

# CEN Guide 414 (ISO Guide 78) guidance for drafting Machinery Safety Standards

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# CEN Guide 414 - Overview



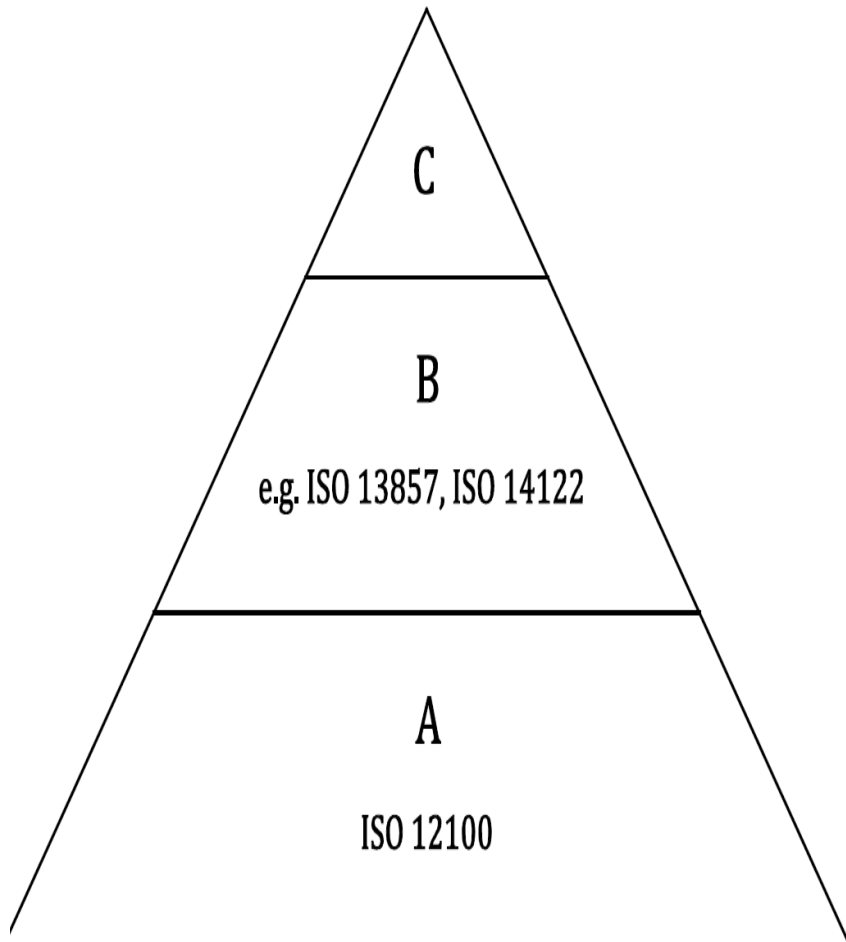
## CEN GUIDE 414

Safety of machinery – Rules for the  
drafting and presentation of safety  
standards

Edition 3, 2017-10-11

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

# CEN Guide 414 – System of type -A, -B and -C standards



## **type-C standard** (machine safety standard)

standard dealing with detailed safety requirements for a particular machine or group of machines

## **type-B standard** (generic safety standard)

standard dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery

## **type-A standard** (basic safety standard)

standard giving basic concepts, principles for design and general aspects that can be applied to machinery

# CEN Guide 414 – General principles for type-C standards

- ▶ Type-C standards should deal 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 requirements prescribing protective/risk reduction measures that add value to relevant subclauses of EN ISO 12100:2010, Clause 6, originating from the significant hazard(s)
  - The means of verifying the protective/risk reduction measures
  - The information for use

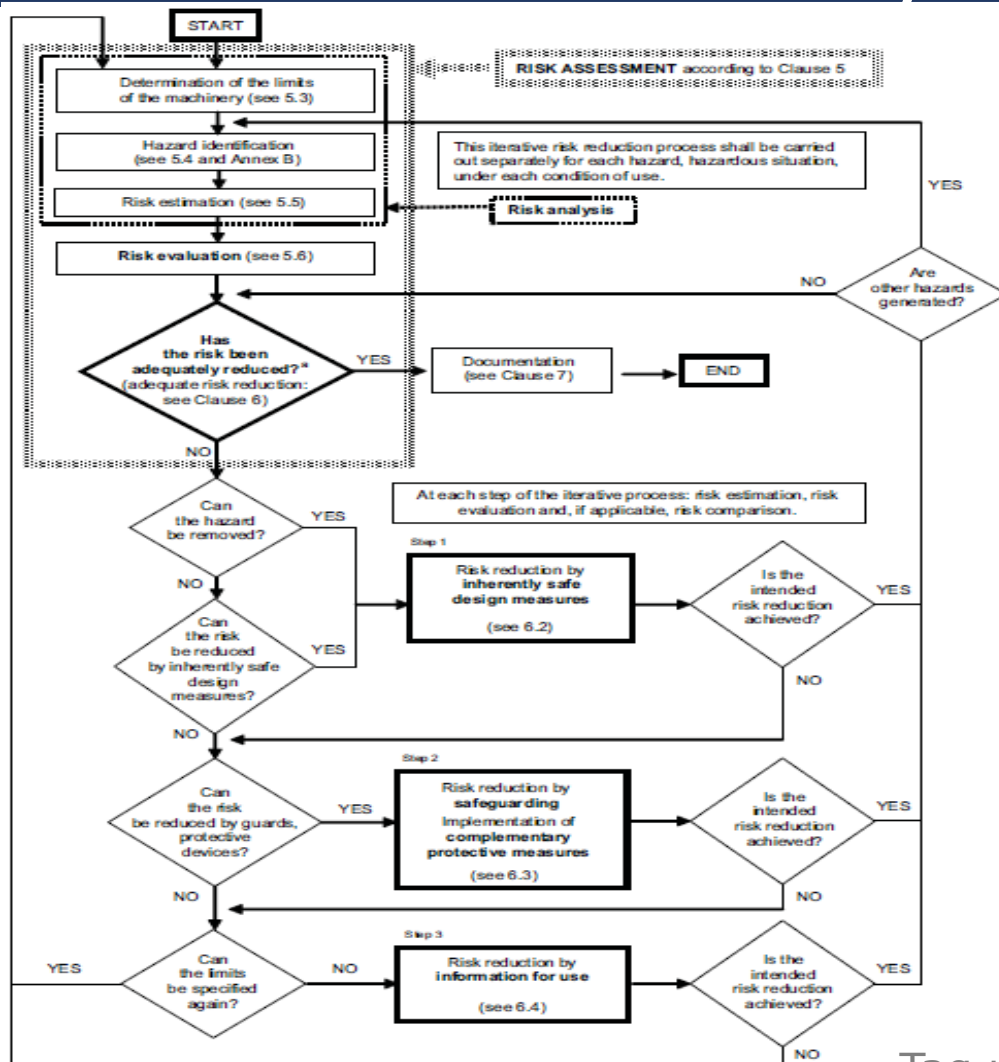
# CEN Guide 414 – Principles to be considered before/during drafting

- ▶ List of criteria for determine the necessity/feasibility of drafting a new or revised standard; among others:
  - Expressed market need by relevant stakeholders
  - Sufficient population of related machines
  - Are related machines generating significant hazards (accidents)
  - In case of new technologies – are they sufficiently stable and representing the state of the art
  - Availability of technical expertise/knowledge from main stakeholders (industry + health safety bodies) and experience for standardisation
  - Is there sufficient feedback on the use of the existing standard (in case of a revision)

# CEN Guide 414 – Principles to be considered before/during drafting

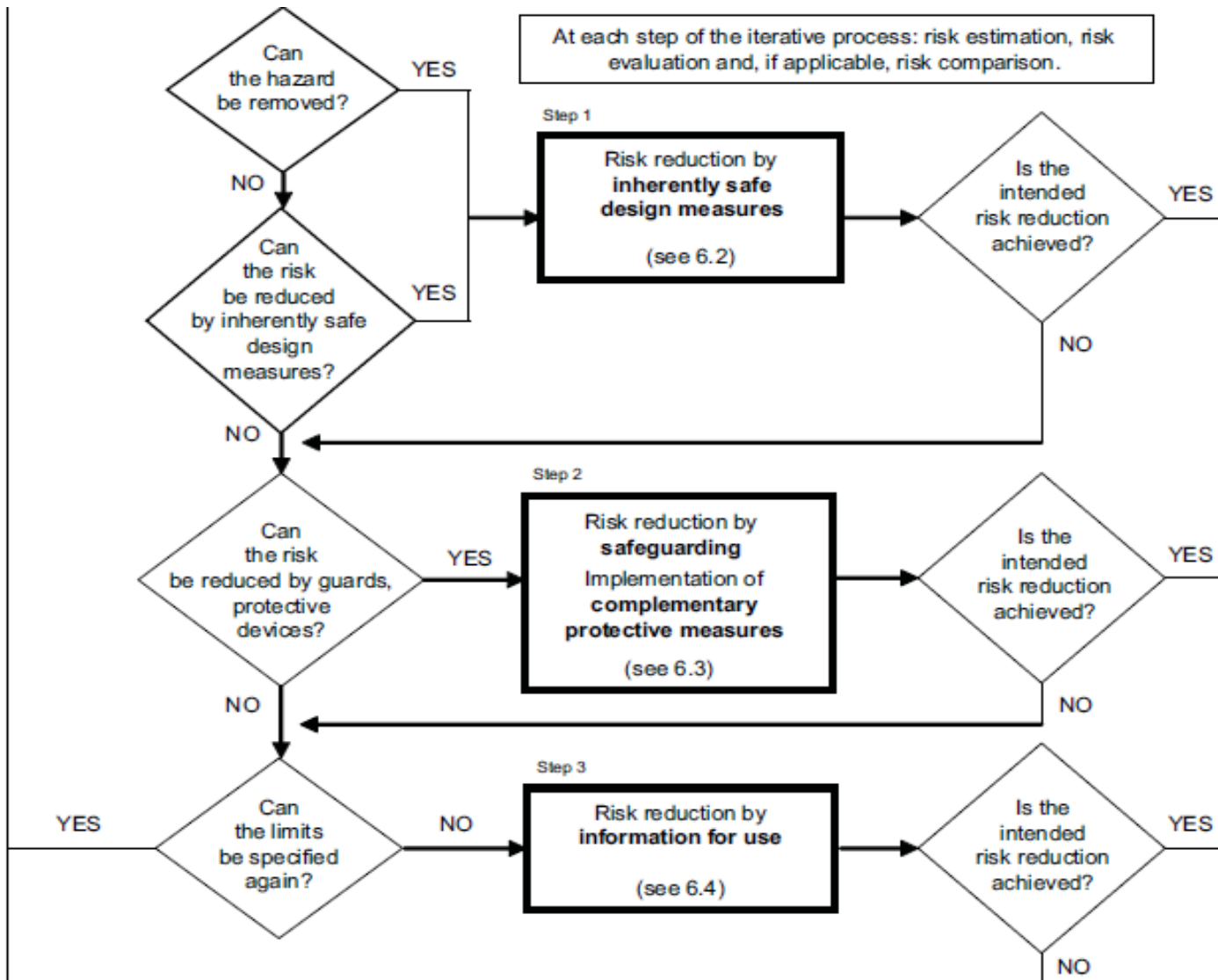
- ▶ Particular guidance on necessary step for establishing the following elements of a type-C standard:
  - Definition of the scope
  - Identification of hazards, hazardous situations or hazardous events
  - Determination of protective/risk reduction measures for eliminating hazards and/or limiting risks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

# CEN Guide 414 – Principles to be considered before/during drafting





# CEN Guide 414 – Principles to be considered before/during drafting



# 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 (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 Z (table format & Option C)

# CEN Guide 414 – Annex B

## Model Format E/F/D

### Annex B (informative)

#### Model format of a type-C European draft standard

Contents	Page	Sommaire	Page	Inhalt	Seite
Foreword		Avant-propos		Vorwort	
Introduction		Introduction		Einleitung	
1 Scope		1 Domaine d'application		1 Anwendungsbereich	
2 Normative references		2 Références normatives		2 Normative Verweisungen	
3 Terms and definitions		3 Termes et définitions		3 Begriffe	
4 Safety requirements and/or protective/risk reduction measures		4 Prescriptions de sécurité et/ou mesures de prévention/réduction du risque		4 Sicherheitsanforderungen und/oder Schutz-/ Risikominderungsmaßnahmen	
5 Verification of safety requirements and/or protective/risk reduction measures		5 Vérification des prescriptions de sécurité et/ou des mesures de prévention/réduction des risques		5 Feststellung der Übereinstimmung mit den Sicherheitsanforderungen und /oder Schutz-/ Risikominderungsmaßnahmen	
6 Information for use		6 Informations pour l'utilisation		6 Benutzerinformation	
<i>Additional clauses, if needed</i>		<i>Articles supplémentaires, s'il y a lieu</i>		<i>Zusätzliche Abschnitte, falls erforderlich</i>	
Annex A (normative)		Annexe A (normative)		Anhang A (normativ)	

# CEN Guide 414 – Annex C “Guide for extended transition period”

- To allow industry (manufacturers) an ordered conversion to the new hEN an extension of the transition period (**dow** from **dav**+6 months (default) up to **dav**+36 months) may be requested by the responsible TC
- As the European Commission will normally use the date for the **dow** as the “Date of cessation of presumption of conformity of the superseded standard” this will have the effect, that for an resulting transitional period both the old and the new version of an hEN will provide presumption of conformity
- Content of this Annex C is build on guidance document "Date of withdrawal" from CEN BOSS  
(<https://boss.cen.eu/reference%20material/guidancedoc/pages/dow.aspx>)

# CEN Guide 414 – Annex D “Link between hazards and ERs of MD”

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

**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
<i>General, for many machines relevant</i>		
<b>1</b>	<b>Mechanical hazards</b>	
1.1	Due to machine parts or workpieces, e.g. <ul style="list-style-type: none"> <li>— by potential energy (falling objects, height from the ground, gravity)</li> <li>— by kinetic energy (acceleration, deceleration, moving/rotating elements)</li> <li>— by mechanical strength (break-up)</li> </ul>	1.3.3 Risks due to falling or ejected objects 1.3.7 Risks related to moving parts 1.1.3 Materials and products 1.3.2 Risk of break-up during operation
1.2	by stored energy, e.g.: <ul style="list-style-type: none"> <li>— elastic elements (springs)</li> </ul>	1.3.9 Risks of uncontrolled movements 1.5.3 Energy supply other than electricity 1.6.3 Isolation of energy sources

# CEN Guide 414 – Relation to other documents/initiatives

- ▶ CEN Guide 414 is identical with ISO Guide 78 “Safety of machinery – Rules for drafting and presentation of safety standards” with the exception of all European elements in relation to MD 2006/42/EC, e. g.:
  - Information for use: declaration of noise/vibration emission values
  - Annex Z “Correspondence between this European Standard and Annex I of Directive 2006/42/EC”
- ▶ CEN Guide 414 is compatible with the CEN/CENELEC pilot project for a self-assessment of harmonized standards by Technical Bodies (5 step approach)

# CEN Guide 414 – Helpful tool for the machinery sector

Thank you  
for your attention!

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# QUESTIONS & ANSWERS



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