TECHNICAL REPORT

ISO/TR 22100-1

First edition
2015-05-15

Safety of machinery — Relationship with ISO 12100 —

Part 1: How ISO 12100 relates to type-B and type-C standards

Sécurité des machines — Relation avec l'ISO 12100 —

Partie 1: Relation entre l'ISO 12100 et les normes de type B et type C

Reference number
ISO/TR 22100-1:2015(E)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 199, Safety *of machinery*.

ISO/TR 22100 consists of the following parts, under the general title *Safety of machinery — Relationship with ISO 12100*:

— *Part 1: How ISO 12100 relates to type-B and type-C standards*

— *Part 2: How ISO 12100 relates to ISO 13849-1*

The following parts are under preparation:

— *Part 3: Implementation of ergonomic principles in safety standards*

Introduction

This Technical Report is written to assist the designer/manufacturer of machinery and related components in understanding and navigating the different types of ISO machinery safety standards. It identifies the different kinds of documents in ISO (see Table B.1) and explains the type-A, type-B and type-C structure of machinery safety standards and their interrelationship with regard to the practical design of machinery subjected to adequate risk reduction to achieve tolerable risk.

This part of ISO/TR 22100 might be helpful for standard writing committees (type-B and type-C), too. However, it does not provide specification of the general content that is expected to be included in the different types of machinery safety standards. This specification is given in ISO Guide 78.

This part of ISO/TR 22100 includes a visual representation of many ISO machinery safety standards to assist in improving understanding of the interrelationships and linkages between these documents.

Safety of machinery — Relationship with ISO 12100 —

Part 1:
How ISO 12100 relates to type-B and type-C standards

1 Scope

This part of ISO/TR 22100 provides assistance to the designer/manufacturer of machinery and related components as to how the system of existing type-A, type-B and type-C machinery safety standards should be applied in order to design a machine to achieve a level of tolerable risk by adequate risk reduction.

It explains the general principles of ISO 12100 and how this type-A standard should be used for practical cases in conjunction with type-B and type-C machinery safety standards.

This part of ISO/TR 22100 provides assistance to standards writing committees on how ISO 12100 and type-B and type-C standards relate and explains their function in the risk assessment and risk reduction process according to ISO 12100.

It includes an overview of existing categories of type-B standards to assist standards readers and writers to navigate the many standards.

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 the following apply.

3.1
adequate risk reduction
risk reduction that is at least in accordance with legal requirements, taking into consideration the current state of the art

[SOURCE: ISO 12100:2010, 3.18, modified — Note 1 to entry not taken over.]

3.2
tolerable risk
level of risk that is accepted in a given context based on the current values of society

Note 1 to entry: The terms “acceptable risk” and “tolerable risk” are considered to be synonymous.

[SOURCE: ISO/IEC Guide 51:2014, 3.15, modified — Wording “For the purpose of this Guide” deleted from Note 1 to entry.]

4 General structure of the system of machinery safety standards

Standards on safety of machinery have the following structure:

— **type-A standards** (basic safety standards) giving basic concepts, principles for design, and general aspects that can be applied to machinery;

— **type-B standards** (generic safety standards) dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery;

— **type-C standards** (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.

As shown in Figure 1, ISO 12100 is the type-A standard specifying the general principles for safety of machinery and applies to all machinery.

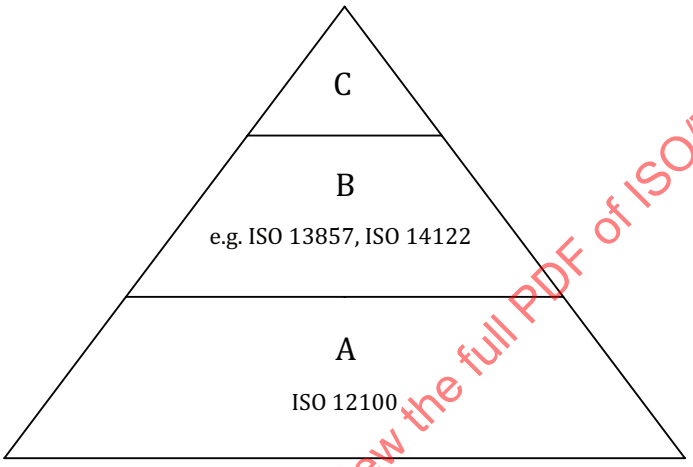


Figure 1 — General structure of the system of machinery safety standards

5 System of type-A, type-B and type-C standards

5.1 Type-A standard (ISO 12100)

The type-A standard ISO 12100 specifies the principle strategy for safety of machinery. Risk assessment and adequate risk reduction by an iterative three-step method are the imperative measures to design a machine to achieve a level of tolerable risk.

To implement risk assessment and risk reduction, the following actions should be taken by the designer in the order given (see Figure 2):

a) determine the limits of the machinery, which includes the intended use and any reasonably foreseeable misuse thereof;

b) identify the hazards and associated hazardous situations;

c) estimate the risk for each identified hazard and hazardous situation;

d) evaluate the risk and decision whether a risk reduction is needed or not;

e) eliminate the hazard or reduction of the risk associated with the hazard by means of protective measures/risk reduction measures.

NOTE 1 For the purposes of this Technical Report, the terms “protective measure” (see ISO 12100:2010, 3.19) and “risk reduction measure” are synonymous and referred to any action or means used to eliminate hazards and/or reduce risks.

Actions a) to d) are related to risk assessment and action e) to risk reduction.

Risk assessment is a series of logical steps to enable, in a systematic way, the identification of hazards as well as the estimation and evaluation of the risks associated with machinery.

As a result of the risk assessment, the hazards requiring risk reduction are determined. Iteration of the process of risk assessment can be necessary to eliminate newly generated hazards as far as reasonably practicable or to adequately reduce associated risks by the implementation of protective measures/risk reduction measures in order to achieve tolerable risk.

Protective measures/risk reduction measures are the combination of the measures implemented by the designer and the user in accordance with Figure 3. Measures which can be incorporated at the design stage are preferable to those implemented by the user and usually prove more effective.

The objective to be met is the greatest practicable risk reduction. The strategy defined in this clause is represented by the flowchart in Figure 2. The process itself is iterative and several successive applications can be necessary to reduce the risk, making the best use of available technology. In carrying out this process, it is necessary to take into account these four factors, in the following order of preference:

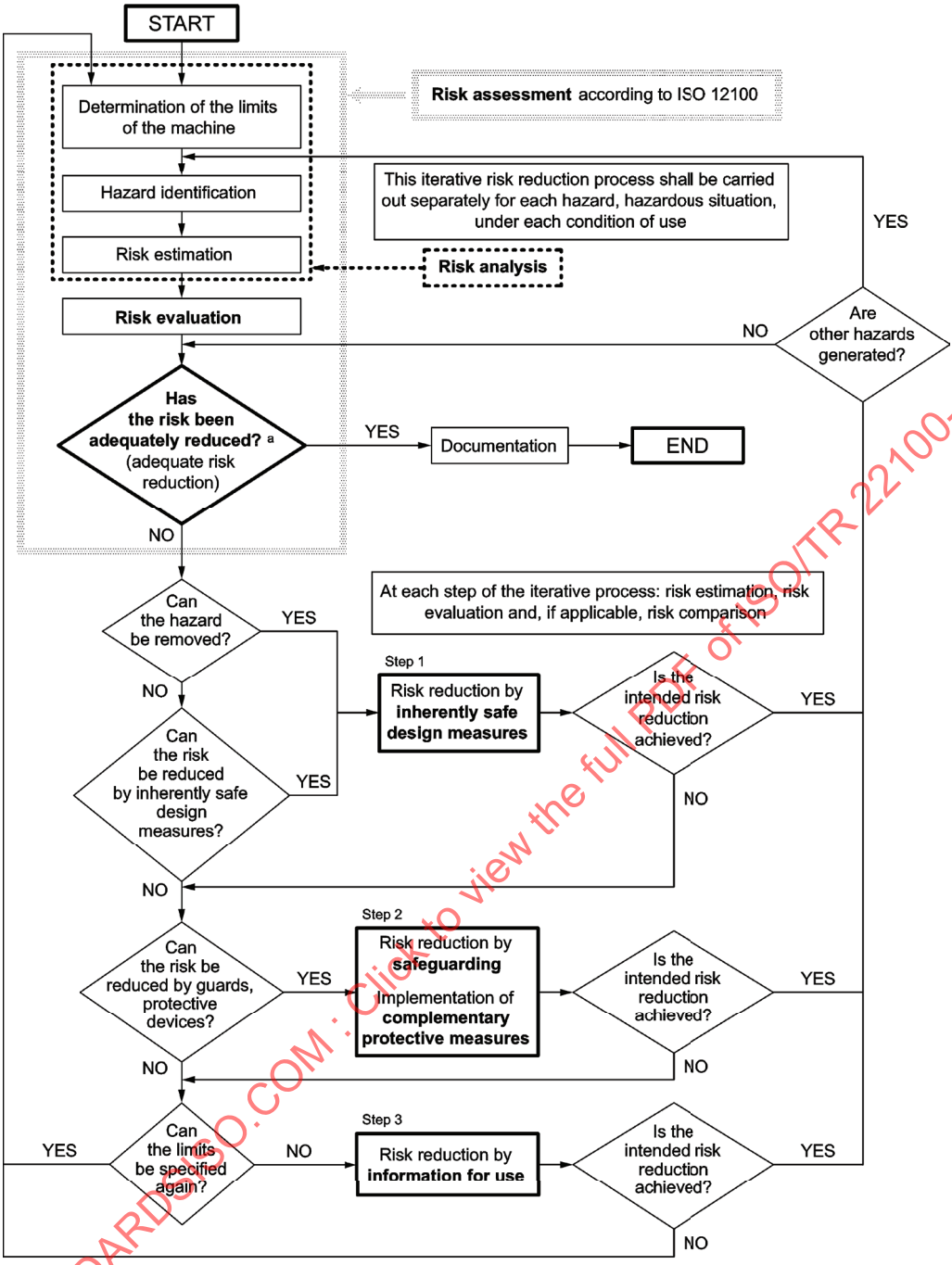
— the safety of the machine during all the phases of its life cycle;

— the ability of the machine to perform its function;

— the usability of the machine;

— the manufacturing, operational and dismantling costs of the machine.

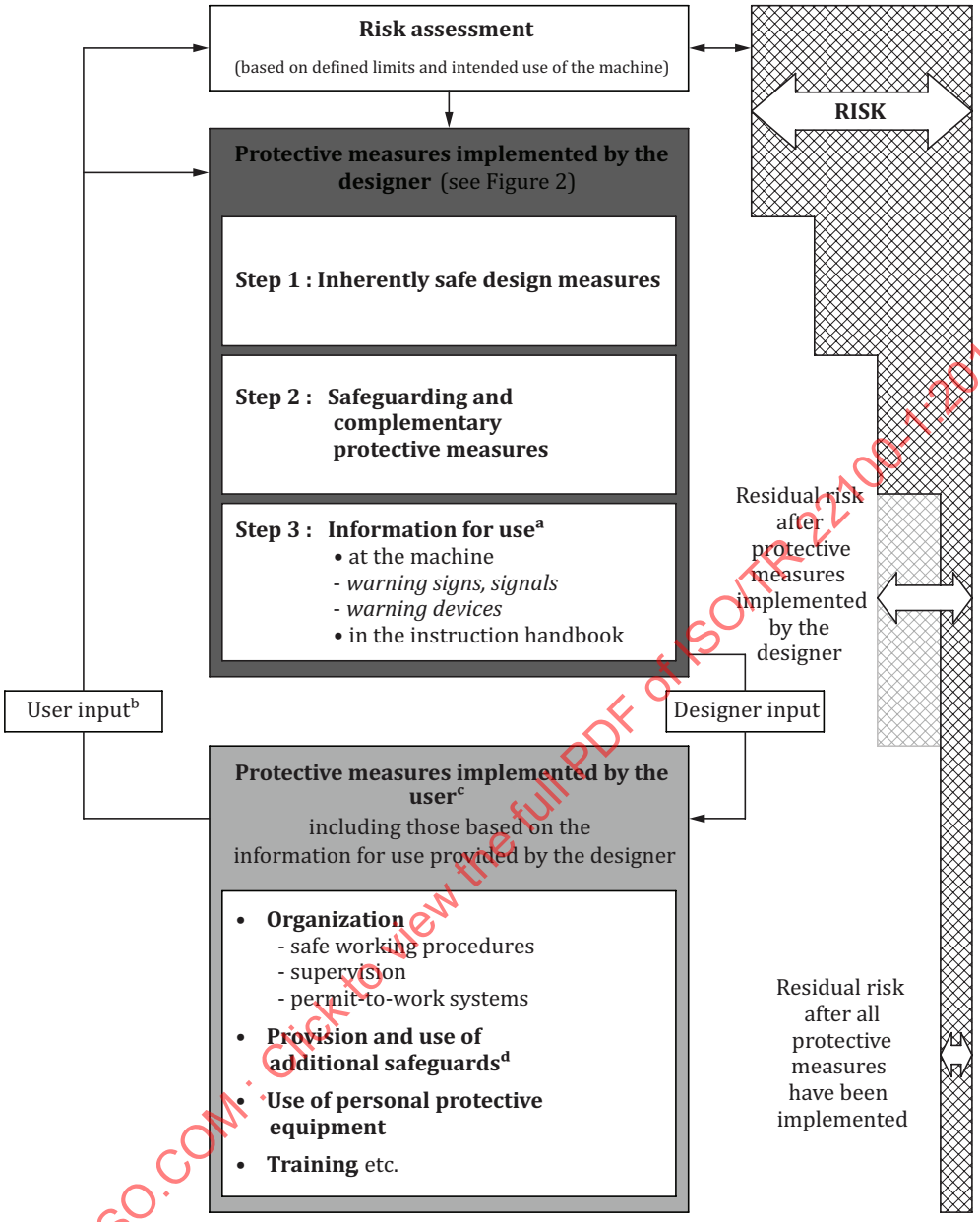
NOTE 2 The ideal application of these principles requires knowledge of the machine design and its intended use, the practical use of the machine, the accident history and health records, available risk reduction techniques, and the legal framework in which the machine is intended to be used (placed on the market).



Key

a The first time the question is asked, it is answered by the result of the initial risk assessment. For further information, see Figure A.1.

Figure 2 — Schematic representation of risk assessment and risk reduction process including iterative three-step method according to ISO 12100:2010, Figure 1



Key

a Providing proper information for use is part of the designer's contribution to risk reduction, but the protective measures concerned are only effective when implemented by the user.

b The user input is that information received by the designer from either the user community regarding the intended use of the machine in general or that which is received from a specific user.

c There is no hierarchy between the various protective measures implemented by the user. These protective measures are outside the scope of this part of ISO/TR 22100.

d Those protective measures required due to specific process(es) not envisaged in the intended use of the machine or to specific conditions for installation that cannot be controlled by the designer.

Figure 3 — Risk reduction process from point of view of designer (see also ISO 12100:2010, Figure 2)

5.2 Type-B standards

5.2.1 General

According to ISO 12100, type-B standards deal either with one safety aspect (type-B1 standard) or one type of safeguard that can be used across a wide range of machinery (type-B2 standard). Type-B standards are intended to support the principle strategy from ISO 12100 in order to

— help determine if a hazard exists, for example, ISO 13857, *Safety of machinery — Safety distances to prevent access to hazard zones being reached by upper and lower limbs*, and

— provide concrete information/measures to perform risk reduction, for example, ISO 14120, *Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards*.

5.2.2 Type-B1 standards

Type-B1 standards deal with particular safety aspects (for example, safety distances, surface temperature, noise) and define by data and/or methodology how these can be addressed. Type-B1 standards can be used directly by the designer/manufacturer or by reference in (a) type C standard(s), including, where relevant, means of verification.

5.2.3 Type-B2 standards

Type-B2 standards provide the performance requirements for the design and construction of particular safeguards (for example, two-hand control devices, interlocking devices, pressure-sensitive protective devices, guards). Type-B2 standards can be applied either directly by the designer/manufacturer or by reference in (a) type-C standard(s). Together with those performance requirements, type-B2 standards specify, where relevant, means of verification.

5.3 Type-C standards

5.3.1 General

According to ISO 12100, type-C standards provide detailed safety requirements for particular machinery or group of machinery.

NOTE The term “group of machinery” means machinery having a similar intended use and similar hazards, hazardous situations, or hazardous events.

Type-C standards are machine specific. Their scope is determining the limits of the machinery and the significant hazards covered.

Type-C standards are written by a team of technical experts (in particular, from machine manufacturers and representatives from health and safety bodies) knowledgeable in the machine design (intended use), the practical use of the machine, the accident history and health records, available risk reduction techniques, and the legal frameworks in which the machine is intended to be used (placed on the market).

Type-C standards deal with all the significant hazards of a particular machine by means of

— reference to relevant and applicable type-B standards,

— reference to other standards (e.g. a type-C standard), where such significant hazards are adequately dealt with,

— 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, and

— dealing as far as possible with objectives rather than design prescriptive details to minimize restrictions on design.

5.3.2 Content provided by type-C standards

Type-C standards are clearly establishing the following:

— the scope (limits of the machinery);

— the significant hazard(s);

— the requirements prescribing protective measures/risk reduction measures which add value to relevant clauses of ISO 12100 originating from the significant hazard(s);

— the means of verifying the protective measures/risk reduction measures.

NOTE Where possible, a type-C standard deals 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 is indicated clearly in the title and scope (e.g. Safety of textile machines — Measurement of noise). Where it is decided not to deal with all significant hazards, hazardous situations, or hazardous events (e.g. by lack of knowledge or because this causes an unacceptable delay in the drafting of the standard), this is indicated clearly in the scope.

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

5.3.3 Deviations in a type-C standard from a type-B standard

Because of the large variety of machinery, it might happen that type-C standards deviate from one or more technical requirements dealt with by a type-B standard. In those cases, the existing machine specific type-C standard takes precedence over the type-B standard.

6 Practical application of ISO 12100, type-B and type-C standards in order to design a machine to achieve a level of tolerable risk by adequate risk reduction

6.1 General

The system of type-A, type-B and type-C standards is intended to provide one means for designers and manufacturers to develop machinery that can be used to achieve a level of tolerable risk by adequate risk reduction.

Figure 4 shows the recommended steps for the practical use of ISO 12100 and existing type-B and type-C standards within this system.

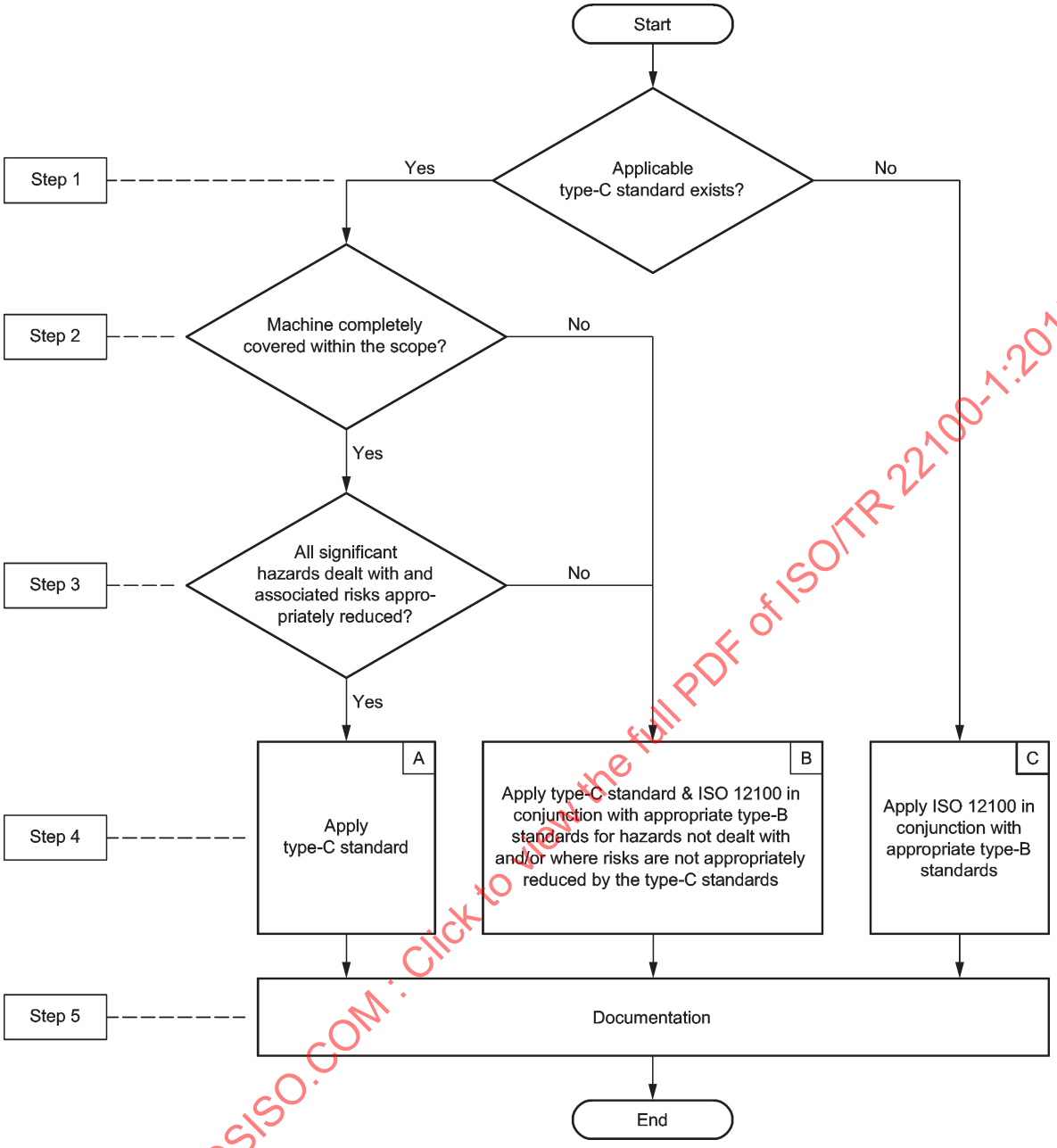


Figure 4 — Recommended steps for the practical use of ISO 12100 and existing type-B and type-C standards within this system

6.2 Application of an appropriate type-C standard

6.2.1 General

The process of risk assessment is facilitated by the application of type-C standards, since these standards for machinery identify the significant hazards that are generally associated with the category of machinery concerned and specify protective measures/risk reduction measures to deal with them. It is assumed that a type-C standard is the result of a risk assessment process carried out by a team of technical experts familiar with the machine in question. However, the application of type-C standards does not dispense the machinery manufacturer from the obligation to carry out a risk assessment according to ISO 12100.

Therefore, a manufacturer who applies the requirements of a type-C standard should ensure that the type-C standard is appropriate to the particular machinery concerned and covers all of the risks it presents. If the machinery concerned presents hazards that are not covered by this part of ISO/TR 22100, a full risk assessment according to ISO 12100 is required for those hazards and appropriate protective measures/risk reduction measures should be taken to deal with them.

Furthermore, where type-C standards specify several alternative requirements without defining criteria for choice between them, the choice of the appropriate requirement for the machinery concerned should be based on a specific risk assessment.

6.2.2 Steps to be followed

Step 1 — Search for a type-C standard

Machine designers and manufacturers should search for an appropriate type-C standard because it provides the most relevant guidance regarding safety of machinery for a particular machine.

Step 2 — Check the scope

If an appropriate type-C standard exists for the machine in question, the designer/manufacturer needs to check carefully if the scope of this type-C standard is fully covering the actual machine in question regarding the limits of the machine (this corresponds to ISO 12100:2010, 5.3).

Step 3 — Check significant hazards according to the type-C standard

If the outcome of step 2 shows that an appropriate type-C standard exists for the machine in question, the designer/manufacturer needs to check carefully that this type-C standard is covering all significant hazards to be associated with the actual machine in question and its application (this corresponds to ISO 12100:2010, 5.4). In addition, the designer has to check carefully that the protective measures/risk reduction measures specified in the type-C standard are appropriate for the application to the particular machine in question.

NOTE 1 Through this process, the risk estimation (see ISO 12100:2010, 5.5) is already covered. For those significant hazards covered by a type-C standard, individual risk estimation by the designer/manufacturer is not necessary anymore.

Step 4A — Application of type-C standard

If steps 2 and 3 are fulfilled, the protective measures/risk reduction measures contained in the type-C standard should be applied (This corresponds to ISO 12100:2010, Clause 6).

The application of the protective measures/risk reduction measures specified in the type-C standard is assumed to achieve tolerable risk for the particular machine in question by adequate risk reduction.

Next, go to step 5.

Step 4B — Application of type-C standard plus determination of any machine parts outside the scope of the type-C standard and identification of related additional hazards, hazardous situation(s) or hazardous event(s)

In case one or both of step 2 and step 3 are not fulfilled, the designer/manufacturer should determine which parts of the machine in question and/or which significant hazard(s), hazardous situation(s), or hazardous event(s) need to be considered in addition to the chosen (appropriate) type-C standard.

For those parts of the machine in question and/or significant hazard(s), hazardous situation(s), or hazardous event(s) not covered by the chosen (appropriate) type-C standard, the principle process of risk assessment and risk reduction according to ISO 12100 (see Figure 2) should be applied. This should be done with the help of relevant type-B standards.

Next, go to step 5.

Step 4C — Application of risk assessment and risk reduction process according to ISO 12100 **supported by type-B standards**

For machines not covered by an applicable type-C standard, the principle process of risk assessment and risk reduction according to ISO 12100 (see Figure 2) should be applied.

Appropriate type-B standards can be used to perform this process.

For the risk assessment process as such practical guidance and examples of methods to be applied are given in ISO/TR 14121-2.

Further, type-B1 standards (e.g. ISO 13732-1) are helpful to evaluate hazardous situations.

When the significant hazard(s), hazardous situation(s), or hazardous event(s) are identified as a result of the risk assessment, appropriate type-B1 and type-B2 standards can be used to specify effective measures for risk reduction.

NOTE 2 In order to facilitate the search for those appropriate type-B standards, Clause 7 provides an overview of what standard(s) exist for which kind of hazard category.

In addition, the designer/manufacturer may specify other protective measures/risk reduction measures independent from existing safety standards.

As a result of this process, it has to be assumed that the particular machine in question results in a design of the machine that can be used with tolerable risk achieved by adequate risk reduction.

Next, go to step 5.

Step 5 — Documentation

Detailed documentation of how step 1 to step 4 have been applied should show that the particular machine in question is designed to a level of tolerable risk achieved by adequate risk reduction.

7 Navigating appropriate type-B machinery safety standards

Machinery suppliers should identify and apply the appropriate type-B machinery safety standards. Standards can be grouped by type of hazard(s) or topic(s) addressed in the standard. Figure 5 outlines the structure of many ISO standards and can aid in navigating the standards.

NOTE Figure 5 provides a principle overview on existing categories of type-B standards but makes no claim to give a complete list of all currently existing type-B standards. See Bibliography for the type-B standards referred to in Figure 5.

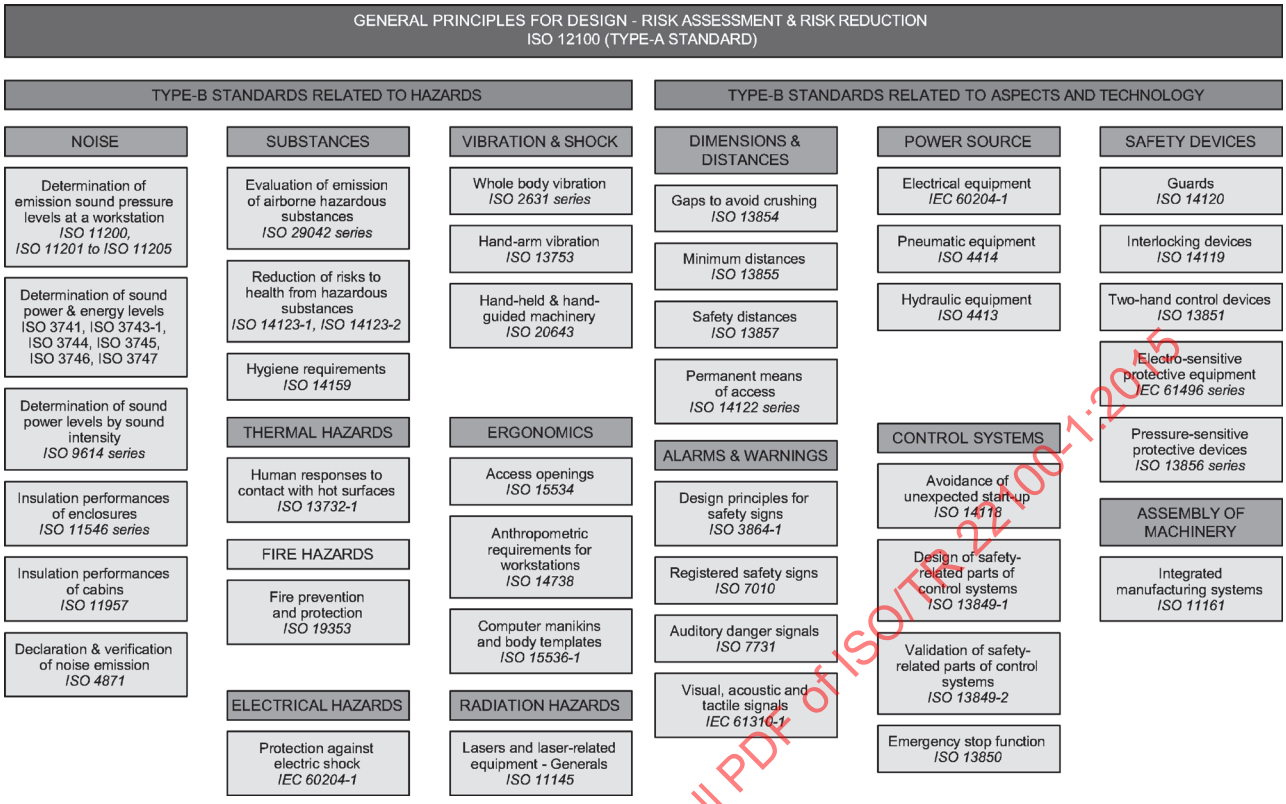
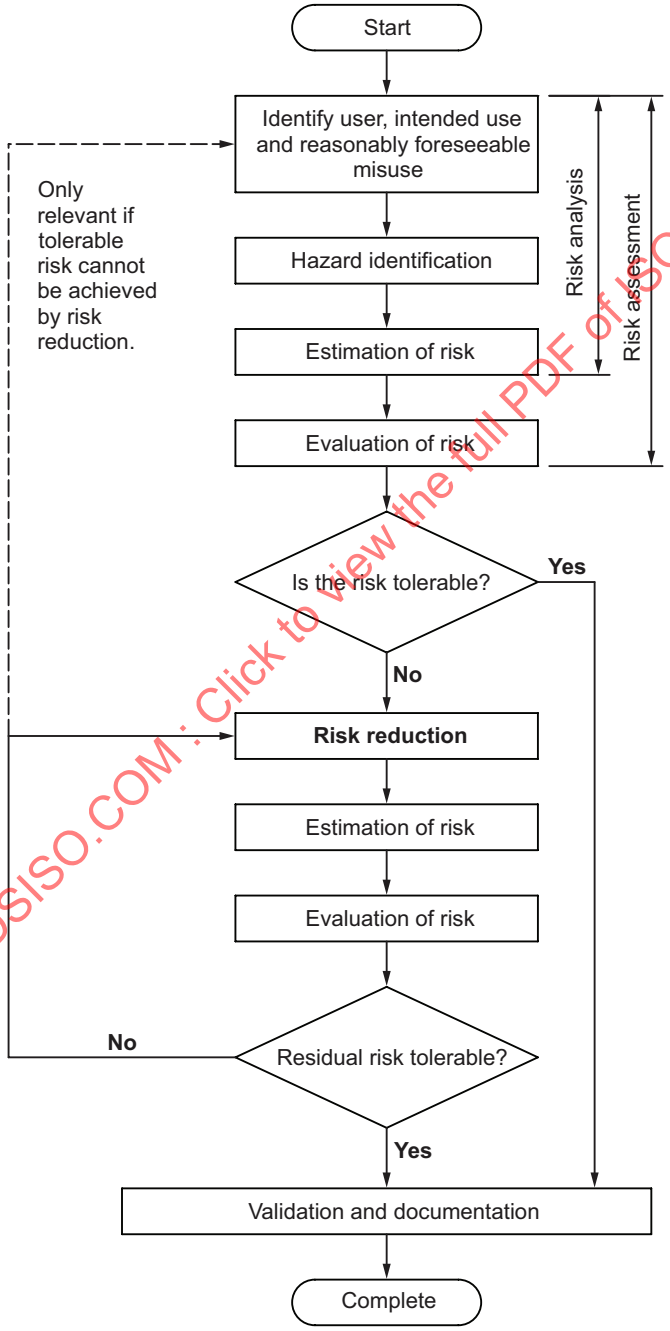


Figure 5 — Overview on type-B standards grouped by hazard category and aspects and technology (not all inclusive)

Annex A
(informative)

Iterative process of risk assessment and risk reduction

Figure A.1 shows another representation of the risk assessment process that links the processes shown in ISO 12100 and ISO/IEC Guide 51.



NOTE Validation is used in Figure A.1 synonymous to verification in ISO 12100.

Figure A.1 — Iterative process of risk assessment and risk reduction according to ISO/IEC Guide 51:2014, Figure 2

Annex B
(informative)

Types of documents

There are different kinds of documents in ISO used in the context of machinery safety standardization as given in Table B.1.

Table B.1 — Types of ISO documents

ISO Document	General description
International Standard	Contains normative and informative safety requirements, written primarily for machinery suppliers. Includes three types: — type-A; — type-B1 and type-B2; — type-C.
Technical Specification (TS)	Contains requirements for provisional application on a particular machine or system, written primarily for machinery suppliers.
Technical Report (TR)	Contains guidance information, written primarily for machinery suppliers and standard writers. TRs contain information (advisory) which is not normative (required).
Guide	Contains informative guidance information, written primarily for standards writers.

See ISO/IEC Directives Part 1 for more details.