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Supersedes: see below

Safety of machinery – General principles for design – Risk assessment and risk reduction (ISO 12100:2010) English translation of DIN EN ISO 12100:2011-03

Sicherheit von Maschinen –
Allgemeine Gestaltungsleitsätze –
Risikobeurteilung und Risikominderung (ISO 12100:2010)
Englische Übersetzung von DIN EN ISO 12100:2011-03

Sécurité des machines –
Principes généraux de conception –
Appréciation du risque et réduction du risque (ISO 12100:2010)
Traduction anglaise de DIN EN ISO 12100:2011-03

Supersedes DIN EN ISO 12100-1:2004-04, DIN EN ISO 12100-1/A1:2009-10, DIN EN ISO 12100-2:2004-04, DIN EN ISO 12100-2/A1:2009-10 and DIN EN ISO 14121-1:2007-12
See start of application

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Start of application

The start of application of this standard is 1 March 2011.

DIN EN ISO 12100-1:2004-04, DIN EN ISO 12100-1/A1:2009-10, DIN EN ISO 12100-2:2004-04, DIN EN ISO 12100-2/A1:2009-10 and DIN EN ISO 14121-1:2007-12 may be used in parallel until 1 November 2013.

National foreword

This document includes safety requirements within the meaning of the *9. Verordnung zum Geräte- und Produktsicherheitsgesetz* (GPSG) (Ninth Ordinance to the Equipment and Product Safety Act).

This document has been prepared by Technical Committee ISO/TC 199 “Safety of machinery” in collaboration with Technical Committee CEN/TC 114 “Safety of machinery”. Germany holds the secretariats of both Technical Committees.

The responsible German bodies involved in its preparation were the *Normenausschuss Sicherheitstechnische Grundsätze* (Safety Design Principles Standards Committee), *Normenausschuss Maschinenbau* (Mechanical Engineering Standards Committee), and the *DKE Deutsche Kommission Elektrotechnik Elektronik Informationstechnik im DIN und VDE* (German Commission for Electrical, Electronic and Information Technologies of DIN and VDE), Joint Working Committee NA 095-01-01 GA *Allgemeine Grundsätze und Terminologie.*

This document includes the contents of the previous standards DIN EN ISO 12100-1:2004 and DIN EN ISO 12100-2:2004 including the Amendments published in 2009 as well as DIN EN ISO 14121-1:2007. According to the decision of ISO/TC 199, technical modifications refer exclusively to those contents which are in connection with the revised Machinery Directive, Directive 2006/42/EC. Therefore documentation based on the replaced documents (e.g. risk assessment, type-C standards) does not need to be updated or revised.

A practical guide to risk assessment, with examples, will be published in English as ISO Technical Report ISO/TR 14121-2:2007.

Explanatory notes regarding the German terms “In Betrieb nehmen“ and “Außer Betrieb nehmen“

According to the revised Machinery Directive 2006/42/EC, the term “putting into service” is defined as “the first use, for its intended purpose, in the [European] Community, of machinery covered by this Directive”. In both the revised Machinery Directive and the “old” Machinery Directive, 98/37/EC this term has been translated into German as “Inbetriebnahme”.

In previous editions of the present standard, the English terms “commissioning” and “de-commissioning” were translated as “Inbetriebnahme” and “Außerbetriebnahme”, respectively. This created an inconsistency between the use of the German terms in the Machinery Directive and in DIN EN ISO 12100-1.

The phase in the life cycle of a machine “commissioning”, which was translated in the previous editions of the present standard as “Inbetriebnahme”, is not to be confused with the “Inbetriebnahme durch den Betreiber” (lit. “putting into service by the operator”).

The correct German translation of the term “commissioning” would be the expression “In Betrieb nehmen”, which would not conflict with the definition of “Inbetriebnahme” given in the current Machinery Directive 2006/42/EC. Thus, in this standard the expression “In Betrieb nehmen” is used instead of “Inbetriebnahme” to refer to this phase in a machine’s life cycle.

The commissioning (“In Betrieb nehmen”) of a machine or installation is carried out to check its proper functioning and characteristics, and to identify and eliminate any faults. It is the final testing phase of a machine or installation and as such is the responsibility of the manufacturer, even when the machine is in the operator’s facilities.

In the manufacturing process, the life cycle phase “commissioning” (“In Betrieb nehmen”) occurs before “putting into service” (“Inbetriebnahme”), without the machine having to conform to the European Machinery Directive.

Likewise, the term “disabling” (which in ISO 12100 replaces the previously used term “de-commissioning”) as a machine life cycle phase has been translated into German correctly as “Außer Betrieb nehmen”.

The DIN Standards corresponding to the International Standards referred to in this document are as follows:

ISO 447	there is no national standard available
ISO 2972	there is no national standard available
ISO 4413	DIN EN ISO 4413
ISO 4414	DIN EN ISO 4414
ISO 6385	DIN EN ISO 6385
ISO 7000	DIN ISO 7000
ISO 9355-1	DIN EN 894-1
ISO 9355-3	DIN EN 894-3
ISO 10075	DIN EN ISO 10075-1
ISO 10075-2	DIN EN ISO 10075-2
ISO/TR 11688-1	DIN EN ISO 11688-1
ISO 11689	DIN EN ISO 11689
ISO 13849-1	DIN EN ISO 13849-1
ISO 13850	DIN EN ISO 13850
ISO 13851	DIN EN 574
ISO 13854	DIN EN 349
ISO 13855	DIN EN ISO 13855
ISO 13856 (all parts)	DIN EN 1760 (all parts)
ISO 13857	DIN EN ISO 13857
ISO 14118	DIN EN 1037[1)]
ISO 14119	DIN EN 1088
ISO 14120	DIN EN 953[2)]
ISO 14122 (all parts)	DIN EN ISO 14122 (all parts)
ISO 14122-3	DIN EN ISO 14122-3
ISO 14123-1	DIN EN 626-1
ISO 14163	DIN EN ISO 14163
ISO 15667	DIN EN ISO 15667
ISO/IEC Guide 51	DIN 820-120
IEC 60079-11	DIN EN 60079-11
IEC 60204 (all parts)	DIN EN 60204 (all parts)
IEC 60204-1	DIN EN 60204-1
IEC 60335-1	DIN EN 60335-1
IEC 60745-1	DIN EN 60745-1
IEC 60947-5-1	DIN EN 60947-5-1
IEC 61000-6 (all parts)	DIN EN 61000-6 (all parts)
IEC 61029 (all parts)	DIN EN 61029 (all parts)
IEC 61310 (all parts)	DIN EN 61310 (all parts)
IEC 61496 (all parts)	DIN EN 61496-1, DIN CLC/TS 61496-2 and DIN CLC/TS 61496-3
IEC 61508 (all parts)	DIN EN 61508 (all parts)
IEC/TS 62046	DIN CLC/TS 62046
IEC 62061	DIN EN 62061
IEC 62079	DIN EN 62079
IEC 60050-191	IEV 191

1) Replaced by the new edition of 2008 which is no longer identical to ISO 14118:2000.

2) Replaced by the new edition of 2009 which is no longer identical to ISO 14120:2002.

Amendments

This document differs from DIN EN ISO 12100-1:2004-04, DIN EN ISO 12100-2/A1:2009-10, DIN EN ISO 12100-2:2004-04, DIN EN ISO 12100-2/A1:2009-10 and DIN EN ISO 14121-1:2007-12 as follows:

a) the title of the standard has been changed with regard to the contents of the previous standards;

b) the technical contents of the previous standards have been revised and combined in this standard;

c) Amendments DIN EN ISO 12100-1/A1:2009-10 and DIN EN ISO 12100-2/A1:2009-10 have been incorporated;

d) the definition of machinery/machine has been brought in line with Directive 2006/42/EC;

e) the standard has been editorially revised and all references and cross-references have been updated.

Previous editions

DIN 31000/VDE 1000: 1978-03
DIN EN 292-1: 1991-11
DIN EN 292-2: 1991-11, 1995-06
DIN EN 1050: 1997-01
DIN EN ISO 12100-1: 2004-04
DIN EN ISO 12100-1/A1: 2009-10
DIN EN ISO 12100-2: 2004-04
DIN EN ISO 12100-2/A1: 2009-10
DIN EN ISO 14121-1: 2007-12

National Annex NA
(informative)

Bibliography

DIN 820-120, *Standardization — Part 120: Guidelines for the inclusion of safety aspects in standards*

DIN EN 349, *Safety of machinery — Minimum gaps to avoid crushing of parts of the human body*

DIN EN 574, *Safety of machinery — Two-hand control devices — Functional aspects — Principles for design*

DIN EN 626-1, *Safety of machinery — Reduction of risks to health from hazardous substances emitted by machinery — Part 1: Principles and specifications for machinery manufacturers*

DIN EN 894-1, *Safety of machinery — Ergonomics requirements for the design of displays and control actuators — Part 1: General principles for human interactions with displays and control actuators*

DIN EN 894-3, *Safety of machinery — Ergonomics requirements for the design of displays and control actuators — Part 3: Control actuators*

DIN EN 953, *Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards*

DIN EN 1037, *Safety of machinery — Prevention of unexpected start-up*

DIN EN 1088, *Safety of machinery — Interlocking devices associated with guards — Principles for design and selection*

DIN EN 1760 (all parts), *Safety of machinery — Pressure sensitive protective devices*

DIN EN 60079-11, *Explosive atmospheres — Part 11: Equipment protection by intrinsic safety "i"*

DIN EN 60204 (all parts), *Safety of machinery — Electrical equipment of machines*

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

DIN EN 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements*

DIN EN 60745-1, *Hand-held motor-operated electric tools — Safety — Part 1: General requirements*

DIN EN 60947-5-1, *Low-voltage switchgear and controlgear — Part 5-1: Control circuit devices and switching elements — Electromechanical control circuit devices*

DIN EN 61000-6 (all parts), *Electromagnetic compatibility (EMC) — Part 6-1: Generic standards*

DIN EN 61029 (all parts), *Safety of transportable motor-operated electric tools*

DIN EN 61310 (all parts), *Safety of machinery — Indication, marking and actuation*

DIN EN 61496-1, *Safety of machinery — Electro-sensitive protective equipment — Part 1: General requirements and tests*

DIN CLC/TS 61496-2, *Safety of machinery — Electro-sensitive protective equipment — Part 2: Particular requirements for equipment using active opto-electronic protective devices (AOPDs)*

DIN CLC/TS 61496-3, *Safety of machinery — Electro-sensitive protective equipment — Part 3: Particular requirements for Active Opto-electronic Protective Devices responsive to Diffuse Reflection (AOPDDR)*

DIN EN 61508 (all parts), *Functional safety of electrical/electronic/programmable electronic safety-related systems*

DIN CLC/TS 62046, *Safety of machinery — Application of protective equipment to detect the presence of persons*

DIN EN 62061, *Safety of machinery — Functional safety of safety-related electrical, electronic and programmable electronic control systems*

DIN EN 62079, *Preparation of instructions — Structuring, content and presentation*

DIN EN ISO 4413, *Hydraulic fluid power — General rules and safety requirements for systems and their components*

DIN EN ISO 4414, *Pneumatic fluid power — General rules and safety requirements for systems and their components*

DIN EN ISO 6385, *Ergonomic principles in the design of work systems*

DIN EN ISO 10075-1, *Ergonomic principles related to mental work-load — Part 1: General terms and definitions*

DIN EN ISO 10075-2, *Ergonomic principles related to mental workload — Part 2: Design principles*

DIN EN ISO 11688-1, *Acoustics — Recommended practice for the design of low-noise machinery and equipment — Part 1: Planning*

DIN EN ISO 11689, *Acoustics — Procedure for the comparison of noise emission-data for machinery and equipment*

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

DIN EN ISO 13850, *Safety of machinery — Emergency stop — Principles for design*

DIN EN ISO 13855, *Safety of machinery — Positioning of safeguards with respect to the approach speeds of parts of the human body*

DIN EN ISO 13857, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs*

DIN EN ISO 14122 (all parts), *Safety of machinery — Permanent means of access to machinery*

DIN EN ISO 14122-3, *Safety of machinery — Permanent means of access to machinery — Part 3: Stairs, stepladders and guard-rails*

DIN EN ISO 14163, *Acoustics — Guidelines for noise control by silencers*

DIN EN ISO 15667, *Acoustics — Guidelines for noise control by enclosures and cabins*

DIN ISO 7000, *Graphical symbols for use on equipment — Index and synopsis (also see ISO 7000 Database)*

IEV 191, *International Electrotechnical Vocabulary — Chapter 191: Dependability and quality of service*

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 — Risikobeurteilung und Risikominderung (ISO 12100:2010)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Management Centre: Avenue Marnix 17, B-1000 Brussels

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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.

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.

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.