks is missing or not complete	33	154	21,43%
A- 1.2.16.	The Annex Z is not sufficiently detailed	25	154	16,23%
A- 1.2.17.	The Annex Z does not properly refer to the relevant legal requirements	29	154	18,83%
A- 1.2.18.	The document is not aligned with the guidance documents or checklist	0	154	0,00%
A- 1.2.19.	Other comments	9	154	5,84%

(*) data provided by EY

Overview of critical findings (07/2020 to 11/2021)



Lack of compliance reason



- ▶ Contribution to lack of compliance by importance order :
 - Annex ZA (normative references)
 - Annex ZZ
 - Risk assessment
- ▶ Lower impact of critical findings related to standards text

CENELEC BOSS updates

CENELEC BOSS update



- ▶ New page on CENELEC [BOSS](#) for guidance on drafting harmonised EN IEC standards

The screenshot shows the CENELEC BOSS website interface. At the top left is the CENELEC logo. To its right is a navigation menu with three items: 'TECHNICAL STRUCTURES', 'HOMEGROWN DELIVERABLES', and 'FRANKFURT AGREEMENT DELI'. Below the navigation is a main content area. On the left side of this area is a vertical sidebar with four menu items: 'European Standard (EN IEC)', 'Harmonization Document (HD)', 'Common modifications', and 'Other deliverables'. The 'European Standard (EN IEC)' item is highlighted with a dark blue background. To the right of the sidebar is the main content area, which features the title 'Drafting EN IEC standards for citation in the OJEU' in bold. Below the title is a paragraph of text: 'This page provides guidance to Technical Bodies and Working Groups on horizontal aspects to be considered when preparing EN IEC harmonized standards, in support of EU harmonization legislation, intended to be cited in the Official Journal of the European Union (OJEU). Regulation (EU) No 1025/2012 on European standardization defines a harmonized standard as “a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation”.' Below this paragraph is another paragraph: 'For the purpose of this page, the term 'Technical Body' (TB) refers to Technical Committees (TC), Sub-committees (SC), Reporting Secretariats (SR) and Task Force of the Technical Board (BTTF).'

hEN checklist on CENELEC BOSS



► General [checklist](#) for harmonised standards available

	<i>Check the following questions – if you answer yes to all the questions, the draft is probably ready for submission to CCMC (and HAS Consultant assessment).</i>	Check
Normative reference	<p>Are the standards listed in the Normative references Clause 2 normatively referenced within the text (i.e. are they cited in the text in such a way that some or all of their content constitutes requirements of the document, for instance with a “shall”).</p> <p><i>NB: See IR 3 with the preferred verbal form to be used to express a requirement.</i></p>	<input type="checkbox"/>
	<p>Are the normative references dated in Clause 2 and in all clauses of the draft standard?</p> <p>If not, is a justification for using undated normative references provided?</p> <p>Non-dated normative references are only possible if</p> <ol style="list-style-type: none"> 1. The normative reference is not relevant for compliance with essential requirements. <p>or</p> <ol style="list-style-type: none"> 2. The normative reference is relevant for compliance with essential requirements but the implications of modifications to the referenced document for the compliance with essential requirements have been duly considered (to be explained in the justification). <p><i>NB: Additionally, IR 3 requirements on normative references apply, i.e. the complete document is referenced, it will be possible to use all future changes of the referenced document for the purposes of the referring document and the reference will include all amendments to and revisions of the referenced document.</i></p> <p><i>NB: It is not enough to date the normative references in Clause 2 only; they need to be dated also within the main text. For series of standards the expression “all parts” is equal to undated normative references. The expression shall not be used unless a justification is provided.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
	<p>Are all the references used EN, ISO and IEC standards?</p> <p>If not, do suitable EN, ISO and IEC standards exist which could be used instead?</p> <p>If not,</p> <ul style="list-style-type: none"> • Do the references comply with IR 3 conditions (see IR 3:2019 Clause 10.2)? • is the needed TC decision (in CEN) available? • is a justification provided (preferably to be included in the TC decisions)? 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Matrix of responsibilities

Guidance for TC and WG officers, WG experts developing harmonized EN IEC standards



X	=	assigned to – the task can be delegated
O	=	task recommended to be assigned
---	=	not to be assigned to
open box	=	might be assigned to

- Describes in detail the **task distribution** at each stage of the standard development
- Focuses on **harmonized EN IEC standards**
- The document is approved by CEN-CLC Technical Boards
- Will be available on boss.cenelec.eu.

	TASK	TC SECRETARY	WG CONVENOR	WG EXPERTS	CCMC	REMARKS
(stages 20 and 30) 3 rd After Enquiry (stage 40) and before Formal Vote	For the preparation of the ENQUIRY draft (30.99) The CLC TB to prepare the European elements for harmonization (i.e. Annex ZA and ZZ, risk assessment as relevant)	O	O	O	---	Ideally the European elements should be made available in time before launch of the parallel enquiry (parallel CDV) See the relevant CENELEC webinars, notably on the 'granularity of the Annex ZZ' and on the 'use of normative references'
	At the start of the parallel Enquiry at CDV (at the very latest), CLC TB secretary provides the necessary European elements to production@cenelec.eu (with the transmission notice and the CCMC project manager in copy) to trigger the formal assessment at Enquiry stage	X	---	---	X	The TB secretary to provide CCMC - the Annex ZA (beforehand, secretary can request CCMC to deliver a 'draft Annex ZA' consisting of a template completed with identified international normative references and European homologues. TC shall analyse this Annex ZA and provide TB version to CCMC for assessment), - the Annex ZZ (mandatory at this stage) - the responses to the HAS consultant comments at the first working draft - and all elements required according to the transmission notice at the very latest at the start of the parallel Enquiry. The IEC has the <u>lead</u> , therefore it decides on the launch of the CDV. As a consequence, the CLC TB needs to anticipate the timing at IEC level. National Committees can provide the CDV to their secretaries when released. Once these elements will be received by CCMC, CCMC will upload these elements ("assessment package") for assessment.
	Provide information to the IEC TC secretary and the relevant WG convenor about the HAS consultant's assessment and comments	O	O	O	---	Ensure dynamic link between the IEC TC and the CLC TB, through the European National Committees and experts in the IEC TC. The CLC TB secretary is invited to liaise with the CLC TB experts to agree on the best approach to address the compliance issues with the IEC TC.

Thank you for your attention. Questions?

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Nooshin Amirifar & Frédéric Mlanao

10 MINUTES





EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

CENELEC webinar on LVD topics

Safety related risk assessment and risk reduction for low voltage equipment

Giovanni Cassinelli

18 November 2021

Giovanni Cassinelli



CLC TC23E Secretary
giovanni.cassinelli@bticino.it

Standards are about

- ▶ **Safety**
- ▶ Reliability
- ▶ Efficiency
- ▶ Interoperability
- ▶ Environment
- ▶ Inclusiveness

Safety first

- ▶ “Safe” is the state of being sufficiently protected from recognized hazards that are likely to cause harm.
- ▶ Some level of risk is inherent in products or systems.

An iterative structured process of **risk assessment** and **risk reduction** for each hazard is essential in achieving **tolerable risk**

- ▶ **Issue**
 - ▶ For many standards, the process is implicitly applied but not documented
 - ▶ Potential complexity of the process
 - ▶ Not easy to apply for existing work
 - ▶ Acceptance of the results

Guidance for safety in standards

Basis:

[ISO/IEC GUIDE 51](#) - *Safety aspects - Guidelines for their inclusion in standards*

Completed by more specific Guides e.g. (non exhaustive)

[ISO/IEC Guide 50](#) & [CEN-CENELEC GUIDE 14](#) on **Child Safety**

[IEC Guide 104](#) - **safety publications** and their use

[IEC Guide 116](#) & [CLC Guide 32](#) - **Risk Assessment & Reduction LV Equipment**

[IEC Guide 110](#) on **Safety for Home Control Systems** incl .functional safety

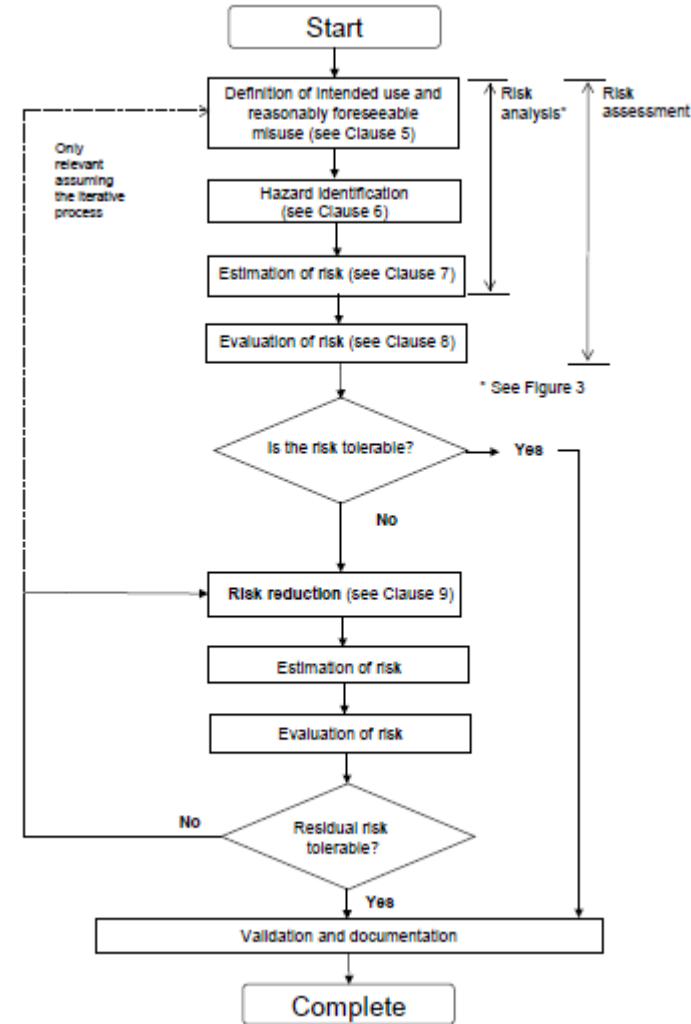
[IEC Guide 117](#) & [CLC Guide 29](#) on **Risk Assessment** on burn from hot touchable surfaces

Overall strategy

- Scope: Determine the limits of the product, including intended use & reasonably foreseeable misuse
- Identify the (relevant) hazards and associated hazardous situations
- Estimate the risk for each identified hazard and hazardous situation
- Evaluate the risk and take decisions about the need for risk reduction
- Eliminate the hazard or reduce the risk associated with the hazard



requirements



Document the product

- **The product**

- Product description
- Relevant Standards, Technical specifications, Legislation
- Experience of use, accident/incident history
- Relevant ergonomic principles

- **Limits of the product**

- Use limits;
intended use, reasonable foreseeable misuse, operating modes, interventions, consumer/commercial/industrial, users, training, experience
- Physical limits;
range of movement, power supply, intended lifetime, environmental, ...

- **Life Phases and related tasks**

- e.g. transport, assembly, commissioning, operation, cleaning, start-up, feeding, stopping.

Use of the product

The standard shall be sufficiently clear on the use of the product considered in the standard:

- Intended use

- Reasonably foreseeable misuse

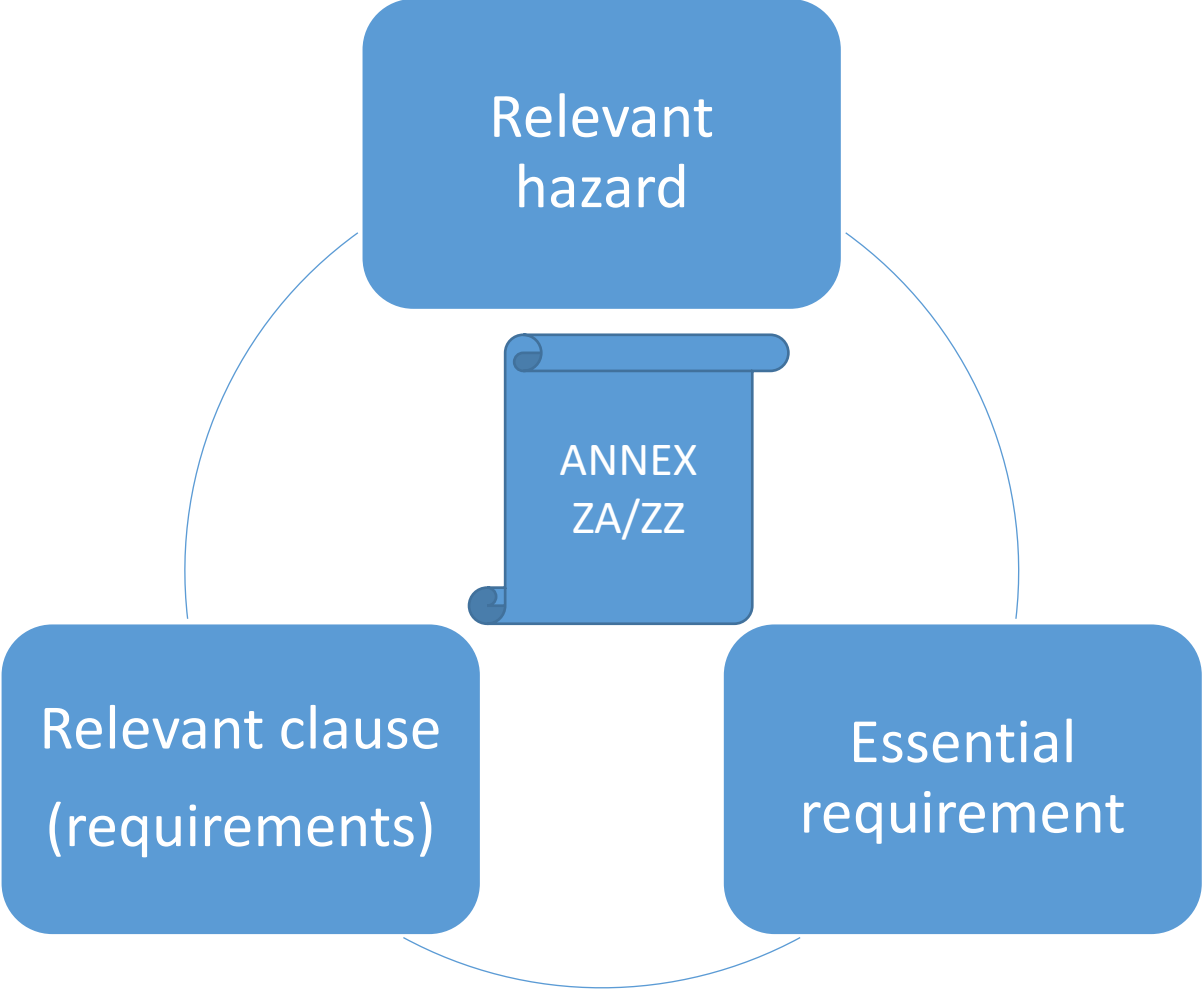
- Other factors to be considered
 - Persons exposed/expected users
 - Exposure type and duration and relationship to effects
 - Human factors
 - Suitability of protective measures & possibility of circumventing
 - Ability to maintain the effectivity of protective measures

Identify relevant hazards

Mechanical	Crushing, shearing, cutting, drawing-in, trapping, entangling impact, stabbing, injection, abrasion,
Electrical	Burns, electrocution, secondary chemical effects,
Thermal	Burns, frostbite, scalds,
Noise	Loss of hearing, awareness or balance; stress,
Vibration	Stress, low back morbidity, traumata,...
Radiation	Skin, tissue or eye damage. Genetic mutation, ...
Material / substance	Poisoning, infections, explosions, cancer, ...
Ergonomic	Discomfort, fatigue, stress, ...
Environment related	Slipping, falling, suffocation,
Combinations	Heat stroke, de-hydration, loss of awareness,

Be very clear on which hazards are deemed 'relevant' and which of them are addressed in the standard.

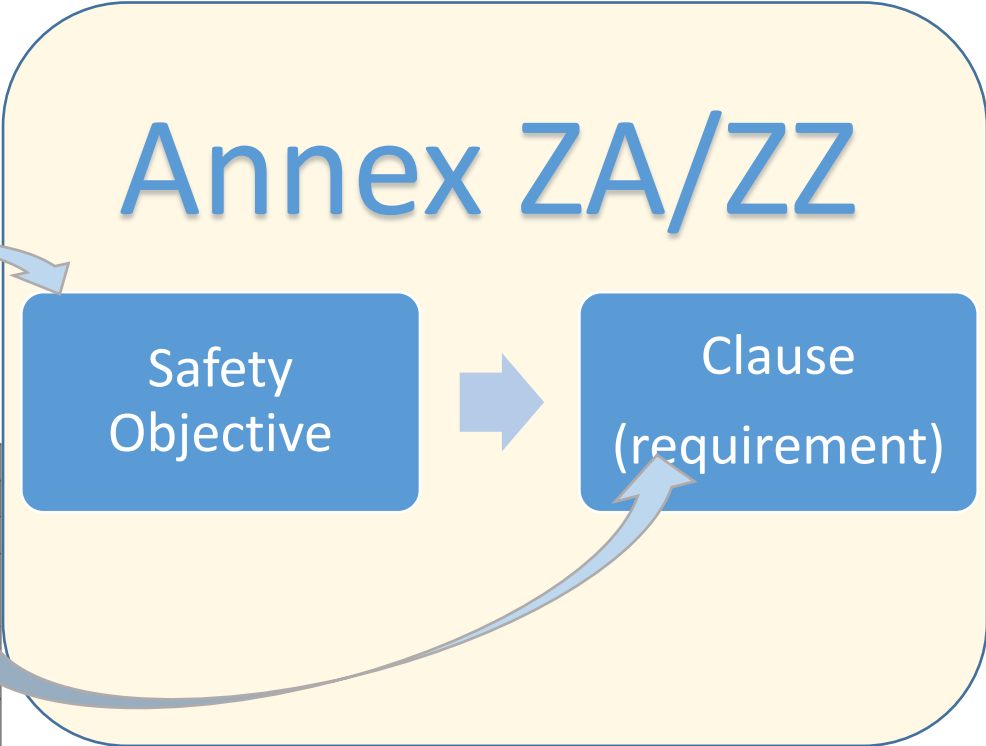
Connecting dots: Annex ZA/ZZ



Connecting dots: Annex ZA/ZZ

EXAMPLE

**Low Voltage Directive
CLC Guide 32 – CLC/TC 23E**



Elements of safety objectives	Risk/Observation	CLC Guide 32 Annex D	Requirements description	Requirement clause	Test clause
2. Protection against hazards arising from the electrical equipment					
Measures of a technical nature shall be laid down in accordance with point 1, in order to ensure that:					
(a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact	Electric shock	A.4.e	Protection against electric shock	8.2, , 9.3	9.1,
		A.4.a and A.4.b	Current in the FE and during the assessment	8.10.8, 8.11	9.18.4, 9.7.4, 9.19.1 and 9.19.2
	Deterioration of automatic operation capability	A.5.b	Mechanical and electrical endurance	8.5	9.13
		A.7.2.a	Test device	8.13	9.20
(b) temperatures, arcs or radiation which would cause a danger, are not produced;	Bad assembly, bad connection	A.7.2.b	Screws, current-carrying parts and connections	8.1.5	9.8
			Terminals for external conductors	8.1.6	9.9

Example: EN 63024



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Example: Risk assessment

The principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits extracted out of annex 1 of the LVD are considered in this analysis covering risk analysis (5 first columns) and self-assessment (6th column) of WG1 of CLC TC23E.

Elements of safety objectives	Risk/Observation	CLC Guide 32 Annex D	Requirements description	Requirement clause	Test clause
1. General conditions					
(a) the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document;	Misuse	A.5.g, A.7.2.b and A.9	Scope	1	
			Normative references	2	
			Definitions	3	
			Classification	4	
			Characteristics	5	
			Marking	6	9.4
(b) the electrical equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected;	Bad assembly, bad connection	A.7.2.b, A.6.13 and A.9	Requirements for construction	6.2 and 8.1.1	
			ARD to be assembled on site	6.2 + 8.1.2.2	
			Correct functioning of the associated protective device	8.1.1 and 8.1.2.1	9.5.1
(c) the electrical equipment shall be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured, providing that the equipment is used	Use outside limits (including voltage and temperature limits)	A.4a, A.4.b, A.6.11, A.7.2.a, A.7.2.b, A7.3 and A.7.4.	Standards conditions	7	
			Operating characteristics	8.10	9.13, 9.18.1 and 9.18.2
			Number of consecutive operations	8.1.2.8 ,8.10.5	9.5.4
			Influence of the distributed capacities	8.10.6	9.18.3.1 and 9.18.3.

Example: Risk assessment

in applications for which it was made and is adequately maintained.			Assessment means	8.11	9.7.4 + 9.19.1. + 9.19.2.
		A.6.12, A.7.2.d, A.7.3 and A.7.4	Interruption and return of supply	8.10.7	Table 3, 9.5.2, 9.5.4, 9.18.1 and 9.18.2.
		.6.4 and A.7.2.a	EMC	8.15	9.22
2. Protection against hazards arising from the electrical equipment Measures of a technical nature shall be laid down in accordance with point 1, in order to ensure that:					
(a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact	Electric shock	A.4.e	Protection against electric shock	8.2, , 9.3	9.1,
		A.4.a and A.4.b	Current in the FE and during the assessment	8.10.8, 8.11	9.18.4, 9.7.4, 9.19.1 and 9.19.2
	Deterioration of automatic operation capability	A.5.b	Mechanical and electrical endurance	8.5	9.13
		A.7.2.a	Test device	8.13	9.20
		A.5.b and A.7.2.a	Ageing	8.14	9.21
(b) temperatures, arcs or radiation which would cause a danger, are not produced;	Bad assembly, bad connection	A.7.2.b	Screws, current-carrying parts and connections	8.1.5	9.8
			Terminals for external conductors	8.1.6	9.9
	Excess of temperature	A.4.f, A.6.6, and A.6.7	Temperature rise	8.4	9.12

Example: Annex ZZ

**Table ZZB.1 – Correspondence between this European standard and Article 3 of Directive 2014/35/EU
[2014 OJ L153]**

Safety Objectives of Directive 2014/35/EU	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
(1)(a)	1, 2, 3, 4, 5, 6 - 9.4	
(1)(b)	6.2, 8.1.1, 8.1.2.1, 8.1.2.2 and 9.5.1	
(1)(c)	7, 8.1.2.8, 8.10, 8.11, 8.15, 9.5.2, 9.5.4, 9.7.4, 9.13, 9.18.1, 9.18.2, 9.18.3, 9.19.1, 9.19.2 and 9.22	
(2) (a)	8.2, 8.5, 9.3, 8.10.8, 8.11, 8.13, 8.14, 9.1, 9.7.4, 9.13, 9.18.4, 9.19.1, 9.19.2, 9.20 and 9.21	
(2) (b)	8.1.5, 8.1.6, 8.4, 9.8, 9.9 and 9.12	
(2) (c)	8.1.2.3, 8.1.2.4, 8.1.2.5, 9.5.2 and 9.5.3	
(2) (d)	8.1.3, 8.1.4, 8.3, 9.6, 9.7 and 9.11	
(3) (a)	8.7 - 9.15	
(3) (b)	8.8, 8.9, 8.15, 9.16, 9.17 and 9.22	
(3) (c)	8.6, 8.12, 9.14 and 9.17	

Connecting dots: Annex ZA/ZZ



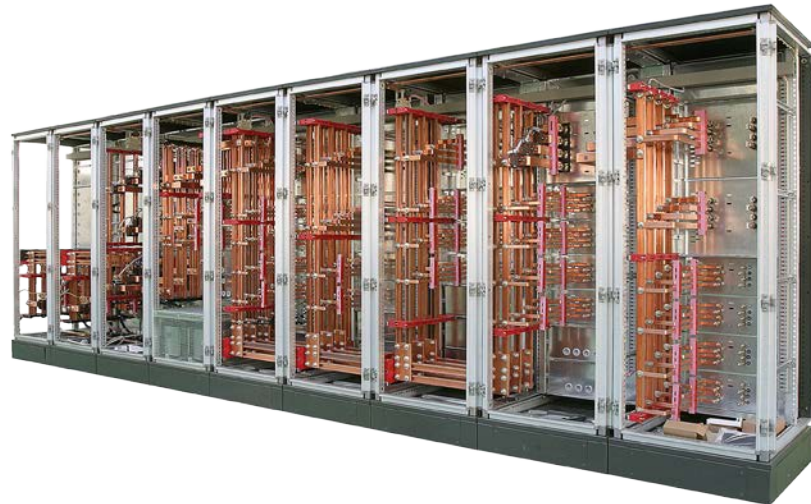
- ▲ Refer to clauses with Requirements (SHALL)
- ▲ Use the templates
- ▲ Structure the standard
 - ▲ Risk Related
 - ▲ Simple
 - ▲ Logical
- ▲ Apply Guidance & Document

- ▲ Refer to clauses 'Scope', 'Definitions', 'Normative references'
- ▲ Use general statements
- ▲ Try to fix problems through the annex ZA/ZZ

KEY POINTS

- 1) Lean on the Guidance – ISO/IEC Guide 51 is the basis
- 2) A systematic approach is key – Seek sectoral coherence
- 3) Be inclusive regarding the stakeholders in the process
- 4) Keep it simple
- 5) Document the drafting of the standard, Risk Assessment is part of that documentation

Thank you





EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

Normative references

Nuno Pargana

1. Normative references: general guidance
2. Normative references in hENs: EC requirements

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)’

Internal
Regulations
Part 3

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

June 2019

This Part 3 of the CEN/CENELEC Internal Regulations is applicable to all enquiry and final drafts registered after 2019-10-01.

Clause 2 'Normative references'

▶ IR-3 Clause 15: Normative references clause

- ▶ **Clause 2 'Normative references'** lists documents which are cited in the body of the standard in such a way that some or all of its content constitutes requirements of the document
- ▶ Clause 2 is **mandatory**, but
 - ▶ **Informative:** a source of reference for the convenience of the user



▶ IR-3 Clause 10: Referencing

- ▶ Permitted referenced documents
- ▶ Undated and dated references

Normative references // IEC

- ▶ **When developing standards in parallel with IEC**
→ Normative references to international publications with their corresponding European publications (For CENELEC only) are listed under **Annex ZA** (IR-3 Clause ZB.3)

- ▶ **Annex ZA:**

- ▶ Normative
- ▶ Replaces references in body of standard
- ▶ Use template
- ▶ **Basic rule:** if not dated in IEC version → should not be dated in EN IEC version since it is pure adoption with no modification

"Annex Z ...
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where 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: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
--------------------	-------------	--------------	--------------	-------------

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 Where 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: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC ...	YYYY	Title	EN ...	YYYY

EC position on normative references

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



Normative references and HAS assessments

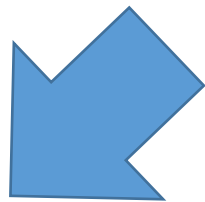
Overview of Critical findings

Part A: Summary of assessments

A total of 154 assessment have been performed on the full assessment template and are considered in this analysis.

AR ref.	Critical findings	Frequency of finding	Total Assessments	Proportion
A- 1.2.1.	Terminology	1	154	0,65%
A- 1.2.2.	Foreword	2	154	1,30%
A- 1.2.3.	Scope covers products not considered by the relevant legal requirements	5	154	3,25%
A- 1.2.4.	The Scope sets requirements or covers aspects which cannot be subject to harmonised standards	1	154	0,65%
A- 1.2.5.	Scope excludes products or aspects that are expected to be covered by the standard	3	154	1,95%
A- 1.2.6.	Normative references that are essential for the assessment of harmonised elements are not available	2	154	1,30%
A- 1.2.7.	Document contains undated normative references without proper justification	26	154	16,88%
A- 1.2.8.	Too long chains of normative references	0	154	0,00%
A- 1.2.9.	Normative references need updating or reconsideration	35	154	22,73%
A- 1.2.10.	Technical content of the document contains requirements that do not align with or contradict relevant EU legislation	20	154	12,99%
A- 1.2.11.	Technical content of the document unsuitably repeats legal requirements as part of its normative requirements	3	154	1,95%
A- 1.2.12.	Absence of reproducible tests or assessment methods	15	154	9,74%
A- 1.2.13.	Neutrality principle is not respected: the document contains clauses imposing requirements or obligations on or between certain economic operators	5	154	3,25%
A- 1.2.14.	Neutrality principle is not respected in requirements for verifications, sampling and testing	7	154	4,55%
A- 1.2.15.	Risk assessment or identification of relevant risks is missing or not complete	33	154	21,43%
A- 1.2.16.	The Annex Z is not sufficiently detailed	25	154	16,23%
A- 1.2.17.	The Annex Z does not properly refer to the relevant legal requirements	29	154	18,83%
A- 1.2.18.	The document is not aligned with the guidance documents or checklist	0	154	0,00%
A- 1.2.19.	Other comments	9	154	5,84%

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



YES → EC requirements and IR-3 apply



NO → IR-3 applies

- ▶ 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 60529:1991,¹ *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)*

EN 60695-2-11:2014, *Fire hazard testing - Part 2-11: Glowing/hot-wire based test methods - Glow-wire flammability test method for end-products (GWEPT) (IEC 60695-2-11:2014)*

EN 60695-11-2:2017, *Fire hazard testing - Part 11-2: Apparatus, confirmatory test arrangement and guidance*

ISO 2768-1:1989, *General tolerances — Part 1: Tolerances on linear dimensions on individual tolerance indications*

12.1.2 Degree of protection – Ingress of foreign solid objects

12.1.2.1 An assembly is made of conduit and conduit fittings using all conduit entries. Where necessary, any open ends of the assembly are plugged, or are not part of the test.

12.1.2.2 The assembly shall be tested in accordance with the appropriate test of EN 60529:1991¹. For numeral 5, category 2 applies.

Guidance on normative references in hENs

► EN IEC standards: normative references **shall be dated through Annex ZA**

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.

IEC 60027-1:1992+**COR1:1993**+AMD1:1997+AMD2:2005, *Letter symbols to be used in electrical technology – Part 1: General*

IEC 60027-4:2006, *Letter symbols to be used in electrical technology – Part 4: Rotating electric machines*

IEC 60034-2 (all parts, -2-1:2014, -2-2:2010, -2-3:2020), *Rotating electrical machines – Part 2: Standard methods for determining losses and efficiency from tests (excluding machines for traction vehicles)*

IEC 60034-3:2020, *Rotating electrical machines – Part 3: Specific requirements for synchronous generators driven by steam turbines or combustion gas turbines*

IEC 60034-5:2020, *Rotating electrical machines – Part 5: Degrees of protection provided by the integral design of rotating electrical machines (IP code) – Classification*

IEC 60034-6:1991, *Rotating electrical machines – Part 6: Methods of cooling (IC code)*

IEC 60034-8:2007+AMD1:2014, *Rotating electrical machines – Part 8: Terminal markings and direction of rotation*

IEC 60034-12:2016, *Rotating electrical machines – Part 12: Starting performance of single-speed three-phase cage induction motors*

IEC 60034-15:2009, *Rotating electrical machines – Part 15: Impulse voltage withstand levels of form-wound stator coils for rotating a.c. machines*

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 Where 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: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60027-1	1992	Letter symbols to be used in electrical technology – Part 1: General	-	
COR1	1993			
AMD1	1997			
AMD2	2005			
IEC 60027-4	2006	Letter symbols to be used in electrical technology – Part 4: Rotating electric machines	EN 60027-4	2007
IEC 60034-2 (all parts -2-1:2014 -2-2:2010 -2-3:2020)		Rotating electrical machines – Part 2: Standard methods for determining losses and efficiency from tests (excluding machines for traction vehicles)	EN 60034-2-1 EN 60034-2-2 EN IEC 60034-2-3	2014 2010 2020
IEC 60034-3	2020	Rotating electrical machines – Part 3: Specific requirements for synchronous generators driven by steam turbines or combustion gas turbines	EN IEC 60034-3	2020
IEC 60034-5	2020	Rotating electrical machines – Part 5: Degrees of protection provided by the integral design of rotating electrical machines (IP code) – Classification	EN IEC 60034-5	2020



► EN IEC standards: normative references **shall be dated through Annex ZA**

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 Where 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: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60065 (mod)	2001	Audio, video and similar apparatus - Safety requirements	electronic EN 60065	2002
-	-		+corrigendum Mar. 2006	
-	-		+corrigendum Aug. 2007	
IEC 60068-2-14	2009	Environmental testing -- Part 2-14: Tests - Test N: Change of temperature	EN 60068-2-14	2009
IEC 60081	-	Double-capped fluorescent lamps - Performance specifications	EN 60081	-
IEC 60085	2007	Electrical insulation - Thermal evaluation and designation	EN 60085	2008
IEC 60112	2003	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003
+A1	2009		+A1	2009
IEC 60216	series	Electrical insulating materials - Thermal endurance properties -- Part 1: Ageing procedures and evaluation of test results	EN 60216	series
IEC 60317-0-1	2013	Specifications for particular types of winding wires -- Part 0-1: General requirements - Enamelled round copper wire	EN 60317-0-1	2014
IEC 60384-14	-	Fixed capacitors for use in electronic equipment -- Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains	EN 60384-14	-
IEC 60417	-	Graphical symbols for use on equipment. HD 243 S12 Index, survey and compilation of the single sheets.	HD 243 S12	-
-	-		+corrigendum Oct. -	
+A1	1979		-	



Example of HAS comment:

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	Proposed change	Observations of the secretariat
HAS		ANNEX ZA			EN 60384-14 undated	EDITION 2013	

Guidance on 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 should be **EN/ISO/IEC published standards**

Exceptionally, other documents could be used but:

- ▶ IR-3 applies
- ▶ Documents must be available for the assessment by consultant/EC
- ▶ **Attention:** EC requests that **national standards** are not used
- ▶ In case of doubt: coordinate with CCMC to clarify with HAS consultant/EC



Guidance on use of normative references in hENs

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



ASTM D3574, *Standard Test Methods for Flexible Cellular Materials – Slab, Bonded, and Molded Urethane Foams*

ASTM D4169-16, *Standard Practice For Performance Testing Of Shipping Containers And Systems*

ASTM D4728-17, *Standard Test Method for Random Vibration Testing of Shipping Containers*

EN 50332-1:2013, *Sound system equipment: Headphones and earphones associated with portable audio equipment – Maximum sound pressure level measurement methodology and limit considerations – Part 1: General method for “one package equipment”*

Example of HAS comment:

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
JR HAS 12	1370 - 1608	2. Normative references		Ed/te	<p>See document “Normative reference” for the numbers (#) referred to. They are highlighted in yellow in this document.</p> <p>Annex ZA is missing, meaning a huge number of the normative references are undated, which can cause legal uncertainty.</p> <p>#9 is a technical report, which normally can not serve as normative reference, since it does not contain requirements.</p> <p>#15, #20, #21, #49, #111, #118 Refers to a complete series of standards – they have to be spelled out – standard by standard in the future Annex ZA.</p> <p>#23, #24 and #25 are included twice, since they are already covered by the standard series listed as #20.</p> <p>#50 is included twice, since it is already covered by the standard series listed as #49.</p> <p>#132 - #136 are ATSM standards, which are normally not allowed for normative references without proper justification.</p>

Guidance on use of normative references in hENs

- ▶ In Clause 2 (homegrown) or Annex ZA avoid referring to “all parts” (series of standards)



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/H applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here 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	1999	Plugs, socket-outlets and couplers for industrial purposes -	EN 60309-1	1999
+ AMD1	2005		+ A1	2007
+ AMD2	2012	Part 1: General requirements	+ A2	2012
IEC 60332	Series	Tests on electric and optical fibre cables under fire conditions	EN 60332	Series

HAS consultant comment:

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
HAS1	444-536	2 Normative references and annex ZA		ge	<p>-Some standards listed are outdated</p> <p>-Series of standards are not individually listed and dated.</p> <p>-Some normative references in the body of the standard do not cope with those listed in 2 Normative references or the annex ZA.</p> <p>For details see the commented annex ZA added to the assessment report.</p>

- ▶ Reference document on normative references: **IR-3**
- ▶ Normative references: common reason for lack of compliance assessment or non-citation
- ▶ Default solution → **dated normative references in Annex ZA of EN IEC harmonized standards**
- ▶ Normative references: **dated, active and published**
- ▶ Flexibility in case the normative reference is not linked with clauses giving presumption of conformity

Useful information

IR-3 Clause 10: permitted references

Basis:

- ▶ documents published by CEN, CENELEC, ISO, IEC
- ▶ CEN and CENELEC standards reached at least the enquiry stage (



Other documents can be referred if:

- ▶ Recognized by TC as having wide acceptance
- ▶ the agreement of the authors/publishers of the referenced document for its inclusion as a reference
- ▶ The document is available under commercial terms which are fair, reasonable and nondiscriminatory



IR-3 Clause 10: not permitted references

Documents to be avoided:

- ▶ Referenced documents which are not publicly available
- ▶ EU legislation, their essential requirements and/or elements of directives
- ▶ Referenced documents which are cited only informatively as bibliographic or background material
- ▶ CEN and CENELEC standards has not reached the enquiry stage (30.99)

*Publicly available
doesn't mean free!*



IR-3: undated normative references

Undated references can be used if:

- ▶ only referring to a **complete document**
AND
- ▶ Possible to use **all future changes of the referenced document** for the **purposes of the referring document**
AND
- ▶ the reference will include **all amendments to and revisions of the referenced document**



Special
attention to
hEN!

Dated References

- ▶ **Default solution**
- ▶ Date when conditions for undated are not met
- ▶ Normative reference amended/revised?
 - ▶ Review dated references
 - ▶ Assess whether they should be updated or not
- ▶ When reference to a specific clause
- ▶ Normative dating happens within the text (not only in clause 2)

Thank you!

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Nuno Pargana



EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

CENELEC webinar on LVD topics Use conditions in standards

Jos Remy

18 November 2021

Jos REMY



CEN-CLC/BTWG 15 convenor
jos.remy@philips.com

Use conditions - history

- ▶ Discussion between EU regulator and standardization on reasonably foreseeable misuse in EMF area
- ▶ Creation of TR by CLC/TC 106X
- ▶ Discussion in various BT groups:
 - ▶ Need for wider alignment of terms across areas (safety, EMC, EMF, environment, security, etc.)
 - ▶ Applicable to all products
- ▶ Result: creation of CEN-CLC/BTWG 15
 - ▶ CEN BT C050/2020
 - ▶ CENELEC BT decision D165/C093

Use conditions - problems

- ▶ Different terms used
 - ▶ Standards are not aligned
 - ▶ Regulations are not aligned
- ▶ Different interpretations of same/similar terms existed
- ▶ Increase of issues with regulators
- ▶ Different needs depending on sector
- ▶ CEN-CLC/BTWG 15 created at start of pandemic

=> Difficult to align

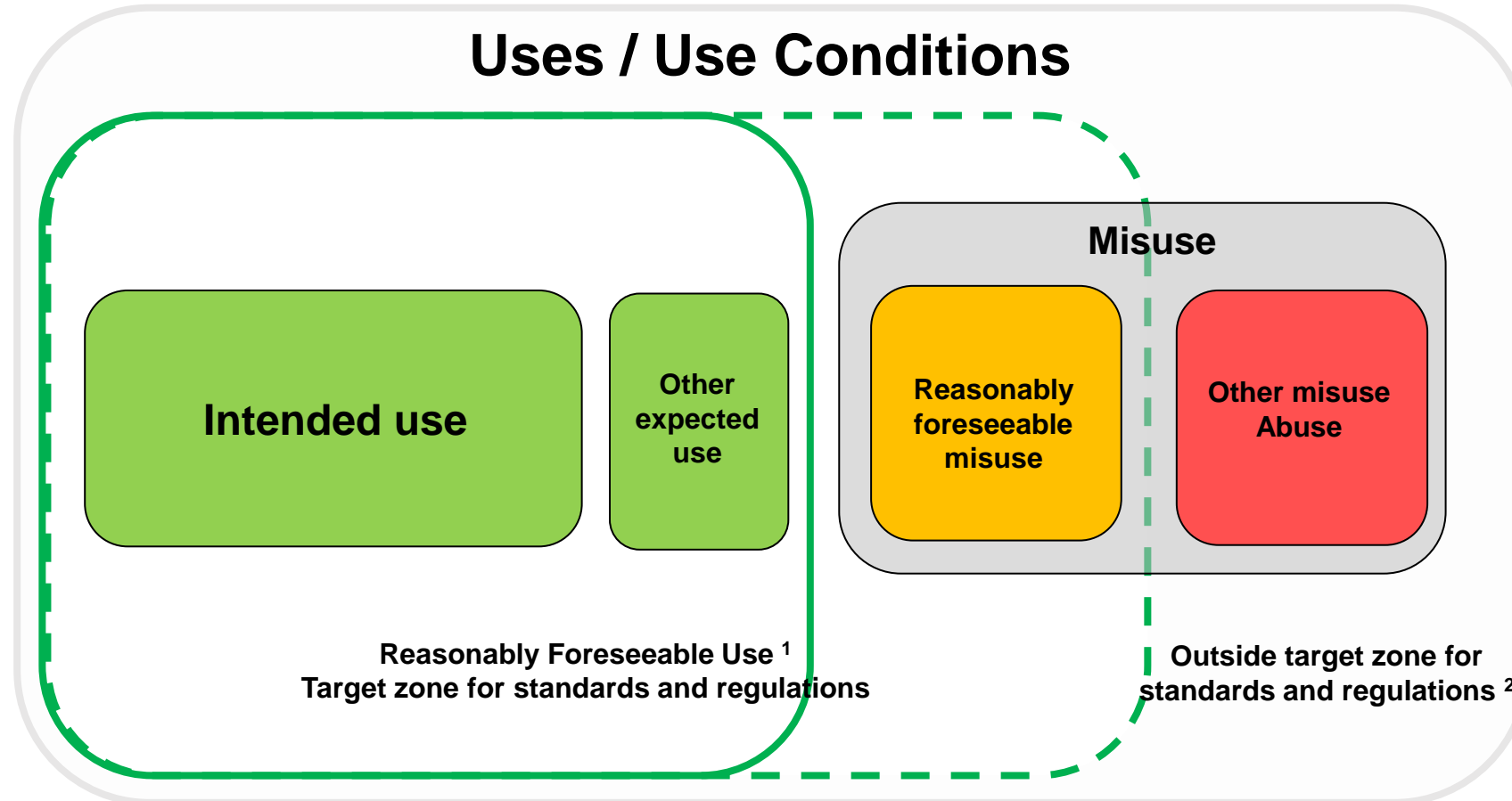


Use conditions - progress

- ▶ CEN-CLC/BTWG 15 held 11 webmeetings
- ▶ Working through drafts and commenting
- ▶ Created matrix of differences in regulations
- ▶ Resulted in guidance document on BOSS
 - ▶ Common understandings rather than definitions
 - ▶ Explanatory information for each use condition
 - ▶ Graphical overview to show relations



Use conditions - overview



1 Depending on the area and the applicable regulation, reasonably foreseeable use conditions may or may not include reasonably foreseeable misuse.

2 While abuse is in general outside the target zone for standards and regulations, it should be noted that some specific areas focus on this misuse, such as the area of security.

Thank
You



EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

CEN-CENELEC Webinar on LVD Conclusions and way forward

Ingrid Soetaert

Electrotechnology – Project Manager

Conclusions:

- ▶ EC has final decision on citation in OJEU

- ▶ Stages for assessment
 - ❑ First working draft / CD → Recommended!
 - ❑ Enquiry / CDV → formal assessment
 - ❑ Formal Vote / FDIS → formal assessment
 - ❑ (Publication → exceptional, only if needed)



Verify your standards against the checklists



Assessment report under service contract SI2.770800 ¹	
Date of the report	XX/XX/20XX
Nature of the report	<input type="checkbox"/> Initial report <input type="checkbox"/> Reviewed report after the initial report was challenged by ESO
Internal reference	Indicate the reference of the work order from EY
Assessed document	standard reference and full title including date or version of the document
ESO work item reference	
Main objective and purpose of the assessed document, including its relation to other standards within the 'harmonised context'	describe briefly to set the context under which the assessment was carried out
Relevant normative references partly or fully verified and assessed	give actual dated reference numbers of those standards checked or assessed as part of this assessment
Nature of the assessed document	New project / Revision of Harmonised standard or a standard that was cited under GPSD / Revision of a standard that was not cited If the draft amends a standard that was cited or non-cited under the relevant Union legislation, please provide information on this, in particular when Lack of Compliance is based on this situation
ESO technical body	Reference of the Technical Body
ISO/IEC related	<input type="checkbox"/> No <input type="checkbox"/> Yes

Checklist – Items to be considered when drafting standards answering a Standardisation Request and to be offered for citation in the OJEU

	Check the following questions – if you answer yes to all the questions, the draft is probably ready for submission to CCMC (and HAS Consultant assessment).	Check
General	Is this draft standard listed in a Standardisation Request / covered by a Mandate? Is this reflected in Projex-online database? <i>NB: This information is normally already provided in the NWIP form. NB: If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (revised) Standardisation Request. This is not applicable if the standard is covered by an open Mandate (e.g. M/396 Machinery)</i>	<input type="checkbox"/> <input type="checkbox"/>
	If the HAS assessment was performed (i.e. optional assessment at First Working Draft (FWD) stage or assessment at Enquiry stage), has the WG answered <u>all</u> comments from the HAS Consultant(s)? <i>NB: The last column of the HAS Assessment Report ('Observations of the secretariat') at previous stage shall be filled in with the information on how the comments have been addressed.</i>	<input type="checkbox"/>
	If the text deals with requirements that are not linked to essential requirements of EU legislation, are these requirements in separate clauses, so that in Annex Z only the clauses covering essential requirements are identified?	<input type="checkbox"/>
European foreword	If the standard is a revision, are the significant changes with respect to the previous edition precisely defined? <i>NB: The list of the significant changes with respect to the previous edition is an important element of the useful information to the standard users. It should not be too vague. NB: When the list of significant technical changes is extensive, it may be included in an informative annex. A reference to that annex shall be included in the foreword, preferably after the generic sentence that refers to the superseded document.</i>	<input type="checkbox"/>
	Does it include the following sentences "The standard has been prepared under a standardisation request given to CEN/CENELEC by the European Commission and the European Free Trade Association, and support essential	<input type="checkbox"/>

Safety first: Be very clear on which hazards are deemed 'relevant' and which of them are addressed in the standard.

Normative references: dated normative references in Annex ZA of EN IEC harmonized standards

Normative references: dated, active and published

Use conditions in standards: BOSS guidance document

International standards

- ▶ Global standards before European common modifications
- ▶ Encourage introduction of changes at IEC
- ▶ Involve asap corresponding IEC convenor in the discussion of the comments from HAS Consultant
- ▶ Failing the IEC, consider to produce common modifications as interim solution

Questions? Suggestions? Need help?



✓ ASK YOUR PROJECT MANAGER

✓ TB TO JOIN CEN-CLC/BTWG 143-1

Useful links

- ▶ European Commission LVD Directive website, with links to the OJEU:
https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage-lvd_en
- ▶ Annex ZZ: https://boss.cenelec.eu/media/wf2hbujf/annexzz_lvd_e.doc
- ▶ Transmission notice: https://boss.cenelec.eu/media/CEN/formtemp/transmission_notice.doc
- ▶ Checklist items to be considered when drafting standards to be offered for citation in the OJEU:
https://boss.cenelec.eu/media/BOSS%20CENELEC/formtemp/checklist_hens.docx
- ▶ CENELEC Guide 32 - Implementation example for TCs :
https://boss.cenelec.eu/media/bs0h2qaf/clc_guide32_implementation_example.pdf
- ▶ Basic elements for a common understanding of use conditions in standards :
https://boss.cenelec.eu/media/guidance_use-conditions-in-standards.pdf

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Please send all your remaining questions to isoetaert@cencenelec.eu

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