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Safety of machinery — Risk assessment —

Part 1: **Principles**

Sécurité des machines — Appréciation du risque —

Partie 1: Principes

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 14121-1 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

This first edition of ISO 14121-1 cancels and replaces ISO 14121:1999, of which it constitutes a technical revision.

ISO 14121 consists of the following parts, under the general title *Safety of machinery — Risk assessment*:

— *Part 1: Principles*

— *Part 2: Practical guidance and examples of methods* [Technical Report]

Introduction

The structure of safety standards in the field of machinery is as follows.

a) Type-A standards (basic standards) give basic concepts, principles for design, and general aspects that can be applied to machinery.

b) Type-B standards (generic safety standards) deal with one or more safety aspect(s) or one or more type(s) of safeguards 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-hands controls, interlocking devices, pressure sensitive devices, guards).

c) Type-C standards (machine safety standards) deal with detailed safety requirements for a particular machine or group of machines.

This part of ISO 14121 is a type-A standard as stated in ISO 12100-1.

When provisions of a type-C standard are different from those which are stated in type-A or type-B standards, the provisions of the type-C standard take precedence over the provisions of the other standards for machines that have been designed and built according to the provisions of the type-C standard.

The purpose of this type-A standard is to describe principles for a consistent systematic procedure for risk assessment as stated in ISO 12100-1:2003, Clause 5.

This part of ISO 14121 gives guidance for decisions related to the design of machinery and will assist in the preparation of consistent and appropriate type-B and type-C standards, so that machines can be produced that are safe for their intended use in accordance with the methodology given in ISO 12100.

Annex A gives, in separate tables, examples of hazards, hazardous situations and hazardous events, so as to clarify these concepts and assist the designer in the process of hazard identification.

The practical use of a number of methods for each stage of risk assessment is described ISO/TR 14121-2, which also gives some guidance on how the selection of protective measures (in accordance with ISO 12100) can reduce the different elements of risk in relation to Figure 2 of this part of ISO 14121.

This part of ISO 14121 can be incorporated in training courses and manuals where appropriate to give basic instruction on risk assessment.

Safety of machinery — Risk assessment —

Part 1: Principles

1 Scope

This part of ISO 14121 establishes general principles intended to be used to meet the risk reduction objectives established in ISO 12100-1:2003, Clause 5. These principles of risk assessment bring together knowledge and experience of the design, use, incidents, accidents and harm related to machinery in order to assess the risks posed during the relevant phases of the life cycle of a machine.

This part of ISO 14121 provides guidance on the information that will be required to enable risk assessment to be carried out. Procedures are described for identifying hazards and estimating and evaluating risk.

It also gives guidance on the making of decisions relating to the safety of machinery and on the type of documentation required to verify the risk assessment carried out.

It is not applicable to risks posed to domestic animals, property or the environment.

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.

ISO 12100-1:2003, *Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology*

ISO 12100-2:2003, *Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles and specifications*

3 Terms and definitions

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

3.1
harm
physical injury or damage to health

[ISO 12100-1:2003, definition 3.5]

3.2
hazard
potential source of harm

NOTE 1 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 The hazard envisaged in 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)

[ISO 12100-1:2003, definition 3.6]

3.3
hazard zone
danger zone
any space within and/or around machinery in which a person can be exposed to a hazard

[ISO 12100-1:2003, definition 3.10]

3.4
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.

3.5
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.

[ISO 12100-1:2003, definition 3.9]

3.6
intended use of a machine
use of a machine in accordance with the information provided in the instructions for use

[ISO 12100-1:2003, definition 3.22]

3.7
machinery
machine
assembly of linked parts or components, at least one of which moves, with the appropriate machine actuators, control and power circuits, joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material

NOTE 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.

[ISO 12100-1:2003, definition 3.1]

3.8
malfunction
failure of a machine to perform an intended function

NOTE For examples, see ISO 12100-1:2003, 5.3 b), item 2).

3.9
protective measure
measure intended to achieve risk reduction

NOTE 1 It is implemented:

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

— 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 2 See ISO 12100-1:2003, Figure 1.

[ISO 12100-1:2003, definition 3.18]

3.10
reasonably foreseeable misuse
use of a machine in a way not intended by the designer, but which may result from readily predictable human behaviour

[ISO 12100-1:2003, definition 3.23]

3.11
residual risk
risk remaining after protective measures have been taken

NOTE See ISO 12100-1:2003, Figure 1.

[ISO 12100-1:2003, definition 3.12]

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

[ISO 12100-1:2003, definition 3.11]

3.13
risk analysis
combination of the specification of the limits of the machine, hazard identification and risk estimation

[ISO 12100-1:2003, definition 3.14]

3.14
risk assessment
overall process comprising a risk analysis and a risk evaluation

[ISO 12100-1:2003, definition 3.13]

3.15
risk estimation
definition of likely severity of harm and probability of its occurrence

[ISO 12100-1:2003, definition 3.15]

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

[ISO 12100-1:2003, definition 3.16]

3.17
task
specific activity performed by one or more persons on or in the vicinity of the machine during its lifecycle

4 General principles

4.1 Basic concepts

Risk assessment is a series of logical steps to enable, in a systematic way, the analysis and evaluation of the risks associated with machinery. Risk assessment is followed, whenever necessary, by risk reduction as described in ISO 12100-1:2003, Clause 5. Iteration of this process can be necessary to eliminate hazards as far as practicable and to adequately reduce risks by the implementation of protective measures.

Risk assessment includes the following (see Figure 1):

a) risk analysis:

   1) determination of the limits of the machinery (see Clause 5);

   2) hazard identification (see Clause 6);

   3) risk estimation (see Clause 7);

b) risk evaluation (see Clause 8).

Risk analysis provides information required for the risk evaluation, which in turn allows judgements to be made about whether or not risk reduction is required.

These judgments shall be supported by a qualitative, or where appropriate, a quantitative, estimate of the risk associated with the hazards present on the machinery

NOTE A quantitative approach can be appropriate when useful data is available. However, a quantitative approach is restricted by the useful data that are available and/or the limited resources of those conducting the risk assessment. Therefore, in many applications, only qualitative risk estimation will be possible.

The risk assessment shall be conducted so that it is possible to document the procedure that has been followed and the results that have been achieved (see Clause 9).

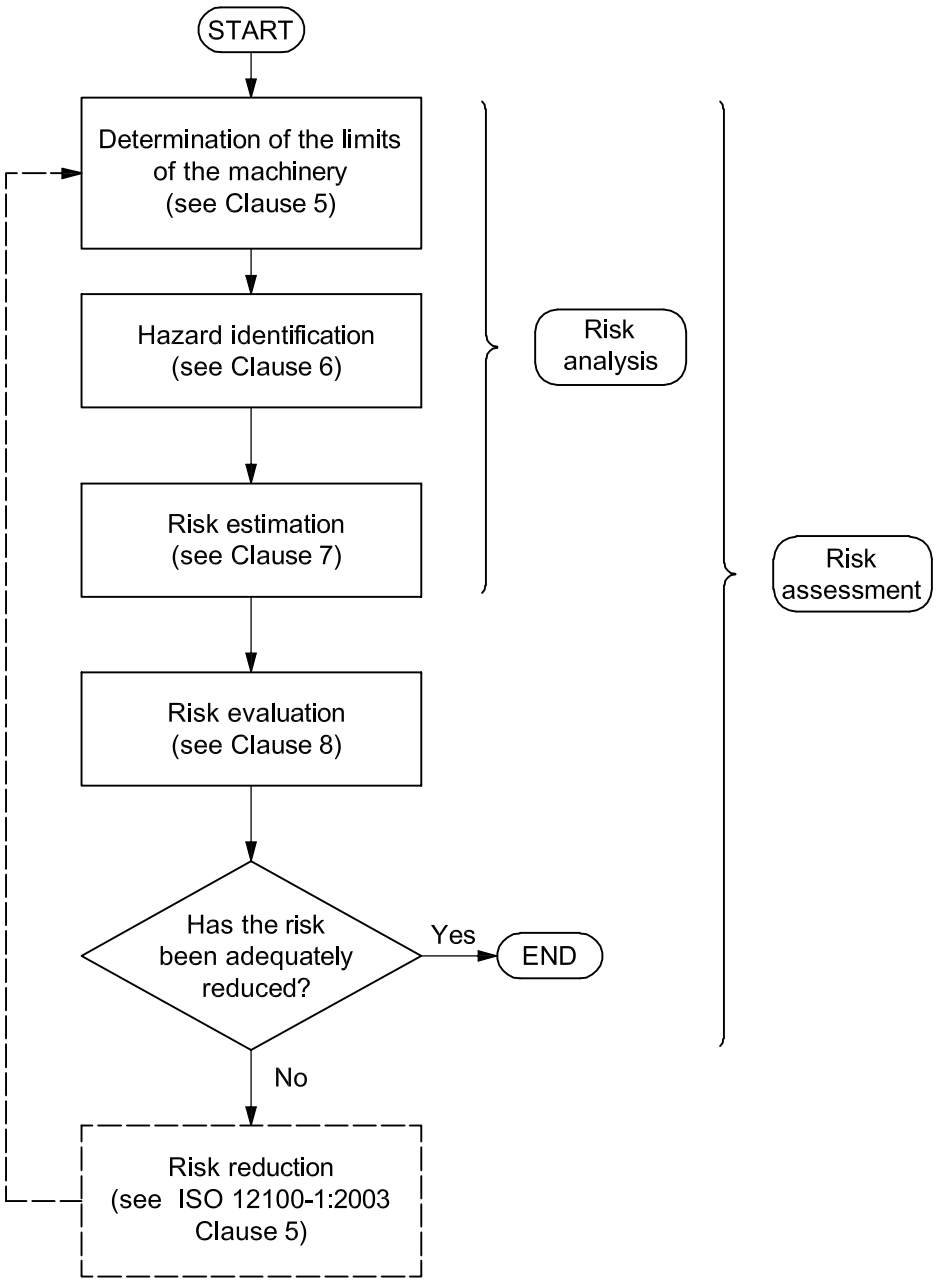

Figure 1 — Iterative process for reducing risk

4.2 Information for risk assessment

The information for risk assessment should include the following:

a) related to machinery description:

   1) user specifications;

   2) anticipated machinery specifications, including

      i) description of the various phases of the whole life cycle of the machinery,

      ii) design drawings or other means of establishing the nature of the machinery, and

      iii) required energy sources and how they are supplied;