

PD ISO GUIDE 78:2012



BSI Standards Publication

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

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National foreword

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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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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General principles	3
4.1 All safety standards.....	3
4.2 Type-B standards.....	3
4.3 Type-C standards.....	4
4.4 Need for a type-B standard.....	6
4.5 Deviations in a type-C standard.....	6
5 Principles to be considered before and during drafting process	6
5.1 General.....	6
5.2 Determination of necessity for standardization and/or revision.....	6
5.3 Definition of scope.....	7
5.4 Identification of hazards, hazardous situations or hazardous events.....	7
5.5 Estimation and evaluation of risk(s) generated by hazard(s).....	7
5.6 Identification of risk reduction objectives.....	8
5.7 Determination of safety requirements and/or protective/risk reduction measures for eliminating hazards and/or limiting risks.....	8
5.8 Verification of compliance with safety requirements and/or protective/risk reduction measures.....	8
6 Format of a safety standard	9
6.1 General.....	9
6.2 Foreword	9
6.3 Introduction	9
6.4 Scope	10
6.5 Normative references	11
6.6 Terms and definitions [symbols and abbreviated terms]	11
6.7 Safety requirements and/or protective/risk reduction measures	12
6.8 Verification of the safety requirements and/or protective/risk reduction measures	13
6.9 Information for use	14
6.10 Annexes.....	15
Annex A (normative) Procedure to be followed if type-B standards do not exist	16
Annex B (informative) Model format of a type-C International Standard	17
Bibliography	21

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);
- addition of the term "risk reduction measure" as a synonym to the term "protective measure" 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.

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*

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]

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: ISO 12100:2010, 3.8]

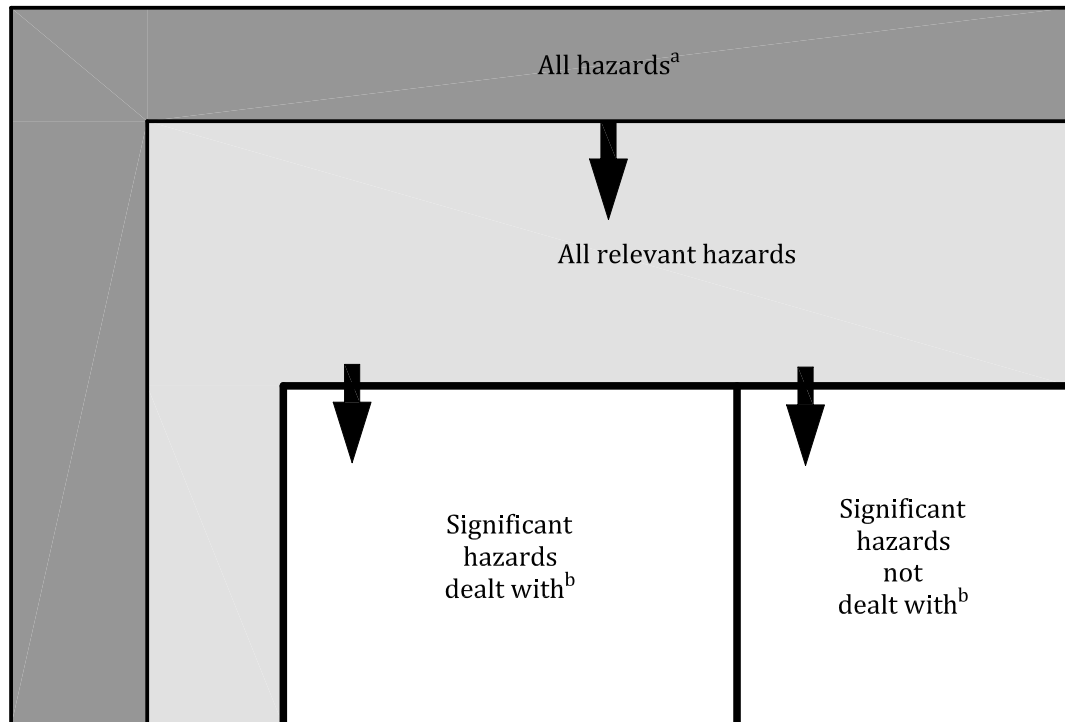
3.6

added value

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

4 General principles

4.1 All safety standards

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

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.

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).

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;
- 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/SC/WG (technical committee/subcommittee/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 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.

4.4 Need for a type-B standard

The creation of a type-B standard (see 6.10.1) shall be considered when requirements appropriate to more than one type of machine or one group of machines have been identified.

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

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.

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 l), as applicable.

- a) Is there a demand for International 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) Can the national implementation of an International Standard be facilitated in the framework of existing agreements between ISO and regional standards development organizations (SDO)?

EXAMPLE The Vienna Agreement between ISO and CEN.

- c) Is there a need for a standard (for example, terminology) to support other safety standards?
- d) Are there significant hazards, hazardous situations or hazardous events generating risk to the safety or health of persons? See ISO 12100:2010, 5.4.
- e) 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?
- f) 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?
- g) Are there national standards/specifications giving specific requirements, either directly or by reference to another document, which can be barriers to international trade?
- h) Are there proven professional, national or international documents or other documents available to give a reasonable expectation of positive and rapid results?
- i) Is there sufficient expertise, collective knowledge and experience for standardization?

- j) Is there sufficient availability of experts (in principle from at least five members), project leader and support (secretariat, financial resources)?
- k) Is there sufficient feedback on the use of the existing safety standard?
- l) 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 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 ISO 12100:2010, 3.23);
- c) determination of the space limits (see 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 ISO 12100:2010, 5.4.

5.4 Identification of hazards, hazardous situations or hazardous events

Considering ISO 12100:2010, especially its Annex B, as guidance:

- a) identify the hazards that the machine is likely to generate;
- b) identify the various hazardous situations for each hazard, taking into account the different operating modes of the machine and the different intervention procedures for the operators as well as the reasonably foreseeable misuse;
- c) identify the hazardous events which can lead to harm.

Particular attention should be paid to the fact that the list given in ISO 12100:2010, Annex B, is not exhaustive, especially in as far as it concerns the hazardous situations.

5.5 Estimation and evaluation of risk(s) generated by hazard(s)

5.5.1 Risk estimation

The risk shall be estimated by combining the following steps.

- a) Estimate the severity of the possible harm for the hazard under consideration.
- b) Estimate the probability of occurrence of that harm which is a function of
 - the exposure of persons to the hazard (for example, frequency, duration),
 - the probability of occurrence of a hazardous event,
 - the technical and human possibilities to avoid or limit the harm.

5.5.2 Risk evaluation

After the risk estimation, a risk evaluation shall be carried out to determine:

- if risk reduction is required;
- whether the risk reduction objectives have been achieved.

5.6 Identification of risk reduction objectives

The following steps shall be carried out using the result of the procedures according to 5.4 and 5.5:

- a) define risk reduction objectives in terms of reduction of the severity of the harm and/or the probability of that harm;
- b) identify the relevant clauses of ISO 12100 applicable for each significant hazard, hazardous situation or hazardous event,
- c) determine for each significant hazard whether it is sufficient to refer to other standards for safety requirements and/or protective/risk reduction measures, or whether there is a need for specific safety requirements and/or protective/risk reduction measures.

The entire above process should preferably be recorded and kept by the responsible body in the standardization file, for example, in a table.

5.7 Determination of safety requirements and/or protective/risk reduction measures for eliminating hazards and/or limiting risks

The risk reduction process according to 5.6 shall be carried out in the following order (three-step method as described in ISO 12100:2010, Figure 1):

- a) by inherently safe design (see ISO 12100:2010, 6.2);
- b) by safeguarding (see ISO 12100:2010, 6.3);
- c) by information for use (see ISO 12100:2010, 6.4).

The principle — for the various phases of the “life” of the machine — is to eliminate the hazard or reduce the risk as much as possible by inherently safe design without relying on guards or other methods of safeguarding. If this is not practicable, other means should be defined to ensure safety.

NOTE For the drafting of safety requirements and for protective/risk reduction measures for eliminating hazards and/or limiting risks, see 6.7.3.

5.8 Verification of compliance with safety requirements and/or protective/risk reduction measures

For each safety requirement and/or protective/risk reduction measure identified and determined in accordance with 5.6 and 5.7 (except if it is self-evident), a method of verification shall be established

- a) by testing (for example, functional test of a two-hand control, strength test of a guard, stability test),
- b) by measurement (for example, measurement of noise emission),
- c) by calculation (for example, position of the centre of gravity), or
- d) by any other method of verification, if testing and calculation are not adequate (for example, by visual inspection).

It shall be determined

- whether adequate testing/calculating methods (or other methods of verification) are available in another standard, or
- whether it is necessary to draft such methods.

NOTE For the drafting of requirements for verification, see 6.8.

6 Format of a safety standard

6.1 General

The format of a safety standard shall comply with the ISO/IEC Directives, Part 2 (see model format given in Annex B of this Guide) and the specific requirements for safety standards on machinery given in 6.2 to 6.10.

The model format given in Annex B is intended to help standards developers and to provide for a consistent presentation for all type-C standards according to Clause 6.

6.2 Foreword

The Foreword is an unnumbered mandatory element. It shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.1.3.

If relevant, the significant technical changes in relation to the previous edition shall be stated.

6.3 Introduction

6.3.1 Although the Introduction is an conditional element according to ISO/IEC Directives, Part 2, it is an unnumbered mandatory element in machinery safety standards. It shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.1.4.

When a subject of a type-B standard is covered by ISO 12100, reference shall be made to the relevant clause of ISO 12100.

6.3.2 At least the following statement shall be inserted in each type-C standard:

“This document is a type-C standard as stated in ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

- *machine manufacturers (small, medium and large enterprises);*
- *health and safety bodies (regulators, accident prevention organisations, market surveillance etc.)*

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

- *machine users/employers (small, medium and large enterprises);*
- *machine users/employees (e.g. trade unions, organizations for people with special needs);*
- *service providers, e. g. for maintenance (small, medium and large enterprises);*
- *consumers (in case of machinery intended for use by consumers).*

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

The machinery concerned and the extent to which hazards, hazardous situations or hazardous events are covered are indicated in the Scope of this document.

When requirements of this type-C standard are different from those which are stated in type-A or type-B standards, the requirements of this type-C standard take precedence over the requirements of the other standards for machines that have been designed and built according to the requirements of this type-C standard."

6.3.3 At least the following statement shall be inserted in each type-B standard:

"This document is a type-B standard as stated in ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

- *machine manufacturers (small, medium and large enterprises);*
- *health and safety bodies (regulators, accident prevention organisations, market surveillance etc.);*

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

- *machine users/employers (small, medium and large enterprises);*
- *machine users/employees (e.g. trade unions, organizations for people with special needs);*
- *service providers, e. g. for maintenance (small, medium and large enterprises);*
- *consumers (in case of machinery intended for use by consumers).*

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

In addition, this document is intended for standardization bodies elaborating type-C standards.

The requirements of this document can be supplemented or modified by a type-C standard.

For machines which are covered by the scope of a type-C standard and which have been designed and built according to the requirements of that standard, the requirements of that type-C standard take precedence."

6.4 Scope

6.4.1 The Scope is a mandatory element. It shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.2.1, and shall be drafted using the result of the procedure according to 5.3 of this Guide. It shall be numbered as Clause 1.

6.4.2 The Scope shall indicate, when applicable, the following:

- a) the limits of the machine, preferably by physical characteristics and taking into account aspects such as intended use as well as reasonably foreseeable misuse (see ISO 12100:2010, 3.23, 3.24 and 5.3);
- b) whether protective/risk reduction measures dealt with in the standard account for all or only some of the significant hazards.

This applies to hazards arising during the various phases of the "life" of the machine as described in ISO 12100:2010, 5.4. The significant hazards dealt with in the standard (see 3.5 and Figure 1) shall be mentioned, as appropriate,

- 1) by listing them in the Scope, when they are few, or
- 2) by a statement in the Scope that they are dealt with in the standard (see 6.10.2.2).

In the case of 2), above, those significant hazards not dealt with shall also be mentioned in the Scope.

- c) whether additional designed-in protective/risk reduction measures are taken into consideration for certain types of machines (e.g. hygiene requirements for food-processing machinery).

The scope shall indicate that the standard is not applicable to machinery or machinery components which are manufactured before the date of publication of the standard. As a minimum requirement, the following statement shall be inserted in Scope:

“This document is not applicable to [<precisely state the machinery or machinery components here>] manufactured before the date of its publication.”

6.5 Normative references

This clause is a mandatory element. It shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.2.2, and shall be numbered as Clause 2.

- a) Only documents (standards) to which normative reference is made in the text of the safety standard shall be listed in this clause. Therefore, at least the following shall always be referenced:

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

Normative references in the text of a standard need to be made using the verbal form “shall”, signifying a requirement.

EXAMPLE “This shall be in accordance with ISO 12345-201x, Clause 6.”

When a reference is made only for information, it shall be introduced by the phrase “see ISO ...” and the standard referenced shall be listed, not in this clause, but in a bibliography (see 6.10.3).

This Guide, even though applicable to the drafting and presentation of the safety standard, shall not be given as a normative reference.

- b) Reference to standardization documents shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.6.7.5, and should be dated in accordance with 6.6.7.5.3 of those Directives.

When a normative reference, e.g. to an ISO/IEC International Standard, is required, the safety standard shall

- either reproduce the text of the normatively referenced document, in the main body of the safety standard or in a normative annex, clearly indicating its origin by “(extract from ISO/IEC ...)”, or
- make dated reference to a specific clause(s) or subclause(s) of the referenced document (without reproducing it), or
- make dated (preferably) or undated reference to the whole of the normatively referenced document, if applicable — for example, in cases where the subject of the normatively referenced document is an applicable test method.

In principle, the referenced documents shall be documents published by ISO and/or IEC. Documents published by other bodies may be referred to in a normative manner provided that the criteria listed in the ISO/IEC Directives, Part 2:2011, 6.2.2, are met (see 4.3.3).

NOTE For regional standardization projects, normative reference can be made to publications of those standardization bodies (e.g. CEN/CENELEC refers to European Standards).

6.6 Terms and definitions [symbols and abbreviated terms]

6.6.1 This clause is a mandatory element. It shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.3.1, 6.3.2 and Annex D, and shall be numbered as Clause 3.

6.6.2 The terms and definitions given in ISO 12100 shall be used. Therefore, at least the following statement shall be given as the first, introductory, paragraph to the terms and definitions clause in each type-B and type-C standard:

“For the purposes of this document, the terms and definitions given in ISO 12100 apply.”

6.6.3 The terms and definitions given in relevant type-B and type-C standards should be used as far as applicable. For new terms and definitions, the association of the word “safety” with the name of a component or a device should be avoided. A recommended approach is to replace, where possible, the word “safety” by an indication of the objective or characteristic.

EXAMPLE “Active optoelectronic protective device” instead of “safety light curtain”.

6.6.4 When there is need to define symbols or abbreviations (especially for test methods), this conditional element shall be included in accordance with the ISO/IEC Directives, Part 2:2011, 6.3.2.

6.7 Safety requirements and/or protective/risk reduction measures

6.7.1 This clause is a mandatory element. It shall be in accordance with ISO/IEC Directives, Part 2:2011, 6.3.3.

As a minimum requirement, the following statement shall appear in this clause in each type-C standard:

“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 ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document.”

This clause should be structured based on the result from 5.6, except for *Information for use*-related issues, which shall be dealt with in a specific clause (see 6.9).

6.7.2 All safety standards shall contain such a clause, stating the safety requirements and/or protective/risk reduction measures to be met to reduce the effect of all hazards determined in accordance with 5.6 b) and c), and which are to be mentioned in the standard. The safety requirements and protective/risk reduction measures shall be defined in accordance with 5.7.

Protective/risk reduction measures to avoid or minimize harm shall be defined, directly or by reference to another standard and/or to the *Information for use* clause, for all the significant hazards dealt with.

6.7.3 The safety requirements and/or protective/risk reduction measures specified shall be expressed in terms of verifiable performance with regard to safety, using performance characteristics (parameters), together with their values, rather than merely descriptive characteristics.

To minimize restraint on design, safety standards should specify requirements in terms of the objective to be met and then define the means for achieving it, such as by giving examples or defining test specifications. The safety requirements and/or protective/risk reduction measures shall be sufficiently precise to allow verifications.

NOTE In many type-C standards, it can be necessary to define acceptable means of achieving the objective, such as particular types of protective/risk reduction measures, in order to ensure that the safety requirements and/or protective/risk reduction measures will be adequate, or to give examples of well-known and proven solutions for reaching and maintaining the level of safety.

More than one solution for reducing the risk may be given if allowing the same objective of risk reduction to be reached.

Measures in terms of objectives, and measures defined by data, limits, results and requirements giving the practical means for achieving the objectives, may be given together or in separate subclauses.

6.7.4 Where requirements contained in relevant type-A or type-B standards are used, reference shall be made to them in accordance with 4.3.

Where type-B standards are not yet available and general requirements (valid for several types of machines) are included in the type-C standard, these requirements shall preferably be included in normative annexes of the type-C standard (see Annex A).

When measures given in another standard are used, specific reference shall be made to that standard.

6.7.5 Type-B standards shall give added value (more specific and/or more detailed requirements) to the requirements of type-A standards and type-C standards shall give added value to the requirements of type-A and type-B standards. See 4.3.3 for more details on *added value*.

6.7.6 Protective/risk reduction measures shall be laid down in precise and clearly understandable terms such that they

- a) ensure that the objective is met,
- b) are technically correct and precise,
- c) are unequivocal as to whether a measure is optional or mandatory, using verbal forms in accordance with the ISO/IEC Directives, Part 2:2011, Annex H, and
- d) can be verified in accordance with 5.8 and 6.8.

Subjective terms or words should not be used unless they are defined in the standard or are consistent with the method of verification.

6.8 Verification of the safety requirements and/or protective/risk reduction measures

6.8.1 Each safety standard shall contain, either in a separate clause or together with the relevant measures, the method to be used to verify conformity with the measures given in accordance with 6.7, unless the methods for verification are self-evident.

The standard shall not contain any instruction on *who* has to carry out the verification (see ISO/IEC Directives, Part 2:2011, 6.7).

The method of verification shall be related to the nature of the safety requirements and/or protective/risk reduction measures, and shall follow the procedure according to 5.8.

If the methods of verification are to be put in a separate clause, the order of presentation should be the same as that of the safety requirements and/or protective/risk reduction measures and there shall be a link between the two.

Priority should be given to the use of existing and standardized methods of verification (as defined in standardization documents) by reference.

When drafting a new method of verification which is not specific to the machine itself (e.g. measurement of dust suction efficiency in a standard on belt sanding machines), this method shall appear either in a normative annex (see 6.10.1), or in a separate part of the standard, or even in a separate standard, so that reference can be made to it in another safety standard.

6.8.2 The wording of methods of verification shall be sufficiently precise to ensure reproducible results. The structure relating to test methods given in the ISO/IEC Directives, Part 2:2011, 6.3.5, and, to sampling, in the ISO/IEC Directives, Part 2:2011, 6.3.4, shall be followed. If there are several test methods

for one safety requirement and/or protective/risk reduction measure, the test method(s) to be used shall be indicated.

Calculation methods, for example, could be appropriate when only destructive testing is possible and for special types of safety requirements and/or protective/risk reduction measures, such as those concerning stability.

Where testing and calculation methods are not practicable for technical reasons or would cause excessive costs compared to the risk reduction that would be achieved, other methods can be more appropriate. Verification may be by inspection, or by examination when sufficiently precise (e.g. inspection to check the colour of warning signs and marking).

6.9 Information for use

6.9.1 General

This clause is a mandatory element and shall be numbered. The safety standard shall make reference to ISO 12100:2010, 6.4, and shall contain additional requirements about the information for use for machines within the scope of the standard.

NOTE As these safety standards deal with machinery design, the *Information for use* clause is the only one in which the standards developer can provide instructions on installation and use of the machinery in relation to residual risks.

6.9.2 Signals and warning devices

Where safety signals or pictograms are fitted to the machine, they shall be described in this clause. The safety signals or pictograms already defined in relevant standardization documents should be used (e.g. IEC 61310).

6.9.3 Accompanying documents (in particular: instruction handbook)

6.9.3.1 General

As the instructions are a mandatory part of the machine, each type-C standard shall contain the requirement that the manufacturer provide an instruction handbook. The type-C standard shall make reference to ISO 12100:2010, 6.4.5, and shall give specific information (e.g. intended use, reasonably foreseeable misuse, training, systems of work and personal protective equipment) to be included in the handbook, compiled from the results of the procedures according to 5.2 to 5.7 of this Guide.

NOTE The instructions are normally the only means available to the user providing information on the use of the machine including maintenance interventions.

6.9.3.2 Noise

If noise is applicable, the requirements concerning both noise emission measurement and declaration shall be specified in a normative annex or by reference to a specific standard (Noise Test Code).

6.9.3.3 Vibration

If vibration is applicable, the requirements concerning both vibration emission measurement and declaration shall be specified in a normative annex or by reference to a specific standard (Vibration Test Code).

6.9.4 Marking

All safety standards shall require at least the marking as specified in ISO 12100:2010, 6.4.4.

6.10 Annexes

6.10.1 Normative annexes

When it is foreseeable that certain parts of the safety standard could be applicable to other documents (e.g. test methods), these parts shall be included as normative annexes.

A normative annex shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.3.8.

NOTE This form of presentation can assist referencing by other documents and allows easier conversion of those parts into a type-B standard at a later date (see 4.4).

6.10.2 Informative annexes

6.10.2.1 General

Informative annexes shall be in accordance with the ISO/IEC Directives, Part 2:2011, 6.4.1.

6.10.2.2 *List of significant hazards*

When 6.4.2 b) 2) applies, the list of significant hazards shall be given in an informative annex, titled *List of significant hazards*.

This annex shall present, for defined danger zones, all the significant hazards, significant hazardous situations (circumstances that lead to exposure of a person to these hazards) and significant hazardous events identified during the risk assessment and covered by this standard. It should also refer to the particular subclause of the *Safety requirements and/or protective/risk reduction measures* clause (see 6.7) and, if appropriate, that of the *Information for use* clause (see 6.9) in which the hazard, hazardous situation or hazardous event is dealt with.

The list of significant hazards, hazardous situations or hazardous events should preferably follow the order given in ISO 12100:2010, Annex B, but not reproduce it. It is not appropriate to list all possible hazards, hazardous situations or hazardous events as described in ISO 12100, indicating those dealt with and those not dealt with.

6.10.2.3 *Significant technical changes between this standard and the previous edition*

This annex shall be drafted only in cases where the significant technical changes from one edition to the next are not stated in the Foreword of the revised standard. See 6.2.

6.10.3 Bibliography

Standards or documents that give only information, or which have served as references in the preparation of the standard, shall appear in a Bibliography in accordance with the ISO/IEC Directives, Part 2:2011, 6.4.2, and not in the Normative references clause.

Documents that are not publicly available shall not be referenced.

Annex A **(normative)**

Procedure to be followed if type-B standards do not exist

Where possible, type-B standards should be prepared first, so that reference can be made to them when preparing type-C standards for specific machines. When a type-C standard needs to use type-B requirements and such standards do not exist, the type-C standard shall give those requirements in annexes. Where this method is adopted, the annexes can be withdrawn when revising the standard and the references in the standard changed to the relevant type-B standard.

In order to facilitate this approach, the following procedure shall be used.

- a) All type-C working groups shall be able to obtain information about the on-going work in type-A and type-B working groups and of all existing type-A and type-B standards including drafts.
- b) If type-C working groups need to formulate type-B requirements, due to a lack of existing type-B standards, the relevant type-B working groups and/or relevant technical committees on safety of machinery shall be involved.
- c) Where applicable, type-C working-group experts should participate in relevant type-B working groups and should influence the creation and content of type-B standards.
- d) Type-B requirements in type-C standards shall be placed in annexes.

Annex B (informative)

Model format of a type-C International Standard

Contents	Sommaire
Page	Page
Fore-word	Avant-propos
Introduction	Introduction
1 Scope	1 Domaine d'application
2 Normative references	2 Références normatives
3 Terms and definitions	3 Termes et définitions
4 Safety requirements and/or protective/risk reduction measures	4 Prescriptions de sécurité et/ou mesures de prévention/réduction du risque
5 Verification of safety requirements and/or protective/risk reduction measures	5 Vérification des exigences de sécurité et/ou des mesures de prévention/réduction du risque
6 Information for use	6 Informations pour l'utilisation
<i>Additional clauses, if needed</i>	<i>Articles supplémentaires, s'il y a lieu</i>
Annex A (normative)	Annexe A (normative)
Annex B (informative)	Annexe B (informative)
Annex C (informative) List of significant hazards	Annexe C (informative) Liste des phénomènes dangereux significatifs
Annex D (informative) Significant technical changes between this standard and the previous edition	Annexe D (informative) Modifications techniques significatives entre la présente norme et l'édition précédente
Bibliography	Bibliographie
Foreword	Avant-propos
[See ISO/IEC Directives, Part 2:2011, 6.1.3.]	[Voir les Directives ISO/CEI, Partie 2:2011, 6.1.3.]

Introduction

This document is a type-C standard as stated in ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

- machine manufacturers (small, medium and large enterprises);
- health and safety bodies (regulators, accident prevention organisations, market surveillance, etc.).

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

- machine users/employers (small, medium and large enterprises);
- machine users/employees (e.g. trade unions, organizations for people with special needs);
- service providers, e.g. for maintenance (small, medium and large enterprises);
- consumers (in the case of machinery intended for use by consumers)

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

The machinery concerned and the extent to which hazards, hazardous situations or hazardous events are covered are indicated in the Scope of this document.

When requirements of this type-C standard are different from those which are stated in type-A or -B standards, the requirements of this type-C standard take precedence over the requirements of the other standards for machines that have been designed and built according to the requirements of this type-C standard.

Introduction

Le présent document est une norme de type C tel que mentionné dans l'ISO 12100.

Le présent document concerne, en particulier, les groupes de parties prenantes suivants, représentant les acteurs du marché dans le domaine de la sécurité des machines:

- fabricants de machines (petites, moyennes et grandes entreprises);
- organismes de santé et de sécurité (autorités réglementaires, organismes de prévention des risques professionnels, surveillance du marché, etc.).

D'autres partenaires peuvent être concernées par le niveau de sécurité des machines atteint au moyen du document par les groupes de parties prenantes mentionnés ci-dessus.

- utilisateurs de machines/employeurs (petites, moyennes et grandes entreprises);
- utilisateurs de machines/salariés (par exemple syndicats de salariés, organisations représentant des personnes ayant des besoins particuliers);
- prestataires de services, par exemple sociétés de maintenance (petites, moyennes et grandes entreprises);
- consommateurs (dans le cas de machines destinées à être utilisées par des consommateurs).

Les groupes de parties prenantes mentionnés ci-dessus ont eu la possibilité de participer à l'élaboration du présent document.

Les machines concernées et l'étendue des phénomènes dangereux, situations dangereuses ou événements dangereux couverts sont indiqués dans le domaine d'application du présent document.

Lorsque des exigences de la présente norme de type C sont différentes de celles énoncées dans les normes de type A ou les normes de type B, les exigences de la présente norme de type C prévalent sur celles des autres normes pour les machines ayant été conçues et fabriquées conformément aux exigences de la présente norme de type C.

1 Scope

This document specifies...

It is applicable to...

and/or

It is not applicable to...

This document deals with all significant hazards, hazardous situations or hazardous events relevant to... machinery, when it is used as intended and under conditions of misuse which are reasonably foreseeable by the manufacturer.

[or]

This document deals with all significant hazards, hazardous situations or hazardous events with the exception of ... relevant to ... machinery, when it is used as intended and under conditions of misuse which are reasonably foreseeable by the manufacturer.

[or]

This document deals with the following significant hazards, hazardous situations or hazardous events relevant to.... machinery, when it is used as intended and under conditions of misuse which are reasonably foreseeable by the manufacturer:

— [details]

—

— .

This document is not applicable to ...precise the machinery or machinery components here ... manufactured before the date of its publication.”

1 Domaine d'application

Le présent document spécifie...

Il s'applique aux

et/ou

Il ne s'applique pas aux

Le présent document traite tous les phénomènes dangereux, situations dangereuses ou événements dangereux significatifs qui sont pertinents pour les machines ..., lorsqu'elles sont utilisées normalement et lorsqu'elles font l'objet d'un mauvais usage raisonnablement prévisible par le fabricant.

[ou]

Le présent document traite tous les phénomènes dangereux, situations dangereuses ou événements dangereux significatifs, à l'exception de ..., qui sont pertinents pour les machines ..., lorsqu'elles sont utilisées normalement et lorsqu'elles font l'objet d'un mauvais usage raisonnablement prévisible par le fabricant.

[ou]

Le présent document traite les phénomènes dangereux, situations dangereuses ou événements dangereux significatifs suivants qui sont pertinents pour les machines ..., lorsqu'elles sont utilisées normalement et lorsqu'elles font l'objet d'un mauvais usage raisonnablement prévisible par le fabricant:

— [préciser]

—

— .

Ce document ne s'applique pas aux ...préciser les machines ou composants de machine ... fabriqués avant sa date de publication.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12100 [and ...] [and the following] apply.

4 Safety requirements and/or protective/risk reduction measures

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 ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document.

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

6 Information for use

Annex A
(normative)

Annex B
(informative)

Annex C
(informative)

List of significant hazards

Annex D
(informative)

Significant technical changes between this standard and the previous edition

[Only in cases where the significant technical changes are not stated in the Foreword.]

Bibliography

2 Références normatives

Les documents suivants, en tout ou partie, font l'objet d'une référence normative dans le présent document et sont indispensables pour son application. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document référencé (y compris les éventuels amendements) s'applique.

ISO 12100:2010, *Sécurité des machines — Principes généraux de conception — Appréciation du risque et réduction du risque*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions donnés dans l'ISO 12100 [et...] [ainsi que les suivants] s'appliquent.

4 Exigences de sécurité et/ou mesures de prévention/réduction du risque

Les machines doivent être conformes aux exigences de sécurité et/ou aux mesures de prévention/réduction du risque du présent article.

De plus, les machines doivent être conçues suivant les principes de l'ISO 12100:2010 pour les phénomènes dangereux pertinents mais non significatifs qui ne sont pas traités dans le présent document.

5 Vérification des exigences de sécurité et/ou des mesures de prévention/réduction du risque

6 Informations pour l'utilisation

Annexe A
(normative)

Annexe B
(informative)

Annexe C
(informative)

Liste des phénomènes dangereux significatifs

Annexe D
(informative)

Modifications techniques significatives entre la présente norme et l'édition précédente

[Uniquement dans le cas où ces modifications techniques significatives ne sont pas signalées dans l'avant-propos.]

Bibliographie

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