
**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



STANDARDSISO.COM : Click to view the full PDF of ISO/TR 22100-1:2021



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General structure of the system of machinery safety standards	2
5 System of type-A, type-B and type-C standards	2
5.1 Type-A standard (ISO 12100)	2
5.2 Type-B standards	6
5.2.1 General	6
5.2.2 Type-B1 standards	6
5.2.3 Type-B2 standards	6
5.3 Type-C standards	6
5.3.1 General	6
5.3.2 Content provided by type-C standards	7
5.3.3 Deviations in a type-C standard from a type-B standard	7
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	7
6.1 General	7
6.2 Application of an appropriate type-C standard	8
6.2.1 General	8
6.2.2 Steps to be followed	9
7 Navigating appropriate type-B machinery safety standards	10
Annex A (informative) Iterative process of risk assessment and risk reduction	12
Annex B (informative) Types of ISO documents	13
Bibliography	14

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

This second edition cancels and replaces the first edition (ISO/TR 22100-1:2015), which has been technically revised.

The main changes compared to the previous edition are as follows.

- the wording "..., hazardous situation(s) or hazardous event(s)" has been deleted from 5.3.2 (NOTE and last paragraph) and 6.2.2 (subheading "Step 4B" and the following two paragraphs as well as Step 4C, fifth paragraph), eight times, in total;
- in 6.2.1, second paragraph, second sentence "this part of ISO 22100" has been corrected to "that type-C standard";
- the sentence given in 6.2.2, Step 4C, as paragraph below the Note has also been inserted as new penultimate paragraph to Step 4B.

A list of all parts in the ISO/TR 22100 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is written to assist the designer/manufacture of machinery and related components in understanding and navigating the different types of ISO machinery safety standards. It presents the different ISO deliverables (see [Annex B](#)) 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 document can 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 document includes a visual representation of many ISO machinery safety standards to assist in improving understanding of the interrelationships and linkages between these documents.

STANDARDSISO.COM : Click to view the full PDF of ISO/TR 22100-1:2021

Safety of machinery — Relationship with ISO 12100 —

Part 1:

How ISO 12100 relates to type-B and type-C standards

1 Scope

This document provides assistance to the designer/manufacture 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.

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

This document 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.

This document 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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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.

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

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

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 has been removed.]

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 — In Note 1 to entry, the words “For the purpose of this Guide” have been deleted.]

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.

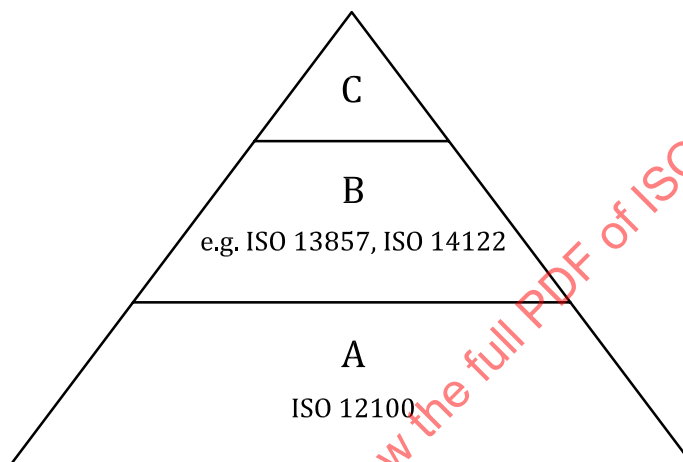


Figure 1 — General structure of the system of machinery safety standards

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

5.1 Type-A standard (ISO 12100)

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](#)):

- determine the limits of the machinery, which includes the intended use and any reasonably foreseeable misuse thereof;
- identify the hazards and associated hazardous situations;
- estimate the risk for each identified hazard and hazardous situation;
- evaluate the risk and decision whether a risk reduction is needed or not;
- 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 document, 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.

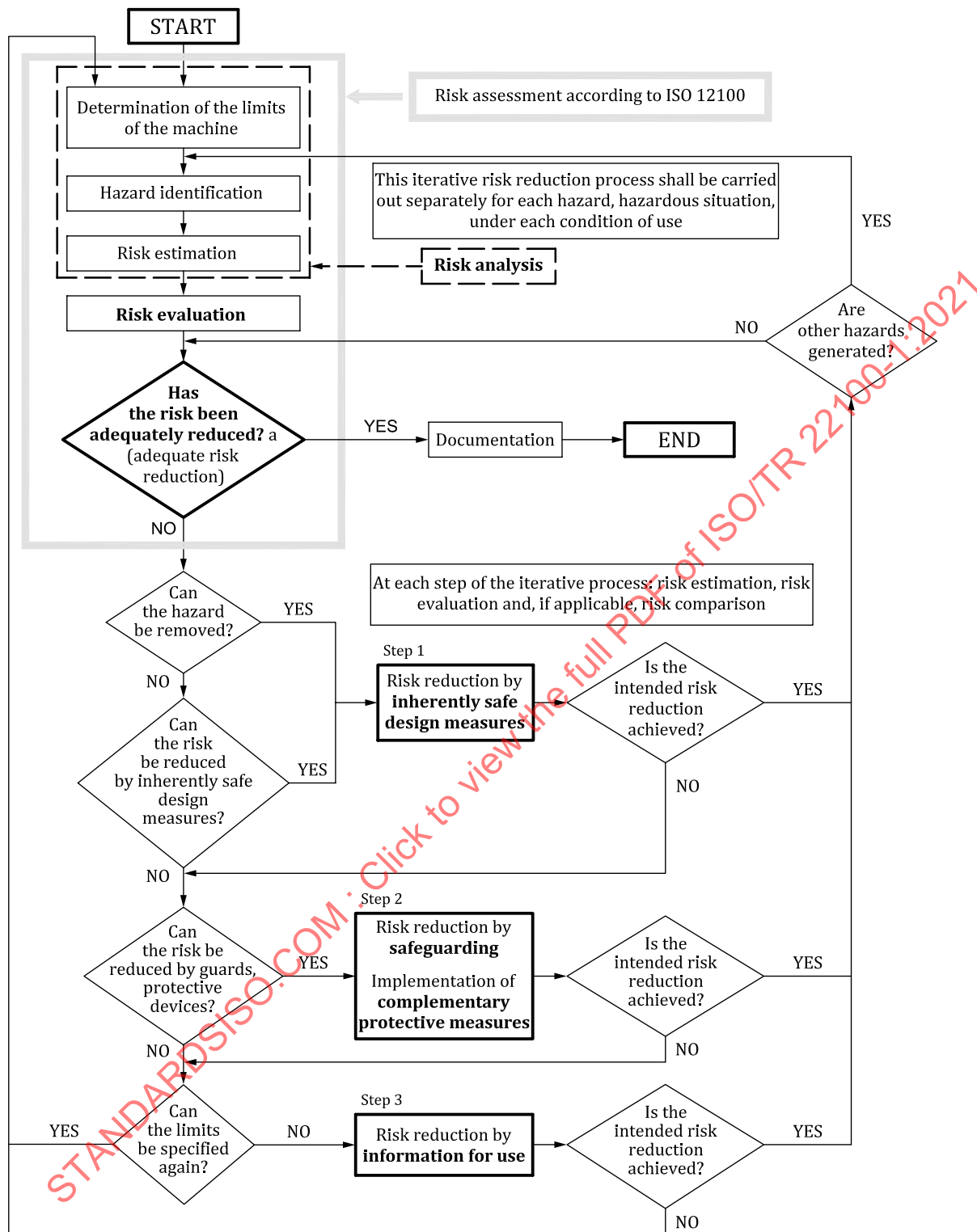
As a result of the risk assessment, the hazards requiring risk reduction are determined. Iteration of the process of risk assessment can be necessary to eliminate newly generated hazards as far as reasonably practicable or to adequately reduce associated risks by the implementation of protective measures/risk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

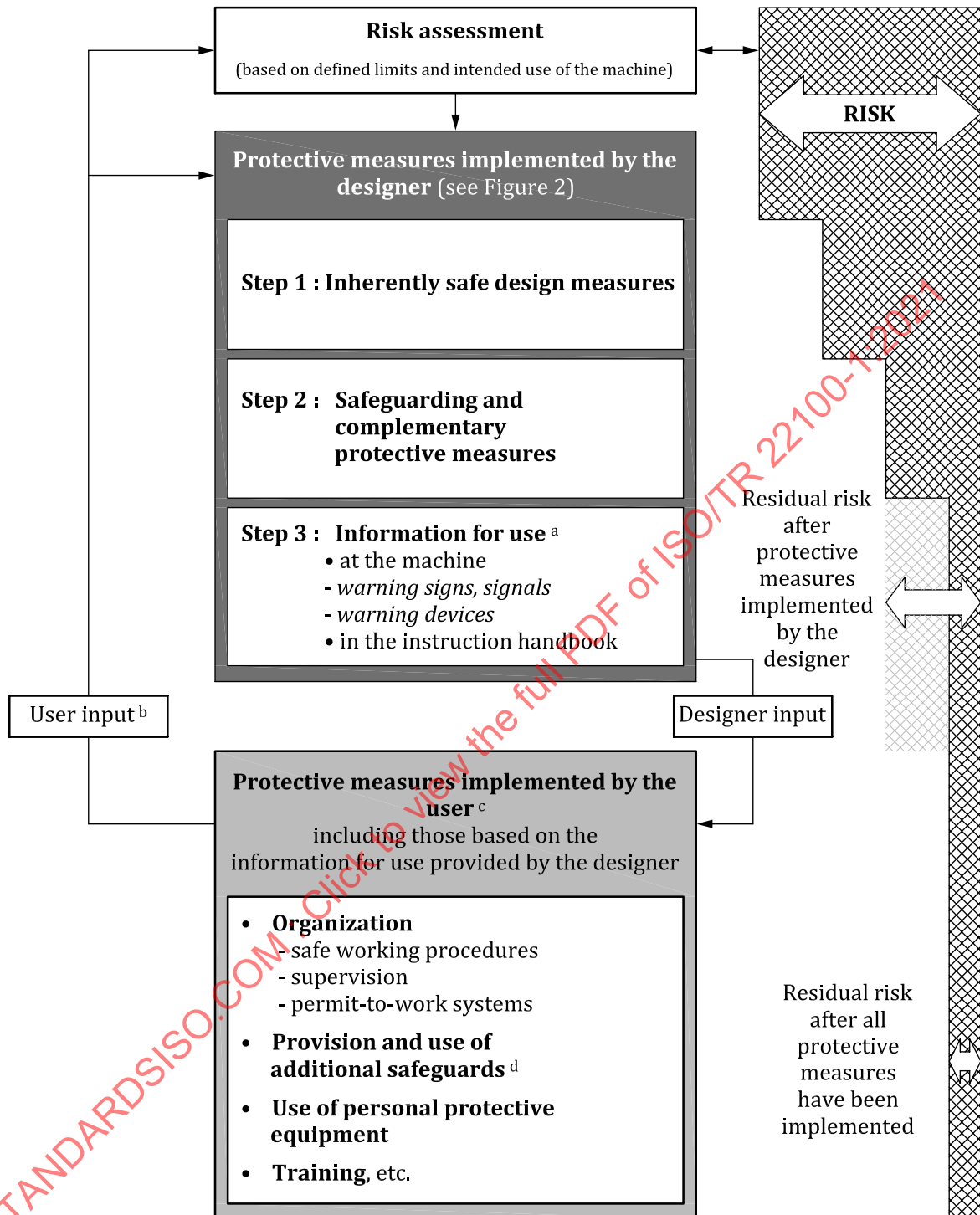
- the safety of the machine during all the phases of its life cycle;
- the ability of the machine to perform its function;
- the usability of the machine;
- the manufacturing, operational and dismantling costs of the machine.

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).



^a The first time the question is asked, it is answered by the result of the initial risk assessment. For further information, see [Annex A](#).

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 document.
- ^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 the point of view of the 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; and
- provide concrete information/measures to perform risk reduction, for example, ISO 14120.

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/manufacture 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/manufacture 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:

- referencing relevant and applicable type-B standards;
- referencing 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 clearly establish 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 identified as arising from the use of the machine. The justifiable exception to this comprehensive treatment of significant hazards 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 (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. 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, type-C standards can deviate from one or more technical requirements covered 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.

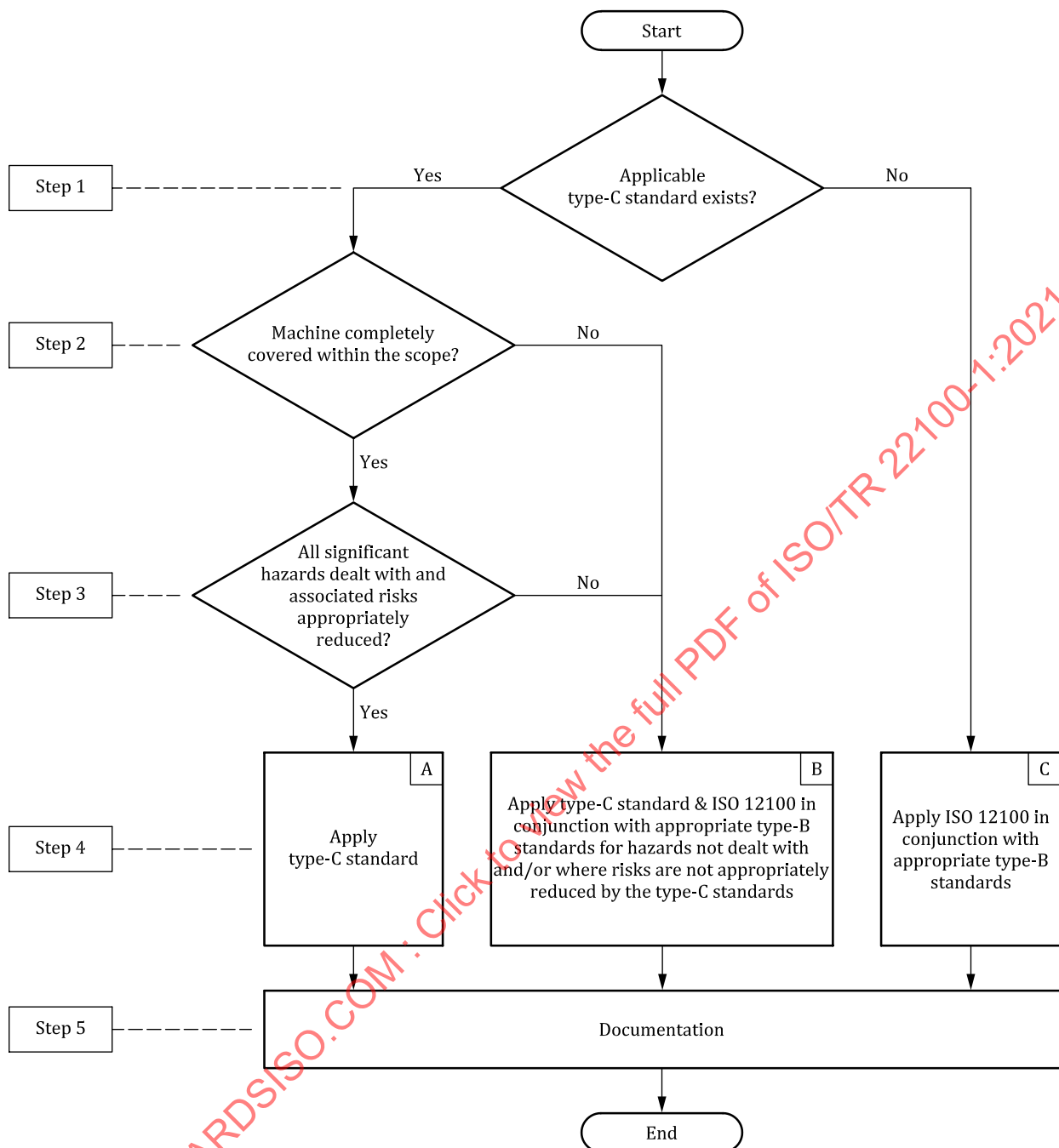


Figure 4 — Recommended steps for the practical use of ISO 12100 and existing type-B and type-C standards within this system

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 that type-C standard, 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 should 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 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

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) 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) 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.

In addition, the designer/manufacturer may specify other protective measures/risk reduction measures independent from existing safety 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 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) 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 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 is 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](#).

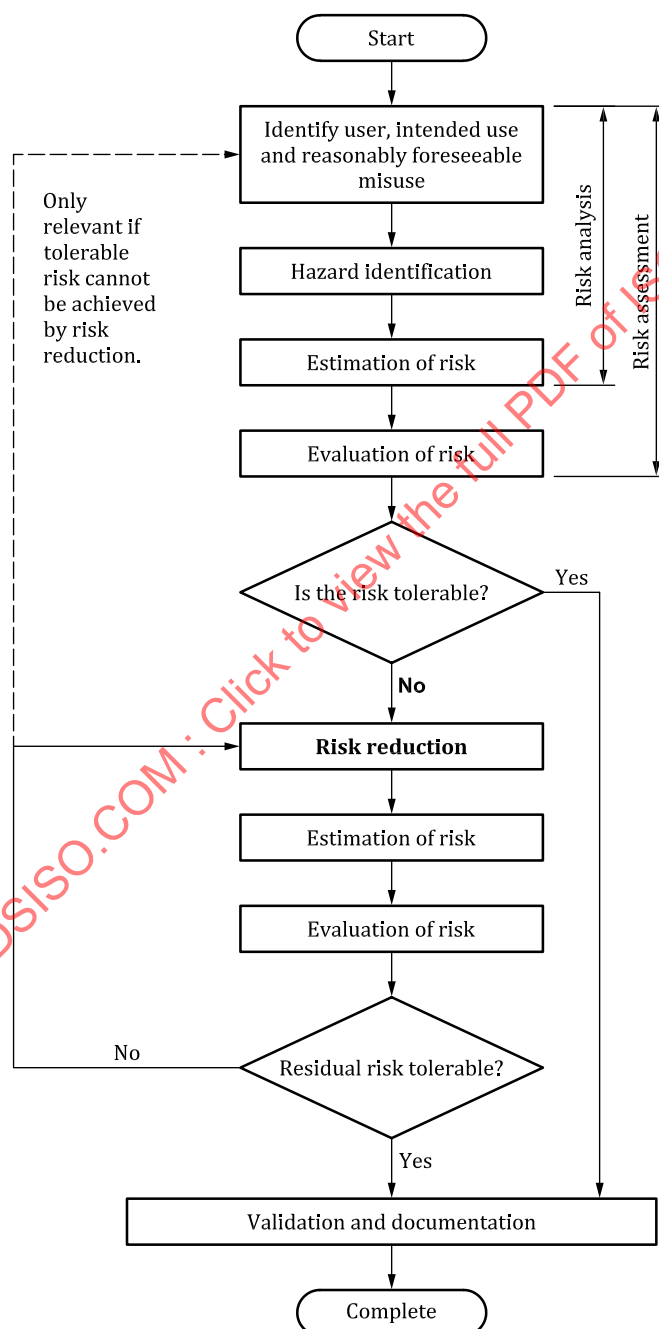
GENERAL PRINCIPLES FOR DESIGN - RISK ASSESSMENT & RISK REDUCTION ISO 12100 (TYPE-A STANDARD)						
TYPE-B STANDARDS RELATED TO HAZARDS			TYPE-B STANDARDS RELATED TO ASPECTS AND TECHNOLOGY			
NOISE	SUBSTANCES	VIBRATION & SHOCK	DIMENSIONS & DISTANCES	POWER SOURCE	SAFETY DEVICES	
Determination of emission sound pressure levels at a workstation <i>ISO 11200, ISO 11201 to ISO 11205</i>	Evaluation of emission of airborne hazardous substances <i>ISO 29042 series</i>	Whole body vibration <i>ISO 2631 series</i>	Gaps to avoid crushing <i>ISO 13854</i>	Electrical equipment <i>IEC 60204-1</i>	Guards <i>ISO 14120</i>	
Determination of sound power & energy levels <i>ISO 3741, ISO 3743-1, ISO 3744, ISO 3745, ISO 3746, ISO 3747</i>	Reduction of risks to health from hazardous substances <i>ISO 14123-1, ISO 14123-2</i>	Hand-arm vibration <i>ISO 13753</i>	Minimum distances <i>ISO 13855</i>	Pneumatic equipment <i>ISO 4414</i>	Interlocking devices <i>ISO 14119</i>	
Determination of sound power levels by sound intensity <i>ISO 9614 series</i>	Hygiene requirements <i>ISO 14159</i>	Hand-held & hand-guided machinery <i>ISO 20643</i>	Safety distances <i>ISO 13857</i>	Hydraulic equipment <i>ISO 4413</i>	Two-hand control devices <i>ISO 13851</i>	
Insulation performances of enclosures <i>ISO 11546 series</i>	THERMAL HAZARDS		Permanent means of access <i>ISO 14122 series</i>		Electro-sensitive protective equipment <i>IEC 61496 series</i>	
Insulation performances of cabins <i>ISO 11957</i>	Human responses to contact with hot surfaces <i>ISO 13732-1</i>	ERGONOMICS	ALARMS & WARNINGS	CONTROL SYSTEMS	Pressure-sensitive protective devices <i>ISO 13856 series</i>	
Declaration & verification of noise emission <i>ISO 4871</i>		Access openings <i>ISO 15534</i>	Design principles for safety signs <i>ISO 3864-1</i>	Avoidance of unexpected start-up <i>ISO 14118</i>	ASSEMBLY OF MACHINERY	
	FIRE HAZARDS	Anthropometric requirements for workstations <i>ISO 14738</i>	Registered safety signs <i>ISO 7010</i>	Design of safety-related parts of control systems <i>ISO 13849-1</i>	Integrated manufacturing systems <i>ISO 11161</i>	
	Fire prevention and protection <i>ISO 19353</i>	Computer manikins and body templates <i>ISO 15536-1</i>	Auditory danger signals <i>ISO 7731</i>	Validation of safety-related parts of control systems <i>ISO 13849-2</i>		
	ELECTRICAL HAZARDS	RADIATION HAZARDS	Visual, acoustic and tactile signals <i>IEC 61310-1</i>	Emergency stop function <i>ISO 13850</i>		
	Protection against electric shock <i>IEC 60204-1</i>	Lasers and laser-related equipment - Generals <i>ISO 11145</i>				

Figure 5 — Overview of type-B standards grouped by hazard category and aspects and technology (not exhaustive)

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 ISO documents

[Table B.1](#) shows the different types of documents that can be developed in the context of machinery safety standardization.

Table B.1 — Types of ISO documents

ISO document	General description
International Standard	Contains safety requirements and recommendations, 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.