SLOVENSKI STANDARD
SIST EN ISO 12100:2011

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Nadomešča:
SIST EN ISO 12100-1:2004
SIST EN ISO 12100-1:2004/A1:2010
SIST EN ISO 12100-2:2004
SIST EN ISO 12100-2:2004/A1:2010
SIST EN ISO 14121-1:2007

Varnost strojev - Splošna načela načrtovanja - Ocena tveganja in zmanjšanje tveganja (ISO 12100:2010)

Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

Sicherheit von Maschinen - Allgemeine Gestaltungsleitsätze - Risikobewertung und Risikominderung (ISO 12100:2010)

Sécurité des machines - Principes généraux de conception - Appréciation du risque et réduction du risque (ISO 12100:2010)

Ta slovenski standard je istoveten z: **EN ISO 12100:2010**

ICS:

13.110	Varnost strojev	Safety of machinery

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 12100

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ICS 13.110

Supersedes EN ISO 12100-1:2003, EN ISO 12100-2:2003, EN ISO 14121-1:2007

English Version

Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

Sécurité des machines - Principes généraux de conception - Appréciation du risque et réduction du risque (ISO 12100:2010)

Sicherheit von Maschinen - Allgemeine Gestaltungsleitsätze - Risikobewertung und Risikominderung (ISO 12100:2010)

This European Standard was approved by CEN on 9 October 2010.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 12100:2010) has been prepared by Technical Committee ISO/TC 199 "Safety of machinery" in collaboration with Technical Committee CEN/TC 114 “Safety of machinery” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2011, and conflicting national standards shall be withdrawn at the latest by November 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 12100-1:2003, EN ISO 12100-2:2003, EN ISO 14121-1:2007.

This second edition cancels and replaces ISO 12100-1:2003, ISO 12100-1:2003/Amd. 1: 2009, ISO 12100-2:2003, ISO 12100-2:2003/Amd. 1: 2009 and ISO 14121-1:2007 of which it constitutes a consolidation without technical changes. Documentation (e.g. risk assessment, type-C standards) based on these replaced documents need not be updated or revised.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 12100:2010 has been approved by CEN as a EN ISO 12100:2010 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EC Directive 2006/42/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission [and the European Free Trade Association] to provide a means of conforming to Essential Requirements of the New Approach Directive Machinery, 2006/42/EC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive and associated EFTA regulations.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 12100

First edition
2010-11-01

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

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard 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 12100 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

This first edition of ISO 12100 cancels and replaces ISO 12100-1:2003, ISO 12100-2:2003 and ISO 14121-1:2007, of which it constitutes a consolidation without technical change. It also incorporates the Amendments ISO 12100-1:2003/Amd.1:2009 and ISO 12100-2:2003/Amd.1:2009. Documentation (e.g. risk assessment, type-C standards) based on these replaced documents need not be updated or revised.

Introduction

The primary purpose of this International Standard 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 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 life cycle where risk has been adequately reduced.

This International Standard is the basis for a set of standards which has 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-B1 standards on particular safety aspects (for example, safety distances, surface temperature, noise);

  — type-B2 standards on safeguards (for example, two-hand controls, interlocking devices, pressure-sensitive devices, guards);

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

This International Standard is a type-A standard.

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

It is desirable that this International Standard 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 International Standard.

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

1 Scope

This International Standard specifies basic terminology, principles and a methodology for achieving 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 life cycle, and for the elimination of hazards or the provision of sufficient risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process.

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

It does not deal with risk and/or damage to domestic animals, property or the environment.

NOTE 1 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 2 The practical use of a number of methods for each stage of risk assessment is described in ISO/TR 14121-2.

2 Normative references

The following referenced documents are indispensable for the application 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.

IEC 60204-1:2005, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements*

3 Terms and definitions

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

3.1
machinery
machine
assembly, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application

NOTE 1 The term “machinery” also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.

NOTE 2 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
ability of a machine to be maintained in a state which enables it to fulfil its function under conditions of intended use, or to be restored to such a state, with the necessary actions (maintenance) being carried out according to specified practices and using specified means

3.4
usability
ability of a machine to be easily used owing to, among others, 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 The term “hazard” can be qualified in order to define its origin (for example, mechanical hazard, electrical hazard) or the nature of the potential harm (for example, electric shock hazard, cutting hazard, toxic hazard, fire hazard).

NOTE 2 The hazard envisaged by this definition either

— is permanently present during the intended use of the machine (for example, motion of hazardous moving elements, electric arc during a welding phase, unhealthy posture, noise emission, high temperature), or

— can appear unexpectedly (for example, 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).

NOTE 3 The French term “*phénomène dangereux*” should not be confused with the term “*risque*”, which was sometimes used instead in the past.

3.7
relevant hazard
hazard which is identified as being present at, or associated with, the machine

NOTE 1 A relevant hazard is identified as the result of one step of the process described in Clause 5.

NOTE 2 This term is included as basic terminology for type-B and type-C standards.

3.8
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 This term is included as basic terminology for type-B and type-C standards.

3.9
hazardous event
event that can cause harm

NOTE A hazardous event can occur over a short period of time or over an extended period of time.

3.10
hazardous situation
circumstance in which a person is exposed to at least one hazard

NOTE The exposure can result in harm immediately or over a period of time.

3.11
hazard zone
danger zone
any space within and/or around machinery in which a person can be exposed to a hazard

3.12
risk
combination of the probability of occurrence of harm and the severity of that harm

3.13
residual risk
risk remaining after protective measures have been implemented

NOTE 1 This International Standard distinguishes

— the residual risk after protective measures have been implemented by the designer,

— the residual risk remaining after all protective measures have been implemented.

NOTE 2 See also Figure 2.

3.14
risk estimation
defining likely severity of harm and probability of its occurrence

3.15
risk analysis
combination of the specification of the limits of the machine, hazard identification and risk estimation

3.16
risk evaluation
judgment, on the basis of risk analysis, of whether the risk reduction objectives have been achieved

3.17
risk assessment
overall process comprising a risk analysis and a risk evaluation

3.18
adequate risk reduction
risk reduction that is at least in accordance with legal requirements, taking into consideration the current state of the art

NOTE Criteria for determining when adequate risk reduction is achieved are given in 5.6.2.

3.19
protective measure
measure intended to achieve risk reduction, implemented

— by the designer (inherently safe design, safeguarding and complementary protective measures, information for use) and/or

— by the user (organization: safe working procedures, supervision, permit-to-work systems; provision and use of additional safeguards; use of personal protective equipment; training)

NOTE See Figure 2.