
Safety of machinery — Rules for drafting and presentation of safety standards

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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO Guide 78 was prepared by ISO/TC 199, *Safety of machinery*, on behalf of the ISO Technical Management Board (TMB).

In addition to a number of editorial changes, the main revisions with respect to the previous edition (ISO Guide 78:2008) are as follows:

- updating of references and their associated requirements with regard to ISO 12100 and the ISO/IEC Directives, Part 2;
- addition of a further question to the checklist to be used to determine the necessity for standardization and/or revision [5.2, question e)];
- extension of the minimum statement to be given in the Introduction of type B- and type C- standards by a general notice concerning the document's relevance, in particular, for those stakeholder groups representing the market players with regard to machinery safety (6.3.2 and 6.3.3);
- ~~the~~ addition of the term “risk reduction measure” as a synonym to the term “protective measure” ~~2012~~ throughout the document;
- replacement of the term “optional element” by “conditional element” and “compulsory element” by “mandatory element” in accordance with the latest edition of the ISO/IEC Directives, Part 2;
- change in the title of Annex A;
- addition of Annex D concerning significant technical changes between a standard and its previous edition, to be added in those cases where the significant technical changes are not already stated in the Foreword.

Introduction

As a response to the increased global trade in machinery, the relevant ISO 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 ISO/IEC Directives, Part 2, which sets out general principles and requirements for all International Standards.

This Guide 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 ISO 12100, and also takes into account, as far as possible, ISO/IEC Guide 51.

International Standards prepared according to this Guide are intended as a means for supporting national or regional technical regulations (for example, legislation) for machinery safety according to the principles of UNECE Recommendation L. In order that machinery safety standards be able to support these technical regulations, the drafting of the standards can necessitate compliance with specific requirements additional to this Guide, in as far as any such additional requirements are accepted by ISO as not contradicting the content of this Guide. For example, in order to support European legislation, the *Guidelines for the implementation of the agreement on technical co-operation between ISO and CEN (Vienna Agreement)* are additionally applicable.

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Safety of machinery — Rules for drafting and presentation of safety standards

1 Scope

This Guide presents rules for the drafting and presentation of International 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 Guide gives requirements that are additional to the ISO/IEC Directives, Part 2, when this is necessary owing to the special requirements of machinery safety standards.

This Guide 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, 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.

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

ISO/IEC Directives, Part 2:2011, *Rules for the structure and drafting of International Standards*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in the ISO/IEC Directives, Part 2, and ISO 12100, and the following apply.

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 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 ISO 12100:2010, *Introduction*.

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 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 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 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

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 ISO 12100:2010, Clause 5.

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

[SOURCE: ISO 12100:2010, 3.7]

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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 review

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

[SOURCE: ISO 12100:2010, 3.8]

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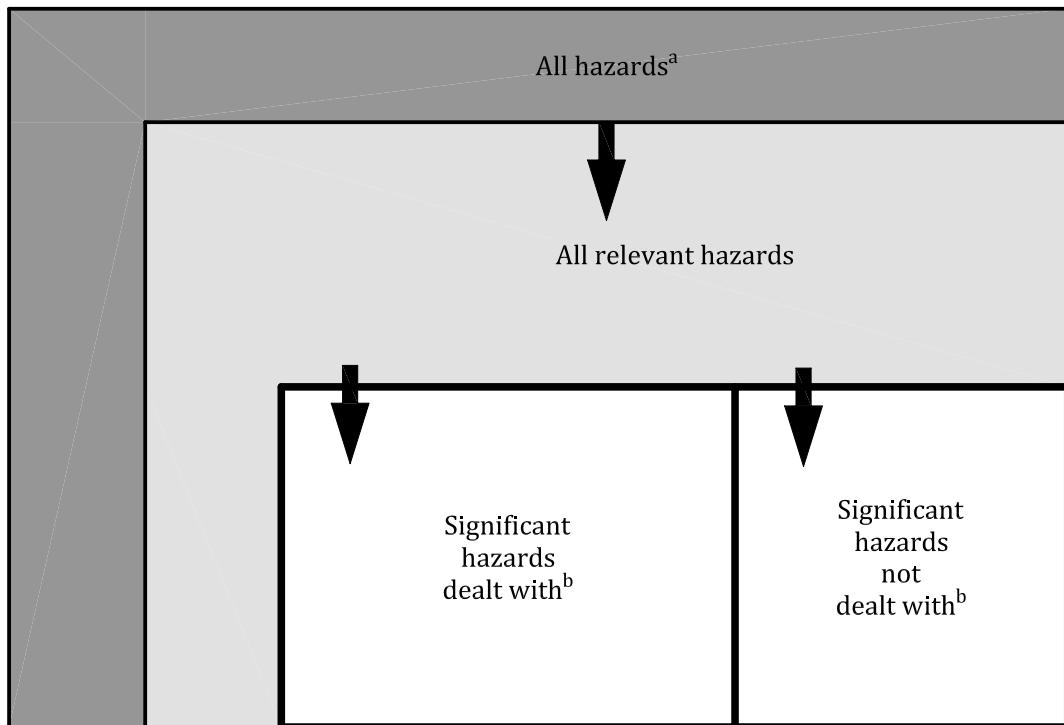
3.6

added value

more detailed description or specification of a requirement than in existing, less specific, documents, according to the structure prescribed in 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.



^a These hazards are listed in ISO 12100:2010, Annex B.

^b See 6.10.2.2.

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

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4 General principles

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The ISO/IEC Directives, Part 2 and ISO 12100 shall be used in conjunction with this Guide 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 reduction¹⁾

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 ISO 12100.

NOTE For the purposes of this document, the terms “protective measure” (see 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.

For regional standardization projects, the internal regulations of regional standardization bodies should be taken into consideration (e.g. CEN/CENELEC Internal Regulations, Part 2).

4.2 Type-B standards

They shall

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

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

- 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.

4.3 Type-C standards

4.3.1 General

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).

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.

When type-B standards offer a choice between various solutions (for example, 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.

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 6.10.2.2);
- the requirements prescribing protective/risk reduction measures that add value to relevant subclauses of 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