SLOVENSKI STANDARD
SIST CEN Vodilo 414:2017

01-december-2017

Varnost strojev - Pravila za načrtovanje in predstavljanje varnostnih standardov

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

Sicherheit von Maschinen - Regeln für die Abfassung und Gestaltung von Sicherheitsnormen

Sécurité des machines - Règles pour l'élaboration et la présentation des normes de sécurité

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Ta slovenski standard je istoveten z: CEN Guide 414:2017

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ICS:

01.120	Standardizacija. Splošna pravila	Standardization. General rules
13.110	Varnost strojev	Safety of machinery

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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

Edition 3, 2017-10-11

Supersedes CEN Guide 414:2014

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European foreword

This document (CEN Guide 414:2017) has been prepared by Technical Committee CEN/TC 114 "Safety of machinery", the secretariat of which is held by DIN.

This document is intended for use by Technical Committees writing type B and type C standards in the field of Safety of Machinery (as defined in 3.2 and 3.3).

It gives the rules for the presentation of standards requested by CEN/BT in the programme mandated from the European Commission in support of the "Machinery Directive" (Directive 2006/42/EU).

This document supersedes CEN Guide 414:2014.

The revision of CEN Guide 414 takes into account ISO Guide 78:2012, relevant ISO/IEC Directives, CEN/CENELEC Internal Regulations, resolutions and guidance of CEN/BT, and the CEN Business Operations Support System. It is also the result of feedback from TCs and WGs using the first edition of CEN Guide 414:2014 when revising type B and type C standards.

The main changes with respect to the second edition (CEN Guide 414:2014) are as follows:

a) The introductory wording to Clause 2 and Clause 3 has been updated in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017.

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b) 5.2, item b) has been deleted.

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c) 6.10 has been updated and re-numbered.

d) Annex B has been updated by introducing the generic template for Annex Z... amended in accordance with decision CEN/BT 23/2016.

e) In Table D.1 the reference to EN ISO 12100 has been stated more precisely.

f) All cross references to the CEN/CENELEC Internal Regulations, Part 3 have been updated with regard to the edition of February 2017.

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Introduction

As a response to the increased global trade in machinery, the relevant CEN/CENELEC Technical Committees have undertaken publication of a series of related machinery safety standards. It has thus been necessary to develop rules for the preparation, drafting and presentation of such safety standards, supplementing the CEN/CENELEC Internal Regulations, Part 3, which sets out general principles and requirements for all European Standards.

This document provides those rules. It is intended for use by Technical Committees writing type-B and type-C standards in the field of safety of machinery (as defined in 3.2 and 3.3). It both makes use of, and refers to, the principles and concepts established in EN ISO 12100, and also takes into account, as far as possible, ISO/IEC Guide 51.

European Standards prepared according to this Guide are intended as a means for supporting European regulations, in particular, the "Machinery Directive" (Directive 2006/42/EC).

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1 Scope

This document presents rules for the drafting and presentation of European Standards dealing with machinery safety and their revisions, primarily to achieve consistency and acceptable quality of the various standards to be prepared.

It also gives requirements on the criteria for the selection of new work items and for procedures to prepare, produce or revise standards in an efficient and effective way.

This document gives requirements that are additional to the CEN/CENELEC Internal Regulations, Part 3, when this is necessary owing to the special requirements of machinery safety standards.

This document is primarily intended for the drafting of type-C standards. It is also applicable to the drafting of type-B standards; however, the foreseeable variation in the format of these standards prevents general application. When its requirements are specific to type-B standards, this is indicated.

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 ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

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CEN/CENELEC Internal Regulations, Part 3:2017, *Principles and rules for the structure and drafting of CEN and CENELEC documents (ISO/IEC Directives, Part 2:2016, modified)*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in the CEN/CENELEC Internal Regulations, Part 3 and EN ISO 12100, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
type-A standard
basic safety standard
standard giving basic concepts, principles for design and general aspects that can be applied to machinery

Note 1 to entry: See EN ISO 12100:2010, Introduction.

3.2
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

Note 1 to entry: See EN ISO 12100:2010, Introduction.

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3.2.1
type-B1 standard
type-B standard on particular safety aspects (for example, safety distances, surface temperature, noise)

Note 1 to entry: See EN ISO 12100:2010, Introduction.

3.2.2
type-B2 standard
type-B standard on safeguards (for example, two-hand control devices, interlocking devices, pressure-sensitive devices, guards)

Note 1 to entry: See EN ISO 12100:2010, Introduction.

3.3
type-C standard
machine safety standard
standard dealing with detailed safety requirements for a particular machine or group of machines

Note 1 to entry: See EN ISO 12100:2010, Introduction.

Note 2 to entry: The term "group of machines" means machines having a similar intended use and similar hazards, hazardous situations or hazardous events.

3.4
relevant hazard
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hazard which is identified as being present at or associated with the machine

Note 1 to entry: A relevant hazard is identified as the result of one step of the process described in EN ISO 12100:2010, Clause 5.

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Note 2 to entry: This term is included as basic terminology for type B- and type C-standards.

[SOURCE: EN ISO 12100:2010, 3.7]

3.5
significant hazard
hazard which has been identified as relevant and which requires specific action by the designer to eliminate or to reduce the risk according to the risk assessment

Note 1 to entry: This term is included as basic terminology for type B- and type C-standards.

[SOURCE: EN ISO 12100:2010, 3.8]

3.6
added value
more detailed description or specification of a requirement than in existing, less specific, documents, according to the structure prescribed in EN ISO 12100

Note 1 to entry: A type-B standard gives added value to the requirements of type-A standards, while a type-C standard gives added value to the requirements of type-A and type-B standards.

Note 2 to entry: The added value results from the design requirements applied to the product, by consensus of the interested parties, when the standard was prepared.

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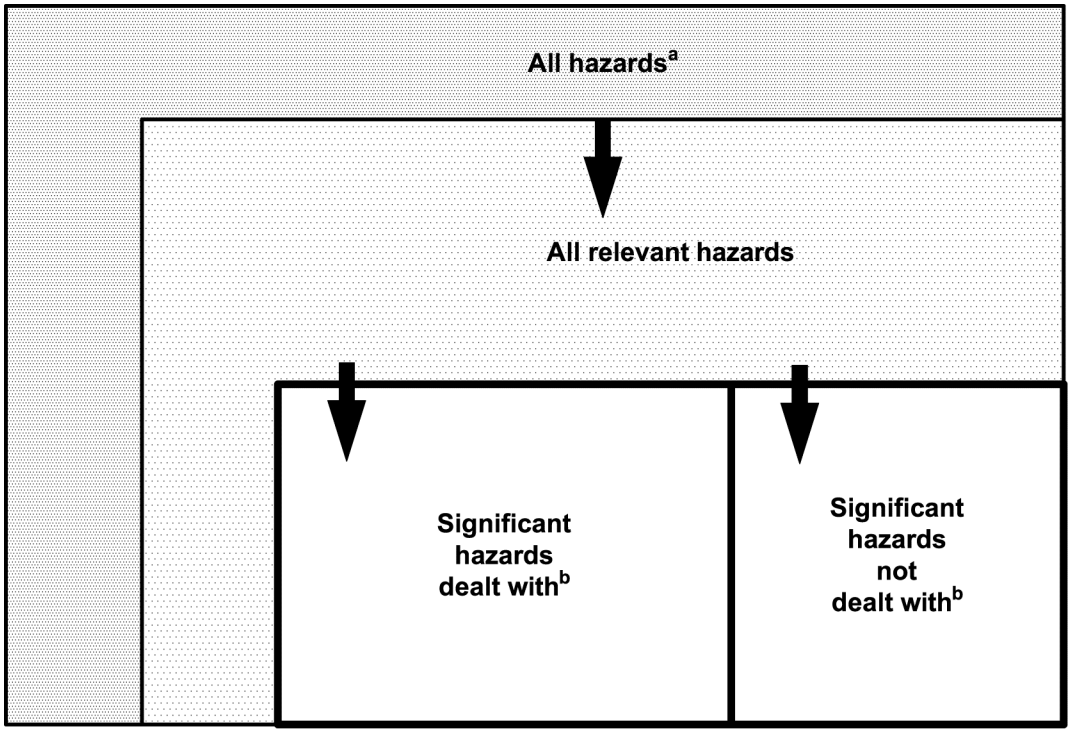

Key

[a] These hazards are listed in EN ISO 12100:2010, Annex B.

[b] See 6.10.3.1.

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Figure 1 — Dealing with hazards of a particular machine or group of machines

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4 General principles

4.1 All safety standards

The CEN/CENELEC Internal Regulations, Part 3 and EN ISO 12100 shall be used in conjunction with this document when preparing a new safety standard or revising an existing one.

A safety standard shall not contradict the basic concepts and general principles for design stated in a type-A standard, but can deviate from specific requirements. The overall purpose of the type-A standard is to provide manufacturers, designers, etc. with the strategy or framework necessary to achieve adequate risk reduction.[1)]

In general, the standards should not repeat or paraphrase the text of other reference standards; however, for better understanding of safety standards, it is acceptable to repeat a basic definition or concept, the scope of the standard, and/or a basic requirement given in EN ISO 12100.

NOTE For the purposes of this document, the terms "protective measure" (see EN ISO 12100:2010, 3.19) and "risk reduction measure" are synonymous and defined as any action or means used to eliminate hazards and/or reduce risks.

1) A definition of adequate risk reduction is given in EN ISO 12100:2010, 3.18.

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4.2 Type-B standards

They shall

a) deal either with one safety aspect (type-B1 standard) or a safeguard (type-B2 standard),

b) for type-B1 standards, define the basic principles of the safety topic and define by data and/or methodology how these can be applied to type-C standards, including, where relevant, the means of verification,

c) for type-B2 standards, give the performance requirements for the design and construction of the safeguard together with the means of verification, and

d) establish, as necessary and practicable, performance requirements (for example, types or performance levels) based on the application.

NOTE Possible reasons for establishing different performance requirements are:

— the severity of the possible harm from the considered hazard,

— the frequency and duration of the hazardous situation,

— the probability of occurrence of a hazardous event, and

— the possibility to avoid or limit the harm.

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4.3 Type-C standards

4.3.1 General

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Type-C standards should deal with all the significant hazards concerning one type of machine or one group of machines in one standard, as follows.

a) By reference to relevant and applicable type-B standards (see 6.7.4).

   1) Any type-B standard available as a draft standard (stage 40.20) may be used as a reference standard on the condition that the reference is dated.

   2) When type-B standards offer a choice between various solutions (for example, EN ISO 13857:2008 offers the alternative of Table 1 for low risks and Table 2 for high risks, for reaching over protective structures), the type-C standard shall state which solution(s) shall be used.

b) By reference to other standards (such as another type-C standard) where such significant hazards are adequately dealt with (see 4.4).

c) By specifying safety requirements in the standard, when reference to other standards is not possible or not sufficient and where risk assessment and priorities show this is required (see 5.4 to 5.6).

d) By dealing as far as possible with objectives rather than design details to minimize restrictions on design.

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4.3.2 Mandatory provisions

Type-C standards shall clearly establish the following:

— the scope (see 5.3 and 6.4);

— the significant hazard(s) (see 6.10.3.1);

— 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) (see 4.3.3, 5.7 and 6.7);

— the means of verifying the protective/risk reduction measures (see 5.8 and 6.8);

— information for use (see 6.9).

This means that, wherever possible, a type-C standard should deal with all significant hazards, hazardous situations or hazardous events identified as arising from the use of the machine. The justifiable exception to this comprehensive treatment of significant hazards, hazardous situations or hazardous events is where a type-C standard deals with one or more hazard(s) that are sufficiently important to require special treatment. Where a type-C standard deals with specific hazard(s), this should be indicated clearly in the title and scope (for example, *Safety of textile machines — Measurement of noise*). These standards may be produced as a series of parts forming a complete standard or as several discrete standards that could be combined at a subsequent revision.

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Where it is decided not to deal with all significant hazards, hazardous situations or hazardous events (for example, by lack of knowledge or because this will cause an unacceptable delay in the drafting of the standard) this shall be clearly indicated in the scope (see 6.4.2).

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A special case requiring careful consideration are those type-C standards dealing with "common requirements". Common requirements are defined as those requirements adding value to existing type-A or type-B standards that can be used to minimize or eliminate a risk occurring across the range of defined machines and that can be applied to all or most of these machines. Any machines not covered by a particular aspect of a common requirement should be identified as an exclusion. Too many exclusions from any common requirement would indicate that it is not common. The standard dealing with "common requirements" should not contain unspecific general principles.

4.3.3 Provisions with added value

It is a basic principle that type-C standards shall contain sufficient added value to the requirements of existing type-A and type-B standards. Added value will normally consist of a description of specific protective/risk reduction measure(s) dealing with the significant hazard, hazardous situation or hazardous event. However, this may also include reference to type-B standards or to other reference standards (see 6.7).

In the absence of a published type-B standard, common requirement standard or other reference standard, the following options are available:

— repeat in full the relevant sections of the draft type-B standard, draft common requirement standard, or any other suitable technical document;

— refer to the relevant section of a draft standard identified by number and date of issue;

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— refer to a technical specification produced by a professional organization - this can be done following the specific policy on normative references;

— seek help from the TC/WG (technical committee/working group) preparing the relevant type-B standard;

— provide self-drafted data/specification.

Dealing with a significant hazard by direct reference to the relevant subclauses of EN ISO 12100:2010, Clause 6 is only acceptable

a) where this reference gives sufficient requirements (particularly the *Information for use* clause, see 6.9), and

b) if the drafting of requirements would cause an unacceptable delay in the preparation of the standard.

However, in the case of b):

— it shall be stated in the scope that the hazard concerned is not dealt with in the current version of the standard;

— the TC shall make every effort to complete as soon as possible the drafting of the needed requirements.

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4.4 Need for a type-B standard

The creation of a type-B standard (see 6.10.2) shall be considered when requirements appropriate to more than one type of machine or one group of machines have been identified.

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4.5 Deviations in a type-C standard

When a type-C standard deviates from one of several aspects or requirements dealt with by a type-A or type-B standard, then the existing type-C standard shall take precedence over the type-A or type-B standard (see 6.3.2).

The reason for any deviation shall be carefully justified and kept by the responsible body in the standardization file or, in case of comments at draft stage (40.20), in the CRM (comments resolution meeting) file.

5 Principles to be considered before and during drafting process

5.1 General

Whereas the Machinery Directive 2006/42/EC states in its Annex I Essential Requirements, the general methodology for safety of machinery specified in EN ISO 12100 is based on the consideration of significant hazards basically without any specific reference to the Essential Requirements of Directive 2006/42/EC. Annex D gives as far as possible examples of significant hazards, hazardous situations, hazardous events and their relation to this Essential Requirements.

Before a standard is drafted, the need for it shall have been established, using the criteria given in 5.2.

NOTE The result of the procedure can provide information which can be used in the scope (see 5.3).

During the drafting process and the revision of a standard, the procedure given in 5.3 to 5.8 shall be carried out in the order indicated, in order to provide information that will allow an appropriate standard to be drafted.

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5.2 Determination of necessity for standardization and/or revision

The need for standardization and/or for the revision of an existing standard and the respective priorities shall be determined from the answers to the questions posed in 5.2 a) to 5.2 k), as applicable.

a) Is there a demand for European Standards arising from interested bodies (relevant market players such as regulatory bodies, manufacturers' associations, employees' or employers' associations, trade unions, accident prevention organizations or consumer organizations)?

b) Is there a need for a standard (for example, terminology) to support other safety standards?

c) Are there significant hazards, hazardous situations or hazardous events generating risk to the safety or health of persons? See EN ISO 12100:2010, 5.4.

d) If a new technology is to be standardized, is it sufficiently stable and established in the market and can it be therefore considered as state-of-the-art?

e) Is there, or will there be in the foreseeable future, a sufficient number of related machines or safeguards to justify the production of a standard?

f) Are there national standards/specifications giving specific requirements, either directly or by reference to another document, which can be barriers to international trade?

g) Are there proven professional, national or international documents or other documents available to give a reasonable expectation of positive and rapid results?

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h) Is there sufficient expertise, collective knowledge and experience for standardization?

i) Is there sufficient availability of experts (in principle from at least five members), project leader and support (secretariat, financial resources)?

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j) Is there sufficient feedback on the use of the existing safety standard?

k) Has the state of the art changed such that the existing safety standard has become at least partly obsolete?

5.3 Definition of scope

The precise limits of the machine or group of machines to be standardized shall be established and shall include the following (see EN ISO 12100:2010, 5.3):

a) definition of the machine or group of similar machines;

b) determination of the intended use of the machine (see EN ISO 12100:2010, 3.23);

c) determination of the space limits (see EN ISO 12100:2010, 5.3.3);

d) determination of the foreseeable "life limit", when applicable;

e) definition of the field of application.

Any machines and/or hazards not covered by the standard shall be clearly stated in the scope.

The various phases in the life of the machine to be dealt with in the standard shall be established. See EN ISO 12100:2010, 5.4.