



SLOVENSKI STANDARD

oSIST prEN ISO 12100:2026

01-september-2026

Varnost strojev - Splošna načela načrtovanja - Ocena tveganja in zmanjšanje tveganja (ISO/DIS 12100:2026)

Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO/DIS 12100:2026)

Sicherheit von Maschinen - Allgemeine Gestaltungsleitsätze - Risikobeurteilung und Risikominderung (ISO/DIS 12100:2026)

Sécurité des machines - Principes généraux de conception - Appréciation du risque et réduction du risque (ISO/DIS 12100:2026)

Ta slovenski standard je istoveten z: **prEN ISO 12100**

ICS:

13.110

Varnost strojev

Safety of machinery

oSIST prEN ISO 12100:2026

en,de

Sample Document

get full document from standards.iteh.ai



DRAFT International Standard

ISO/DIS 12100.3

Safety of machinery — General principles for design — Risk assessment and risk reduction

*Sécurité des machines — Principes généraux de conception —
Appréciation du risque et réduction du risque*

ICS: 13.110

ISO/TC 199

Secretariat: **DIN**

Voting begins on:
2026-07-20

Voting terminates on:
2026-09-14

This document has not been edited by the ISO Central Secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 12100.3:2026(en)

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© ISO 2026

Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

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

ISO/DIS 12100.3:2026(en)

Contents

Page

Foreword	v
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Strategy for risk assessment and risk reduction	9
5 Risk assessment	16
5.1 General	16
5.2 Information for risk assessment	16
5.3 Determination of the limits of machinery	18
5.3.1 General	18
5.3.2 Use limits	18
5.3.3 Space limits	18
5.3.4 Time limits	19
5.3.5 Other limits	19
5.4 Hazard identification	19
5.4.1 General	19
5.4.2 Human interaction with machinery during the lifecycle of the machine	19
5.4.3 Possible states of the machine	20
5.4.4 Unintended behaviour of the operator or reasonably foreseeable misuse of the machine	21
5.5 Risk estimation	21
5.5.1 General	21
5.5.2 Elements of risk	21
5.5.3 Aspects to be considered during risk estimation	24
5.6 Risk evaluation	25
5.6.1 General	25
5.6.2 Adequate risk reduction	26
5.6.3 Comparison of risks	26
6 Risk reduction	26
6.1 General	26
6.2 Inherently safe design	27
6.2.1 General	27
6.2.2 Consideration of geometrical factors and physical aspects	27
6.2.3 Taking into account general technical knowledge of machine design	28
6.2.4 Choice of appropriate technology	29
6.2.5 Applying principle of positive mechanical action	30
6.2.6 Provisions for stability	30
6.2.7 Provisions for maintainability	30
6.2.8 Observing ergonomics principles	30
6.2.9 Electrical hazards	31
6.2.10 Pneumatic and hydraulic hazards	32
6.2.11 Limiting exposure to hazards through reliability of equipment	32
6.2.12 Limiting exposure to hazards through mechanization or automation of loading (feeding) or unloading (removal) operations	32
6.2.13 Limiting exposure to hazards through location of setting and maintenance points outside hazard zones	33
6.2.14 Hygiene aspects	33
6.2.15 Noise	33
6.2.16 Vibration	33
6.3 Safeguarding and complementary risk reduction measures	33
6.3.1 General	33
6.3.2 Selection and implementation of guards and protective devices	34

ISO/DIS 12100.3:2026(en)

6.3.3	Requirements for design of guards and protective devices	37
6.3.4	Safeguarding to reduce emissions	39
6.3.5	Design of control systems	40
6.3.6	Complementary risk reduction measures	48
6.3.7	Risk reduction measures for stability	50
6.3.8	Other protective devices	50
6.4	Information for use	51
6.4.1	General requirements	51
6.4.2	Location and nature of information for use	52
6.4.3	Signals and warning devices	52
6.4.4	Markings, signs (pictograms) and written warnings	52
6.4.5	Accompanying documents (in particular — instruction handbook)	53
7	Documentation of risk assessment and risk reduction	56
Annex A	(informative) Schematic representation of a machine	57
Annex B	(informative) Examples of hazards, hazardous situations and hazardous events	58
Annex C	(informative) Using the system of type-A, type-B and type-C standards to design a machine to achieve tolerable risk by adequate risk reduction	68
Annex D	(informative) How this document relates to ISO 13849-1	72
Annex E	(informative) Trilingual lookup and index of specific terms and expressions used in this document	77
Annex ZA	(informative) Relationship between this European Standard and the essential requirements of Regulation (EU) 2023/1230 aimed to be covered	90
Annex ZB	(informative) Relation of this document to the Regulation (EU) 2023/1230	91
Bibliography		92

get full document from standards.iteh.ai

ISO/DIS 12100.3:2026(en)

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 114, *Safety of machinery*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition of ISO 12100 cancels and replaces ISO 12100:2010, ISO/TR 22100-1:2021 and ISO/TR 22100-2:2013.

The main changes are as follows:

- the Scope has been modified;
- additional normative references were added to [Clause 2](#);
- terms and definitions have been modified in [Clause 3](#);
- new [Figure 1](#) added, and [Figure 4](#) from previous edition deleted;
- requirements for control systems moved to [6.3.5](#);
- reference to self-evolving behaviour of applied artificial intelligence added to [5.4.3](#), b) 7);
- new subclause “Hygiene aspects” added as [6.2.14](#);
- subclause “Safeguarding to reduce emissions” shortened on general aspects only;
- subclause on “Software aspects” completely rewritten;
- updates made to requirements for guards and protective devices ([6.3.2](#));
- new subclauses “Indirect control” and “Remote software updates” added as [6.3.5.11](#) and [6.3.5.12](#), respectively;
- new subclause “Cybersecurity and protection against corruption” added as [6.3.5.17](#);
- ISO/TR 22100-1 and ISO/TR 22100-2 incorporated as new [Annexes C](#) and [D](#).

ISO/DIS 12100.3:2026(en)

In addition to text written in the official ISO languages (English, French, Russian), this document gives text in German. This text is published under the responsibility of the member body for Germany (DIN) and is given for information only. Only the text given in the official languages can be considered as ISO text. 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.

Sample Document

get full document from standards.iteh.ai

ISO/DIS 12100.3:2026(en)

Introduction

The primary purpose of this document is to provide designers with an overall framework and guidance for decisions during the development of machinery to enable them to design machines that are adequately safe for their intended use. It also provides a strategy for standards developers and will assist in the preparation of consistent and appropriate type-B and type-C standards.

The concept of safety of machinery considers the ability of a machine to perform its intended function(s) during its lifecycle where risk has been adequately reduced.

This document is the basis for a set of standards which has the following structure:

- a) **type-A standards** (basic safety standards) giving basic concepts, principles for design, and general aspects that can be applied to all machinery;
- b) **type-B standards** (generic safety standards) dealing with one safety aspect or one or more type(s) of safeguard that can be used across a wide range of machinery:
 - type-B1 standards on particular safety aspects (e.g. safety distances, surface temperature, noise);
 - type-B2 standards on safeguards (e.g. two-hand control devices, interlocking devices, pressure-sensitive devices, guards);
- c) **type-C standards** (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.

This document is a type-A standard.

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 organizations, market surveillance);

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 in the drafting process of this document.

When a type-C standard deviates from one or more technical provisions dealt with by this document or by a type-B standard, the type-C standard takes precedence.

It is desirable that this document be referred to in training courses and manuals to convey basic terminology and general design methods to designers.

ISO/IEC Guide 51 has been taken into account as far as practicable at the time of drafting of this document.

A trilingual lookup and index of specific terms and expressions used in this document is given in [Annex E](#).

Sample Document

get full document from standards.iteh.ai

Safety of machinery — General principles for design — Risk assessment and risk reduction

1 Scope

This document defines basic terminology and specifies principles and a methodology for safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine lifecycle, and for the elimination of hazards or the provision of adequate risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process.

This document covers principal implications on machinery safety in case of implementation of artificial intelligence/machine learning, and vulnerability to cyber threats and data corruption regarding their impact on safety. It specifies generic measures to address both aspects.

Safety of machinery includes hygiene aspects.

This document is also intended to be used as a basis for the preparation of type-B or type-C safety standards.

This document covers neither risk nor damage to domestic animals, property or the environment.

NOTE 1 While this document refers to risks of harm to persons, the risk assessment process set out in this document can be equally effective in assessing other types of risks such as damage to domestic animals, property or the environment.

NOTE 2 [Annex B](#) gives, in separate tables, examples of hazards, hazardous situations and hazardous events, in order to clarify these concepts and assist the designer in the process of hazard identification.

NOTE 3 The practical use of a number of methods for each stage of risk assessment is described in ISO/TR 14121-2.

NOTE 4 As used in this document, the designer of a machine can include the manufacturer, integrator, supplier, or the user in case of safety-relevant modifications.

NOTE 5 This document can also be used for existing machinery.

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/DIS 12895-2:2025, *Safety of machinery — Identification of whole body access and prevention of associated risk(s)*

ISO 13849-1:2023, *Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design*

ISO 20607, *Safety of machinery — Instruction handbook — General drafting principles*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO/DIS 12100.3:2026(en)

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

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

3.1

machinery

machine

assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application

Note 1 to entry: The term “machinery” can include an assembly of machines, which achieves the same purpose, when they are arranged and controlled to function as an integral whole.

Note 2 to entry: [Annex A](#) provides a general schematic representation of a machine.

3.2

reliability

ability of a machine or its components or equipment to perform a required function under specified conditions and for a given period of time without failing

3.3

maintainability

characteristic of a machine that allows it to be kept in a state which enables it to fulfil its function under conditions of intended use, or to be restored to such a state

3.4

usability

characteristic of a machine that allows it to be easily used including properties or characteristics that enable its function(s) to be easily understood

3.5

harm

physical injury or damage to health

3.6

hazard

potential source of harm

Note 1 to entry: The term “hazard” can be qualified in order to define its origin (e.g. mechanical hazard, electrical hazard) or the nature of the potential harm (e.g. electric shock hazard, cutting hazard, toxic hazard, fire hazard).

Note 2 to entry: The hazard envisaged by this definition either:

- is permanently present during the intended use of the machine (e.g. motion of hazardous moving elements, electric arc during a welding phase, unhealthy posture, noise emission, high temperature); or
- can appear unexpectedly (e.g. explosion, crushing hazard as a consequence of an unintended/unexpected start-up, ejection as a consequence of a breakage, fall as a consequence of acceleration/deceleration).

3.7

significant hazard

hazard which has been identified as associated with the machine and which requires specific action to eliminate or to reduce its risk in accordance with the risk assessment

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

Note 2 to entry: The prior term “relevant hazard” is included as being a significant hazard.

ISO/DIS 12100.3:2026(en)**3.8****hazardous event**

event that can cause harm

Note 1 to entry: A hazardous event can occur over a short period of time or over an extended period of time.

3.9**hazardous situation**

circumstance in which a person is exposed to at least one hazard

Note 1 to entry: The exposure can result in harm immediately or over a period of time.

3.10**hazard zone**

danger zone

any space either within or around machinery, or both, in which a person can be exposed to a hazard

3.11**risk**

combination of the probability of occurrence of harm and the severity of that harm

3.12**residual risk**

risk remaining after risk reduction measures have been implemented

Note 1 to entry: This document distinguishes:

- the residual risk after risk reduction measures have been implemented by the designer;
- the residual risk remaining after all risk reduction measures by the designer and the user have been implemented.

Note 2 to entry: See also [Figure 3](#).

3.13**risk estimation**

defining likely severity of harm and probability of its occurrence

3.14**risk analysis**

combination of the specification of the limits of the machine, hazard identification and risk estimation

3.15**risk evaluation**

procedure based on the risk analysis to determine whether further risk reduction is required

[SOURCE: ISO/IEC Guide 51:2014, 3.12, modified — The wording “tolerable risk has been exceeded” has been replaced with “further risk reduction is required”.]

3.16**risk assessment**

overall process comprising a risk analysis and a risk evaluation

Note 1 to entry: See [Figure 1](#).

3.17**risk reduction measure**

DEPRECATED: protective measure

action or means to eliminate hazards or reduce risks

Note 1 to entry: See [Figure 2](#) and [Figure 3](#).

ISO/DIS 12100.3:2026(en)

3.18

complementary risk reduction measure

risk reduction measure used in conjunction with inherently safe design, safeguarding or information for use to enhance risk reduction

3.19

tolerable risk

acceptable risk

adequately reduced risk

level of risk that is accepted in a given context based on the current values of society at a minimum in accordance with legal requirements

Note 1 to entry: Tolerable risk usually refers to the level at which further technologically, functionally and financially feasible risk reduction measures or additional expenditure(s) of resources will not result in significant reduction in risk.

Note 2 to entry: Criteria for determining when adequately reduced risk is achieved are given in [5.6.2](#).

3.20

inherently safe design

risk reduction measure which either eliminates hazards or reduces the risks associated with hazards by changing the design or operating characteristics of the machine without the use of guards or protective devices

Note 1 to entry: See [6.2](#).

3.21

safeguarding

risk reduction measure using safeguards to protect persons from the hazards which cannot reasonably be eliminated or risks which cannot be sufficiently reduced by inherently safe design

Note 1 to entry: See [6.3](#).

3.22

information for use

risk reduction measure consisting of details used separately or in combination, to convey information to the user

Note 1 to entry: See [6.4](#).

Note 2 to entry: Details of information of use can comprise e.g. of text, words, signs, signals, symbols, diagrams, photos.

3.23

intended use

use of a machine in accordance with the information for use

3.24

reasonably foreseeable misuse

use of a machine in a way not intended by the designer, but which can result from readily predictable human behaviour

3.25

task

specific activity performed by one or more persons on, or in the vicinity of, the machine during its lifecycle

3.26

safeguard

guard or protective device

ISO/DIS 12100.3:2026(en)

3.27

guard

physical barrier, designed as part of the machine to provide protection

Note 1 to entry: A guard acts either:

- alone, in which case it is only effective when “closed” (for a movable guard) or “securely held in place” (for a fixed guard); or
- in conjunction with an interlocking device with or without guard locking, in which case protection is ensured whatever the position of the guard.

Note 2 to entry: Depending on its construction, a guard may be described as, for example, casing, shield, cover, screen, door, enclosure.

Note 3 to entry: The terms for types of guards are defined in [3.27.1](#) to [3.27.6](#). See also [6.3.3.2](#) and ISO 14120 for more information about types of guards and their requirements.

3.27.1

fixed guard

guard affixed in such a manner (e.g. by screws, nuts, welding) that it can only be opened or removed by the use of tools or by destruction of the affixing means

3.27.2

movable guard

guard which can be opened without the use of tools

3.27.3

adjustable guard

fixed or movable guard which is adjustable as a whole or which incorporates adjustable part(s)

3.27.4

interlocking guard

guard associated with an interlocking device, such that, together with the control system of the machine,

- prevents the operation of the hazardous machine functions associated with the guard until the guard is closed;
- and, if the guard is opened while hazardous machine functions are operating, a command to bring the machine to a safe state is given

Note 1 to entry: An interlocking guard can contain/be equipped with one or more interlocking devices. These interlocking devices can also be of different types.

Note 2 to entry: The generation of the command to bring the machine to a safe state when the guard is open does not apply to guards locked with a trapped key interlocking system.

Note 3 to entry: ISO 14119 gives detailed provisions.

3.27.5

interlocking guard with guard locking

guard associated with an interlocking device and a guard locking device so that, together with the control system of the machine, the following functions are performed:

- the hazardous machine functions associated with the guard cannot operate until the guard is closed and locked;
- the guard remains closed and locked until the risk due to the hazardous machine functions associated with the guard has ceased;
- when the guard is closed and locked, the hazardous machine functions associated with the guard can operate (the closure and locking of the guard do not by themselves start the hazardous machine functions)