TECHNICAL REPORT

ISO/TR 22100-1

Second edition
2021-01

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 22100-1:2021(E)

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

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/manufacturer 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.

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/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.

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.

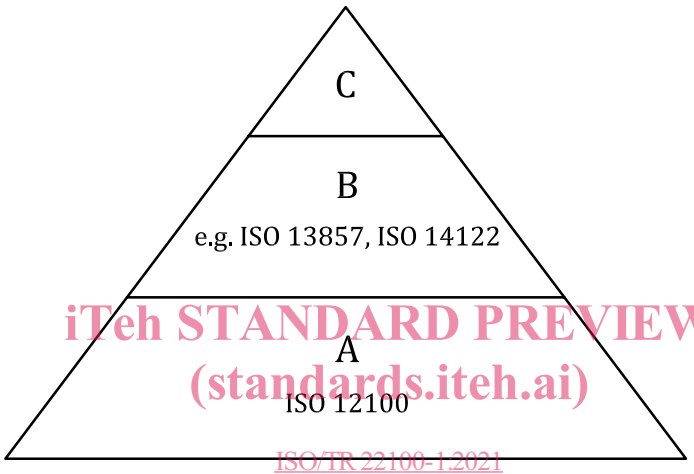


Figure 1 — General structure of the system of machinery safety standards

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):

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 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:

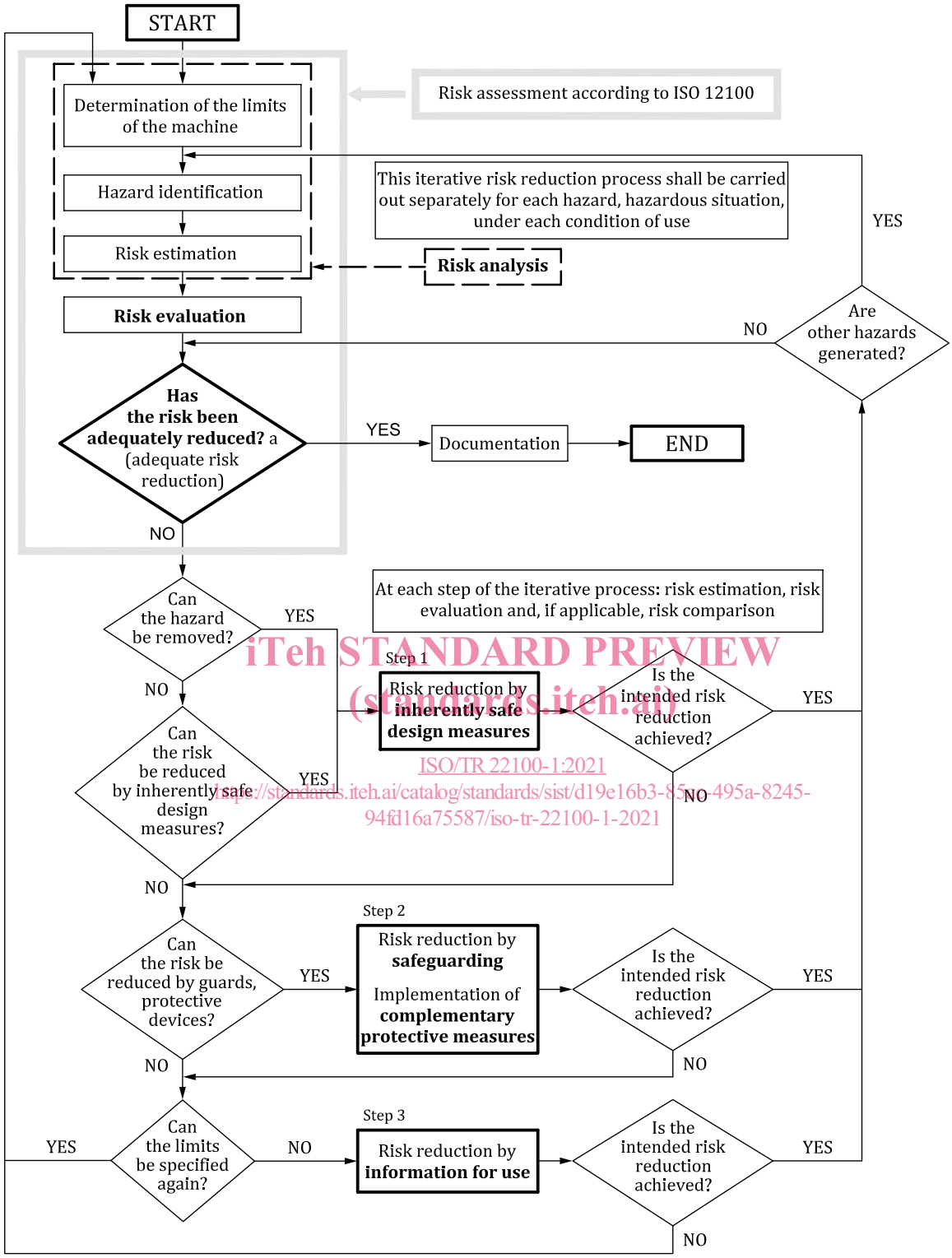
— the safety of the machine during all the phases of its life cycle;

— the ability of the machine to perform its function;

— the usability of the machine;

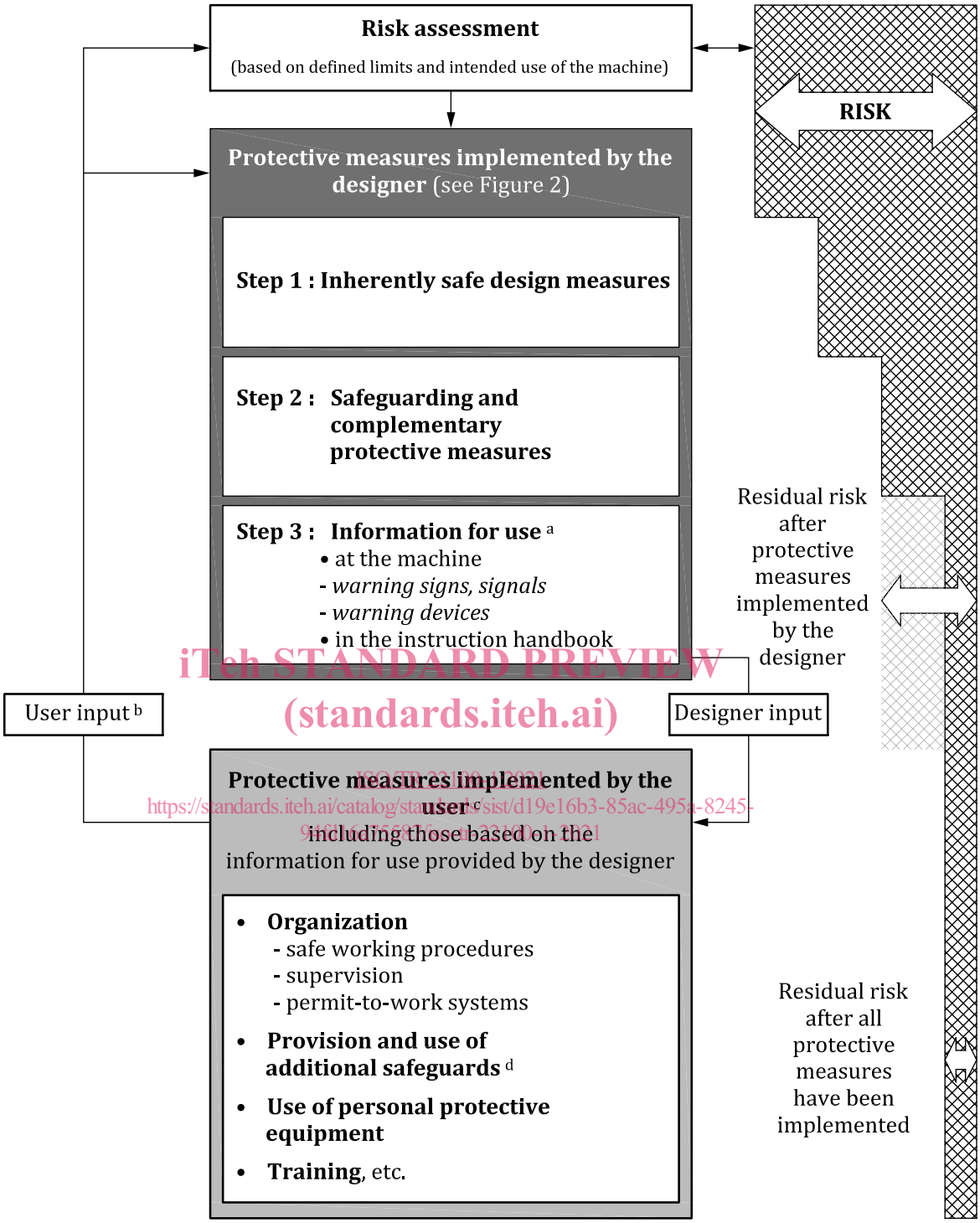
— the manufacturing, operational and dismantling costs of the machine.

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