Webinar

Harmonized Standards under Machinery Directive

18 October 2021

We start at 14:00 CEST

Your webinar moderator

Els Somers

Project Manager Engagement Governance & Partnerships

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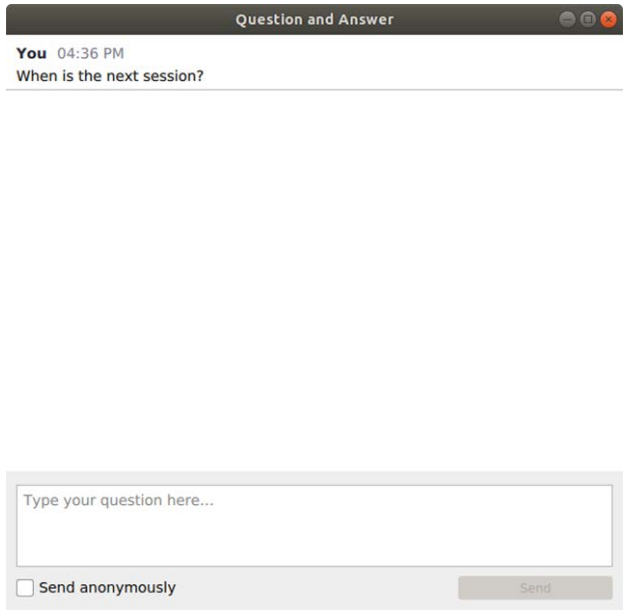

- Talk about us on Twitter #training4standards @Standards4EU

Agenda

00	14:00-14:05	Introduction & Practicalities	Els Somers (CEN-CENELEC)
01	14:05-14:40	Risk assessment and basic approach with reference to EN ISO 12100 and CEN Guide 414	Gerhard STEIGER (CEN-CENELEC Sector Rapporteur on Machinery)
02	14:40-15:15	Requirements in the standards: specificity and verifiability	Mikhail SIMONOV (EC Policy Officer for Machinery Directive DG GROW.H2)
03	15:15-15:25	BREAK	
04	15:25-16:15	Drafting a detailed informative Annex ZA/ZZ under the Machinery Directive	Lisa ALMKVIST (SIS) Sara BERGGEN (SIS) Joanna FRANKOWSKA (CEN-CENELEC – Project Manager Manufacturing)
05	16:15-16:50	Dating of normative references on harmonized standards	Nuno PARGANA (CEN-CENELEC Account Manager Manufacturing)
06	16:50-17:00	Closing	Gerhard STEIGER (CEN-CENELEC Sector Rapporteur on Machinery)

Your speakers today

Dr. Gerhard STEIGER

DIN-NAM/VDMA Frankfurt/Main

CEN-CENELEC Sector Rapporteur on Machinery

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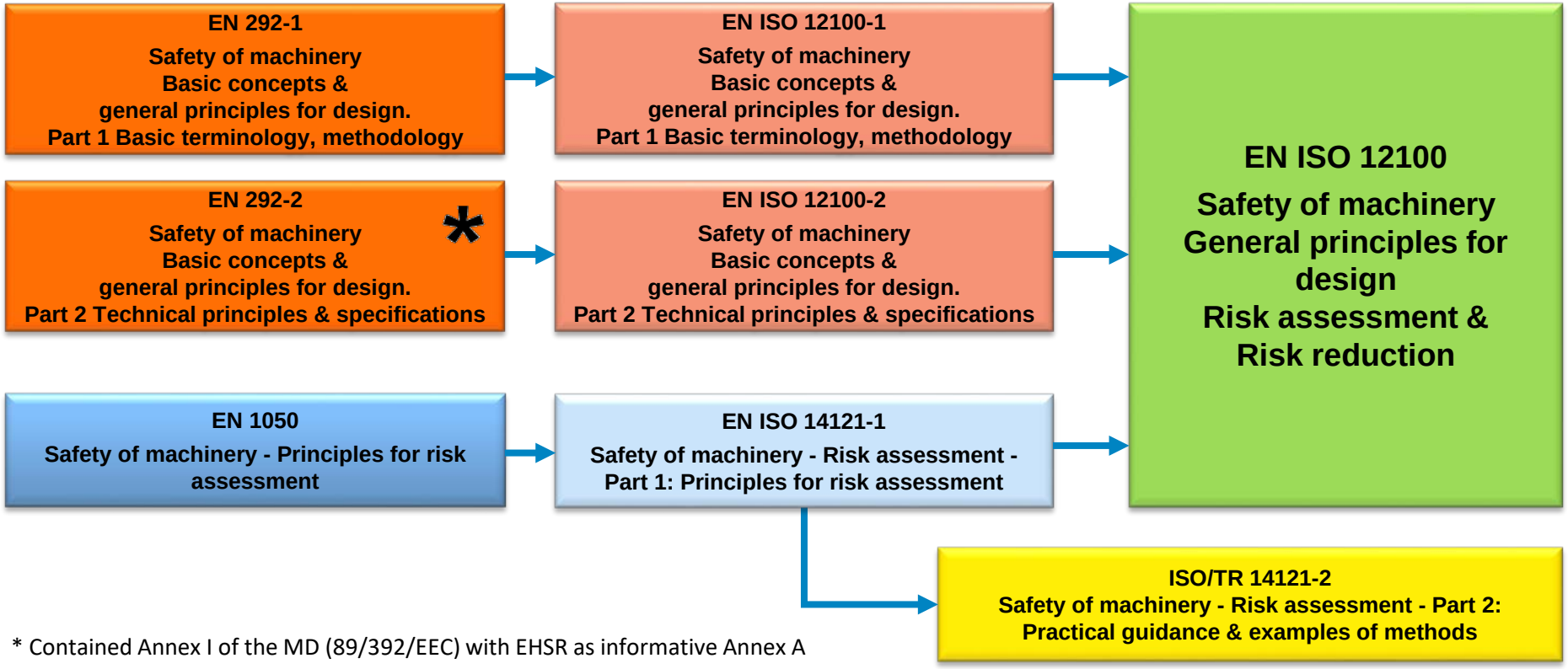
Risk assessment and basic approach with reference to EN ISO 12100 and CEN Guide 414

by Dr Gerhard STEIGER

EN ISO 12100 - History

European idea achieving global acceptance

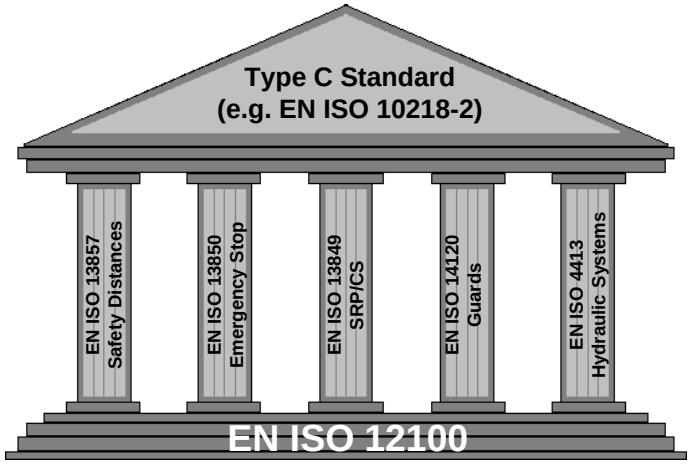


* Contained Annex I of the MD (89/392/EEC) with EHSR as informative Annex A

EN ISO 12100 - Basis

Structure of Machinery Safety Standards

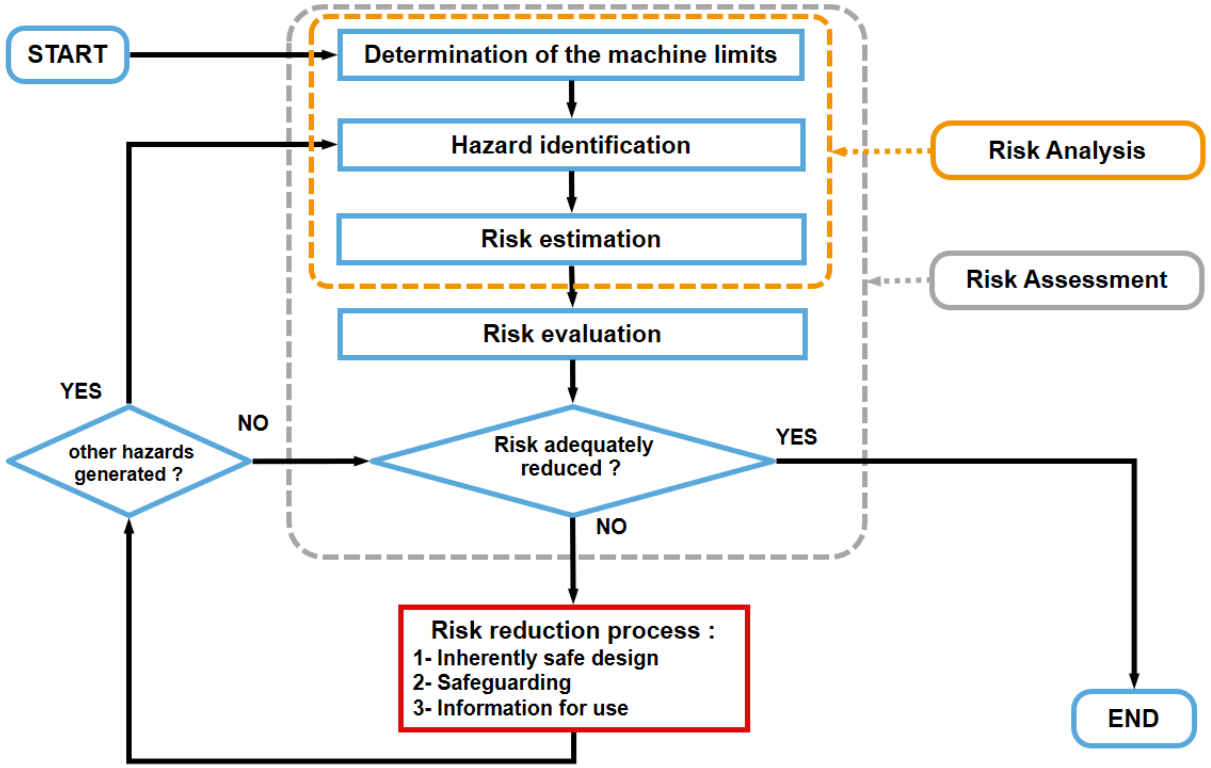
- Type-A standards (basic safety standards) giving basic concepts, principles for design and general aspects that can be applied to machinery;
- Type-B standards (generic safety standards) dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery:
  - Type-B1 standards on particular safety aspects (for example, safety distances, surface temperature, noise);
  - Type-B2 standards on safeguards (for example, two-hand controls, interlocking devices, pressure-sensitive devices, guards);
- Type-C standards (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.



EN ISO 12100 - Methodology

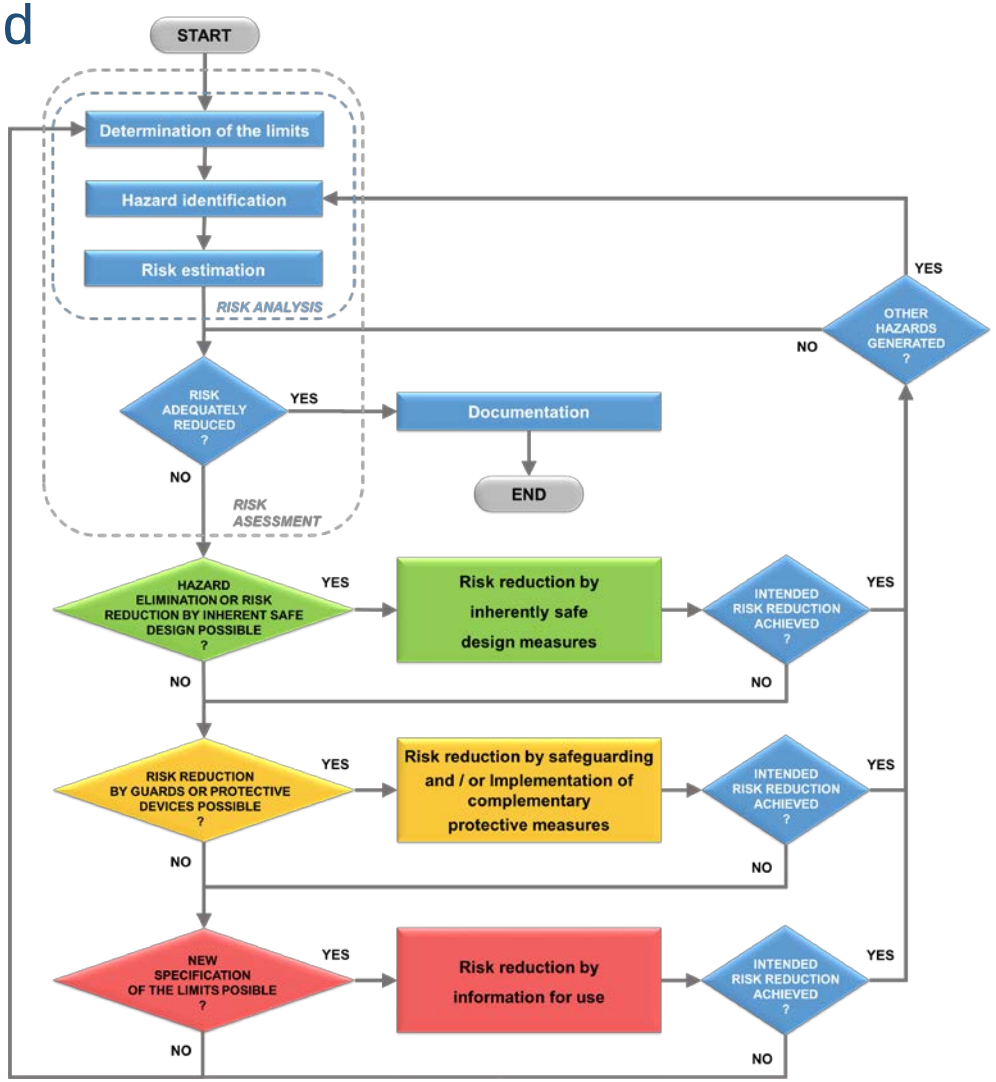
Risk assessment and Risk reduction

- Determine the limits of the machinery, including intended use & reasonably foreseeable misuse
- Identify the 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



EN ISO 12100 – Risk reduction

The 3-Step Method



Protective measures shall be applied in the following sequence (3-step method):

- Step 1: Inherently safe design measures;

Eliminate hazards or reduce the associated risks by a suitable choice of design

- Step 2: Safeguarding and/or application of complementary protective measures;

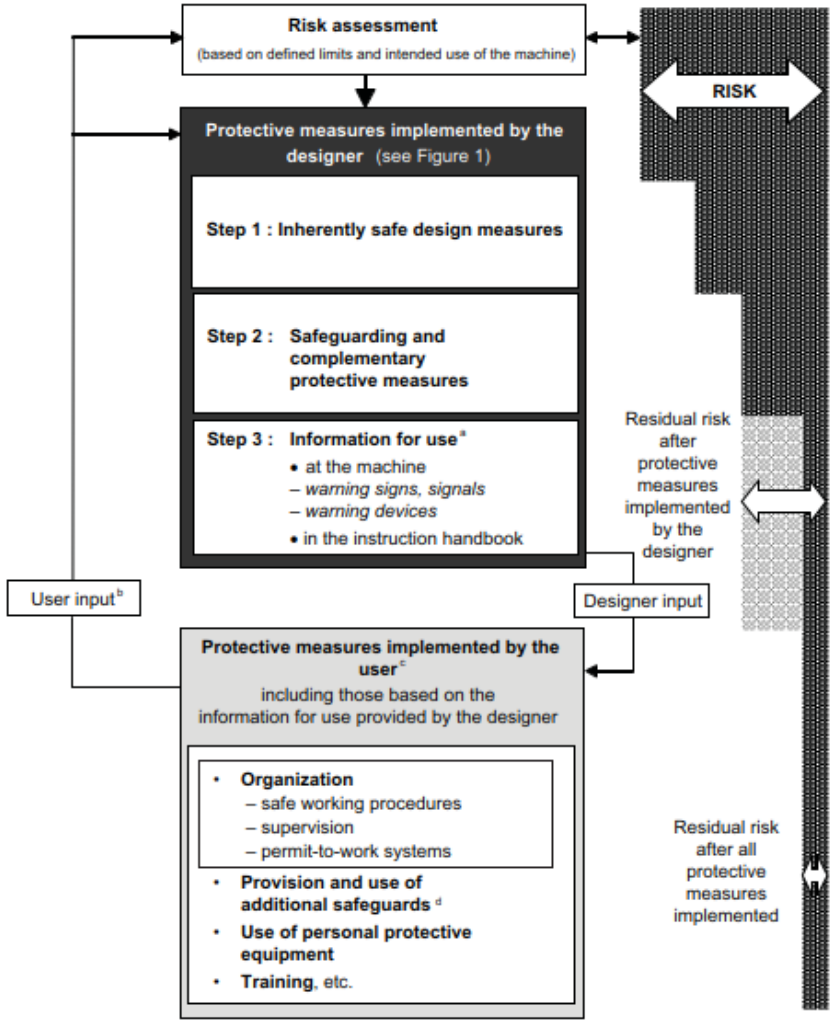
Apply appropriately selected safeguarding and complementary protective measures to reduce risk when it is not practicable to eliminate a hazard, or reduce its sufficiently associated risk with Step 1

- Step 3: Information for use;

Identify in the information for use the risks which remain despite application Step 1 & Step 2

EN ISO 12100 – Machinery use

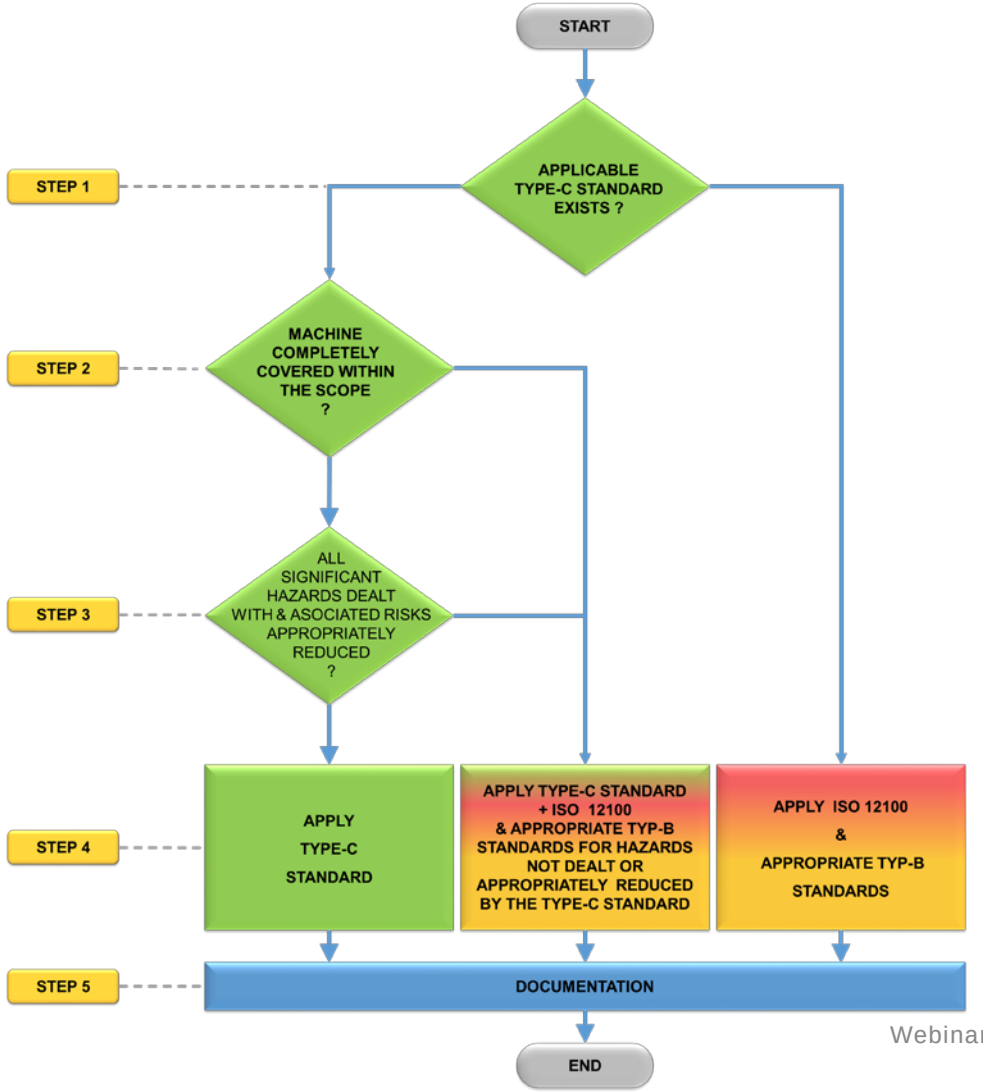
Relationship with user dependent risk reduction



- The information for use provided by the machinery designer is the basis for the design & selection of the protective measures to be implemented by the user.
- For protective measures to be implemented by the user ISO/TR 22100-1 does not specify any hierarchy since these are outside of the scope.
- Available user input may be an important (and useful) part of the information required for the risk assessment !
- Use of additional safeguarding provided by the user may be required at specific uses or installation situations which are not foreseeable for the designer

ISO/TR 22100-1 – User guidance

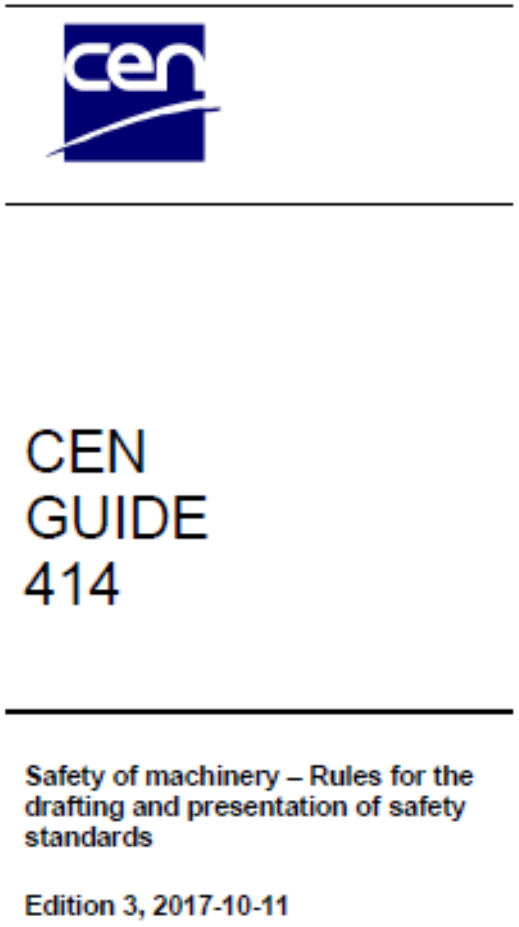
How to use the existing type-A/-B/-C standards



- Explains the general structure and the system of Type-A –B –C standards
- Gives guidance for practical application of ISO 12100, type-B and type-C standards in order to design a machine which achieves a level of tolerable risk by adequate risk reduction
- Supports the user in the selection of appropriate Type-B machinery standards

CEN Guide 414

Overview



- CEN Guide 414 is built on the principles of EN ISO 12100 and addresses mainly type-C standards
- Main content:
  - General principles (mandatory provisions, provisions with added value)
  - Principles to be considered during drafting process
  - Format of a safety standard
  - Annexes (i. e. model format E/F/D with standard text elements)
- Download

CEN Guide 414

General principles for type-C standards

- Type-C standards should deal (as far as possible) with **all** significant hazards concerning one type of machine or one group of machines (preferably in one standard), as follows:
  - By reference to relevant and applicable type-B standards
  - By reference to other standards (such as another type-C standard) where such significant hazards are adequately dealt with
  - By specifying safety requirements in the standard itself, when reference to other standards is not possible or not sufficient and where risk assessment and priorities show this is required
  - By dealing as far as possible with objectives rather than design details to minimize restrictions on design

CEN Guide 414

Specific provisions for type-C standards

- Type-C standards shall contain sufficient added value to type-B standards (Added value: more detailed description/specification of a requirement than in existing, less specific, documents)
- Type-C standards shall clearly establish the following:
  - The scope (with precise limits for the machine covered)
  - The significant hazard(s) covered
  - The (technical) requirements prescribing protective/risk reduction measures that add value to relevant (sub)clauses of EN ISO 12100 originating from the significant hazard(s)
  - The means of verifying the protective/risk reduction measures
  - The information for use

CEN Guide 414

Principles to be considered during drafting

- CEN Guide 414 contains particular guidance on necessary steps for establishing the following elements of a type-C standard:
  - Definition of the scope
  - Identification of hazards, hazardous situations or hazardous events
  - Determination of protective/risk reduction measures for eliminating hazards and/or limiting risks as consequence of:
    - Risk estimation
    - Risk evaluation
    - Identification of risk reduction objectives
  - Verification of specified protective/risk reduction measures

CEN Guide 414

Format of a safety standard

- CEN Guide 414 provides detailed guidance on the format (incl. standard text elements) of the following clauses:
  - European Foreword and Introduction
  - Scope
  - Normative references (strong recommendation for dated references)
  - Safety requirements and/or protective/risk reduction measures
  - Verification of safety requirements and/or protective/risk reduction measures
  - Information for use (i. e. declaration of noise/vibration values)
  - List of significant hazards
  - Annex ZA *(adaptation to current rules required!)*

CEN Guide 414

Annex b: Model format E/F/D

Annex B
(informative)

Model format of a type-C European draft standard

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CEN Guide 414

Annex D: Link between hazards and EHSRs of MD

- Whereas the MD 2006/42/EC, Annex I specifies EHSRs, the general methodology for safety of machinery (EN ISO 12100) is based on the consideration of significant hazards (without direct link to the EHSRs)

Table 1 — Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC

Group	Significant hazard in accordance with EN ISO 12100:2010, Table B.1	Directive 2006/42/EC, Annex I	
General, for many machines relevant			
1	**Mechanical hazards**		
1.1	Due to machine parts or workpieces, e.g. — by potential energy (falling objects, height from the ground, gravity)	1.3.3	Risks due to falling or ejected objects
	— by kinetic energy (acceleration, deceleration, moving/rotating elements)	1.3.7	Risks related to moving parts
	— by mechanical strength (break-up)	1.1.3 1.3.2	Materials and products Risk of break-up during operation
1.2	by stored energy, e.g.: — elastic elements (springs)	1.3.9 1.5.3 1.6.3	Risks of uncontrolled movements Energy supply other than electricity Isolation of energy sources

CEN Guide 414

Source of tool to draft an initial detailed Annex Z

No	EHSRs	Group see CEN Guide 414, Annex D		Significant Hazard see CEN Guide 414, Annex D	Clause/Sub-clause of this standard	"x" , if applicable
1.	1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS					
1.1.2 a)*	1.1.2. a) Principles of safety integration				4,5,6	x
1.1.2 c)*	1.1.2. c) Principles of safety integration				4,5,6	x
1.1.2 d)*	1.1.2. d) Principles of safety integration				4,5,6	x
1.1.2 e)*	1.1.2. e) Principles of safety integration				4,5,6	x
1.1.3.	1.1.3. Materials and products	1.1	Mechanical hazards	Due to machine parts or workpieces, e.g. — by mechanical strength (break-up)		
1.1.3.	1.1.3. Materials and products	7.1	Material/ substance hazards	Hazards from contact with inhalation of harmful fluids, gases, mists, fumes and dusts	4.1.2	x
1.1.3.	1.1.3. Materials and products	7.4	Material/ substance hazards	Biological and microbiological (viral or bacterial) agent	4.1.3	x
1.1.3.	1.1.3. Materials and products	9.2	Hazards associated with the environment in which the machine is used	Moisture		
1.1.3.	1.1.3. Materials and products	9.3	Hazards associated with the environment in which the machine is used	Pollution		
1.1.3.	1.1.3. Materials and products	9.4	Hazards associated with the environment in which the machine is used	Snow, water, wind, temperature		
1.1.4.	1.1.4. Lighting	8.4	Ergonomic hazards	Inadequate local lighting	5.6	x
1.1.4.	1.1.4. Lighting	8.7	Ergonomic hazards	Flicker, dazzling, shadow, stroboscopic effect		
1.1.5.	1.1.5. Design of machinery to facilitate its handling	1.13	Mechanical hazards	Instability		
1.1.5	1.1.5. Design of machinery to facilitate its handling	8.1	Ergonomic hazards	Unhealthy postures or excessive effort		

CEN Guide 414

Valuable tool for the Machinery sector

Official recognition of CEN Guide 414 for the elaboration of harmonized standards (hENs) in the machinery sector (incl. HAS-consultant system) would facilitate efficiency and consistency of the work!

Thank you
for your attention!

Dr. Gerhard Steiger, DIN-NAM/VDMA, Frankfurt/Main
CEN/CLC Rapporteur Machinery

Your speakers today

Mr. Mikhail SIMONOV

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European Commission

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Requirements in the standards: specificity and verifiability

by Mr Mikhail SIMONOV – DG GROW.H2

Introduction

European Commission

Let us start from the semantic similarity between “high quality” and “world class”.

- a certified Quality Management System ensures the high quality of products and services made by voluntarily using technical standards (to be supplied to customers)
- A “burden of proof” is inverted for commercial transactions insisting on “certified quality” products (use of the “Presumption of Conformity”)

Therefore, the “quality” of a standard is an issue of the most importance in the harmonization process (cfr. “prEN” becoming “hEN”).

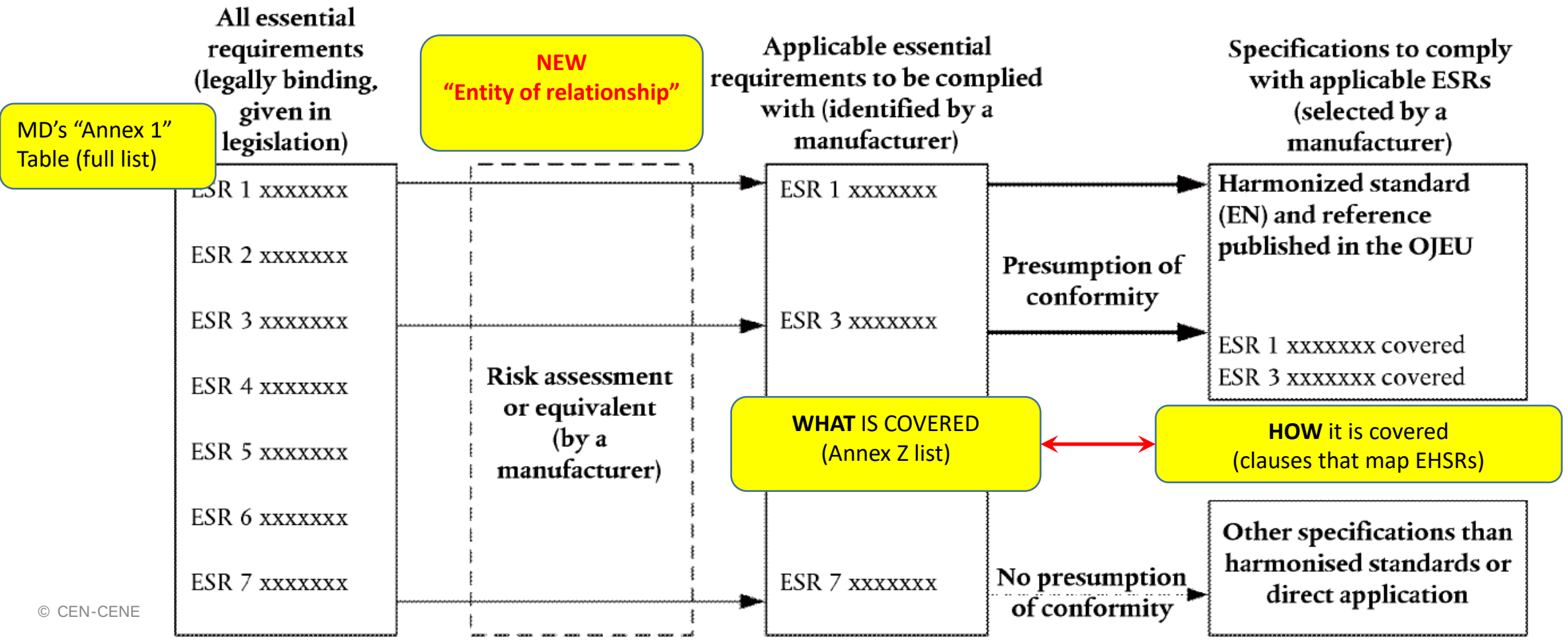
How a requirement makes testable/measurable/verifiable the qualifier “high” + “quality”?

Mix of requirements

- A standard in draft starts from the “essential requirements” from the EU harmonised legal act it aims to support (list of all EHSRs).
- For each supported “legal requirement” a technical standard specifies measurable technical requirements.
- There is no obligation to support an EHSR, an EHSR can remain “not supported”, but if an EHSR is technically supported, it shall be made measurable, verifiable, etc.
- In all cases, the “Annex Z” is the main tool that allows verifying how the EHSR were satisfied by the product’s implementation.
- Some requirements can be made “by reference”.

Starting point

- Annex Z presents how the “legal” requirements are “technically” implemented.



Making measurable?

European Commission

This talk is about making measurable some categories:

- What does it mean “high” + “quality” in a standard?
- How to write “good” + “enough” technical specifications? (what is “good”)
- How to deliver a technical standard that can be “used efficiently” by users? (what can be made “measurable”)
- How to find a right balance between “too generic”, “reasonable”, and “too specific” specifications?

The discipline ruling the requirements is called “System Engineering” practice.

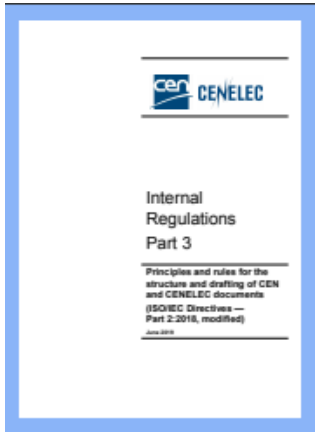
Taxonomy of Technical Requirements

A requirement needs to meet several criteria to be considered a “good requirement”. Good requirements have the following characteristics:

1. Unambiguous
2. **Verifiable (Testable)**
3. Clear (concise, terse, simple, precise)
4. Correct
5. Understandable
6. Feasible (realistic, possible)
7. Independent
8. **Atomic (Testable)**
9. Necessary
10. Implementation-free (abstract)

It requires:

1. Measurability (criteria)
2. Metrics
3. Methods for verification
4. Tools for testing



All coming from the state of the art

Other requirements can be expressed as a combination of the listed ones

Attributes of Requirements

Besides the criteria for individual requirements, three criteria apply to the set of requirements:

1. Consistent
2. Non-redundant
3. Complete

A good requirement has more criteria. However, they can be expressed as a combination of the criteria (just discussed):

- Modifiable: (is atomic) and (is non-redundant) → is modifiable.
- Traceable: (is atomic) and (has a unique ID) → is traceable.

Our practice (1/3)

Our service analyses findings of the “lack of compliance”

in the candidates for harmonization (technical standards). The most common (let ignore the frequency of occurence) issues are:

- prENs imposing obligations to parties, e.g. “carrying out a risk assessment is mandatory”(it is an obligation of the manufacturer, not a product technical specification).
  The Clause 4 ‘Requirements’ shall contain only product requirements.
  Cfr. the CEN Guide 414 + Requirement engineering.
- prENs containing normative clauses about the external influence to a product, for example requirements for the building into which a product will be installed
  (not acceptable because building codes are under national competence; Standards cannot act outside the scope of EU legislation.
  Cfr. the CEN Guide 414.

Our practice (2/3)

- prENs dealing with aspects from other pieces of EU product harmonization legislation.
  There are more complex hENs with several Annexes Z to support two or more pieces of EU legislation.
  Special writing style and an additional quality check is required.
- TCs are not able to document how the candidate for harmonisation (prEN) reflects the generally acknowledged State-Of-The-Art (SOTA).
  (the standard is not a “representative” of the SOTA, but a mirror that “reflects” the accumulated scientific knowledge and best engineering practice.
  TC shall keep trace about the concerned and used “generally acknowledged state of the art”.

Our practice (3/3)

- prEN containing too generic Annexes Z. A sufficient level of granularity (level of details) of Annexes Z is mandatory in order to map the EU product legislation (cfr. Blue Guide). Annexes Z shall not bluntly refer to an entire clause 4 ‘Requirements’.
- The “mapping” of the EHSR from an EU legal act (the aim) drives the inclusion of the clauses in a standard. The Annex I “entry point” goes to the Annex Z first. Wording a clause(s) starts then (non-invertible).

What if:

- prEN containing no verification methods/tools?
- prEN containing verification by inspection, but no measurable indicators
- prENs violating – over time - referential integrity
- …

Verifiable (1/4)

Testers should be able to verify whether the requirement is implemented correctly.

The test should either pass or fail.

To be testable, requirements should be clear, precise, and unambiguous.

Each attribute shall be measurable.

- Which procedure tester will use?
- What number should be considered “many”—10, 100, 1.000?
- What is the acceptable value, threshold, or a range?

Verifiable (2/4)

Linguistic ambiguity.

Some words can make a requirement untestable:

- adjectives: robust, safe, accurate, effective, efficient, expandable, flexible, maintainable, reliable, user-friendly, adequate
- adverbs and adverbial phrases: quickly, safely, in a timely manner
- non-specific words or acronyms: etc., and/or, TBD

Example *REQ1*

- *The search facility should allow the user to find an item based on Name, Date, etc.*
  (all search criteria should be explicitly listed. No guess what "etc." means)

Verifiable (3/4)

Linguistic ambiguity.

Phrasing & linguistic expressions that might lead to ambiguity.

Modifying phrases: as appropriate, as required, if necessary, shall be considered

- Vague words: manage, handle
- Passive voice: the subject of the sentence receives the action of the verb rather than performing it
- Example of passive voice
  - REQ1 The numeric code shall be entered by the user.
    In active voice it would read “The user (actor) shall enter (action) the numeric code (patient).”
  - REQ2 The numeric code shall be entered (by whom?).
    The agent performing the action is sometimes omitted. Who should enter this code—the system or the user?

Verifiable (4/4)

Linguistic ambiguity. Phrasing and linguistic expressions that might lead to vagueness.

- Indefinite pronouns: few, many, most, much, several, any, anybody, anything, some, somebody, someone, etc.

- Example *REQ1*
  The system shall resist concurrent usage by many users.
  (What is the value to be tested for “many”?)

Atomic

- The atomic requirement should contain a single traceable element.
- Sentences including the words “and”, “or”, “but” should be reviewed to see if they can be broken into atomic requirements.
- *Example of non-atomic REQ1*
  The system shall provide the opportunity to book the flight (1), purchase a ticket (2), reserve a hotel room (3), reserve a car (4), and provide information about attractions (5).
  (combines five atomic requirements, which makes traceability very difficult)

NOTE: Examples are not taken from machinery stock of hENs

Consistent (1/3)

- There should not be any conflicts between the requirements.
- Conflicts may be direct or indirect. Direct conflicts occur when, in the same situation, different behavior is expected:
- *REQ1 Dates shall be displayed in the mm/dd/yyyy format.*
- *REQ2 Dates shall be displayed in the dd/mm/yyyy format.*
- Conflict shall be resolved by analyzing the conditions under which the requirement takes place. For example, if REQ1 was submitted by an American user and REQ2 by a French user, the preceding requirements may be rewritten as follows:
- *REQ3 Dates shall be displayed based on the format defined in the user's web browser.*

NOTE: Examples are not taken from machinery stock of hENs

Consistent (2/3)

- Direct conflict occurs when requirements do describe the same functionality.

  It is not obvious how to fulfill both requirements at any time: arbitrary solutions can be proposed.
- *REQ1 System shall be small enough (intention: volume).*
- *REQ2 System shall be big enough (intention: length).*
- Some requirements here are non commeasurable or non comparable to describe the same concept: big vs small.
- Conflict resolution techniques exist (for example TRIZ) and shall be used to disambiguate dependencies.

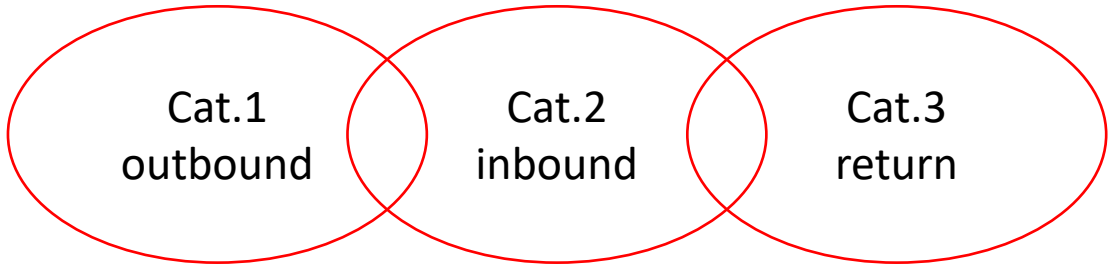
- What is dominating (size or volume)?
- What is improving vs. worsening (height or length)?
- How to separate categories?

Worsening Feature → / Improving Feature ↓		1 Weight of moving object	2 Weight of stationary object	3 Length of moving object	4 Length of stationary object	5 Area of moving object	6 Area of stationary object	7 Volume of moving object	8 Volume of stationary object
1	Weight of moving object	+	-	15, 8, 29,34	-	29, 17, 38, 34	-	29, 2, 40, 28	-
2	Weight of stationary object	-	+	-	10, 1, 29, 35	-	35, 30, 13, 2	-	5, 35, 14, 2
3	Length of moving object	8, 15, 29, 34	-	+	-	15, 17, 4	-	7, 17, 4, 35	-
4	Length of stationary object		35, 28, 40, 29	-	+	-	17, 7, 10, 40	-	35, 8, 2,14
5	Area of moving object	2, 17, 29, 4	-	14, 15, 18, 4	-	+	-	7, 14, 17, 4	
6	Area of stationary object	-	30, 2, 14, 18	-	26, 7, 9, 39	-	+	-	

NOTE: Examples are not taken from machinery stock of hENs

Consistent (3/3)

- Indirect conflict occurs when requirements do not describe the same functionality, but it is not possible to fulfill both requirements at the same time:
- *REQ1 System should have a natural language interface.*
- *REQ2 System shall be developed in three months.*
- The terminology usage should be consistent. Some requirements might use inconsistent terminology to describe the same concept.
- *REQ1 For outbound and inbound flights, the user shall be able to compare flight prices.*
- *REQ2 The outbound and return flights shall be sorted by the smallest number of stops.* ("inbound" vs. "return")

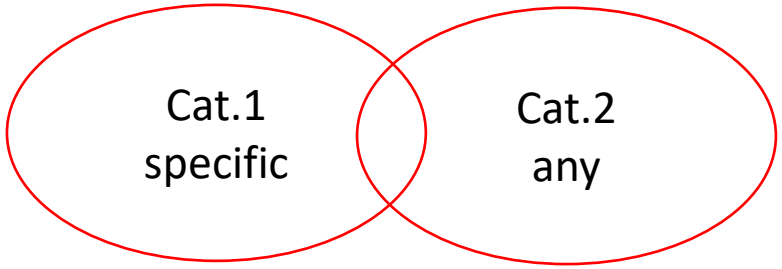


NOTE: Examples are not taken from machinery stock of hENs

Non-redundant

- Each requirement should be expressed only once and should not overlap with another requirement:
- *REQ1 A calendar shall be available to help with entering the flight date.*
- *REQ2 The system shall display a pop-up calendar when entering any date.*

(First requirement - related to only the date - is a subset of the second requirement - related to any date entered).

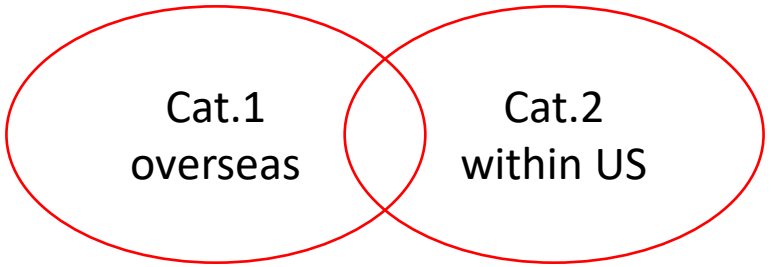


NOTE: Examples are not taken from machinery stock of hENs

Complete

- A requirement should be specified for all conditions that can occur:
- All applicable requirements should be specified. This is the toughest condition to be checked. There is really no way to be sure that all the requirements are captured and that a stakeholders won't say, "I forgot to mention that I need one more feature."
- *REQ1 A destination country does not need to be displayed for flights within the U.S.*
- *REQ2 For overseas flights, the system shall display a destination country.*

(Flights to Canada and Mexico are neither "within the U.S." nor "overseas.")



NOTE: Examples are not taken from machinery stock of hENs

Verification, Validation, and Testing (1)

It would be recommended that requirements consider using a Requirement Verification Matrix (RVM), which is usually composed of

(1) a requirement identification code,

(2) requirement traceability to higher level documents,

(3) verification methods to be used,

(4) the stage(s) where verification takes place and

(5) the verification procedure identification code.

Requirement ID	Requirement traceability	Verification method						Verification stage					Procedure ID
		None	Analysis	Inspection	Demonstration	Test	Certification	Definition	Design	Implementation	Integration	Qualification	

Verification methods often listed in the RVM are

1) Analysis,

2) Inspection,

3) Demonstration,

4) Testing and

5) Certification

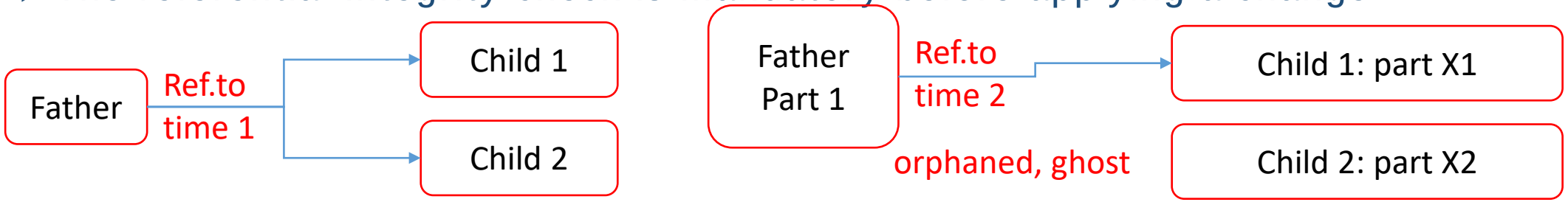
Verification, Validation, and Testing (2)

- A system ***verification by inspection*** method typically includes the use of human senses (e.g., sight, hearing, smell and/or touch) or simple physical tools for manipulation or mechanical and electrical gauging and measurements.
- A ***system analysis*** method may be used when other verification methods are not possible (e.g., verifying system reliability) or are too expensive (e.g., verifying system behavior in destructive conditions) or endanger humans or property (e.g., test flights outside the normal flight envelope).
- A ***measure-based*** method is the better solution. The metrics can be based on the following means: mathematical models, simulations, algorithms, calculations, charts, graphs and so on.

Referential integrity

- Standards are designed at time 0. It fixes the requirements (atomic).

  Some requirements can be made "**by reference**" to other standards. The "reference" has a temporal validity.
- Standards can evolve over time. The requirements/references might become inconsistent.
- The "referential integrity" is about the validity of links over time. The (orphan control) technique applies to the standards, but also to the chain of normative references and technical requirements. Example: multi-part series.
- Withdrawal of a standard at time 2, or replacing a standard by another standard at time 3, it can destroy (formerly valid) references.
- The referential integrity check is mandatory before applying a change.



What the IR3 says about the requirements (1/2)

- **Requirement:** expression in the content of a document **conveying objectively verifiable criteria to be fulfilled** and from which no deviation is permitted if compliance with the (voluntary) document is to be claimed (IR3, 3.3.3)
- **Verbal forms:** must make a clear distinction between requirements, recommendations, permissions, possibilities, capabilities and normative and informative references (IR3, 7)
- **Performance principle (for requirements)**: Requirement is preferably expressed in **terms of performance** rather than design or descriptive characteristics (IR3, 5.4)
- **Verifiability principle (for requirements):** Requirements shall be **objectively verifiable**. Only those requirements which can be verified shall be included (IR3, 5.5)
- **Absence of legal references or requirements**: A document does not include legal or statutory requirements and must not contain requirements specifying compliance with legislation (IR3, 4)
- **Contractual requirements or obligations** are not included (IR3, 4)
- **Note, Footnotes, Examples** must not contain requirements (IR3, 24.5, 25.5, 26.5)

What the IR3 says about the requirements (2/2)

- **<u>Requirements set by other documents</u> (normative references):**
- The verbal expressions between normative and informative references must be clear (IR3, 7.1)
- The referenced document must be publicly available (IR3, 10.2)
- The referenced document should be **expected to remain valid** for the expected life of the referring document (IR3,10.3)
- In case of **dated references** the standards identifier used in the provisions must be also dated; however, when IEC text is taken 'as it is' together with European modifications, the references in the text may remain undated, if the dated references are set in a normative European Annex ZA in CENELEC.
- In case of **an undated normative reference <u>all</u>** possible future changes **in its requirements** (including any new requirements set in its possible new future parts) must be possible to use **for the purposes of the referring document** (IR3, 10.4). Among other issues, this limits use of undated references in harmonised standards since the future content and scope of later editions are not known.
- All principles set for drafting requirements in IR3 are, of course, also valid, like 'Verifiability principle' meaning that a normative reference, whether dated or undated, must end up to objectively verifiable requirements from the referring document point of view.

Conclusions

- Take any book about requirement engineering, for example
- Always start mapping exercise from the EHSR
  - WHY? WHAT? HOW?
- Linguistic unambiguity: each word has one meaning only
- Well-defined metrics and measurement methods
- Use the active voice:
  WHO (NP = actor)
  IS DOING (VP = repeatable action)
  WHAT (NP = patient)

cfr. Hull, Elizabeth, Kenneth Jackson, and Jeremy Dick. Requirements Engineering, London: Springer, 2005.

European Commission

Thank you

Your speakers today

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Drafting a detailed informative Annex ZA/ZZ under the Machinery Directive

by Lisa ALMKVIST & Sara BERGGEN (SIS)
and Joanna FRANKOWSKA (CEN-CENELEC)

Question time

Content

1. Introduction
   - Role of Annex ZA/ZZ as indicated in European Commission's document
   - What is an Annex ZA/ZZ
   - EHSR in the MD
   - Example of Annex ZA
2. How to draft a detailed Annex ZA/ZZ
   - How to start
   - Drafting
   - Dos and don'ts
3. Multi Part standards
4. Final remarks

Content

1. **Introduction**
   - Role of Annex ZA/ZZ as indicated in European Commission's document
   - What is an Annex ZA/ZZ?
   - EHSR in the MD
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What is an Annex ZA/ZZ?

All harmonised standards must include an **Annex ZA**,

Annex ZZ (for CENELEC) demonstrating the relationship between the clauses of the standard and the regulatory requirements.

ANNEX ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive2006/42/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request "M/396 Mandate to CEN and CENELEC for Standardisation in the field of machinery" to provide one voluntary means of conforming to essential requirements of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table Z....1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2. Principles of safety integration		
1.1.2 a)	4,5,6	
1.1.2 c)	4,5,6	
1.1.2 d)	4,5,6	
1.1.2 e)	4,5,6	
1.1.3. Materials and products	4.5.2; 4.5.3; 4.5.4; 4.9; 4.11; 4.14	
1.1.4. Lighting		Not covered
1.1.5. Design of machinery to facilitate its handling	4.3; 4.4; 4.5; 4.10; 4.13; 4.14	
1.1.6. Ergonomics	4.4; 4.13	
1.1.7. Operating positions		Not covered

EHSR in the Machinery Directive

The EHSRs are found in Annex 1 in the MD

L 157/24 EN Official Journal of the European Union 9.6.2006

DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 May 2006

on machinery, and amending Directive 95/16/EC (recast)

(Text with EEA relevance)

Examples:

3.2. WORK POSITIONS

3.2.1. ***Driving position***

Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.

PROTECTION AGAINST MECHANICAL HAZARDS

Uncontrolled movements

Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2. ***Moving transmission parts***

By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.

3.4.3. ***Roll-over and tip-over***

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.

This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

Example Annex ZA

EHSR from the MD

1.7.1.2. **Warning devices**

Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times. ...

Clause from EN ISO 5010

4.7.1.1 A warning device indicating a primary steering power source failure is required and shall be activated upon failure of the primary steering power source. This warning device shall readily attract the operator's attention by providing a continuous visual and audible warning. The warning may be either steady or pulsating.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.7.1.1. Information and information devices	4.8.3	
1.7.1.2. Warning devices	4.7.1.1	
1.7.4.2. Contents of the instructions	10	

Content

1. Introduction
   - Role of Annex Z as indicated in European Commission's document
   - What is an Annex ZA
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2. **How to draft a detailed Annex ZA/ZZ**
   - How to start
   - Dos and don'ts
3. Multi Part standards
4. Final remarks

How to start (1/3)

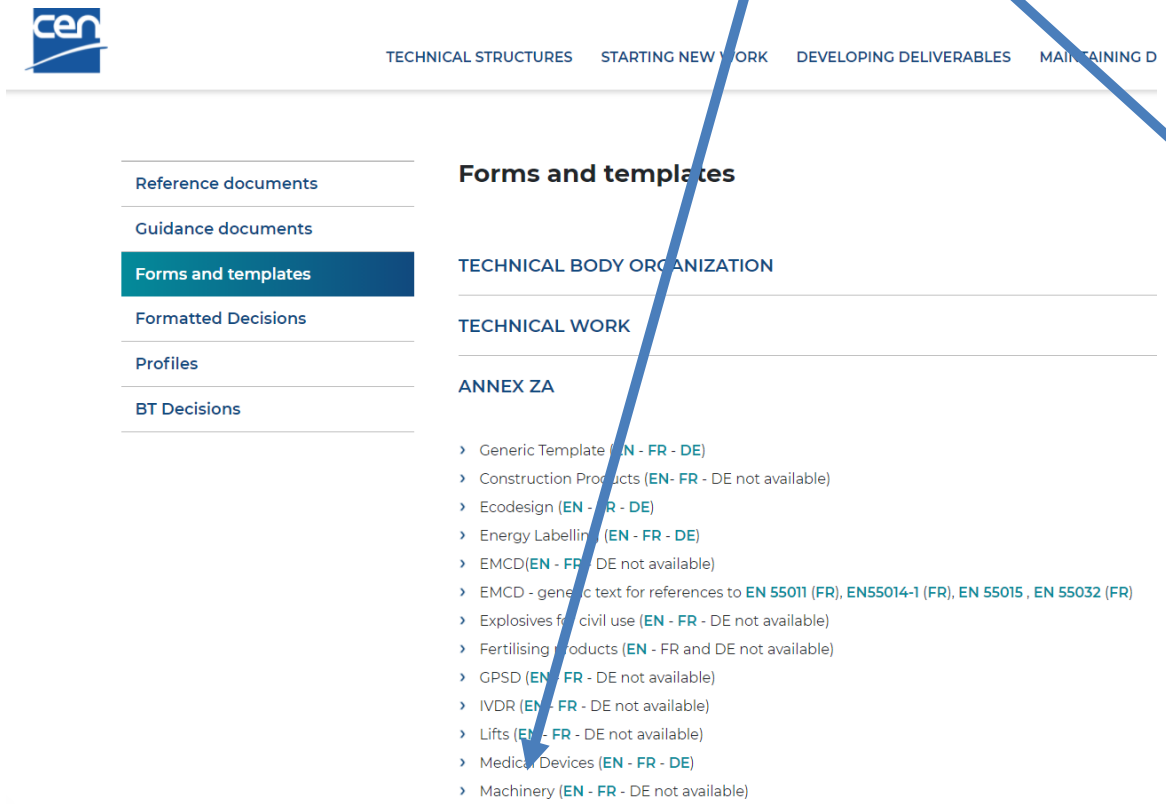
- Know your Machinery Directive, there is no way around it…
- Designate a group of people (not a single person) to be responsible for the Annex ZA/ZZ
- Start with the Annex ZA/ZZ at a **very early** stage of the project
- At the very start of the project, evaluate which EHSR are:
  - not relevant (not mentioned in Annex ZA/ZA)
  - relevant but not be covered by the standard (mentioned in Annex ZA/ZZ as **”Not covered**”)
  - relevant and covered by the standard
- Make notes of your reasoning for every EHSR!
  (It will help you remember later…)

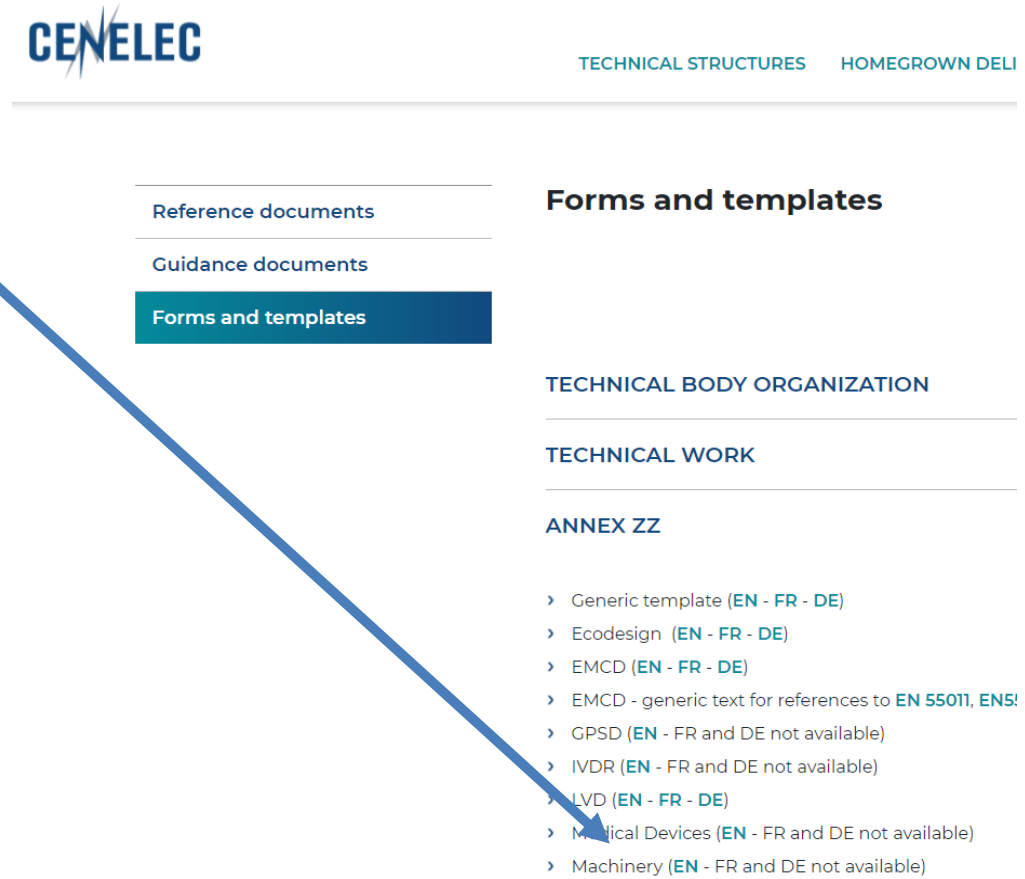
How to start (2/3)

- Work in parallel throughout the project with:
  - drafting the clauses
  - Annex ZA/ZZ
  - List of Significant Hazards (safety standards only, see CEN Guide 414)
  - verification of the EHSR and/ or protective/risk reduction measures (safety standards only, See CEN Guide 414)

How to start (3/3)

- Annex ZA (CEN): CEN BOSS website: Reference Material/Forms and templates/Technical Work (link is here)
- Annex ZZ (CENELEC): CENELEC BOSS → Reference Material → Forms and Templates → Annex ZZ (link is here)





Drafting (1/5)

"The relevant" shall be indicated in the heading of the 1st column of an informative Annex Z of type-B and type-C standards

Table Z....1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
[Per row: an essential requirement]	[The relevant normative clauses linked to the individual essential requirement]	
[Per row: an essential requirement]	-	not covered
[Example] / *1.7.4.2 u)*		not covered

Non-covered elements shall only be indicated in an informative Annex Z of type-C standards

Drafting (2/5)

The Excel tool helping to draft an initial Annex ZA

	A	B	C	D	E	F	G
1	**No**	**EHSRs**	**Group** see CEN Guide 414, Annex D		**Significant Hazard** see CEN Guide 414, Annex D	**Clause/Sub-clause of this standard**	**"x" , if applicable**
2	**1.**	1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS					
3	**1.1.2 a)***	1.1.2. a) Principles of safety integration				4,5,6	x
4	**1.1.2 c)***	1.1.2. c) Principles of safety integration					
5	**1.1.2 d)***	1.1.2. d) Principles of safety integration					
6	**1.1.2 e)***	1.1.2. e) Principles of safety integration					
7	**1.1.3.**	1.1.3. Materials and products	1.1	Mechanical hazards	Due to machine parts or workpieces, e.g. — by mechanical strength (break-up)		
8	**1.1.3.**	1.1.3. Materials and products	7.1	Material/ substance hazards	Hazards from contact with inhalation of harmful fluids, gases, mists, fumes and dusts		
9	**1.1.3.**	1.1.3. Materials and products	7.4	Material/ substance hazards	Biological and microbiological (viral or bacterial) agent		
10	**1.1.3.**	1.1.3. Materials and products	9.2	Hazards associated with the environment in which the machine is used	Moisture		
11	**1.1.3.**	1.1.3. Materials and products	9.3	Hazards associated with the environment in which the machine is used	Pollution		
12	**1.1.3.**	1.1.3. Materials and products	9.4	Hazards associated with the environment in which the machine is used	Snow, water, wind, temperature		

The Excel tool will produce an Excel table that can easily be pasted into the Annex ZA template.

It is only a tool, you need to do the work!

Drafting (3/5)

Granularity:

- All EHSRs having a number (except 1.1.1; 3.1.1 and 4.1.1) should be referenced assuming that all the sub-parts under these EHSRs are covered
- Reference to subparts of a numbered EHSR (subclauses starting with a letter, indent or without any marking) is not required (except EHSR 1.1.2).
- It is acceptable to cover ALL numbered sub-EHSRs of a main EHSRs by making reference to the main EHSR, only (e. g. covering sub-EHSRs 1.2.1, 1.2.2 and 1.2.3 by reference to EHSR 1.2 “Control systems”)
- Type C- standards should reference the particular normative clauses/annexes which address an individual EHSRs (it is acceptable to cover all sub-clauses of a main clause by making reference to the main clause, only)
- For type B-standards (normally addressing one or very few EHSRs) it is acceptable to reference to particular normative clauses/annexes at the highest clause numbering level only.

Drafting (4/5)

Provide a detailed mapping between clauses of standard and EHSRs

Extract from the European Commission's letter on the rejection of citation:

- Concerning the Annex Z, the sub-clause 4.4 is missing in Table A.1 and in Table ZA.1. To improve the norm, the table ZA.1 should be modified, for example in the following way: the sub-clause 4.1.2 should be added also in correspondence with the EHSRs 1.3.1, 1.3.2, 4.1.2.1 and 4.1.3. Clause 6 should be added also in correspondence with the EHSR 1.7.3. The EHSR 1.7.4.3 should be considered "not covered".

Double-check the mapping before submitting the standard to CCMC for procedures!

Drafting (5/5)

Refer to specific and verifiable clauses

Extract from the European Commission's letter on rejection of citation:

- Almost all listed clauses in the Annex Z do not provide specific technical requirements able to cover the corresponding EHSRs. For several EHSRs that are declared as "covered", the listed clauses gives no required correspondence. Therefore clauses are "not covered".

EHRS 1.1.2 Principles of safety integration (1/2)

- As EHRS 1.1.2 **indent (b)** is covering “procedural aspects” it should not be covered at all in Annex ZA/ZZ.
- EHRS 1.1.2 indents (a); (c); (d) and (e) should be covered as follows:

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2 (a)	4, 5, 6 [1)]	
1.1.2 (c)	4, 5, 6 [1)]	
1.1.2 (d) [2)]	4, 5, 6 [1)]	
1.1.2 (e) [2)]	4, 5, 6 [1)]	

[1)] Clauses according to CEN Guide 414:

4 Safety requirements and/or protective/risk reduction measures

5 Verification of safety requirements and/or protective/risk reduction measures

6 Information for use

[2)] To be integrated only in case aspect stated in indent is relevant for machinery covered by hEN and to the extent these product requirements are dealt with in the concerned standard

EHRS 1.1.2 Principles of safety integration (2/2)

The correct example of addressing EHSR 1.1.2:

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2 a)	4,5,6	
1.1.2 c)	4,5,6	
1.1.2 d)	4,5,6	
1.1.2 e)	4,5,6	

DOs and DON'Ts (1/4)

- Use the **correct template**

  and do not add text or change order of columns
- When **Amendment** – update ZA!
- Make sure to **match correctly EHSR and clause of EN** –
  read the actual EHSR
- Use **correct granularity**

- Double-check the mapping between clauses of standard and EHSRs before submitting the draft to Enquiry or Formal Vote

DOs and DON'Ts (2/4)

- Don't indicate Clause 1 (Scope) or Clause/Annex with List of Significant Hazards in table
- Don't indicate Essential Requirements 1.1.1, 3.1.1 or 4.1.1 about definitions in table
- Don't indicate other standards or legislation in the table

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
		Compliance with the requirements of EN 13001-1, EN 13001-2, EN 13001-3-1 and EN 13557 this specific part is necessary to achieve presumption of conformity.
1. ESSENTIAL HEALTH AND		

DOs and DON'Ts (3/4)

Do not refer to not significant hazards e.g.:

- Extract from the main body of hEN:

5.1 General

Machinery shall comply with the safety requirements and/or protective/risk reduction measures of this Clause.

In addition, the machine shall be designed according to the principles of EN ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document.

- Extract from Annex ZA":

1.1.2. Principles of safety integration	4, ~~5.1~~	

DOs and DON'Ts (4/4)

- Do not refer in Annex ZA/ZZ to the (sub) clauses which do not address EHRSs of Machinery Directive so as such are outside the harmonization aspect

  -> product requirements cannot be mixed in the same (sub) clause with other requirements but need to be put in the separate sub-clauses which are not referred to in Annex ZA

Consultant's comment:

"EHSR 1.5.10 concerns only radiations emitted by the machinery and which have adverse effects on persons. Electromagnetic emissions which can impair the function of other equipment are outside the field of application of MD if they do not have adverse effects on persons."

Revised Annex ZA after resolution of Consultant's comments:

1.5.9 Vibrations	4.4.1.4/~~6.2.2~~/D.2.1.2~~.3~~	-
~~1.5.10 Radiation~~	~~4.5.7/4.16~~	-
1.5.11 External radiation	4.16	-
1.5.12 Laser radiation		Not covered

Question time

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Multipart standards (1/5)

Part 1 – general/common specifications

Part X – provides specific requirements for a particular category of machinery by supplementing or modifying requirements in Part 1

Part X will address;

- *Supplemented requirements from part 1*
- *If common requirements from part 1 are not applicable*
- *If there are additional technical measures not addressed in part 1*

Part 1 and part X used in combination

Multipart standards (2/5)

Part 1 – Annex ZA/ZZ

Part 1 – link with specific parts

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC [2006 L157]

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
		To cover all the relevant safety requirements for the product(s) in its scope, this standard (providing general/common requirements for a whole machine family) has to be applied together with one of those standards as specified in the scope (providing specific requirements for a particular category of machinery within this family).

Required Note in exact word)!

Multipart standards (3/5)

Part X – requirement from Part 1 modified

Part 1 – Annex ZA/ZZ

EN 474 Part 1

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
		To cover all the relevant safety requirements for the products(s) in its scope, this standard (providing general/common requirements for a whole machine family) has to be applied together with one of those standards as specified in the scope (providing specific requirements for a particular category of machinery within this family).
1.5 9 Vibrations	4.4.1.4, 5	

Part X – Annex ZA/ZZ

EN 474 Part 2 (Part X)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.5.9 Vibrations	4.2	

4.2 Seat

FprEN 474-1:2021, 4.4 applies with the following addition:

The seat shall meet the input spectral according to EN ISO 7096:2020:

— EM6 for crawler dozers less than 50 000 kg operating mass according to ISO 6016:2008;

— EM5 for wheel dozers;

— for crawler dozer greater than or equal to 50 000 kg, see EN ISO 7096:2020.

Multipart standards (4/5)

Part X – requirement from Part 1 not applicable

Part 1 – Annex ZA/ZZ

EN 474 Part 1

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
3.4.3 Roll-over and tip-over	4.3.3	

"4.3.3 Roll-over protective structures (ROPS)

Earth-moving machinery with a seated ride-on operator shall be fitted with a roll-over protective structure (ROPS), complying with EN ISO 3471:2008.

EN ISO 3164:2013 applies for deflection limiting volume (DLV)."

Part X – Annex ZA/ZZ

Write in Remarks:

"Not applicable for this type of machinery in the scope"

EN 474 Part 12 (Part X)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
3.4.3 Roll-over and tip-over	4.3.2	Not applicable for this type of machinery in the scope

4.3.2 Roll-over protective structures (ROPS)

FprEN 474-1:2021, 4.3.3 does not apply for cable excavators.

Multipart standards (5/5)

Part X – additional technical measures

Part 1 – Annex ZA/ZZ

EN 474 Part 1

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes

Part X – Annex ZA/ZZ

EN 474 Part 12 (Part X)

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC

The Relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.2.5 Selection of control or operating modes.	4.5.2/4.9.3.2/4.9.3.4/4.9.3.5/ 4.12.2	

Multipart standards – coming soon

- Requests from TCs and Consultants to clarify better in the instruction the case when a given requirement of Part 1 applies to Part X of the series without any modification =>
- The 2nd edition of the instruction under finalisation with few (limited number) modifications;
- Once finalised and approved by CEN-CENELEC Sector Forum on Machinery will be provided by CCMC to TCs

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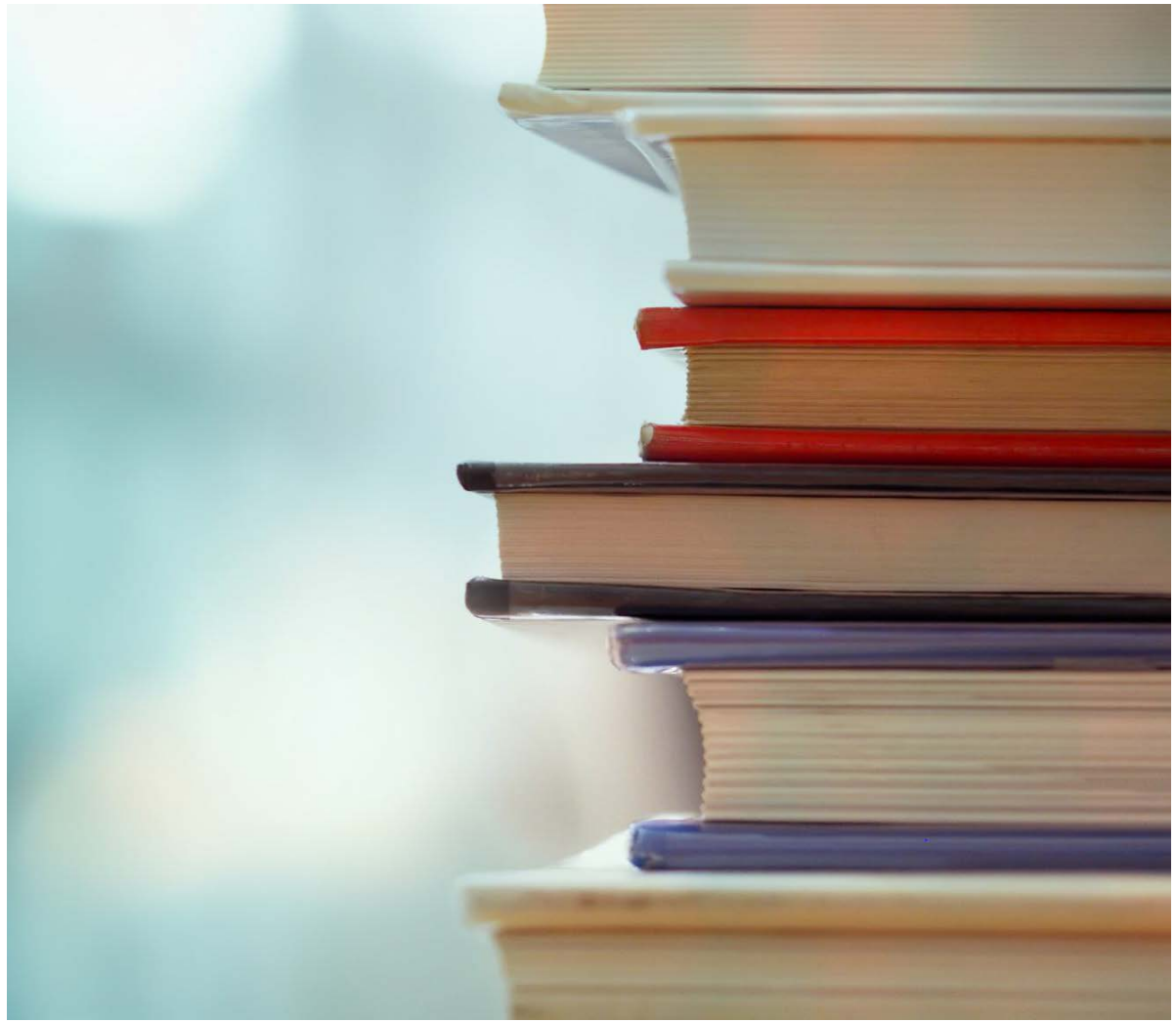
Key learning points

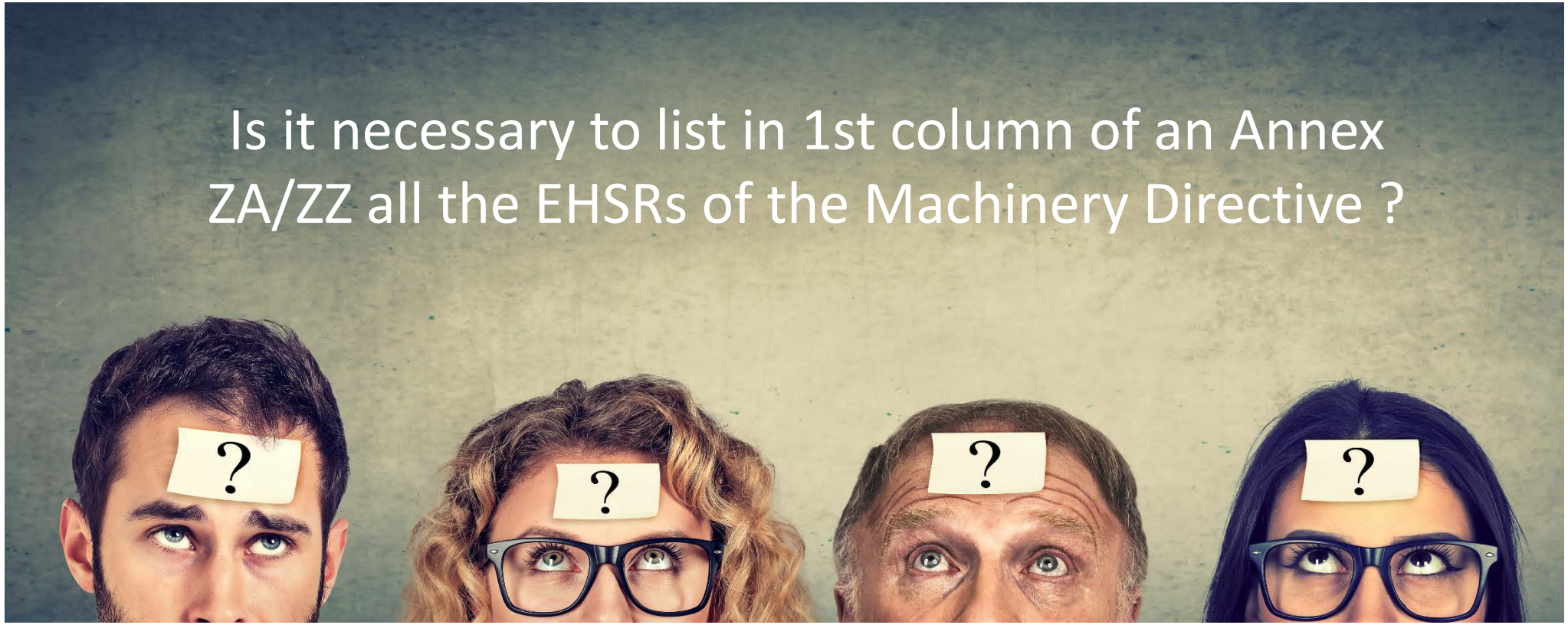
- Use the official template for Annex ZA/ZZ and do not deviate from its wording;
- Provide a detailed **mapping** between clauses of hEN and EHSRs and double-check before you submit to CCMC;
- Refer only to the relevant EHSRs and state “not covered” in 3rd column of the table if applicable
- When developing an amendment adapt the Annex ZA/ZZ of the main standard if not in line with the current requirements;
- Don’t indicate other standards or legal acts in the table;
- Follow the instructions agreed in the CEN-CLC Sector Forum on Machinery which are provided by CCMC.

Useful links

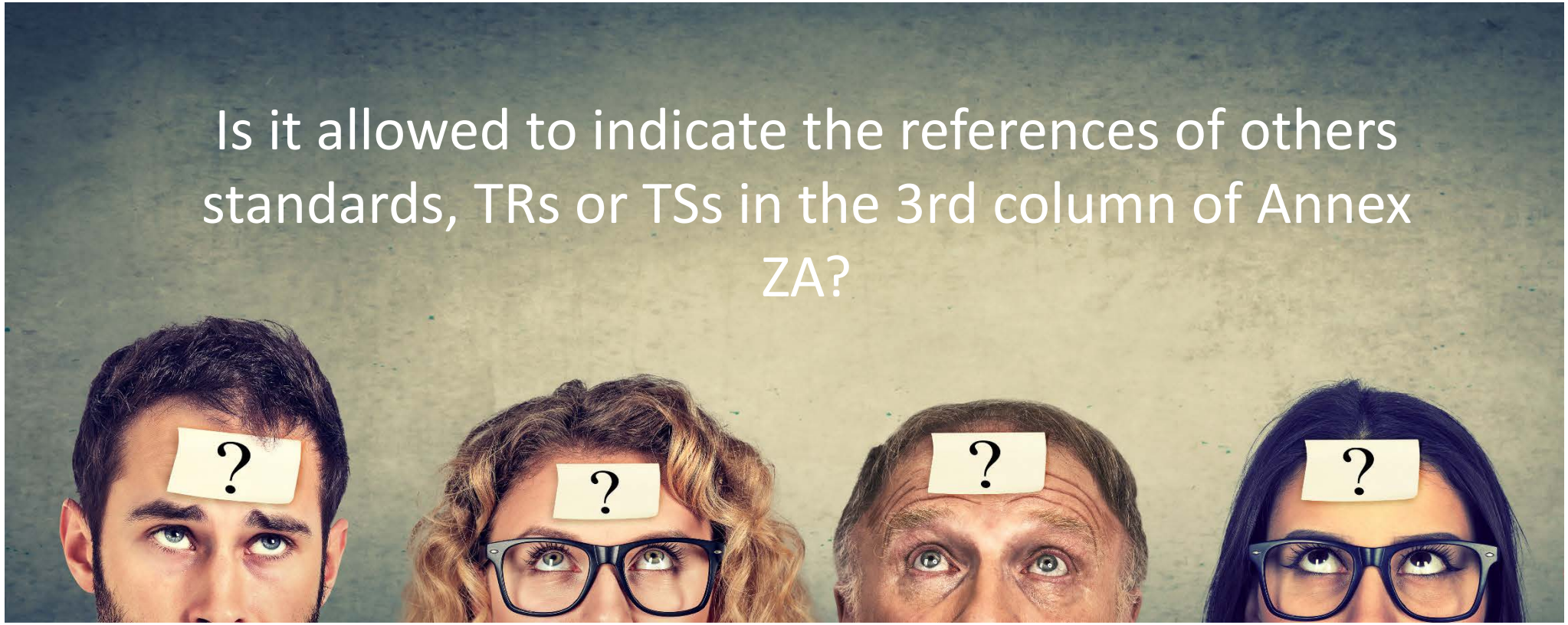


- HAS assessment reports
- Template of Annex ZA in CEN and of Annex ZZ in CENELEC
- CEN Guide 414 Safety of machinery
- Machinery Directive
- Guide to application of the Machinery Directive
- Official Journal for Machinery

Question time



Question time



Question time

Your speakers today

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Manufacturing

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Dating of normative references on harmonized standards

by Nuno PARGANA (CEN-CENELEC)

Content

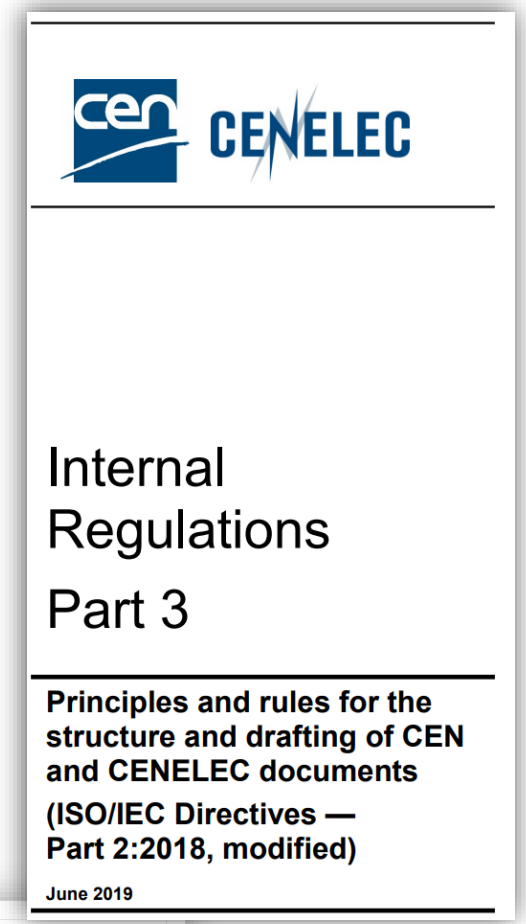
1. Normative references: general guidance
2. Normative references in hENs: EC requirements
3. Checklist for harmonized standards

1. Normative references: general guidance

CEN-CENELEC IR-3: rules for normative references

Internal Regulations Part 3 (IR-3)

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



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
- It shall not be subdivided

Clause 2 ‘Normative references’

IR-3 Clause 15: Standard wording

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.

OR

There are no normative references in this document.

IR-3 Clause 10: permitted references

Basis:

- documents published by CEN, CENELEC, ISO, IEC
- CEN and CENELEC standards reached at least the enquiry stage (30.99)

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

Publicly available doesn't mean free!

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)

IR-3: undated normative references

Undated references are allowed when:

- 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!

IR-3: dated normative references

Dated References (10.5)

- **Default solution**
- Date when conditions for undated are not met
- When reference to a specific clause
- Normative dating happens within the text (not only in clause 2)
- When revising a standard: assess whether dated normative references should be updated or not

2. Normative references in hENs: EC requirements

Normative references & legislation

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

European Commission

Normative references and HAS assessments

Overview of Critical findings

Part A: Summary of assessments

A total of 196 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	17	196	8,67%
A- 1.2.2.	Foreword	7	196	3,57%
A- 1.2.3.	Scope covers products not considered by the relevant legal requirements	3	196	1,53%
A- 1.2.4.	The Scope sets requirements or covers aspects which cannot be subject to harmonised standards	1	196	0,51%
A- 1.2.5.	Scope excludes products or aspects that are expected to be covered by the standard	4	196	2,04%
A- 1.2.6.	Normative references that are essential for the assessment of harmonised elements are not available	8	196	4,08%
A- 1.2.7.	Document contains undated normative references without proper justification	42	196	21,43%
A- 1.2.8.	Too long chains of normative references	2	196	1,02%
A- 1.2.9.	Normative references need updating or reconsideration	31	196	15,82%
A- 1.2.10.	Technical content of the document contains requirements that do not align with or contradict relevant EU legislation	64	196	32,65%
A- 1.2.11.	Technical content of the document unsuitably repeats legal requirements as part of its normative requirements	18	196	9,18%
A- 1.2.12.	Absence of reproducible tests or assessment methods	33	196	16,84%
A- 1.2.13.	Neutrality principle is not respected: the document contains clauses imposing requirements or obligations on or between certain economic operators	6	196	3,06%
A- 1.2.14.	Neutrality principle is not respected in requirements for verifications, sampling and testing	1	196	0,51%
A- 1.2.15.	Risk assessment or identification of relevant risks is missing or not complete	14	196	7,14%
A- 1.2.16.	The Annex Z is not sufficiently detailed	57	196	29,08%
A- 1.2.17.	The Annex Z does not properly refer to the relevant legal requirements	107	196	54,59%
A- 1.2.18.	The document is not aligned with the guidance documents or checklist	23	196	11,73%
A- 1.2.19.	Other comments	93	196	47,45%

Guidance on normative references in hENs

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

YES → EC requirements and IR-3 apply

NO → IR-3 apply

European Commission

Guidance on normative references in hENs

1. 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 81-43:2009, *Safety rules for the construction and installation of lifts - Special lifts for the transport of persons and goods - Part 43: Lifts for cranes*

EN 363:2018, *Personal fall protection equipment - Personal fall protection systems*

EN 894-1:1997+A1:2008, *Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 1: General principles for human interactions with displays and control actuators*

EN 894-2:1997+A1:2008, *Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 2: Displays*

EN 12077-2:1998+A1:2008, *Cranes safety - Requirements for health* [illegible] *indicating devices*

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

EN 12644-2:2000+A1:2008, *Cranes - Information for use and testing - P*

EN 13001-1:2015, *Cranes - General design - Part 1: General principles a*

EN 13001-2:2014, *Crane safety - General design - Part 2: Load actions*

EN 13001-3-1:2012+A2:2018, *Cranes - General Design - Part 3-1: Limit States and proof competence of steel structure*

5.6.2 Guarding and access

5.6.2.1 The crane shall have permanent access to all control stations, in accordance with EN 13586:2004+A1:2008.

Where access is provided by means of a permanent personnel lift, it shall comply with EN 81-43:2009.

Guidance on normative references in hENs

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

- **Example** of 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	Proposed change	Observations of the secretariat
AB-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. This is not accepted by the EC, which requires dated normative references not only in clause 2 but also in the main text	Please, updated the normative text, using exclusively dated normative references.	

Guidance on normative references in hENs

1. 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.

ISO 4254-1, *Agricultural machinery — Safety — Part 1: General requirements*

ISO 9533, *Earth-moving machinery — Machine-mounted audible travel alarms and forward horns — Test methods and performance criteria*

ISO 11684, *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 13850, *Safety of machinery — Emergency stop function — Principles for design*

ISO 13857:2019, *Saf*

and lower limbs

4.3 Visibility

4.3.1 Self-propelled machines shall be fitted with an audible warning alarm complying with ISO 9533. This alarm shall be automatically engaged during reversing manoeuvres.

Guidance on normative references in hENs

2. 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

Guidance on normative references in hENs

- EC view: at the time of adoption (DAV) of hEN → **latest edition of normative references** (Vademecum)

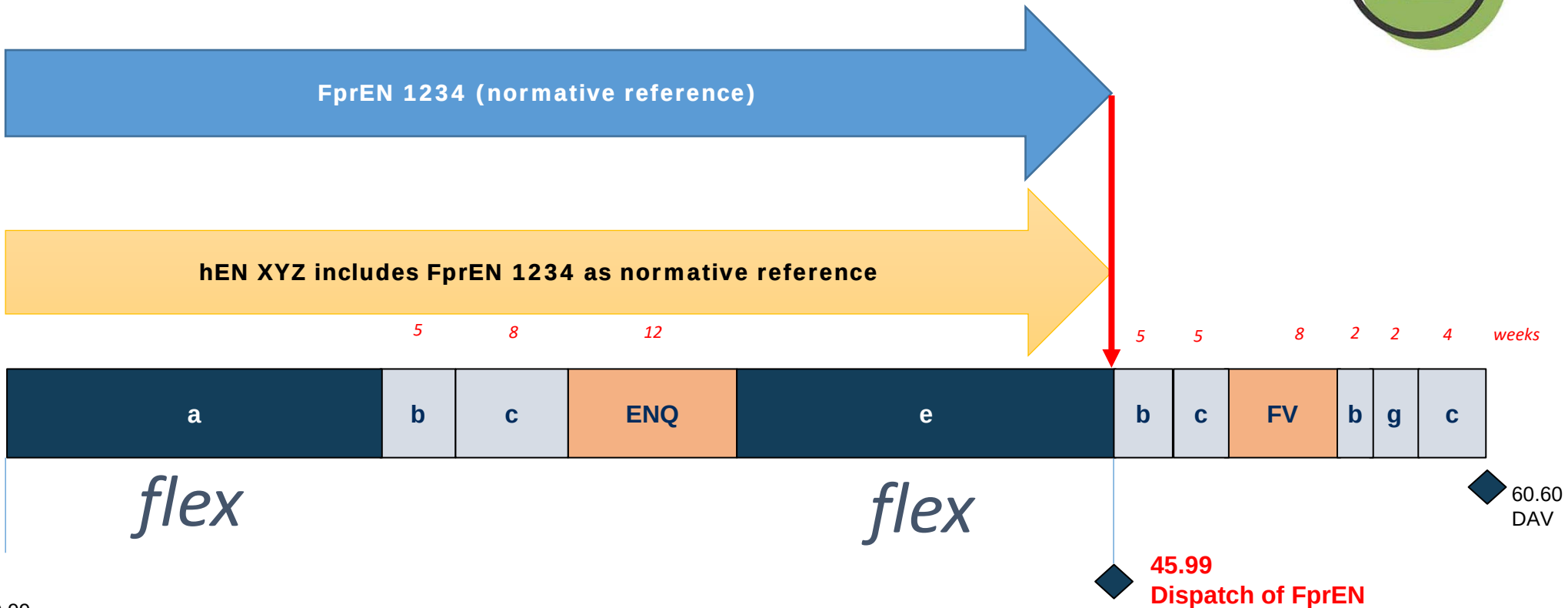
Guidance on normative references in hENs

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

Example 1:

Harmonized standards: **hEN XYZ**

Normative reference in hEN XYZ: **EN 1234**



10.99
Approval of WI

Guidance on normative references in hENs

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

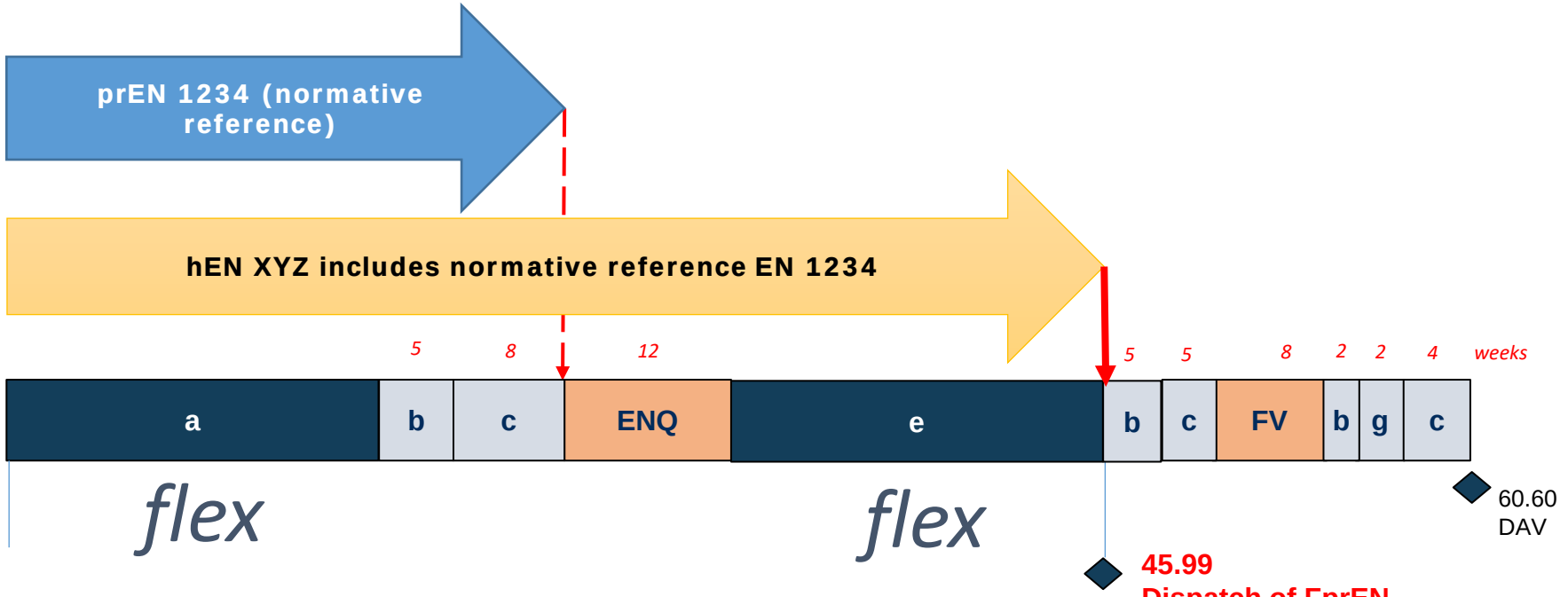
Example 2:

Harmonized standards: **hEN XYZ**

Normative reference in hEN XYZ: **EN 1234**

Option 1: Use published normative reference

Option 2: align development of documents



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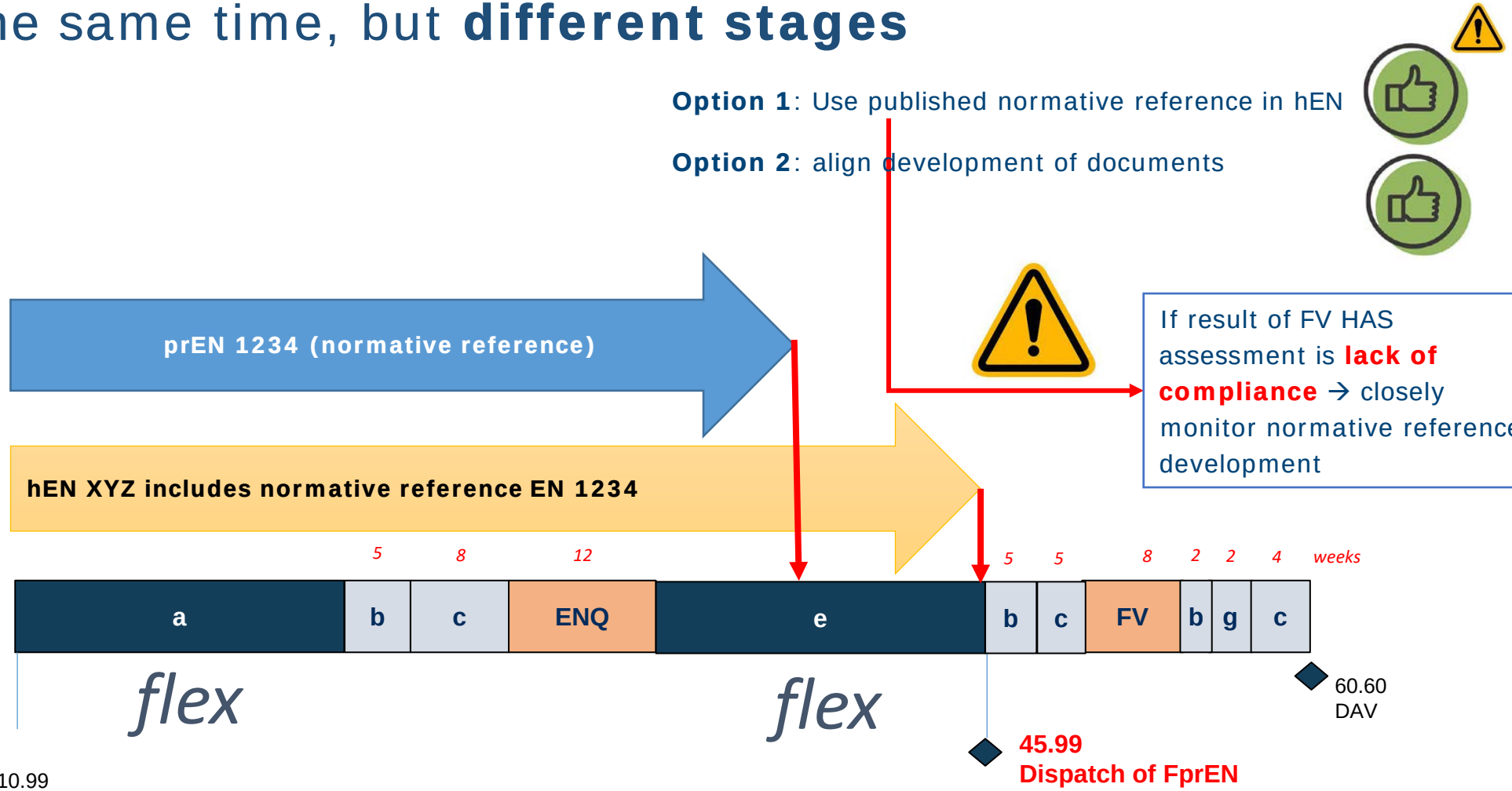
Guidance on normative references in hENs

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

Example 3:

Harmonized standards: **hEN XYZ**

Normative reference in hEN XYZ: **EN 1234**



10.99 Approval of WI

Guidance on normative references in hENs

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

Example 4:

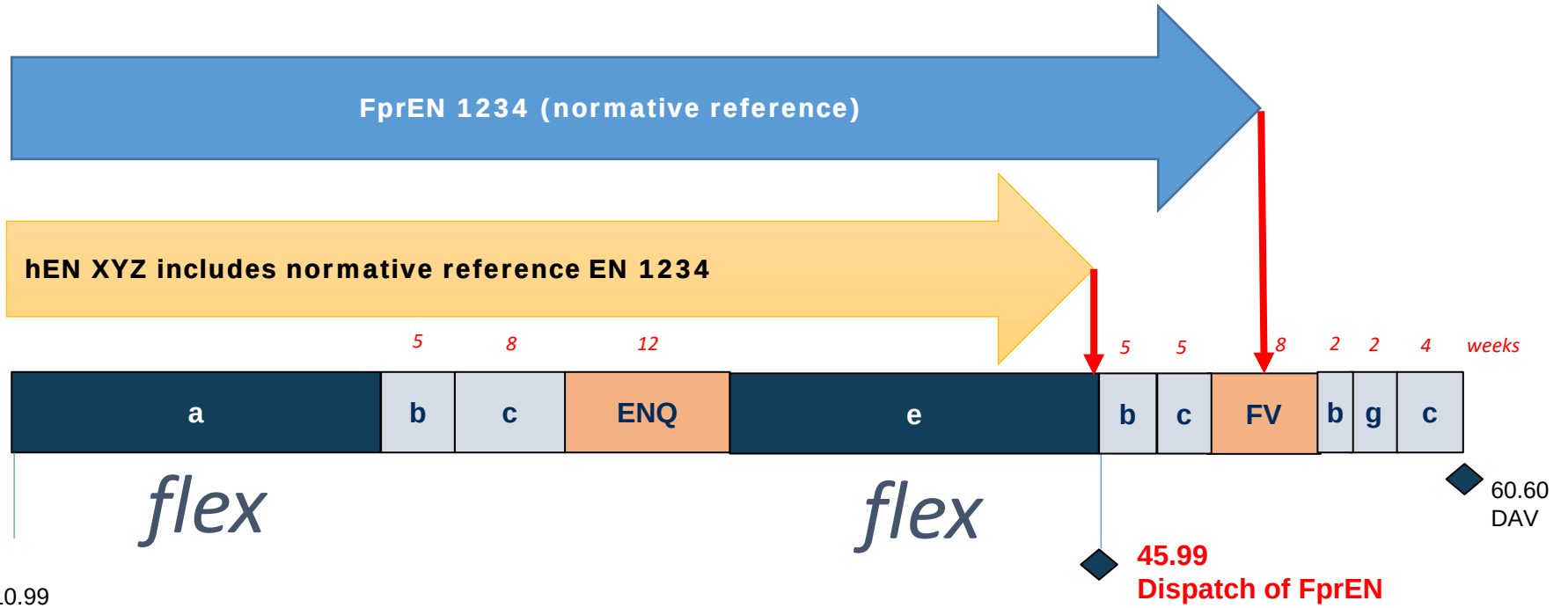
Harmonized standards: **hEN XYZ**

Normative reference in hEN XYZ: **EN 1234**

Option 1: Use published normative reference

Option 2: Use in hEN the FprEN normative reference

Option 3: wait for normative reference to be published



10.99
Approval of WI

Guidance on use of normative references in hENs

5. Normative references should be **EN / ISO / IEC published standards**

- **Exceptionally**, other documents could be used but:
  - IR-3 applies
  - TC decision (in CEN) and justification is needed
  - 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

5. 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*

Guidance on use of normative references in hENs

6. Special consideration on the use of hENs as normative references in hEN

- hENs **can** include normative references intended to be cited OJEU citation, but

- hEN **shall not** include normative references that have been rejected by EC for citation

- hEN **shall not** include normative references removed from OJ due to formal objection

Guidance on use of normative references in hENs

7. 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*

Guidance on use of normative references in hENs

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

Example 1:

3 Modifications to 2, "Normative references"

Replace "EN 614-1, *Safety of machinery — Ergonomic principles for design — Part 1: Terminology and general principles*"

by

"EN 614-1:2006+A1:2009, *Safety of machinery — Ergonomic principles for design — Part 1: Terminology and general principles*".

Example 2:

3 Modification to Clause 2, Normative references

Replace "

EN ISO 13857:2008, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs (ISO 13857:2008)*

" *with* "

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

".

Guidance on use of normative references in hENs

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

Example:

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

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

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

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

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

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

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

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

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

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

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

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

HAS consultant comment:

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

Guidance on use of normative references in hENs

9. **Undated references are possible when**:

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

Dated References

Default solution

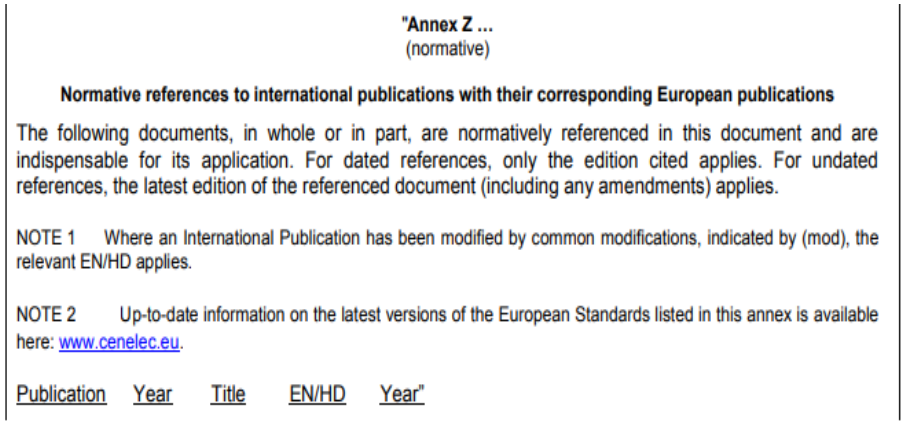
Parallel work with ISO and IEC

When developing EN ISO standard (VA)

- Listed in Clause 2
- Same EU requirements apply
- Dated normative references are default solution
- Additional solutions under discussion

When developing EN IEC standard (FA)

- Normative references to international publications with their corresponding European publications (For CENELEC only) are listed under **Annex ZA**
- Annex ZA → normative
- It replaces references in body of standard



"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.

Publication	Year	Title	EN/HD	Year"

3. Checklist for harmonized standards

Checklist for drafting hENs

- Last months: increase outcome HAS assessment ‘Lack of compliance’

- Need to support Technical Bodies to increase HAS assessment ‘Compliant’

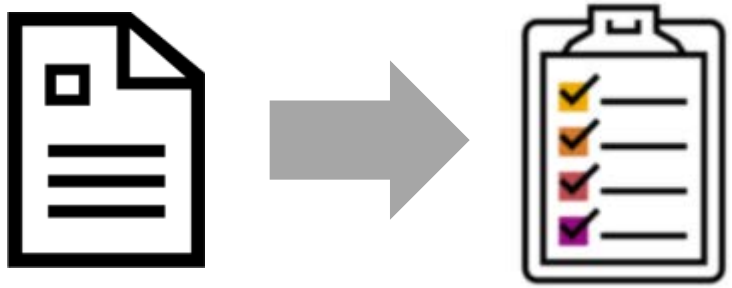
- **Technical Boards approved checklist to assist Technical Bodies in drafting harmonized standards** (decision BT C089/2021 and D168/C108)

Checklist for hENs: main principles

1) When drafting homegrown hENs, harmonized standards under VA (CEN lead) or European Common modifications (CENELEC) → **Technical Bodies shall check their compliance against a dedicated checklist**

2) TC secretary in CEN and Technical body secretary/ Reporting Secretariat in CENELEC → **ensure checklist is filled out and submitted to CCMC with the draft hEN and supporting documents** (where relevant)

3) During the ENQ and FV procedures: **CCMC will reject, as of 2021-10-01, the submission of draft hEN if the completed checklist and relevant documents were not submitted**



Checklist for hENs

- **CEN** and **CENELEC** BOSS pages guidance on hENs published

v2021-04-14

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

This checklist was prepared following the format of Internal Regulations CEN/CENELEC Part 3 – Annex A "Checklist for writers and editors of document". All CEN/CENELEC standards and deliverables shall follow the provisions of IR 3.

This checklist is applicable for all sectors, except construction.

This checklist shall be fulfilled before dispatch for:

1. the First Working Draft for optional assessment (if any),
2. the draft for Enquiry,
3. the final draft for Formal vote,
4. In case of lack of compliance assessment, a new optional assessment after Formal vote (PUB assessment).

The Technical Committee secretary in CEN and the Technical body secretary / Reporting Secretariat in CENELEC are responsible for ensuring that the checklist below is filled out and submitted to CCMC with the draft candidate harmonized standards and their supporting documents/justifications where relevant. In CEN, the matrix of responsibilities shall be followed (see decision BT C081/2018).

It is strongly recommended to use of the checklist for the drafting of harmonized standards in support of EU Legislation under VA and FA (with ISO or IEC lead).

	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? *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)*	☐ ☐
	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 all comments from the HAS Consultant(s)? *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.*	☐
	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?	☐
European foreword	If the standard is a revision, are the significant changes with respect to the previous edition precisely defined? *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.*	☐
	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 requirements of EU Directive / Regulation. For relationship with EU Directive / Regulation, see informative Annex Z, which is an integral part of this document."? *NB: Annex ZA in CEN and Annex ZZ in CENELEC.*	☐
Scope	Is the scope concise and clear? Is it worded as a series of statements of fact? Are the title, scope and annex Z consistent regarding exclusion / content covered by the standard? *NB: The scope of the standard could be broader than the relationship between this standard and the requirements of the EU legislation.* *NB: The scope shall not include requirements, permission or recommendation (in line with IR 3).*	☐ ☐
Normative reference	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"). *NB: See IR 3 with the preferred verbal form to be used to express a requirement.*	☐
	Are the normative references dated in Clause 2 and in all clauses of the draft standard?	☐Yes ☐No

Checklist for hENs: ENQ/FV process (CEN)

WG

- WG drafts hENs
- WG Qualified support checks that the draft hEN fulfils requirements to be cited
- WG Qualified support ensures that checklist is filled out
- WG Qualified support/convenor submits to TC secretary:
  1) **Final draft hENs**
  2) **Checklist filled out**
  3) **ENQ HAS assessment report with last column filled on how consultant comments were addressed** (applicable for FV only)

CEN: **matrix responsibilities** to be followed (decision BT C081/2018)

TC secretary

- Checks that checklist is filled out
- Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?

ENQ/FV procedure could start

Checklist not submitted?

CCMC will reject hEN submission

Checklist for hENs: ENQ/FV process (CENELEC)

WG

- WG drafts hENs
- WG ensures that following docs are submitted to TC secretary:
  1) **Final draft hENs**
  2) **Checklist filled out**
  3) **ENQ HAS assessment report with last column filled on how consultant comments were addressed** (applicable for FV only)

CENELEC: **matrix of responsibilities** under discussion

TC secretary

- Checks that checklist is filled out
- Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?

ENQ/FV procedure could start

Checklist not submitted?

CCMC will reject hEN submission

Key learning points

- Reference document on normative references: **IR-3**
- Normative references: common reason for lack of compliance assessment
- Default solution → **dated normative references in hENs**
- Normative references: **dated**, **active** and **published**
- Flexibility in case the reference is not linked with clauses giving presumption of conformity
- Special consideration when normative references and hEN are developed at the same time (same or different stages)
- **Checklist on hENs** is mandatory as of 2021-10-01

Thanks!

Thank you for your attention!

Nuno PARGANA

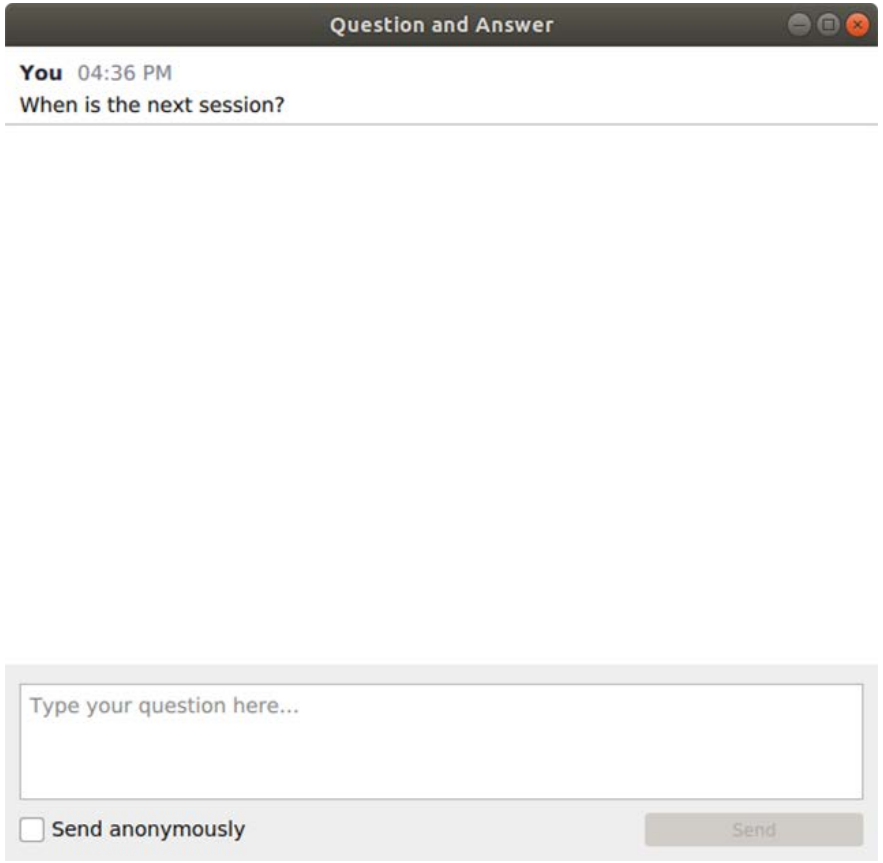
Account Manager

Manufacturing

nparganа@cencenelec.eu

Question time

- Use the Q&A panel to submit your questions



Thank you for your participation!

Next webinar

2021-11-30: Webinar 'Anthropometric and strength data of children for use in standardization'